CLINICAL SUMMARY

Long-term outcomes following repair of nasal valve collapse with temperature-controlled radiofrequency treatment for patients with nasal obstruction

VivAer® Pivotal Study 4-year Follow-up

Authors & Investigators

- Ofer Jacobowitz, MD PhD (New York, NY)*^
- Dale Ehmer, MD (Plano, TX)
- Brent Lanier, MD (Fresno, CA)
- William Scurry, MD (Winston-Salem, NC)
- Bryan Davis, MD (Colorado Springs, CO)

**Corresponding author, ^Principal investigator*

Study Overview

This investigation was the long-term follow-up to an initial prospective, single-arm, multicenter study that enrolled patients with chronic severe or extreme nasal airway obstruction (NAO) with nasal valve collapse (NVC). All patients underwent bilateral treatment with VivAer® (VivAer), a minimally-invasive temperature-controlled radiofrequency (TCRF) procedure. Of the 49 patients in the initial study, 29 patients participated in this long-term follow-up that assessed patient NOSE Scale scores at 12-, 18-, 24-, 36- and 48-months post procedure. NOSE scores decreased from 81.0 at baseline to 32.3 and 25.7 at 36- and 48-months, respectively. Based on a ≥15-point improvement on the NOSE Scale score, 92.9% and 96.4% of patients were considered responders at the 36- and 48-month follow-ups, respectively. In this longest follow-up report of patient outcomes to date, significant and sustained improvements in symptoms of NAO were shown through 4 years following treatment of NVC with VivAer.

Objective

To assess the long-term durability of TCRF treatment of NVC for relief of symptoms of NAO through 48 months in a cohort of patients enrolled in a prospective study with previously reported results.

Outcome measures

Primary outcome measures
• Change from baseline NOSE score to 12-, 18-, 24-, 36- and 48-months post-procedure • Responder rate (≥15-point NOSE score vs. baseline) at 12-. 18-. 24-. 36-. And 48-months post procedure

Patient eligibility

All subjects enrolled in this long-term follow-up previously completed participation in the initial 6-month pivotal study[1], which was amended to track patient outcomes to the 48-month timepoint. The patient eligibility criteria of the pivotal study was:

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 • Participated through 24 months in original study	• 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

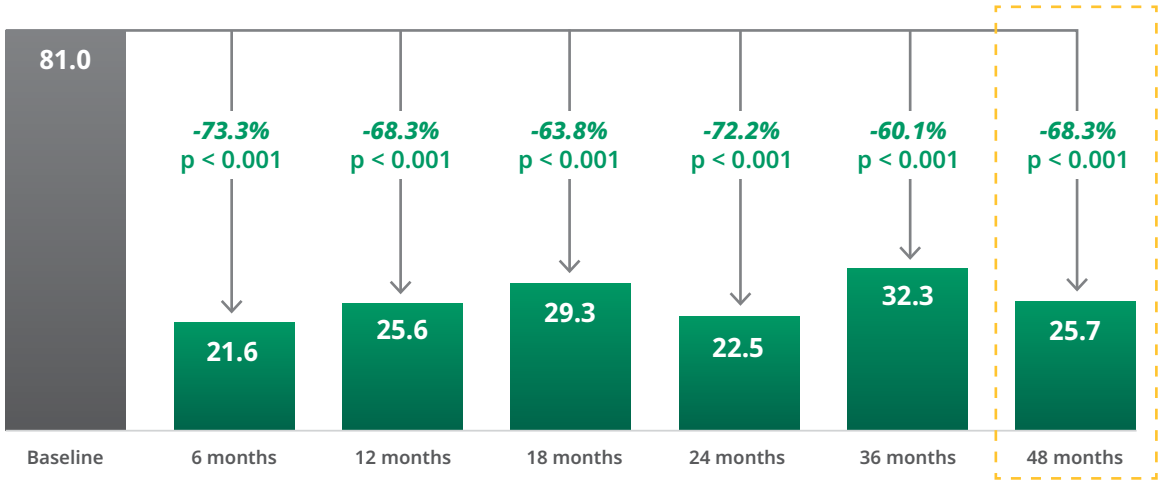
[1]*Jacobowitz, O., Driver, M. and Ephrat, M. (2019), In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device. Laryngoscope Investigative Otolaryngology, 4: 211-217. https://doi.org/10.1002/lio2.247*

KEY FINDINGS

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

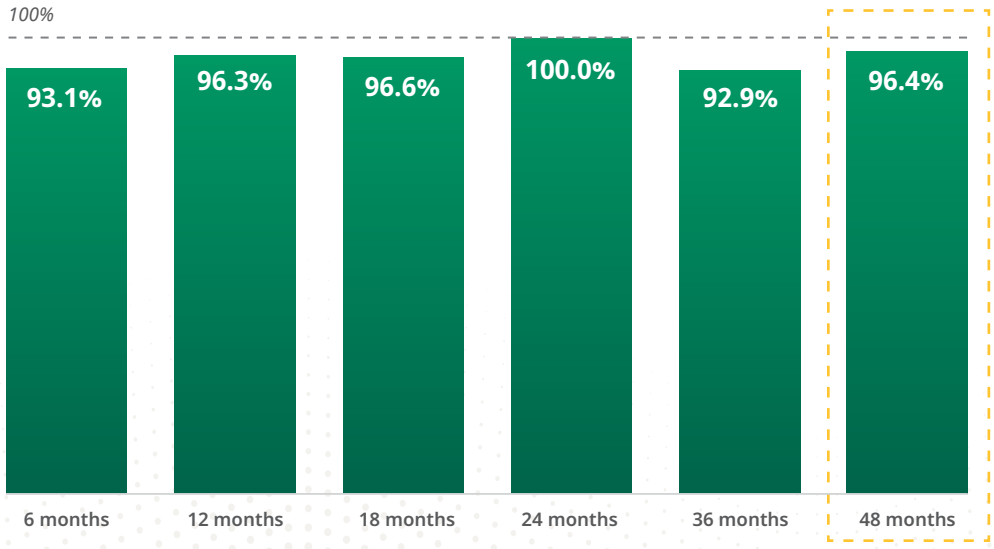
- Patients sustained a significant (p<0.001), 68.3% improvement in their NOSE Scale score at four years, which is comparable with the >60% NOSE Scale score improvements observed at the 6-, 12-, 18-, 24-, and 36-month timepoints

Improvement (Decrease) in NOSE Score from Baseline to 6, 12, 18, 24, 36, and 48 months



- The >90% treatment responder rate (≥15-point improvement on the NOSE Scale score versus baseline) observed through 48 months was similar to responder rates observed at all other timepoints for this cohort of patients

Responder Rate at 6, 12, 18, 24, 36, and 48 months (%)



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

International Forum of Allergy & Rhinology: https://doi.org/10.1002/alr.23019

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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