CLINICAL SUMMARY

A PROSPECTIVE, MULTI-CENTER NON-RANDOMIZED STUDY TO EVALUATE THE QUALITY OF LIFE IMPACT AFTER TREATMENT OF NASAL AIRWAY OBSTRUCTION USING THE AERIN VIVAER® ARC STYLUS

Published Title

Quality-of-life impact after in-office treatment of nasal valve obstruction with a radiofrequency device: 2-year results from a multicenter, prospective clinical trial

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Study Overview

This investigation was a prospective, non-randomized, multi-center, extended follow-up study of patients with symptoms of severe or extreme nasal obstruction who participated in and completed a multi-center trial that evaluated the safety and efficacy of the VivAer® ARC Stylus (VivAer[1]) treatment on the nasal valve. The 39 participants in this follow-up study provided self-administered evaluations of NOSE Scale score and Quality of Life (QoL) measures at 12, 18, and 24 months after the treatment procedure. The 68.7% improvement in NOSE Scale score at 6 months was similarly observed at the 12-, 18-, and 24-month evaluations, with statistically significant ($p<0.0001$) improvements of 65.2%, 59.6%, and 66.5%, respectively. Additionally, respondents at the 12-, 18-, and 24-month evaluations indicated improvements across a broad set of QoL measures which included improved sleep quality, lower daytime fatigue, increased overall well-being, and less frequent use of oral medications, nasal sprays, and nasal breathing strips. The results of this study demonstrate that VivAer treatment of the nasal valve in select patients presenting with nasal obstruction was safe and was associated with durable improvement in symptoms of nasal obstruction and nasal obstruction related QoL over 2 years.

[1]VivAer is the next generation of the original study device (Vivaer® ARC Stylus), both of which are functionally equivalent and have the same indication for use

Objective

To determine if the safety and efficacy results achieved at the 6-month timepoint for the VivAer pivotal trial would be sustained at the 24-month timepoint

Outcome measures

Primary outcome measures

- Change from baseline NOSE score to 12-, 18-, and 24-months post-procedure
- Number and percentage of participants with positive response on QoL assessment items at 12-, 18-, and 24-months post-procedure
- Change from baseline NOSE score to 36-, 48-, and 60-months post-procedure
- Number and percentage of participants with positive response on QoL assessment items at 36-, 48-, and 60-months post-procedure

Patient eligibility:

All subjects enrolled in this trial previously completed participation in the original 6-month publication[2], which adhered to the following patient eligibility criteria:

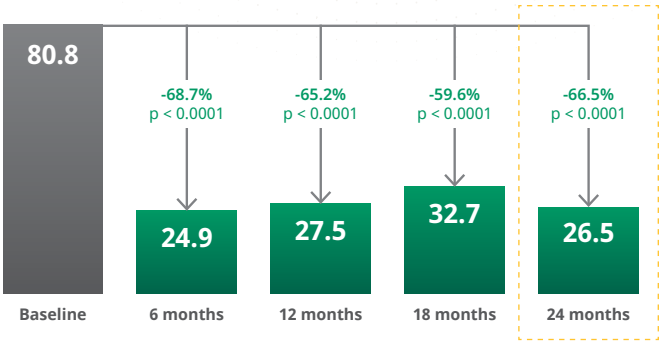
Key inclusion criteria	Key exclusion criteria
• Age 22-75 years • NOSE score of ≥60 at baseline • Nasal valve collapse as primary or a significant contributor to nasal obstruction • Positive response to temporary measure like external nasal dilator strips (e.g., Breathe Right Strips), Q-tip test, nasal stents, and Cottle Maneuver	• Prior surgical treatment of the nasal valve • Surgical nasal procedure (e.g., rhinoplasty, septoplasty, etc.) within the past twelve (12) months • Chronic sinusitis, recurrent sinusitis, or allergies leading to nasal obstruction • Septal deviation, turbinate hypertrophy, polyps, or ptotic nose (“droopy” or long nose) believed to be a significant contributor to nasal obstruction symptoms

[2]In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device (https://onlinelibrary.wiley.com/doi/10.1002/lio2.247)

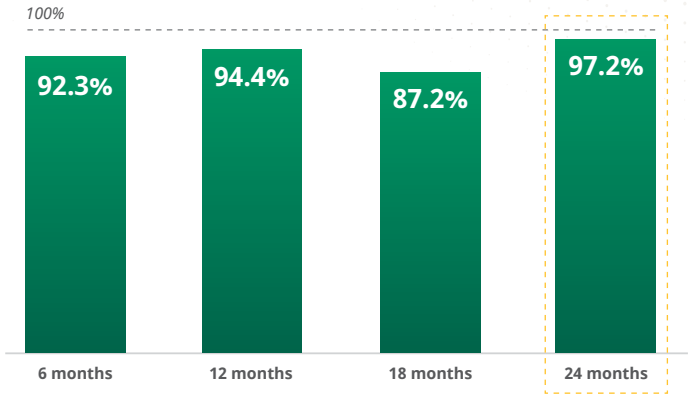
KEY FINDINGS

VivAer was an effective and durable treatment for reducing the symptoms of nasal obstruction

Improvement (Decrease) in NOSE Score from Baseline to 6, 12, 18, and 24 months



Responder Rate[3] at 6, 12, 18, and 24 months (%)



- Patients sustained a 66.5% improvement in their NOSE Scale score at two years, which is comparable with the 68.7% improvement observed at the 6-month original study endpoint
- 97.2% of patients, who are responders at 24 months, had a significant and sustained reduction in their nasal obstruction symptoms

[3]Responder rate defined as percentage of patients with a ≥15-point decrease in NOSE Scale score compared to baseline

VivAer delivered lasting improvements across a broad set of QoL measures associated with nasal obstruction

Select QoL measures reported at 24 months

Experience since the procedure	Agree or agree strongly at 24 months
Less difficulty falling asleep	77.8%
Less waking at night	69.4%
Better sleep throughout the night	72.2%
Woke up feeling rested	61.1%
Less fatigue during the day	52.8%
Increased sense of overall well-being	63.9%
Use of medication or mechanical aids	**Less or much less frequent at 24 months**
Oral medications	66.7%
Nasal sprays	63.9%
Nasal breathing strips	80.6%

Note: comprehensive list of all 21 QoL measures reported at the 12- and 24-month timepoints can be found in TABLE 3 in the original published article

- Respondents reported improvements with sleep, with 77.8% agreeing or strongly agreeing that they had less difficulty falling asleep at two years
- Additionally, >60% of respondents agreed or strongly agreed that they had less waking at night, better sleep throughout the night, and woke up feeling rested at two years
- Over half of the respondents agreed or strongly agreed that they felt less fatigue during the day and increased sense of overall well-being at two years
- Respondents reported reduced reliance on medication or mechanical aids, with >60% decreasing or less frequently using oral medications, nasal sprays, and nasal breathing strips at two years

ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT03290300

International Forum of Allergy & Rhinology: https://onlinelibrary.wiley.com/doi/10.1002/alr.22667

Please scan QR code to access the full online publication

Indication for use: the VivAer® Stylus is indicated for use in otorhinolaryngology (ENT) surgery for the coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area.

To learn more about VivAer, please visit VivAer.com

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