A Retrospective, Real-World Analysis of the Efficacy of VHT in the Skilled Nursing Facility

Introduction

More than 16% of US Medicare beneficiaries were diagnosed with a wound in 2021, representing an estimated 10.8 million patients and over $26 billion in costs [1]. The prevalence of these wounds, including pressure injuries, diabetic foot ulcers (DFUs), and wounds of vascular etiologies (e.g. venous leg ulcers (VLUs)), continues to grow with an aging population and increased prevalence of comorbidities like diabetes. Skilled nursing facilities (SNFs) play a major role in wound management for Medicare beneficiaries, with many transitioning to SNFs for post-acute wound care while managing other medical needs. Indeed, wound management is a key role of SNFs, not only for their patients but also as a quality measurement and a Centers for Medicare and Medicaid Services (CMS) payment concern for the facility. With pressure injury prevalence alone estimated as high as 28% in SNFs [2], there remains a significant need for effective wound management solutions for these facilities and their patients.

Vaporous hyperoxia therapy (VHT, Vaporox Inc., Denver, CO, USA) is a US FDA-cleared device that combines low-frequency, non-contact, and non-thermal ultrasonic mist with concentrated topical oxygen as a novel adjunct therapy in wound management and treatment. VHT is indicated for use on a variety of wound types, including pressure injuries, VLUs, DFUs, burns, skin graft sites, amputations, and gangrenous lesions.

VHT applies hydrating vapor and concentrated oxygen topically to the wound 2-3 times per week to hyper-saturate tissue, reduce bioburden, and support angiogenesis. As an adjunct therapy, VHT is compatible with indicated standard and advanced wound care including sharp debridement and application of cellular, acellular, and matrix-like products (CAMPs). VHT easily incorporates into existing wound care protocols for both inpatient and outpatient SNF therapy. A recent retrospective analysis demonstrated that VHT is effective in supporting wound closure of DFUs and other wound types in the outpatient center [3]. The purpose of this work is to evaluate the real-world efficacy of VHT in the SNF setting.

Methods

Intent-to-Treat Population

A total of 58 records were collected from a skilled nursing facility and rehabilitation center in Florida, USA, that is part of a multi-center regional system. All patients received VHT treatment between July 1, 2024 and November 5, 2025. This site was selected because it represented the largest SNF cohort treated with VHT to date within the regional system. This cohort included 38 unique patients, some of whom were seen for multiple episodes during the data collection period, and 70 total wounds. Patients received VHT therapy at least twice per week for at least 30 minutes per session. All patients also received standard of care (SOC) wound treatment, including sharp debridement, offloading, compression, and nutritional support, as indicated. The data was extracted from patient records, with review and analysis performed by a third-party.

Per Protocol Population

To better understand the efficacy of VHT when applied as indicated, patient records were excluded if they did not finish the prescribed course of VHT, had a Wagner grade 4 or 5 DFU (by clinical definition of gangrene present), or presented with sepsis at any point during the treatment. Overall, 20 patient records were excluded for the following reasons: under active treatment for sepsis (2), Wagner 4/5 wound defined by gangrene present (1), did not complete prescribed treatment (17).

Reasons for not completing the prescribed course of VHT treatment were the following: discharged early to hospital (10), patient expired (2), discharged from the facility with recommendation to continue VHT (1), refused treatment (1), exhausted insurance benefits (1), discharged to hospice (1), and change in medical status that required withdrawl of therapeutic services (1).

The final population analyzed in this study included 38 treatment records of 26 patients with a total of 42 wounds. Patient and wound characteristics for this analysis are detailed in **Table 1**.

Table 1: Patient and wound characteristics. Summary data are presented as median (95% CI). BMI body mass index; DFU diabetic foot ulcer; VHT vaporous hyperoxia therapy.

Characteristic	value	percentage
Sex		
Male	9	35.0%
Female	17	65.0%
Race		
White	7	26.9%
Black	1	3.85%
Hispanic	1	3.85%
Other	17	65.4%
Patient age, years	82.5 (79,90)	
BMI		
<20	6	23.1%
20-25	5	19.2%
>25	10	38.5%
No Data	5	19.2%
Baseline Wound Area, cm^2	0.78 (0.5,1.68)	
Baseline Wound Age, days	2 (1, 9)	
Wound Type		
Diabetic	2	4.76%
Venous	3	7.14%
Arterial	2	4.76%
Pressure Injury	33	78.57%

Stage 1	1	2.38%
Stage 2	5	11.90%
Stage 3	20	47.62%
Stage 4	5	11.90%
Unstageable	2	4.76%
Other	2	4.76%
Number of VHT Treatments	9.5 (7,16)	
Payor for Services		
Medicare Part A	6	15.8%
Medicare Part B	31	81.6%
Other	1	2.60%

The patient population for this study included more women than men, and primarily elderly patients: only one patient (3.8%) was under the age of 65 (56 years old), and 8 patients (31%) were greater than 90 years of age. This is reflective of the US SNF population overall, as 2021 CMS data shows more women (60%) than men and 92% of patients older than 65 [4]. Indeed, the SNF services in this analysis–including VHT treatments–were primarily paid for by Medicare Part A or Part B (97.4%).

While pressure injuries are among the most prevalent types of wounds in SNFs, with one study reporting prevalence as high as 17% [5], an even higher prevalence was observed in this analysis. This could be explained by other factors in this patient population: most of the patients analyzed had impaired mobility or were bedridden, and were also receiving physical therapy for other conditions at this SNF and rehabilitation center.

These patients had a number of comorbidities contributing directly or indirectly to their wound. More than half of patients (17 patients, 65%) were admitted to the SNF for 2 or more unique medical ICD 10 codes, and their medical histories included on average 14.2 ± 6.4 unique ICD 10 codes per patient (mean ± standard deviation). In addition to diabetes (50%) and vascular conditions (peripheral artery/vascular disease (PAD/PVD), 15%), many patients were overweight as classified by a BMI >25 (10 patients, 38%). These specific concerns are growing globally, and their known contribution to wounds [6] and wound nonhealing provides additional context for the present analysis and shows the growing need for effective wound treatments in these populations.

Patient Outcomes

Overall Analysis

Wound healing outcomes were evaluated for the 42 wounds and 26 individual patients included in the per protocol population. Two wounds were still being treated with VHT as of the end of data collection and are considered unhealed in this analysis. Overall, 37 wounds (88.1%) healed with VHT treatment in this analysis (**Figure 1a**). A Kaplan-Meier analysis of this group

showed an 87.3% probability of healing within 12 weeks and 90.4% probability of healing overall (**Figure 1b**).

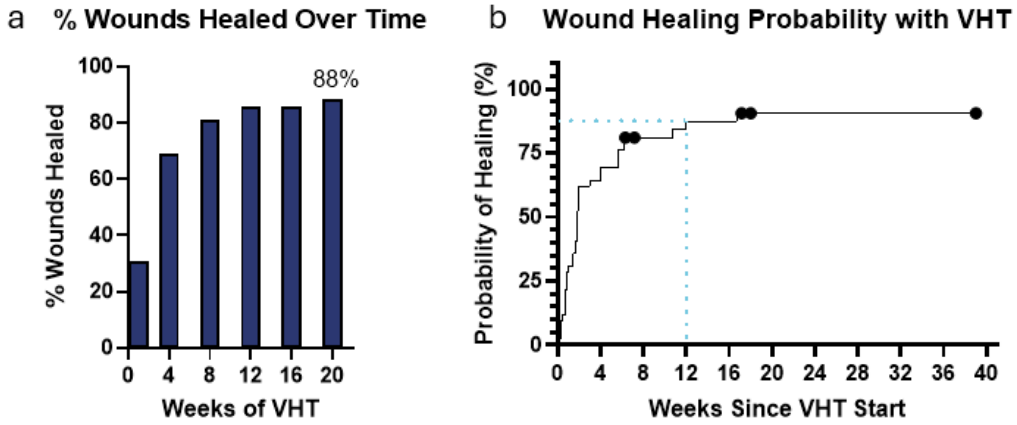


Figure 1: *Overall analysis of 42 wounds. a) Cumulative percentage of healed wounds at various timepoints. b) Kaplan-Meier survival curve of wound healing probability.*

Due to the nature of this data set, where weekly healing records were not provided uniformly and records for many patients included only intake and discharge records, percent area reduction (PAR) of wounds over time was not calculable. However, initial and final wound sizes were analyzed. **Figure 2** visualizes paired data for each wound. All but 2 wounds (4.76%) decreased in size with VHT treatment, and these were unhealed wounds. The median initial wound size was 0.78 cm^2 (95% CI: 0.50, 1.68) and the median final wound size was 0 (95% CI: 0,0). This occurred with a median of 9.5 (95% CI: 7,16) VHT treatments. The greatest number of VHT treatments for a patient was 112, which is the current count for one of the patients still being treated. However, for healed wounds, 52 was the greatest number of VHT treatments required, and 1 wound (2.38%) healed after just 1 VHT treatment.

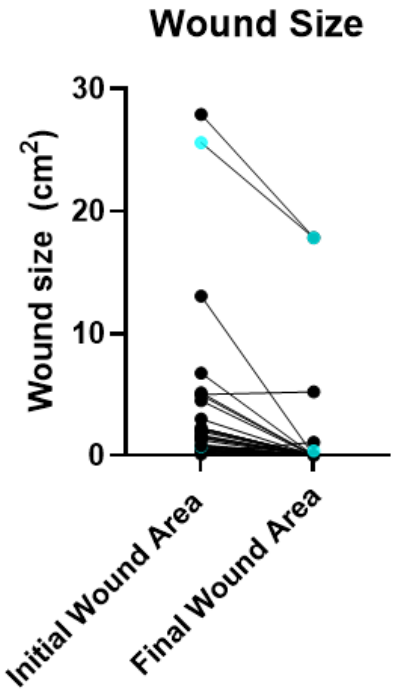


Figure 2: *Paired graph showing initial and final wound size. Blue points represent wounds still undergoing treatment.*

Of the 38 treatment instances analyzed, only 2 (5.26%) patients were discharged to the hospital. Neither hospitalization was considered wound-related by the clinical care team: one for urosepsis and one following a fall. The most commonly noted discharge location was to the patient's usual residence, either home or a long-term care facility (13 patients, 34.2%). Only one patient (3.85%) developed an infection during the course of their treatment. This was attributed by the provider to a pilonidal cyst and not the VHT treatment.

Overall, these data demonstrate positive outcomes for patients, payors, and SNFs when using VHT. Patients with healed or smaller wounds are not only at reduced risk for severe complications such as amputation or infection, but also experience an improved quality of life and may be able to return to their previous living situation. Healing these wounds quickly also reduces wound care costs. With a greater than 50% probability of healing in just two weeks, VHT may support reduced expenditures in the multi-billion-dollar wound care industry while still providing quality healthcare. Medicare, as a payor, also provides incentive payments to SNFs for positive outcomes through the CMS SNF Value-Based Purchasing Program. This program evaluates SNFs on 4 outcome measures: 30-day all-cause readmission, infections requiring hospitalization, nursing staff turnover, and staffing hours per resident day [7]. No patients developed infections requiring hospitalization in this cohort and only 2 patients were discharged from the SNF to the hospital. This data set did not provide 30-day follow-up for discharged patients. This analysis highlights how VHT may provide value to SNFs, both in terms of efficacy and in supporting CMS quality measures.

Subgroup Analyses

The unique dataset used for this analysis included a variety of wound types of varying complexity, reflecting real-world wound care in SNFs. Factors, including wound age, size, and etiology, can impact wound healing rates. Additional analysis of this data, stratified by various characteristics, was performed to better understand the effect of VHT.

<u>Wound Age</u>

Chronicity is a key factor in wound healing. Wounds become less likely to resolve over time due to the risk of additional complications such as infection, and biological changes in the wound area as cell and growth factor function becomes impaired [8]. Chronic wounds are typically defined as wounds that have not made significant progress to closure within 30 days of presentation [9]. In this dataset, 9 wounds (21.4%) were considered chronic based on their date of presentation to the facility, and 22 wounds (52.4%) were reported as less than 1 week old (**Figure 3a**). Among the wounds that healed in this cohort, there was no statistical difference in healing time based on wound age at presentation (**Figure 3b**).

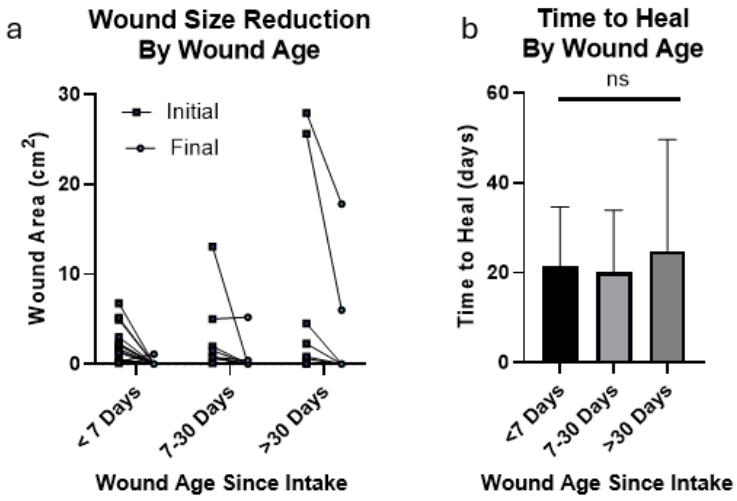


Figure 3: *Subgroup analysis stratified by wound age since SNF intake. a) Paired representation of initial (square) and final (circle) wound size. b) Bar graph showing time to heal (mean ± 95% CI) of wounds healed with VHT. ns: not significant by Kruskal-Walis non-parametric ANOVA, p=0.5749.*

However, this likely underestimates the true age of the wounds in this analysis. Wound age in this data set was reported as time since the wound was first seen for treatment by the facility or any referring providers. It is possible wounds were present for longer before “Day 1” of care at the SNF, particularly for patients who were not residents of the SNF prior to starting treatment. This further suggests VHT as an effective treatment for older or chronic wounds.

In the fee-for-service utilization setting, Medicare Part B reimbursement for VHT (procedure code 97610) typically requires the wound to be chronic for 30 days, unable to tolerate sharp debridement, or too painful to debride. However, the SNF has no such requirements to begin VHT therapy as SNFs operate within a value-based environment focused on reducing hospitalizations, faster healing rates, and improving quality. As a result, the SNF may initiate VHT therapy immediately when clinically appropriate to support patient outcomes, avoid negative quality events, and promote Medicare sequestration earn-back. This highlights the ability of VHT to effectively treat more wounds more quickly in the SNF setting, a unique advantage in this site of care.

There are other unique advantages of VHT in SNFs for the treatment of acute and chronic wounds. Within wound care, many advanced tissue and biologic based products have been developed for the treatment of chronic wounds, known as Cellular, Acellular, and Matrix-like Products (CAMPs). Though effective, CAMPs can be quite costly, and are typically not applied in the SNF setting. With nearly 70% of wounds in this cohort healed within 4 weeks (**Figure 1a**), VHT may heal wounds in lieu of products such as CAMPs, thereby improving outcomes. However, previous data have also shown that VHT optimizes the wound bed for more effective CAMP application in other care settings, highlighting the role of VHT in supporting wound care practices across the continuum of care [3].

Wound Type

DFUs, VLUs, arterial ulcers, and pressure injuries are considered among the “hard-to-heal” wounds due to the underlying systemic and patient factors that contribute to their formation. In clinical trial settings, these wounds are typically studied individually. This cohort contained these wound types as well as post-surgical wounds, and the data was stratified by etiology to identify differences in VHT effectiveness.

In this data set, all wounds of surgical, diabetic, and venous etiology healed, though no wounds of arterial etiology healed during the observation period (**Figure 4a**). However, sample sizes were small for these wound types. Pressure ulcers were the most common wound type in this cohort and only three wounds did not heal, of which two are currently undergoing VHT treatment and have reduced in size. Among wounds that did heal, there was no statistical difference in the time required to heal with VHT (**Figure 4b**), though high variance and small sample sizes limit the conclusions to be drawn from this. Still, these data show that facilities who treat multiple wound types, including SNFs, may be able to incorporate VHT treatment effectively for the diverse populations they see.

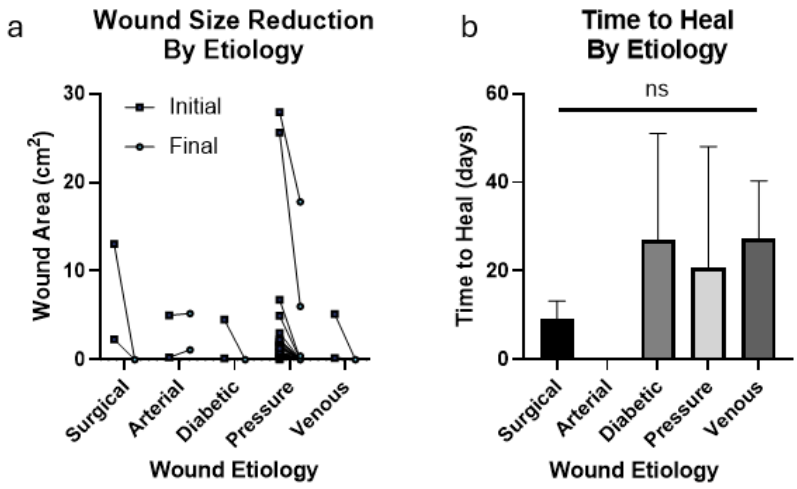


Figure 4: *Subgroup analysis stratified by wound etiology. a) Paired representation of initial (square) and final (circle) wound size. b) Bar graph showing time to heal (mean ± standard deviation) of wounds healed with VHT. ns: not significant by Kruskal-Walis non-parametric ANOVA, p=0.2889.*

Initial Size

Larger wounds are also traditionally considered harder to heal because more tissue needs to be restored [10], though many chronic wounds can be quite small. Most wounds in this cohort (39, 92.9%) were less than 10 cm^2 in area (**Figure 5a**). Among the wounds larger than 10 cm^2 (3, 7.1%), one wound healed and one has reduced in size and is still undergoing treatment. Among healed wounds, there was also no difference in the average time to healing with VHT treatment dependent on

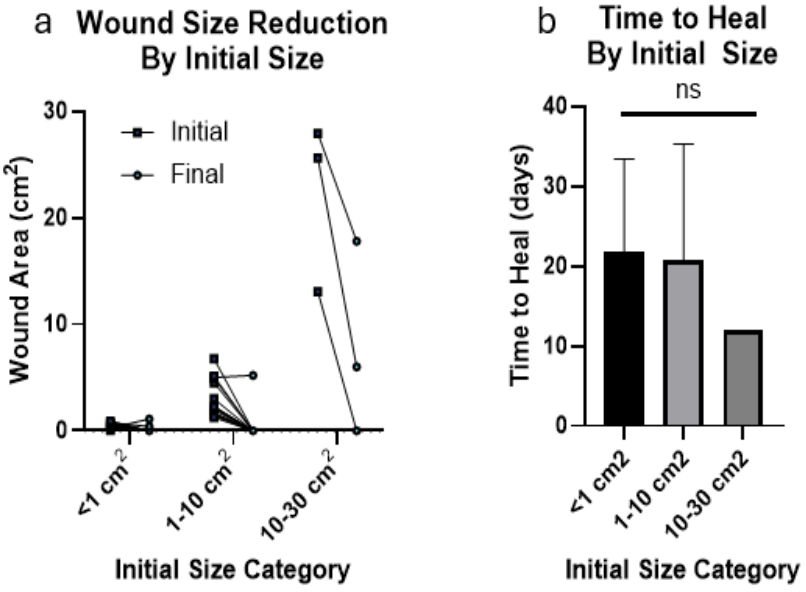


Figure 5: *Subgroup analysis stratified by wound size at presentation. a) Paired representation of initial (square) and final (circle) wound size. b) Bar graph showing time to heal (mean ± 95% CI) of wounds healed with VHT. ns: not significant by Kruskal-Walis non-parametric ANOVA, p=0.5685.*

initial wound size (**Figure 5b**), though only one wound could be analyzed in the largest wound size category.

Different wound types can vary significantly in size, though many are <10 cm^2 in area upon presentation. Both wound age and etiology can contribute to initial wound size, depending on the cause and extent of the tissue breakdown. Combined with other factors in this analysis, these data support VHT as an effective treatment for a variety of wounds.

Observations of Wound Healing in Advanced Tissue Failure

End-of-life skin breakdown is a unique type of wound that was observed in this cohort due to the primarily elderly population. These ulcers are often only managed for pain and infection palliative care, without a specific goal for healing. Across multiple cases in this cohort, clinically meaningful wound improvement and closure was observed in patients receiving VHT under terminal care. These observations do not suggest reversal of true Kennedy terminal ulcers, which present rapidly in the final days of life, but indicate that not all late-stage skin breakdown follows an irreversible trajectory.

In several instances, wounds that would typically be expected to stagnate or deteriorate instead demonstrated progressive healing. Three patients, including 2 greater than 90 years of age, had wounds close within 6 months prior to death. These cases illustrate that, even in the context of advanced tissue failure and declining systemic reserve, localized wound healing can occur. This raises important considerations for how clinicians assess prognosis, interpret tissue failure, and determine treatment goals in end-of-life care, and represents a unique potential application for VHT.

Conclusion

The findings from this small, single-facility, retrospective analysis demonstrate that VHT was highly effective in supporting wound healing within a skilled nursing setting. While the sample size limits broad generalizability, the results align with previously published evidence and further strengthen the case for VHT as a valuable therapeutic option. Notably, its efficacy was consistent regardless of wound age or size at presentation, and closed most wound types observed in this cohort. This suggests broad applicability of VHT within the diverse SNF patient population.

VHT may also contribute directly or indirectly to all four of the CMS Value-Based Purchasing Program measures: 30-day all-cause readmission, infections requiring hospitalization, nursing staff turnover, and staffing hours per resident day. Few hospital readmissions and no wound infections requiring hospitalization were observed in this cohort, representing direct benefits for the SNF in this Medicare earn-back program. Communications with facility also noted an overall decrease in staffing time as wounds resolve and therefore do not require continuous care. Furthermore, improved wound outcomes were reported as an asset in talent recruitment and staff retention, reducing staff turnover. Overall, VHT use was reported to align resident well-being with financial benefit for the SNF.

Additional study is warranted to further elucidate the full value of VHT treatment in wound care: potential analysis of the intent-to-treat population of this cohort, additional studies

of larger patient populations, and further healthcare economics and outcomes research (HEOR) analysis. Overall, the data strongly indicate that VHT is an effective wound treatment complementary to standard of care practices and, in the context of previous work, as an adjunct to advanced wound care techniques.

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