

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

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Background

Nitric oxide 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.

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.

Nitric Oxide Delivering Foam

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

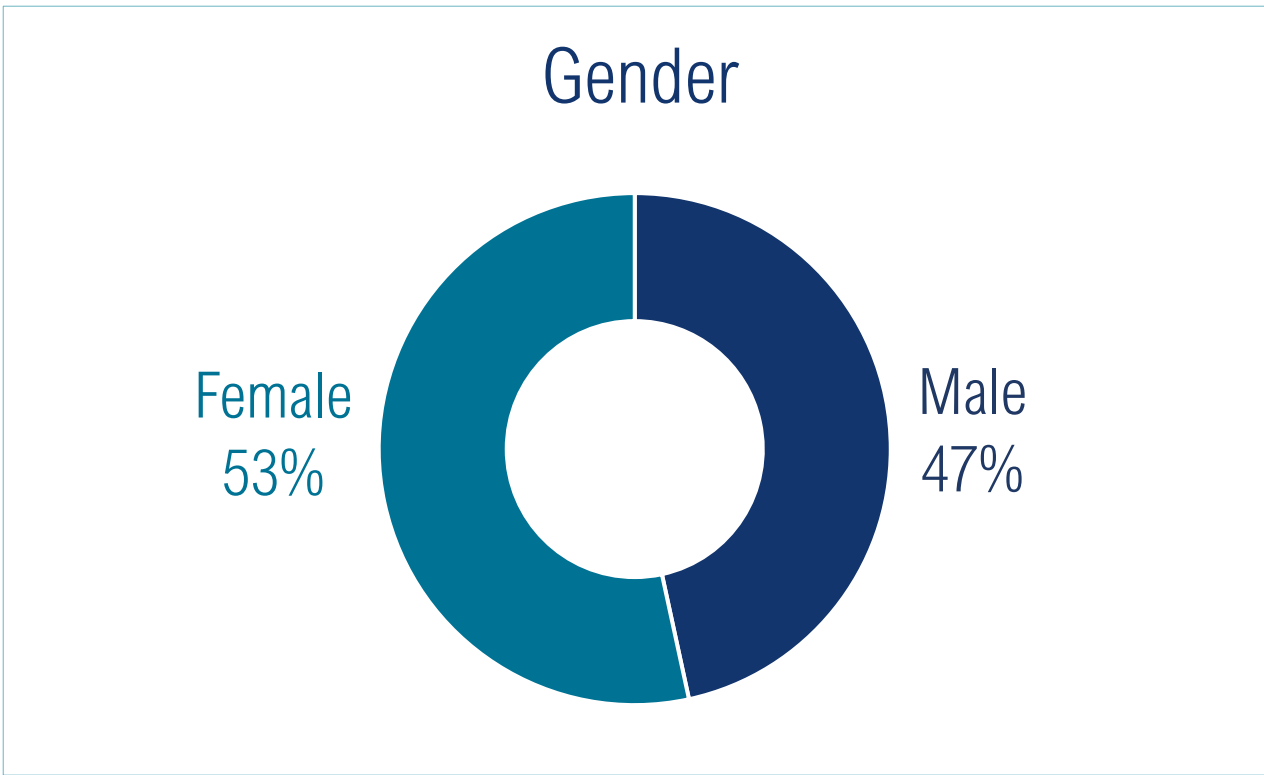
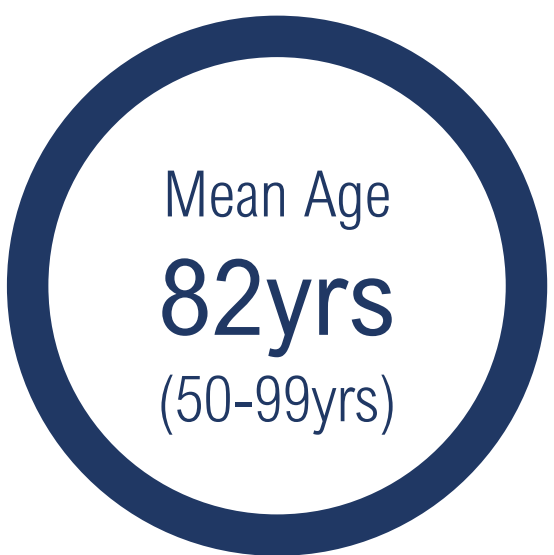


Methods

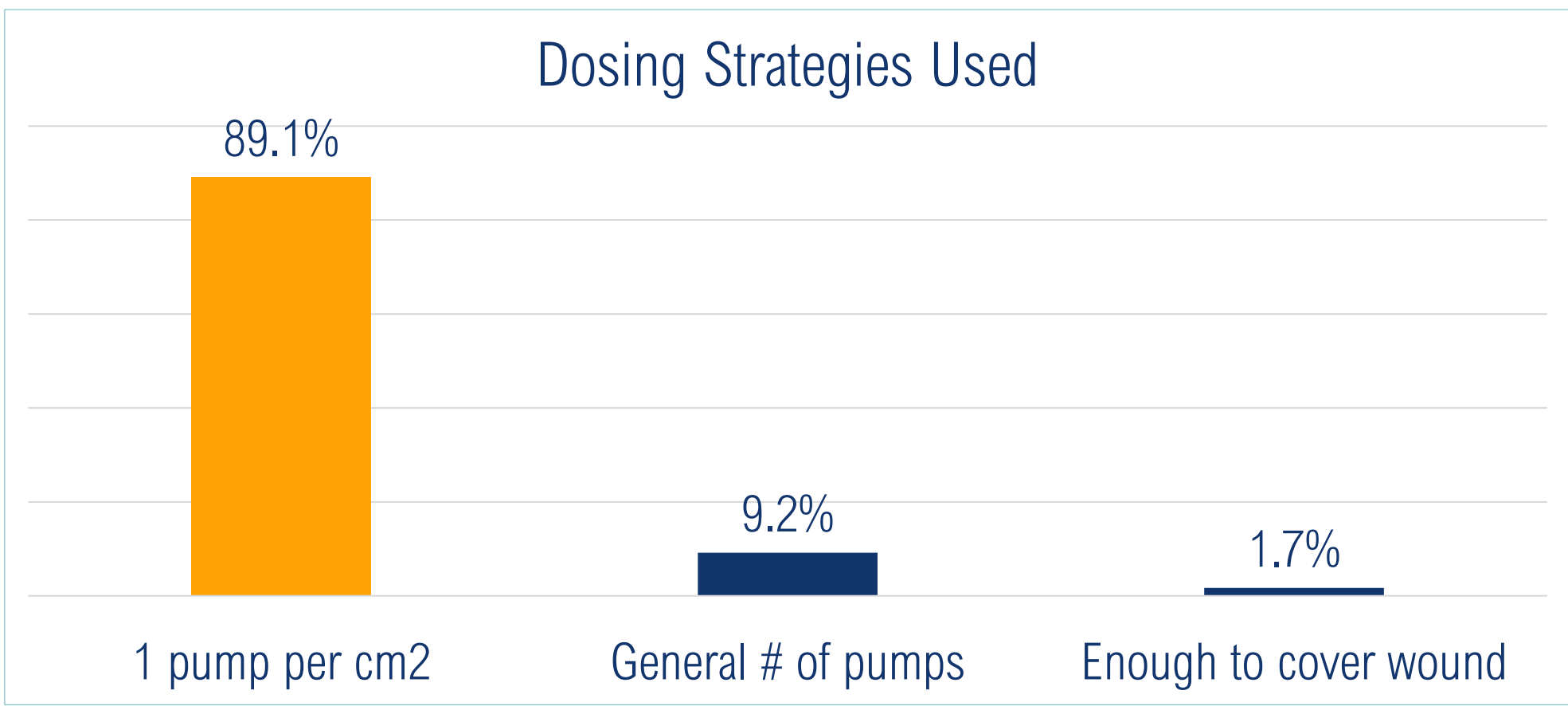
A research protocol, data collection form, and informed consent were developed. A data registry was designed to automate the data collection form. Product and data registry training were provided to facility staff by facility leadership. A topical nitric oxide delivering foam was implemented in 21 skilled 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, due to complete closure, discharge, or treatment with the NO delivering foam stopped for any reason. 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.

174
CLINICAL
CASES

PATIENT DEMOGRAPHICS



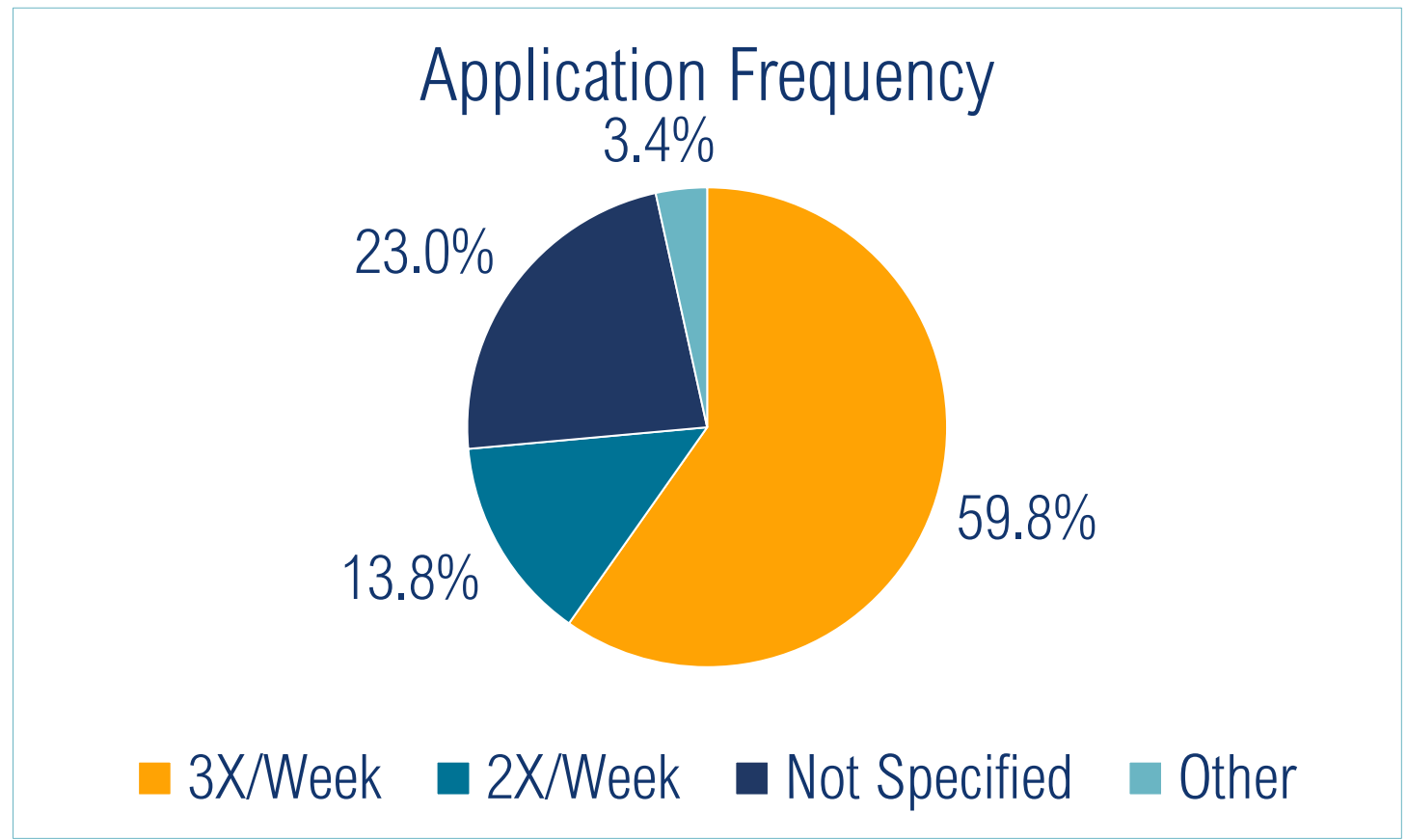
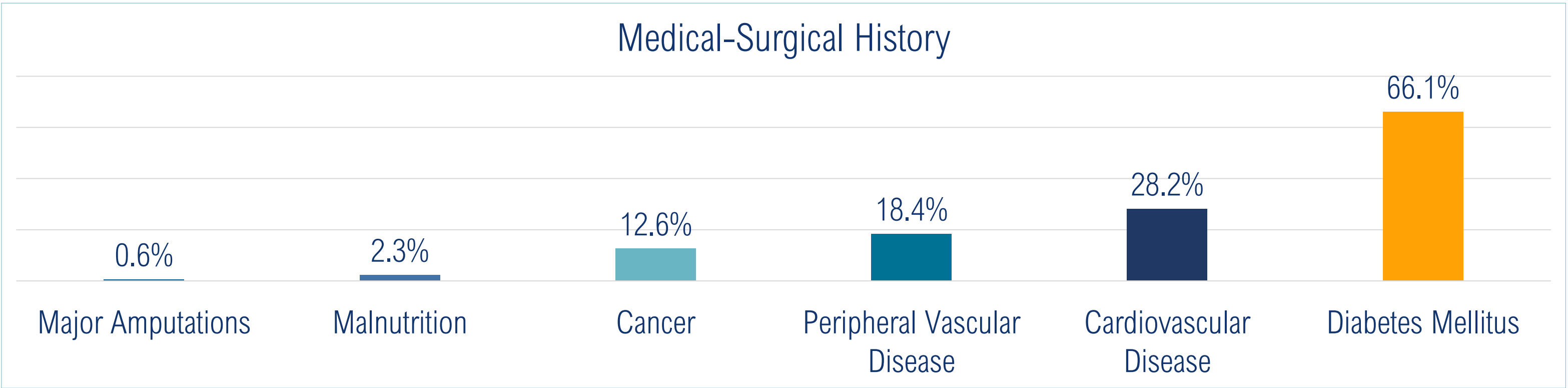
PRODUCT USAGE



OUTCOMES: HEALED WOUNDS

OUTCOMES: NON-HEALED WOUNDS

Results



Discussion

The NO delivering foam cost approximately \$5.00 per treatment. Based on MWF application for 2 weeks, the most common dose and duration across the registered wound cases; the total cost to heal even severe wounds could be as little as \$30.00.

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

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