

A Registry-based Study Assessing the Efficacy of a Nitric Oxide Delivering Foam for Wound Healing

Rhonda Sullivan DNP, PhD, MSN, MBA, CWON, LNCC, NE-BC, CSPHA, CLSSBB • Vice President, Clinical Development • NOxy Health Products, Inc.

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 scarring¹⁻³; all processes necessary for effective wound healing.⁴

In the healthy adult, 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 the study was to assess the effectiveness of a first-of-its-kind topical nitric oxide-delivering foam for wound healing.

Methods

A research protocol, data collection form, and informed consent were developed. 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. Patient selection for product use was guided by physician judgement. Clinical cases were submitted to the registry by facility staff following the subject's last visit, where the nitric oxide delivering foam was administered. Last visits were due to discharge, expiration, or treatment changed. 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.

225
CLINICAL
CASES

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 (89.3%)

Preferred Frequency: 2-3 times per week (69.3%)

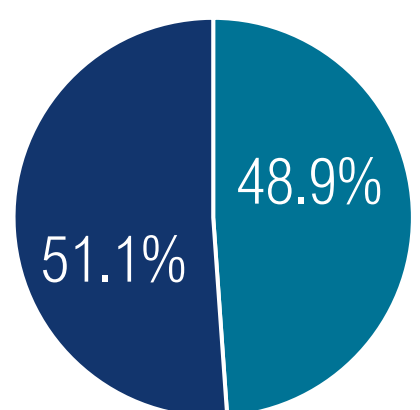
Results

Patient Demographics

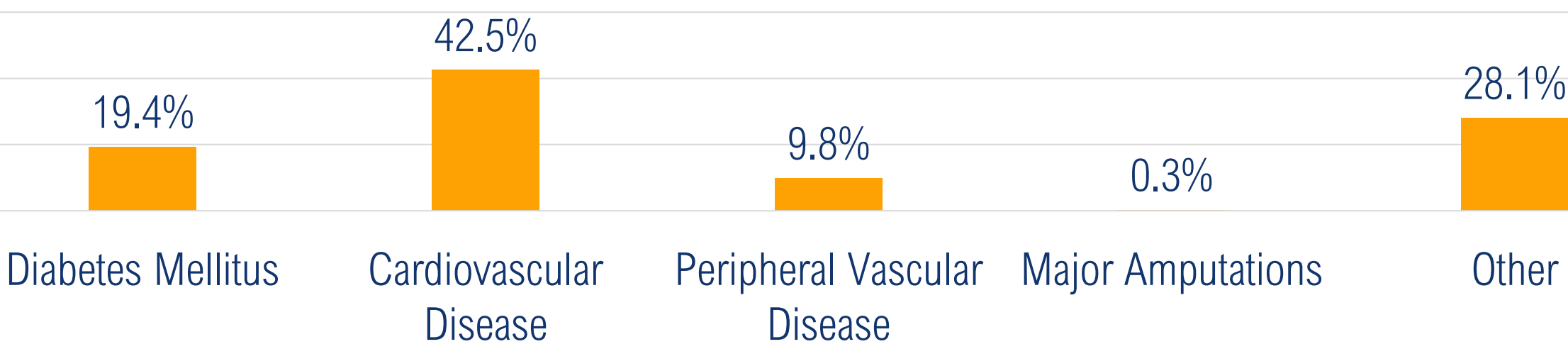
Mean Age
82yrs
(50-99yrs)

By Gender

■ Male
■ Female



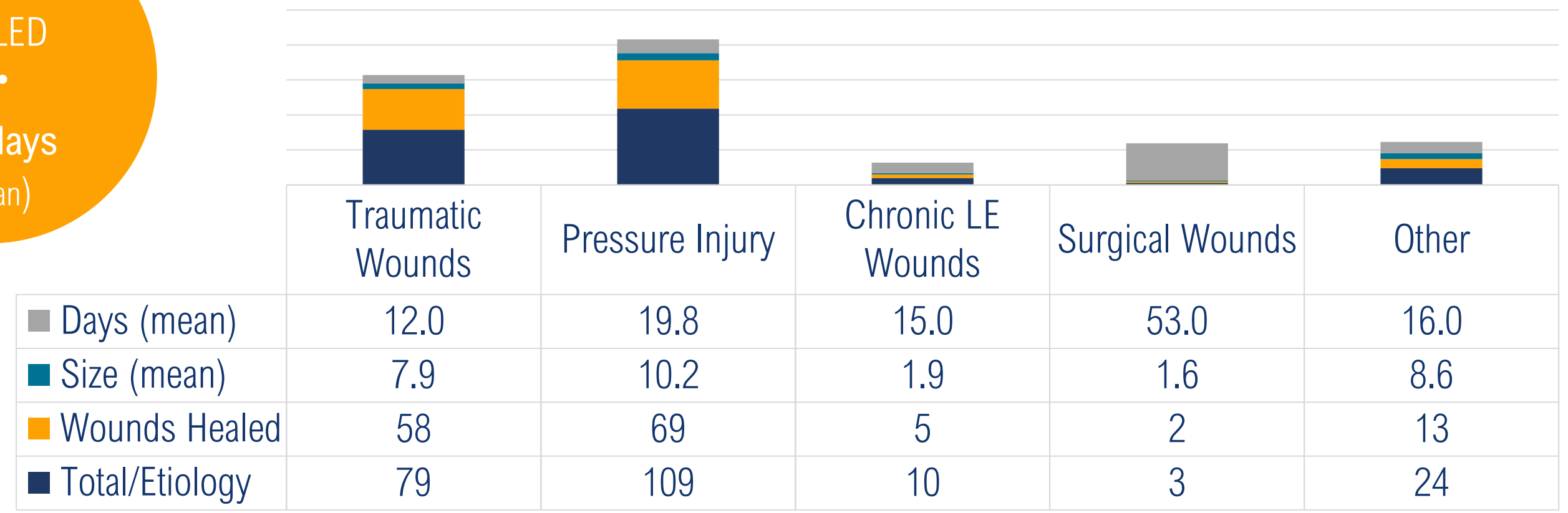
Medical & Surgical History



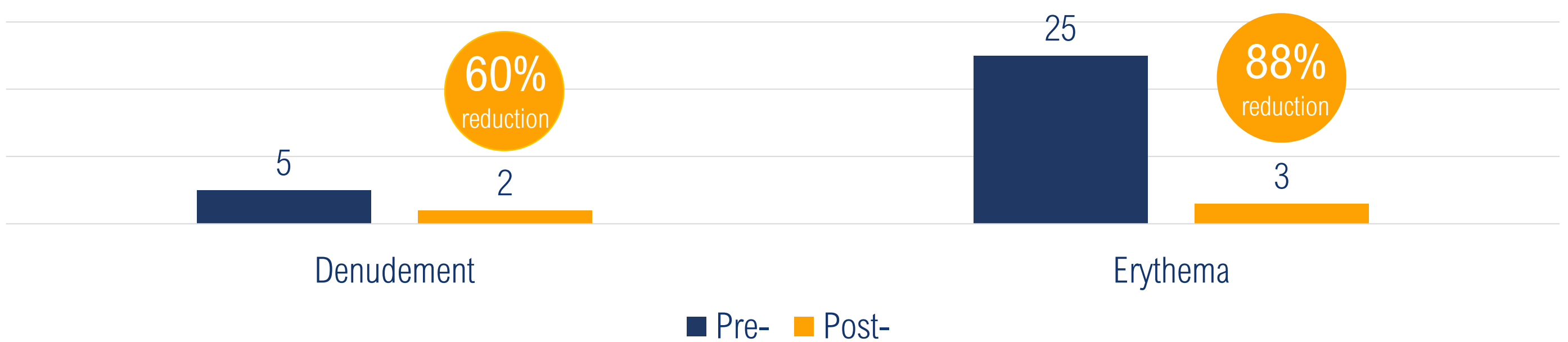
Healed Wounds

65.3%
HEALED
...
23 days
(mean)

Wound Healing Outcomes



Peri-Wound Skin Outcomes



Non-Healed Wounds

Clinical cases represent care provided between the first and last facility visits, during which the NO delivering foam was administered. Wounds not healed at the last visit demonstrated progression toward healing, as detailed below.

Wound
Contraction

33% Percent Area Reduction (PAR)

38% Increase in Granulation

Angiogenesis

Debridement

30% Decrease in Necrosis

50% of Infections Resolved

Antimicrobial

Vasodilation

ZERO DTPI's opened

Discussion

Wounds not healed at the last visit were three times larger and treated on average, three days less than healed wounds. Seventy-four percent of the last visits were due to discharge or expiration. Data supports that these wounds were healing at the same rate as the healed wounds but due to the size of the wound, required additional treatment time.

Cost

The NO delivering foam cost approximately \$5.00 per treatment. Using the common dose, frequency, and treatment time from the registry, the total cost to heal the average registry wound, including severe or complex wounds would be \$20-\$30.

Conclusion

Data collection is ongoing, but this data demonstrates that the topical nitric oxide-delivering foam is a cost-effective option for timely wound healing across various wound etiologies and severities of injury.

References:

- Goedeke, R. (2024). Decoding the Benefits of Nitric Oxide for Skin Health: A New Horizon in Dermatology. Available at <https://www.biospherenutrition.co.nz/blogs/nitric-oxide/decoding-the-benefits-of-nitric-oxide-for-skin-health-a-new-horizon-in-dermatology>.
- 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>
- 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>
- Wu, M., Lu, Z., Wu, K., Nam, C., Zhang, L., & Guo, J. (2021). Recent advances in the development of nitric oxide-releasing biomaterials and their application potentials in chronic wound healing. *Journal of materials chemistry. B*, 9(35), 7063–7075.

Notes: Study Product: NOxyDERM™ • Means used for area, treatment time, & PAR

Learn More

