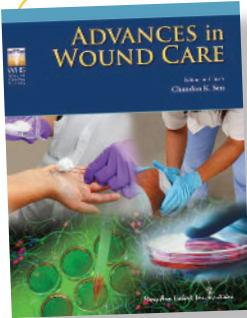


REAL WORLD EVIDENCE STUDY



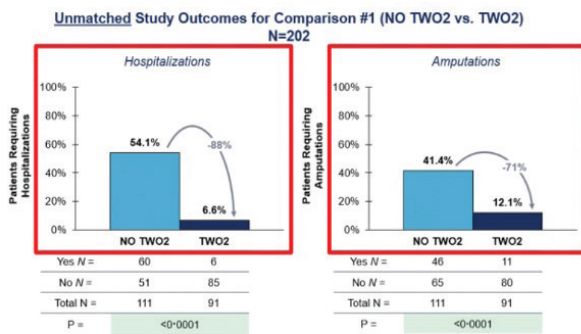
Reduced Hospitalizations and Amputations in Patients with Diabetic Foot Ulcers Treated with Cyclical Pressurized Topical Wound Oxygen Therapy: Real-World Outcomes

Jessica Izhakoff Yellin, Julia A. Gaebler, Frank F. Zhou, Timothy Niecko, Olivia Novins, Amelia Ockert, Darcy Krzynowek, Matthew G. Garoufalidis, Aliza M. Lee, and Robert G. Frykberg

#1 Ranked Journal in Wound Care

RESULTS:

OUTCOMES: Unmatched Cohort at 360 Days



88%

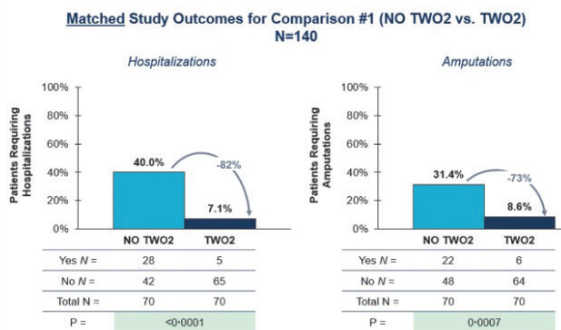
REDUCTION in Hospitalizations

71%

REDUCTION in Amputations

- Unmatched cohort representing the real world heterogenic mix of patients treated for DFU

OUTCOMES: Matched Cohort at 360 Days



82%

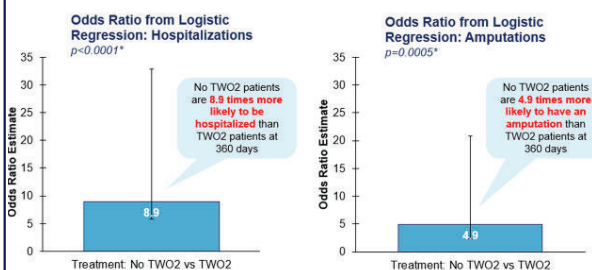
REDUCTION in Hospitalizations

73%

REDUCTION in Amputations

- Matched cohort of DFU patients with balanced covariants demonstrates similar outcomes to unmatched cohort

ODDS RATIO from Logistic Regression



9X

HIGHER RISK of Hospitalization

5X

HIGHER RISK of Amputation

- The logistic regression of matched cohorts demonstrate the odds of hospitalization and amputation when **not** treated with TWO2

RESEARCH DESIGN:

- Study was performed at two U.S. Veterans Affairs hospitals
- Medical records were reviewed for demographic information such as age, sex, ethnicity, wound characteristics, wound duration, Wagner classification, wound area, CVD, PVD, kidney disease, HbA1c, history of amputation, and neuropathy.
- The Primary Outcomes were patients requiring hospitalization and/or amputation within 360 days of initial wound documentation.

UNMATCHED Cohorts 202

91 received TWO2 therapy, 111 did NOT receive TWO2.

MATCHED Cohorts 140

70 received TWO2 therapy, 70 did NOT receive TWO2.

BOTH cohorts received Standard of Care (SOC) and may have received adjunct therapies including negative pressure wound therapy (NPWT), skin substitutes (SS), and/or growth factors (GF).

CONCLUSION: This retrospective cohort study demonstrates that **treating patients with DFU with TWO2 is associated with significant reductions in hospitalizations and amputations in the real-world setting.**

MULTI-MODALITY TWO2 WORKS LIKE NO OTHER



OXYGEN

High-pressure delivery results in greater tissue diffusion critical to restoring normal wound metabolism, resulting in **more effective and durable healing.**



COMPRESSION

Non-contact cyclical compression addresses edema and **helps correct the underlying peripheral vascular disease.**



HUMIDIFICATION

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



FIND OUT WHAT TWO2 CAN DO FOR YOUR PATIENTS.
Visit www.AOTInc.net for more information.

AOTI, Inc. Recognized as a leader in wound care technology around the world.

AOTI is an FDA QSR, ISO 13485 2016 and ACHC accredited company, which demonstrates our commitment to quality in all that we do.



Health
Canada



REFERENCES:

- National Health Interview Survey by the Centers for Disease Control and Prevention and the U.S. Census Bureau.
- Reduced Hospitalizations and Amputations in Patients with Diabetic Foot Ulcers Treated with Cyclical Pressurized Topical Wound Oxygen Therapy: Real-World Outcomes; Jessica Izhakoff Yellin, Julia A. Gaebler, Frank F. Zhou, Timothy Niecko, Olivia Novins, Amelia Ockert, Darcy Krzynowek, Matthew G. Garoufalis, Aliza M. Lee, and Robert G. Frykberg; *Advances in Wound Care* 2022; <http://doi.org/10.1089/wound.2021.0118>
- A Multinational, Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy of Cyclical Topical Wound Oxygen (TWO2) Therapy in the Treatment of Chronic Diabetic Foot Ulcers; The TWO2 Study; *Diabetics Care* 2020;43:616-624 | <https://doi.org/10.2337/dc19-0476>.

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