

Outcomes 12 Months After Temperature-Controlled Radiofrequency Device Treatment of the Nasal Valve for Patients With Nasal Airway Obstruction

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[+ Supplemental content](#)

IMPORTANCE Nasal valve collapse is a primary cause of nasal airway obstruction (NAO). Patients with NAO and nasal valve collapse experience a variety of symptoms that lower their quality of life, such as nasal congestion, headache, sleep disturbance, daytime sleepiness, and snoring.

OBJECTIVE To determine if active treatment of the nasal valve with a temperature-controlled radiofrequency (TCRF) device, previously demonstrated superior to a sham procedure at 3 months, was safe and associated with sustained improvements in symptoms of NAO through 12 months.

DESIGN, SETTING, AND PARTICIPANTS In a prospective, multicenter, single-blinded, randomized clinical trial, patients in 16 centers in the US with index procedures between August and December 2020 were assigned to TCRF device treatment of the nasal valve or a sham control procedure (no RF energy). Patients had a baseline Nasal Obstruction Symptom Evaluation (NOSE) Scale score of 55 or greater with nasal valve collapse as the primary or substantial contributor to NAO. After primary end point evaluation at 3 months, eligible patients in the sham control arm crossed over to active treatment. Data analysis was performed between April and May 2022.

INTERVENTIONS Patients were treated bilaterally with the TCRF device at 4 or fewer nonoverlapping areas on the nasal mucosa at the junction of the upper and lower lateral cartilage on the lateral nasal wall.

MAIN OUTCOMES AND MEASURES The primary end point measure was responder rate, defined as 20% or greater reduction in NOSE Scale score or 1 or greater reduction in NOSE Scale clinical severity category.

RESULTS A total of 108 patients received active treatment (77 as index active treatment, 31 after crossover). The mean (SD) age of patients was 48.5 (12.3) years; 66 (61.1%) were women. The combined group of patients receiving active treatment had a mean baseline NOSE Scale score of 76.3 (95% CI, 73.6-79.1). At 12 months (n = 88), the responder rate was 89.8% (95% CI, 81.7%-94.5%). The NOSE Scale score improved from baseline (mean change, -44.9 [95% CI, -52.1 to -37.7]). No device/procedure-related serious adverse events were reported.

CONCLUSIONS AND RELEVANCE In this follow-up of a cohort from a randomized clinical trial, the minimally invasive TCRF device, previously demonstrated to be superior to a sham procedure, was safe and associated with improvement in symptoms of NAO through 12 months postprocedure.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: [NCT04549545](#)

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JAMA Otolaryngol Head Neck Surg. doi:10.1001/jamaoto.2022.2293
Published online September 1, 2022.

Nasal valve collapse is recognized as a primary cause of nasal airway obstruction (NAO).¹⁻³ Treatment options for nasal valve collapse include external/internal nasal dilators, surgical functional rhinoplasty and/or nasal valve repair, and bioabsorbable graft techniques.⁴⁻⁷ Temperature-controlled radiofrequency (TCRF) device treatment on the nasal mucosa at the junction of the upper and lower lateral cartilage on the lateral nasal wall has been shown to improve the symptoms of nasal valve collapse and NAO through 2-year follow-up.⁸⁻¹⁰ Treatment with a TCRF device is designed to cause tissue tightening effects within the submucosal layer of the lateral nasal wall. Radiofrequency-induced heating has been shown to induce tissue tightening and contraction through immediate contraction of existing collagen proteins and through the induction of the production of new collagen over the long term.^{11,12} The procedure is performed in the office, and it has been demonstrated that the device/procedure does not create aerosol above background levels in an in-office awake (exhaling) patient cadaveric model.¹³ The procedure is minimally invasive, does not involve implanting a foreign body that may extrude, and may provide an alternative for some patients who either wish to avoid surgery or may not be good surgical candidates.

A 3-month report on this randomized clinical trial (RCT) demonstrated the superiority of a minimally invasive TCRF device over a sham control procedure for the treatment of nasal valve collapse and NAO.¹⁴ Here, 12-month outcomes of all patients who underwent active TCRF device treatment of the nasal valve are reported—a combination of patients in the index active treatment arm and patients in the index sham control arm who were eligible and elected to crossover to active treatment after primary end point analysis.

Methods

Trial Design

This was a cohort follow-up of a prospective, single-blinded (patient) RCT with a sham procedure control arm. The design was a superiority trial with crossover available to eligible sham control-arm patients after 3-month follow-up and primary end point analysis. The trial will continue follow-up through 2 years. Patients were enrolled at 16 centers in the US, and index procedures were performed between August and December 2020. The WCG Institutional Review Board (IRB) (20201804) approved the trial at all enrolling centers except Eastern Virginia Medical School (EVMS), where the trial was approved by the EVMS IRB (20-09-FB-0189). All center principal investigators were board-certified otolaryngologists-head and neck surgeons. Patients gave written informed consent prior to enrollment. The trial protocol is available in [Supplement 1](#).

Trial Arm and Baseline Definitions

Arms are referred to as index active treatment, index sham control, and crossover active treatment. The combined active treatment group contains patients from the index active treatment arm and the crossover active treatment arm. The term *baseline in the index active treatment* arm refers to the out-

Key Points

Question Is temperature-controlled radiofrequency device treatment of the nasal valve safe and associated with improvement in symptoms of nasal airway obstruction through 12 months postprocedure?

Findings At 12-month follow-up of 108 patients treated in a randomized clinical trial with 3-month crossover available to patients in the index sham control arm, patients in the combined active treatment group exhibited a sustained improvement in symptoms over baseline, measured by the Nasal Obstruction Symptom Evaluation Scale.

Meaning Temperature-controlled radiofrequency device treatment of the nasal valve was associated with a sustained improvement in symptoms of nasal airway obstruction through 12 months.

come measure value prior to original active treatment procedure, and in the case of the crossover active treatment arm, *baseline* refers to the value reported at the time of requalification for crossover.

Patients self-identified race and ethnicity. Race and ethnicity classifications were adapted from US Food and Drug Administration-recommended classifications. These data were assessed to aid in interpretation of trial generalizability and conclusions and frame any relevant implications for clinical care.

Unblinding and Crossover

Patients were originally randomized to either the index active treatment arm or the index sham control arm via a web-based randomization module integrated into the trial's electronic data capture system. A 2:1 randomization scheme was used, and patients were blinded to their index assignment. Patients were also blindfolded during the procedure. The VivAer System consists of the Aerin Console and VivAer Stylus (Aerin Medical). For the sham procedure, the stylus was applied in the same manner but without RF energy delivery, while audible tones mimicking activation of the console were played. At 3 months, index sham control arm patients were invited to crossover to active treatment if they still met eligibility criteria. Index sham control patients who were not eligible for crossover or did not want to further participate in the trial were exited from the trial. Patients who underwent additional nasal procedures at any time during follow-up were exited from the trial.

Eligibility Criteria

A complete list of eligibility criteria is available in [eTable 1 in Supplement 2](#). Key inclusion criteria were patients aged 18 to 85 years seeking treatment for nasal obstruction; a baseline Nasal Obstruction Symptom Evaluation (NOSE) Scale score of 55 or greater; nasal valve collapse as the primary or substantial contributor to the nasal obstruction; a positive response to a temporary nasal dilation measure, such as the modified Cottle maneuver; and patient dissatisfaction with medical management. However, no standard medication regimen prior to inclusion or intervention was dictated by the protocol. Key exclusion criteria were prior surgery of the lateral nasal wall and

a severe case of septal deviation, turbinate hypertrophy, polyps, or ptotic nose tip believed to be the primary contributor to the nasal obstruction symptoms and warranting surgical intervention.

Intervention

Crossover active treatment patients underwent the same procedure and follow-up regimen as index active treatment patients. Topical anesthesia was applied to the mucosal surface of treatment area, followed by injection of lidocaine/epinephrine. The VivAer System consists of the Aerin Console and VivAer Stylus. Patients were treated bilaterally with the VivAer Stylus on 4 or fewer nonoverlapping areas on the nasal mucosa at the junction of the upper and lower lateral cartilage on the lateral nasal wall. Treatment settings were temperature, 60 °C; power, 4 W; treatment time, 18 seconds; cooling time, 12 seconds. No repeat touch-up procedures were allowed.

Outcome Measures

Outcome instruments were the NOSE Scale^{15,16} and the Epworth Sleepiness Scale.^{17,18} Adverse events were recorded throughout and classified based on relationship to the device and/or procedure. The primary and secondary end point measures of this trial analyzed at 3, 6, and 12 months postprocedure were (1) responder rate, where a responder was defined as 20% or greater improvement (decrease) in NOSE Scale score or 1 or greater NOSE Scale severity category improvement¹⁶ from baseline, and (2) the mean change in NOSE Scale score from baseline. The mean change in Epworth Sleepiness Scale score from baseline was also analyzed at 3, 6, and 12 months postprocedure. NOSE Scale and Epworth Sleepiness Scale data were also collected at 1 month postprocedure; however, they are not included here because of the long-term follow-up focus of this report.

Nasal Valve Collapse Mechanism Definitions

Patients were divided into 4 groups for subgroup analysis based on nasal valve collapse mechanism: bilateral dynamic collapse, bilateral static collapse, bilateral static and dynamic collapse, and complex. Definitions were as follows: dynamic—movement of the nasal valve during the Cottle Maneuver; static—no movement during the Cottle Maneuver; and dynamic and static (combined in one nostril)—movement and no movement of the nasal valve at different stages of the respiratory cycle. The complex group included patients with a different or mixed mechanism on each side, ie, dynamic on 1 side, static on the other; or static and dynamic on 1 side, static or dynamic on the other side.

Statistical Analysis

The pretrial sample size calculation of 120 total patients was calculated on an expected responder rate of 50% in the control arm and 80% in the treatment arm, 80% power, and a 10% dropout rate. Analysis was performed using the intention-to-treat principle. Continuous data are presented as mean and 95% CI except where noted, and categorical data as number (percentage of total). The NOSE Scale and Epworth Sleepiness Scale outcomes were assessed using lin-

ear mixed-effects model to test for an overall change over time; adjusted (least squares) means are presented, with Tukey-Kramer comparisons between baseline and follow-up visits. A negative change indicates an improvement (decrease) in each measure. Generalized estimating equations were used to assess repeated binomial outcome measures (responder rate) and repeated multinomial ordered categorical distributions (NOSE Scale clinical severity categories). Statistical analysis was performed using SAS/STAT, version 15.2 (SAS Institute Inc).

Results

Patient Disposition

A total of 119 eligible patients were randomized, and 117 (77 active treatment and 40 sham control) were included in the analysis of the 3-month primary end point (Figure 1).¹⁴ After primary end point analysis and unblinding, 31 patients were eligible for crossover, and all elected to undergo active treatment. Two patients who crossed over were found to be ineligible during trial monitoring but were included in data analysis. Therefore, a total of 108 patients underwent active treatment in the trial. The baseline demographics and characteristics of the patients in the combined active treatment group are shown in the Table. The crossover active treatment arm (n = 31) had a mean baseline NOSE Scale score of 75.5 (95% CI, 68.8-82.1), which was comparable to that of the index active treatment arm (76.7 [95% CI, 73.8-79.5]).

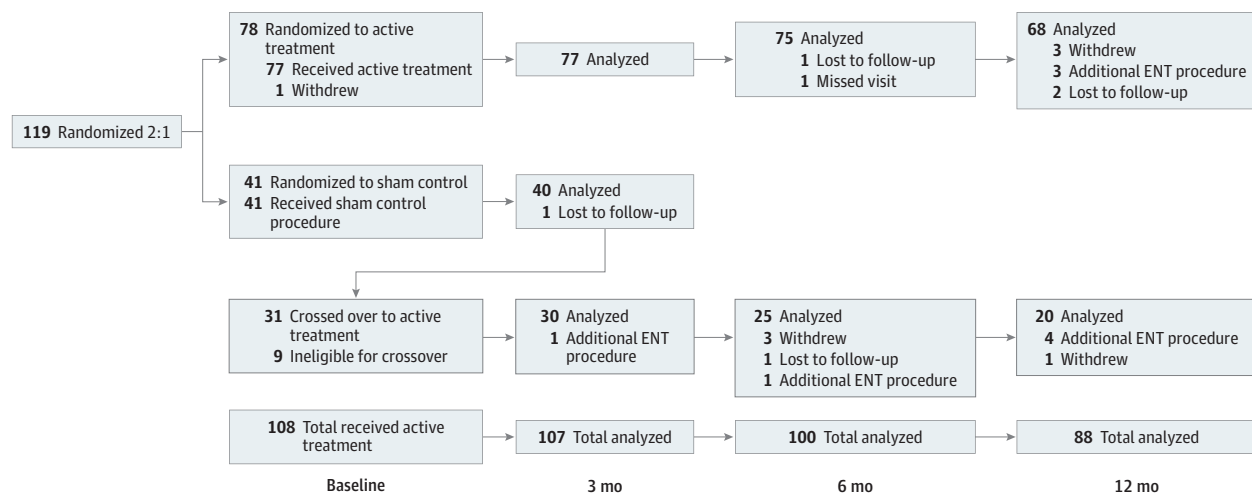
NOSE Scale Results

The mean baseline NOSE Scale score of the combined active treatment group was 76.3 (95% CI, 73.6-79.1). The responder rate of the combined active treatment group was 86.0% (95% CI, 78.2%-91.3%), 91.0% (95% CI, 83.8%-95.2%), and 89.8% (95% CI, 81.7%-94.5%) at 3, 6, and 12 months, respectively (Figure 2; eTable 2 in Supplement 2). For context, primary end point analysis at 3 months previously showed a greater responder rate of 88.3% (95% CI, 79.2%-93.7%) in the index active treatment arm vs 42.5% (95% CI, 28.5%-57.8%) in the index sham control arm.¹⁴

The NOSE Scale score of the combined active treatment group improved from baseline at all follow-up time points: an adjusted mean change of -40.9 (95% CI, -47.3 to -34.6), -43.2 (95% CI, -50.1 to -36.3), and -44.9 (95% CI, -52.1 to -37.7) at 3, 6, and 12 months, respectively (Figure 3; eTable 2 in Supplement 2). These data represent 53.6%, 56.6%, and 58.8% improvement in NOSE Scale score from baseline at 3, 6, and 12 months, respectively. Secondary end point analysis at 3 months previously showed a greater mean change in NOSE Scale score from baseline of -42.3 (95% CI, -47.6 to -37.1) in the index active treatment arm vs -16.8 (95% CI, -26.3 to -7.2) in the sham control arm.¹⁴

In the combined active treatment group, 106 (98.1%) patients were classified as having extreme or severe obstruction at baseline based on the NOSE Scale severity classification system.¹⁶ At 3 months after active treatment and thereafter, there was a shift toward lower severity categories comparing

Figure 1. Patient Disposition



ENT indicates ear, nose, and throat.

each follow-up time point with baseline (Figure 4; eTable 3 in Supplement 2).

The adjusted mean changes in each NOSE Scale component score (ie, nasal congestion/stuffiness, nasal blockage/congestion, trouble breathing through the nose, trouble sleeping, and unable to get enough air through the nose during exercise or exertion) in the combined active treatment group represent an improvement from baseline at each follow-up time point through 12 months (eTable 2 and eFigure in Supplement 2).

NOSE Scale Subgroup Analyses

Patients with different nasal valve collapse mechanisms, including static and dynamic nasal valve collapse, were treated in the trial. Subgroup analysis of the combined active treatment group showed TCRF device treatment was effective in reducing the symptoms of NAO regardless of the mechanism of nasal valve collapse; the NOSE Scale scores in each of the 4 groups were comparable at all follow-up time points through 12 months. For example, the adjusted mean change in NOSE Scale score for bilateral dynamic nasal valve collapse ($n = 43$) was -42.8 (95% CI, -56.9 to -28.8) and -48.9 (95% CI, -66.4 to -31.3) for bilateral static nasal valve collapse ($n = 26$) at 12 months (further details in eTable 4 in Supplement 2).

Prior nasal surgery (detailed in eTable 5 in Supplement 2) did not have an association with the extent of improvement through 12 months. The mean baseline NOSE Scale score of patients in the combined active treatment group without prior nasal surgery ($n = 77$) was 75.8 (95% CI, 72.6 - 79.1) and of patients with prior nasal surgery ($n = 31$) was 77.6 (95% CI, 72.5 - 82.7). The adjusted mean change in NOSE Scale score at 12 months for those without prior nasal surgery ($n = 64$) was -46.7 (95% CI, -56.7 to -36.6) and for those with prior nasal surgery ($n = 24$) was -40.5 (95% CI, -56.6 to -24.4).

Epworth Sleepiness Scale Results

The mean baseline Epworth Sleepiness Scale score of patients in the combined active treatment group was 10.3 (95% CI, 9.2 - 11.4). The score improved from baseline at all follow-up time points, and the adjusted mean change at 12 months was -4.8 (95% CI, -6.0 to -3.7) (eTable 6 in Supplement 2). In the 51 (47.2%) patients with baseline scores of 11 or higher, indicative of excessive daytime sleepiness,¹⁸ the improvement was larger; the mean score at baseline was 15.6 (95% CI, 14.8 - 16.4), and the adjusted mean change in score at 12 months was -7.4 (95% CI, -9.1 to -5.8) (eTable 6 in Supplement 2).

Patients Exited From the Trial or Lost to Follow-up (With Follow-up Data)

Of the 11 patients lost to follow-up or who withdrew after either index or crossover active treatment, 9 had an improvement in NOSE Scale score and 6 were responders at their last visit. Of the 9 patients who were exited from the trial to undergo an additional nasal procedure after active treatment, 8 had an improvement in NOSE Scale score and 6 were responders at the time of trial exit. The additional nasal procedures were primarily to address turbinate hypertrophy ($n = 4$) and/or sinus disease ($n = 3$) (eTable 7 in Supplement 2). Patients who exited the trial for additional nasal procedures did not have any ongoing related adverse events at the time of trial exit.

Concomitant Medication and Mechanical Nasal Aid Analysis

Medications tracked during the trial were antihistamines, decongestants, leukotriene inhibitors, intranasal steroids, anticholinergics, and immunotherapy. Use of nasal strips/cones was also tracked. The baseline use of medication/mechanical nasal aid classes in the combined active treatment group is shown in the Table. Analysis of medication/mechanical nasal aid use revealed an overall decrease in use over baseline at 12 months. In the 88 patients who reached

Table. Demographic and Baseline Characteristics

Characteristic	No. (%) (n = 108)
Sex	
Female	66 (61.1)
Male	42 (38.9)
Age, mean (SD), y	48.5 (12.3)
BMI, mean (SD)	29.0 (5.9)
Race	
American Indian or Alaska Native	2 (1.9)
Asian	2 (1.9)
Black or African American	6 (5.6)
White	96 (88.9)
Declined choices	2 (1.9)
Medical history	
Nasal surgery ^a	31 (28.7)
Allergic rhinitis ^b	43 (39.8)
Nonallergic rhinitis ^b	15 (13.9)
Sinus disease ^c	15 (13.9)
Obstructive sleep apnea	21 (19.4)
NOSE Scale score, mean (SD) ^d	76.3 (14.3)
Nasal valve collapse mechanism^e	
Bilateral dynamic	51 (47.2)
Bilateral static	34 (31.5)
Bilateral static and dynamic	15 (13.9)
Complex	8 (7.4)
Overall symptom management^d	
Medical management only ^f	63 (58.3)
Mechanical nasal aids only	3 (2.8)
Medical and mechanical management ^f	26 (24.1)
No medical/mechanical management	16 (14.8)
Medication and mechanical nasal aid use^d	
Antihistamines	53 (49.1)
Decongestants	28 (25.9)
Leukotriene inhibitors	14 (13.0)
Intranasal steroids	51 (47.2)
Anticholinergics	4 (3.7)
Immunotherapy	4 (3.7)
Nasal strips/cones	29 (26.9)

Abbreviations: BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; NOSE, Nasal Obstruction Symptom Evaluation.

^a Includes inferior/middle turbinate reduction/excision, septoplasty, rhinoplasty, sinuplasty, and functional endoscopic sinus surgery. Some patients may have undergone multiple procedures. A complete list is available in eTable 5 in Supplement 2.

^b Based on patient or clinician knowledge, no tests were performed as part of the trial.

^c A combination of acute sinusitis or chronic rhinosinusitis.

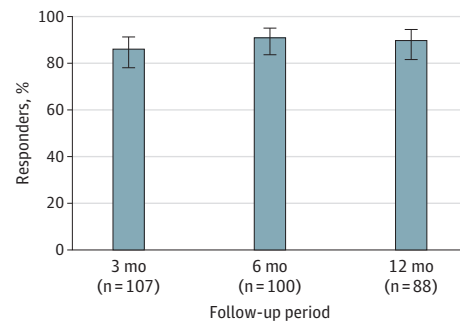
^d In the case of patients originally in the index active treatment arms, baseline is prior to the active treatment procedure. In the case of patients in the crossover active treatment arm, baseline refers to the outcome measure value reported at the time of requalification for crossover.

^e Definitions of nasal valve collapse mechanism groups are in the Methods.

^f Includes saline.

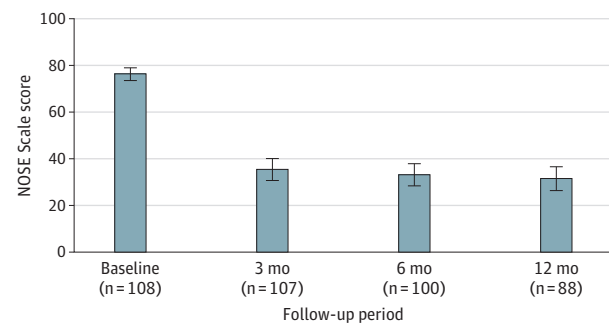
12 months, there was no change in medication/mechanical aid use in 24 (27.3%). The number of patients who decreased/stopped use in at least 1 class of medication/

Figure 2. Outcome Results: Responder Rate



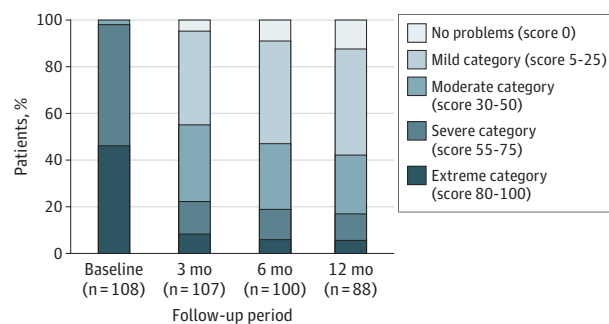
The percentage of patients designated responders, defined as 20% or greater improvement (decrease) in Nasal Obstruction Symptom Evaluation (NOSE) Scale score or 1 or greater NOSE Scale severity category improvement from baseline. Error bars indicate 95% CIs.

Figure 3. Outcome Results: Nasal Obstruction Symptom Evaluation (NOSE) Scale



Adjusted mean NOSE Scale score. Error bars indicate 95% CIs.

Figure 4. Outcome Results: Nasal Obstruction Symptom Evaluation (NOSE) Scale Severity Classification System



The percentage of patients classified in ordered NOSE Scale severity categories over time. There was a shift toward lower severity categories comparing each follow-up time point with baseline.

mechanical nasal aid was 59 (67.0%), of which only 2 coincidentally increased use in at least 1 other class. When considering individual classes that greater than 25% of patients were taking at baseline, 12 of 45 (26.7%), 12 of 23 (52.2%), 18 of 45 (40.0%), and 17 of 24 (70.8%) patients using antihistamines,

decongestants, intranasal steroids, and nasal strips/cones at baseline had completely stopped use at 12 months postprocedure, respectively. The number of patients who increased/started use of at least 1 class of medication/mechanical nasal aid was 7 (8.0%), of which 2 coincidentally decreased/stopped use in at least 1 other class. Further details are in eTable 8 in Supplement 2.

Safety Results

No serious adverse events with a relationship to the device/procedure occurred at any time in the trial to date. A total of 8 reported adverse events in 7 patients were designated with at least a possible relationship to either the device or procedure (eTable 9 in Supplement 2). One patient experienced a mild vasovagal reaction intraprocedure. Three patients reported nasal congestion: 1 with severe congestion at baseline reported ongoing severe nasal congestion as well as severe intermittent headache, and 2 (1 severe and 1 moderate) reported late events (>6 months postprocedure). One patient reported intermittent headache that self-resolved. Two patients reported nasal bleeding: 1 mild, occurring the day of the procedure, that self-resolved, and 1 severe, occurring 26 days postprocedure, that resolved within 48 hours with nasal packing and was thought to be related to nasal scab removal.

Discussion

This report provides 12-month results for patients in an RCT who received active TCRF treatment of the nasal valve to treat NAO in either the index active treatment arm or the crossover treatment arm. The results showed that active TCRF device treatment of the nasal valve area was associated with a durable reduction in the symptoms of NAO. The 12-month responder rate and reduction in NOSE Scale score were on par with the values that were superior to the sham control procedure at 3 months.¹⁴ At 12 months, patients who received active TCRF treatment were exhibiting improvement in all symptoms of NAO measured by the NOSE Scale. The safety profile of the active device treatment was excellent, with no device or procedure-related serious adverse events and few device or procedure-related adverse events observed.

To benchmark the 12-month treatment effect size (responder rate of 89.9% and NOSE Scale score of -44.9) with other procedures to treat NAO associated with nasal valve collapse, meta-analyses have reported pooled changes in NOSE Scale score of -49 (>6 months),¹⁹ and -43 (6-12 months)²⁰ after functional rhinoplasty. Furthermore, 12-month follow-up of an RCT evaluating a bioabsorbable implant treatment for dynamic nasal valve collapse reported a 85.2% responder rate (using the same definition of a responder as the current trial) and a change in NOSE Scale score from baseline of -41.²¹ However, it is noted that patient populations differ across studies, and this should be taken into consideration when comparing overall population data, including relevant outcomes.

NOSE Scale-based minimal clinically important differences from an anchor-based approach have been reported for nasal septoplasty (19.4)²² and functional, cosmetic, or combined rhinoplasty (24.4),²³ which are smaller than the mean changes in NOSE Scale score observed from 3 through 12 months postprocedure in this trial (where -40.9 was the minimum mean change in NOSE Scale score from baseline).

The treatment effect was durable regardless of the mechanism of nasal valve collapse (static or dynamic). Patients with prior nasal surgery also exhibited an improvement from baseline over time, and the improvement was comparable to those without prior nasal surgery. The mechanism of action of TCRF device treatment is to increase the cross-sectional area of the nasal valve, and this simple approach does not appear to be affected by different nasal valve collapse mechanisms or prior procedure status.

Patients with NAO and nasal valve collapse experience symptoms including sleep disturbance, daytime sleepiness, and snoring.^{24,25} The combined active treatment group as a whole had a slightly abnormal baseline score (10.3), and an improvement was still observed at 12 months (score, 5.5). The cohort of patients with a baseline score indicative of excessive daytime sleepiness (15.9) exhibited improvement to a score reflecting more normal daytime sleepiness¹⁸ at 12 months (score, 8.2). For comparison, 12-month follow-up of an RCT evaluating a bioabsorbable implant treatment for dynamic nasal valve collapse reported a mean Epworth Sleepiness Scale score of 6.5 in the entire cohort and 9.4 in patients with a baseline score indicative of excessive daytime sleepiness.²¹

This trial was pragmatic in its design in that medication use was not dictated by the protocol as patients are usually taking medications for a variety of indications. Sensitivity analysis on the primary end point previously demonstrated that the active treatment effect was greater than that of the sham procedure even when the change in NOSE Scale score for patients with an increase in medication/mechanical nasal aid use was imputed to zero.¹⁴ Although this trial was not designed to evaluate changes in medication use, the overall decrease in medication and/or mechanical aid use is encouraging.

Limitations

Medication use was not dictated by the protocol and could potentially have had some confounding effect on symptom relief; however, an overall decrease in medication use was observed. The results reported here are through 12 months, and although consistent with previously reported data for this technology,⁹ continued follow-up in this trial will provide additional data on the longer-term durability of effect. While this trial included patients who may have had additional potential contributors to NAO, only patients with nasal valve collapse as the primary driver of NAO symptoms were enrolled. For this reason, the eligibility criteria, particularly exclusion criteria, should be taken into account when considering the results of this trial and patient selection in clinical practice. The majority of the trial population were White, potentially limiting the generalizability of the results to patients of different races and ethnicities who may have meaningful differences in nasal anatomy.

Conclusions

In this follow-up of an RCT, the results of patients receiving active TCRF device treatment of the nasal valve demonstrate that the treatment effect was durable, and patients exhibited

a reduction in the symptoms of NAO from 3 through 12 months postprocedure. The long-term safety profile of TCRF device treatment of the nasal valve is excellent; there were no serious adverse events with a relationship to the device and/or procedure reported through 12 months postprocedure.

ARTICLE INFORMATION

Accepted for Publication: July 3, 2022.

Published Online: September 1, 2022.
doi:10.1001/jamaoto.2022.2293

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Author Contributions: Drs Han and Silvers had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Han, Silvers.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Han, Rosenthal.

Critical revision of the manuscript for important intellectual content: Han, Silvers, McDuffie, Yen.

Statistical analysis: Han, Silvers.

Administrative, technical, or material support: Han, Silvers, McDuffie.

Supervision: Han, Yen.

Conflict of Interest Disclosures: Dr Han reported receiving personal fees from Aerin Medical (research consultant) during the conduct of the study; and personal fees (research consultant) from Medtronic, Intersect ENT, Genentech, Sanofi Genzyme, AstraZeneca, and GlaxoSmithKline outside the submitted work. Dr Silvers reported receiving personal fees (consultant) from Aerin Medical and Intersect ENT outside the submitted work. Dr Yen reported receiving research funding from Aerin Medical during the conduct of the study; and personal fees from OptiNose US, Stryker ENT, Regeneron, Sanofi Genzyme, Genentech, Oyster Point Pharma, Neurent Medical; stock options from Cyran Therapeutics and Sound Health; and research funding from GlaxoSmithKline, OptiNose US, Gossamer Bio, Septal Solutions, Stryker ENT, Lyra Therapeutics, Neurent Medical, AstraZeneca, and Sound Health outside the submitted work. No other disclosures were reported.

Funding/Support: The trial was sponsored by Aerin Medical.

Role of the Funder/Sponsor: Aerin Medical was involved in the design and conduct of the trial; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: The authors thank the trial center principal investigators: Nadim Bikhazi, MD, The Ogden Clinic, Ogden, Utah; Steven E. Davis, MD, Breathe Clear Institute, Torrance, California; V. Vasu Kakarlapudi, MD, Advanced ENT and Allergy, New Albany, Indiana; J. Pablo Stolovitzky, MD, Emory University School of Medicine, Atlanta, Georgia; Jonathan M. Sykes, MD, University of California Davis Medical Center; John T. Lanza, MD, ENT and Allergy Associates of Florida, Port St Lucie; Lee M. Mandel, MD, ENT and Allergy

Associates of Florida, Fort Lauderdale; W. Cooper Scurry, Jr, MD, Piedmont Ear, Nose, and Throat Associates, Winston-Salem, North Carolina (currently at HKB Plastic Surgery, Greensboro, North Carolina); Douglas D. Reh, MD, The Centers for Advanced ENT Care, Towson, Maryland; Alfredo Archilla, MD, Center for Advanced Sinus and Nasal Care at Otolaryngology Consultants, Boynton Beach, Florida. The statistical analyses were performed by independent statistician Jeff Doerzbacher, MS, a consultant to Aerin Medical. Aerin Medical also provided support for Julie Perkins, PhD, for assistance with manuscript preparation, also an independent consultant to Aerin Medical. These individuals received compensation to perform clinical study work.

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