Accelerated Wound Healing with Nitric Oxide Delivering Foam: Insights from Real-World Data

Mervin Low[1], MD MAPWCA; Sarah Langbord[2], PhD; C. Michael Miller[2], MS; Lex Schindler[2] , MS; Tim Jacobson[2], CFA

[1]Newport Wound, Newport Beach, CA, USA [2]NOxy Health Products, Inc. Anaconda, MT, USA.

Background

Nitric Oxide (NO) is a highly diffusible, endogenous vasodilator, antimicrobial, and cell signaling molecule. Nitric oxide also modulates hemostasis, inflammation, immune response, debridement, matrix metalloprotease activity, perfusion, angiogenesis, collagen synthesis, granulation formation, wound contraction, epithelialization, and reduced scarring[1-3]; all processes necessary for effective wound healing.[4]

In healthy adults, nitric oxide is produced in sufficient amounts for effective wound healing. However, persons with advanced age, critical illness, malnutrition, or chronic illnesses such as cardiovascular disease, diabetes, and obesity may be deficient in nitric oxide, leading to delayed wound healing.[1]

Aim

The aim of this study was to evaluate the effectiveness of a novel topical nitric oxide-delivering foam (NODF) for wound healing using real-world evidence (RWE) collected from Skilled Nursing Facilities (SNFs).

Methods

A research protocol was developed, along with a data collection form and informed consent process. A data registry was designed to automate the data collection form. Product and data registry training were provided to facility staff by facility leadership. A topical nitric oxide-delivering foam was implemented in 21 skilled nursing facilities across California and Nevada. Patient selection for product use was guided by physician judgment. Clinical cases were submitted to the registry by facility staff following the subject's last visit, where the NODF was administered. Last visits were due to discharge or a change in treatment. Data collection included healthcare provider demographics, patient demographics, wound and treatment history, and wound assessment and treatment details. No protected health information was collected. Data were analyzed in aggregate form.

40 CLINICAL CASES

Results

Nitric Oxide-Delivering Foam

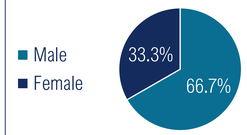
- FDA-registered Over-the-Counter product
- A liquid foam with Benzalkonium Chloride (an antiseptic)
- Formulated to deliver Nitric Oxide
- 5-minute topical application

Preferred Dose: Three pumps
Preferred Frequency: 3 times per week

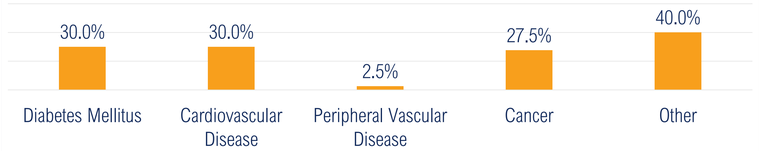
Patient Demographics

Mean Age 83yrs (60-94yrs)

By Gender



% of Wounds in Patients with the Following Medical & Surgical History



Historical Intervention Data (NODF)

NODF RWE registry data shows positive results across various wound types. Forty chronic, non-healing wounds were treated for on average >75 days and failed to heal. After intervention with NODF, the wounds closed in an average time of 24 days. Severe wounds treated with NODF that were not closed at SNF discharge, reduced in size by an average of 48%. The subset of wounds analyzed had a recorded age of 1-3 months, 4-6 months, or 6-12 months, as reported by the SNF. The midpoint of these ranges was used to calculate average wound age.

Wound Type	Count	Pre-NODF Intervention (Wound Age and Size)	Post-NODF Intervention (Days and % Reduction)
Severe Wounds (Not closed)	14	90.0 days, Avg Size = 13.3cm²	34.8 days, 48.6% area reduction
Severe Wounds (Healed)	25*	80.4 days, Avg Size = 13.3cm²	30.0 days, 100% wound closure
Chronic Lower Extremity	9	76.7 days, Avg Size = 11.9cm²	23.0 days, 100% wound closure
Full-Thickness Pressure Injuries	15	84 days, Avg Size = 12.2cm²	34.5 days, 100% wound closure
Trauma (Healed)	15	70 days, Avg Size = 9.0cm²	14.1 days, 100% wound closure
Healed Severe + Trauma Total	**40**	76.5 days, Avg Size = 11.7cm²	**24.0 days, 100% wound closure**

*25 Severe Wounds = Chronic Lower Extremity (9) + FT PI's (15) + Infection (1, not shown)

Discussion

RWE demonstrated improved healing outcomes across all wound types with each wound serving as its own control. On average, wounds transitioned from an average baseline of 76.5 days old and 11.7 cm² in size to healing within 24 days following NODF treatment.

- 60% of wounds received no "Active" therapy before or after NODF indicating NODF alone was the primary driver of healing.
- 22.5% of wounds maintained their existing "Active" therapy alongside NODF demonstrating compatibility with other treatment modalities.
- 12.5% of wounds had "Active" therapy discontinued after NODF suggesting a reduced need for additional interventions.
- 5% of wounds had "Active" therapy added post-NODF indicating some cases may benefit from supplemental therapies.

The self-controlled, registry-based design minimizes inter-patient variability strengthening the observed correlation between NODF use and accelerated wound healing.

Conclusion

These findings suggest that topical NODF is effective in facilitating the healing of various wound types. The results highlight NODF's potential as both a standalone and adjunctive therapy in real-world clinical practice. Further studies are needed to assess the effectiveness of NODF in other real-world settings.

References:

1. Andrabi, S. M., Sharma, N. S., Karan, A., Shahriar, S. M. S., Cordon, B., Ma, B., & Xie, J. (2023). Nitric Oxide: Physiological Functions, Delivery, and Biomedical Applications. Advanced science (Weinheim, Baden-Wurttemberg, Germany), 10(30), e2303259. https://doi.org/10.1002/advs.202303259.
2. Rocha B. S. (2021). The Nitrate-Nitrite-Nitric Oxide Pathway on Healthy Ageing: A Review of Pre-clinical and Clinical Data on the Impact of Dietary Nitrate in the Elderly. Frontiers in aging, 2, 778467. https://doi.org/10.3389/fragi.2021.778467
3. Poh, W. H., & Rice, S. A. (2022). Recent Developments in Nitric Oxide Donors and Delivery for Antimicrobial and Anti-Biofilm Applications. Molecules (Basel, Switzerland), 27(3), 674. https://doi.org/10.3390/molecules27030674

Conference: 2025 SAWC Spring, April 30-May 4, Grapevine, TX.

Learn More