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ORIGINAL RESEARCH

Laryngoscope Investigative Otolaryngology

Two-year outcomes of temperature-controlled radiofrequency device treatment of the nasal valve for patients with nasal airway obstruction

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Abstract

Background: The objective of this study was to evaluate long-term symptom improvements in patients with nasal airway obstruction (NAO) secondary to nasal valve collapse (NVC) following minimally invasive temperature-controlled radiofrequency (TCRF) treatment.

Methods: A prospective, single-arm, multicenter study in patients >18 years with NAO due to NVC. Inclusion criteria were response to nasal valve dilation (e.g., modified Cottle maneuver) and baseline Nasal Obstruction Symptom Evaluation (NOSE) Scale score ≥60. Patients were treated in the nasal valve region with a TCRF device and followed through 2 years. A responder was ≥20% reduction NOSE Scale score or ≥1 reduction in severity class.

Results: A total of 122 patients were treated and 91 reached 2 years. The mean baseline NOSE Scale score was 80.3 (95% CI, 78.1–82.6). The adjusted mean change in score at 2 years was −45.8 (95% CI, −53.5 to −38.1), $p < 0.001$; a 57.0% improvement. The 2-year responder rate was 90.1% (95% CI, 82.3%–94.7%). Significant and sustained symptom improvement was achieved in subpopulations based on sex, age, body mass index, baseline NAO severity, nasal surgery history, NVC mechanism, septal deviation, and other anatomic contributors of NAO. No serious adverse events with a relationship to the study device and/or procedure were reported.

Conclusions: Minimally invasive TCRF device treatment of the internal nasal valve for NAO is well tolerated and leads to significant and sustained improvement in NAO symptom severity through 2 years, including in patients with both static and dynamic NVC, septal deviation, turbinate enlargement, or prior nasal surgery.

Level of Evidence: 2b.

KEYWORDS
nasal airway obstruction, nasal valve collapse, NOSE scale, rhinoplasty, septoplasty

1 | INTRODUCTION

Nasal airway obstruction (NAO) has multiple independent anatomical contributors with primary causes including nasal valve collapse (NVC), septal deviation and turbinate hypertrophy. In all causes, the slightest constriction results in an exponential increase in resistance and restricted air flow within the nasal airway.[1] While NVC is a common contributor to NAO, it remains less likely to be treated relative to septal deviation and turbinate hypertrophy, which may be attributed to inadequate screening.[2] The prevalence of NVC among symptomatic NAO patients with prior septoplasty and/or turbinate reduction has been reported to be as high as ≥80%.[2,3] Furthermore, ~50% of candidates for revision septoplasty also have NVC.[4,5]

A minimally invasive temperature-controlled radiofrequency (TCRF) device designed to induce tissue tightening and contraction of the nasal valve area,[6,7] has been demonstrated to be safe and effective in improving nasal obstruction symptoms in a randomized controlled trial (RCT) against a sham procedure control[8] with follow-up through 1 year[9] and in single-arm studies with up to 4-year follow-up.[10–13] Herein, we present 2-year follow-up data from the largest yet single-arm confirmatory study of patients treated with TCRF for NAO secondary to NVC, including subpopulation analyses in clinically relevant subpopulations.

2 | MATERIALS AND METHODS

2.1 | Study

This was a prospective, single-arm study conducted at 12 locations in the United States. The study was approved by the WCG Institutional Review Board (ID: 20192967) and registered on clinicaltrials.gov (NCT04277507). Patients gave written informed consent prior to enrollment. All site investigators were board-certified otolaryngologists. Three-month outcomes have been previously reported.[14]

Eligible patients were ≥18 years of age and NVC was a primary or significant contributor to their NAO. Baseline NOSE Scale[15] scores were ≥60. Patients also had a positive response to temporary nasal valve dilation, such as the modified Cottle maneuver. Patients expected to require an adjunctive nasal procedure within 3 months of the study procedure were deemed ineligible. A complete list of eligibility criteria is in Table S1.

Patients who had additional nasal procedures after the 3-month follow-up were given the option to remain in the study for extended follow-up.

2.2 | Device and procedure

The TCRF device (Aerin Medical, Mountainview, CA) and procedure have been previously described.[8–14] In brief, the RF stylus monitors tissue temperature and automatically adjusts the current to maintain a therapeutic treatment temperature of ~60°C. Following application of local anesthesia, the RF stylus is placed on the lateral wall of the nasal valve and treatment applied to the mucosal tissue near the caudal end of the upper lateral cartilage at non-overlapping loci. Treatment settings were temperature, 60°C; power, 4 W; treatment time, 18 s; cooling time, 12 s.

2.3 | Subpopulation definitions

Subpopulation characteristics were chosen with consideration for potential relevance for patient selection or potential impact on treatment outcomes. All subpopulation characteristics were recorded at baseline by study investigators. Subpopulation analyses were performed based on sex (female/male), age (<60/≥60 years), body mass index (BMI) (<25/≥25 kg/m^2), and baseline NOSE Scale severity class (severe/extreme).[16] Prior nasal surgeries (Table S2) defined the prior/no prior nasal surgery subpopulations. Patients with different NVC mechanisms were allocated to one of three subpopulations: bilateral dynamic; bilateral static; and other, which included unilateral dynamic, dynamic on one side, static on the other, and unilateral static. Subpopulations of with/without septal deviation, nasal vestibular stenosis, or turbinate enlargement were based on pretreatment endoscopic evaluation reviewed by the site investigators.

2.4 | Data analysis

Patient data were included in the 2-year analyses at each timepoint unless the patient had undergone additional nasal procedures >3 months after the study procedure (analysis cohort in Figure 1); data after the additional procedure were reviewed separately (additional nasal procedures in Figure 1). Missing data were not imputed. Adjusted (least square) mean NOSE Scale scores and 95% confidence intervals (CIs) of the total score are presented. NOSE Scale severity classes, based on score, are extreme (80–100), severe (55–75), moderate (30–50), mild (5–25), no problems (0).[16] Responders were defined as patients with ≥20% improvement in NOSE Scale score or ≥1 severity class improvement from baseline.[8,17] Responders are presented as a percentage of the total patients at follow-up with the 95% CI. NOSE Scale scores across visits were analyzed using repeated measures linear mixed models with Tukey–Kramer multiple comparison adjustments. Generalized estimating equations were used to assess repeated multinomial ordered NOSE Scale severity classes.

In addition to the NOSE Scale instrument, patients were asked a series of questions about medication/nasal breathing aid use at baseline and follow-up. Responses were collapsed into a binary outcome for analysis based on grouping 'much less frequently/less frequently' and 'same/more frequently/much more frequently'.

Individual subpopulations were first examined using univariate repeated measures linear mixed model analysis based on the NOSE Scale score and Tukey–Kramer multiple comparison adjustments were used within each subpopulation analysis, but no adjustments were made for examining multiple outcome measures. For NVC mechanism,

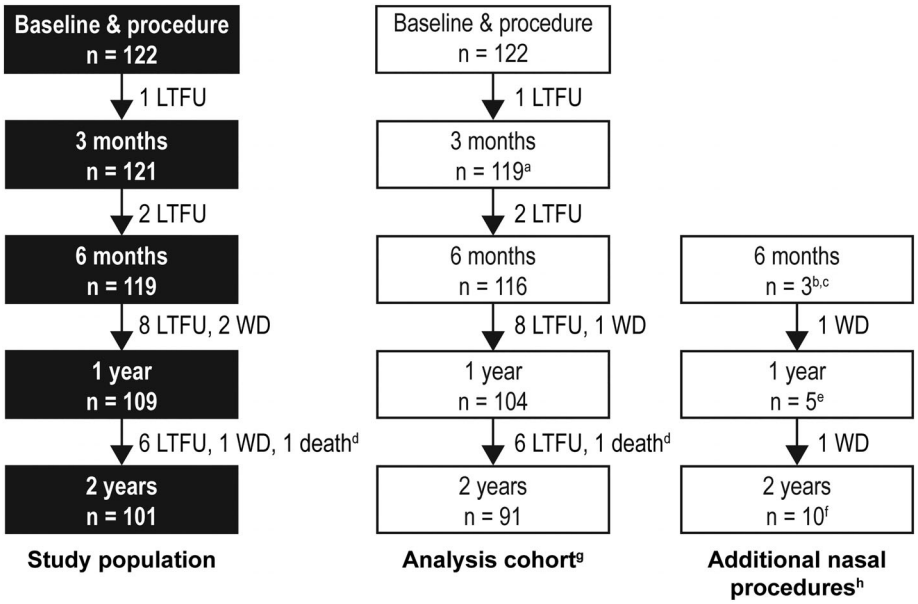

FIGURE 1 Patient disposition.

LTFU = lost to follow-up, WD = withdrew.
[a] Two patients missed the 3-month visit and their data were not available for analysis.
[b] One patient that missed the 3-month visit then had an additional procedure before the 6-month visit.
[c] One of these patients was lost to follow-up after the additional procedure.
[d] COVID-19.
[e] Four with follow-up data.
[f] Nine with follow-up data.
[g] Patient data included in analyses.
[h] Patient data were reviewed separately.

only the bilateral dynamic and bilateral static subpopulations were considered based on the small number of patients in the 'other' subpopulation.

Multivariable logistic regression calculations were performed with the dependent variable of a NOSE Scale score ≤25 versus >25 at 2 years (modeling the probability of achieving a 2-year NOSE Scale score ≤25) and subpopulations as independent variables. Results are reported as odds ratios (OR) with 95% CIs. ORs with 95% CIs that did not contain 1 were considered statistically significant at the 5% level. Statistical analysis was performed using SAS/STAT version 15.2 (SAS Institute, Cary, NC).

3 | RESULTS

3.1 | Patient disposition

A total of 122 patients were treated between February and August 2020. The study population (Figure 1) is summarized in Table 1 and procedural results have previously been reported.[14] A total of 101 patients reached 2-year follow-up, of which 12 had an additional nasal procedure and were reviewed separately (Figure 1). Twenty-one patients exited the study prior to 2 years: 17 were lost to follow-up, 3 withdrew (including 2 with additional procedures), and 1 patient expired due to COVID-19. Of the 18 patients with follow-up data exiting prior to 2 years without additional procedures, 16 had an improvement in NOSE Scale score and 13 were responders at their last visit.

3.2 | Analysis cohort results

The mean baseline NOSE Scale score of the analysis cohort was 80.3 (95% CI, 78.1–82.6). At 2 years, 90.1% (95% CI, 82.3%–94.7%) were responders (Figure 2). The score was significantly improved over baseline at all timepoints from 3 months onwards with an adjusted mean change of −45.8 (95% CI, −53.5 to −38.1), $p < .001$ at 2 years (Figure 3 and the dataset is in Table S3). At 2 years, the change in NOSE Scale score corresponded to a 57.0% improvement from baseline. At baseline, all patients were classified as either severe or extreme per the NOSE Scale severity classification system. Throughout follow-up, the distribution of the ordered classes was significantly different from baseline with a shift toward lower severity classes, $p < .001$ at all follow-up timepoints compared to baseline (Figure 4).

At 2 years, 31 (49.2%) of the 63 patients taking oral medications for NAO symptoms reported much less/less frequent use than at baseline. Furthermore, 34 (51.5%) of the 66 patients using nasal sprays, and 26 (72.2%) of 36 patients using nasal breathing strips reported much less/less frequent use at 2 years than at baseline.

3.3 | Exploratory subpopulation analyses

Univariate analyses of the patient subpopulations showed that all had a similar mean baseline NOSE Scale score, except for severe/extreme baseline NOSE Scale severity class subpopulations (Figure 5 and datasets in Table S3). The adjusted mean changes in NOSE Scale score

TABLE 1 Patient demographics and baseline characteristics.

Characteristic	$N = 122$[a]
Sex, no. (%)	
Female	64 (52.5)
Male	58 (47.5)
Age (years), mean (SD)	50.1 ± 16.4
<60 years, no. (%)	83 (68.0)
≥60 years, no. (%)	39 (32.0)
Race, no. (%)	
White	107 (87.7)
Black or African American	4 (3.3)
Asian	3 (2.5)
Asian, White	2 (1.6)
Black or African American, White	1 (0.8)
Declined available choices	5 (4.1)
Body mass index (kg/m^2), mean (SD)	27.5 ± 6.7
Underweight—normal (<25), no. (%)	49 (40.2)
Overweight—obese (≥25), no. (%)	73 (59.8)
History of nasal surgery,[b] no. (%)	68 (55.7)
Nasal valve collapse mechanism,[c] no. (%)	
Bilateral dynamic	69 (57.0)
Bilateral static	47 (38.8)
Other[d]	5 (4.1)
Nasal exam findings,[c,e] no. (%)	
Septal deviation	35 (28.9)
Nasal vestibular stenosis	65 (53.7)
Turbinate enlargement	31 (25.6)
Septal turbinate (nasal septal swell body) enlargement	37 (30.6)
Nasal polyps	2 (1.7)

[a]Except where noted.
[b]Refer to the Table S2 for a list of prior nasal surgeries.
[c]$n = 121$.
[d]Other includes unilateral dynamic ($n = 2$), dynamic on one side, static on the other ($n = 2$), and unilateral static ($n = 1$).
[e]In addition to nasal valve collapse.

reflected significant and sustained improvements in symptom burden for all subpopulations over time; $p < .001$ at all follow-up timepoints compared to baseline (Figure 5 and datasets in Table S3). For example, the baseline NOSE Scale scores of patients with dynamic and static NVC were 79.2 (95% CI, 76.2–82.2) and 80.4 (95% CI, 76.8–84.1), respectively; at 2 years, the NOSE Scale scores were 33.0 (95% CI, 25.8–40.3) and 35.0 (95% CI, 25.7–44.3), respectively. Additionally, the difference between the mean NOSE Scale scores of patients with dynamic and static NVC at baseline was −1.2 (95% CI, −8.9 to 6.4) (i.e., dynamic was slightly lower than static); the difference was −1.9 (95% CI, −21.2 to 17.3) at 2 years. The differences in the NOSE Scale score between the subpopulations are in Table S4. Significant differences in mean NOSE Scale scores were observed in the

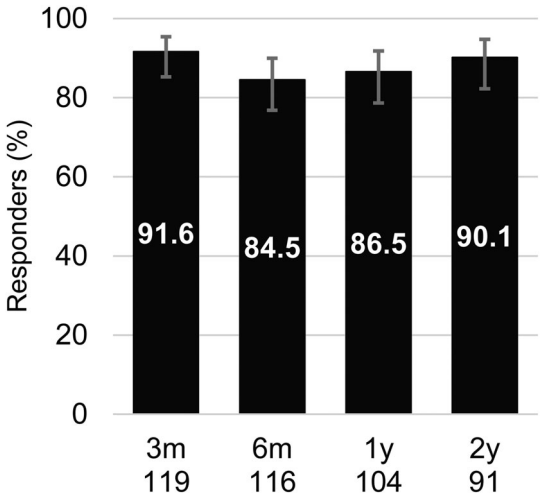

FIGURE 2 Responder rates at all follow-up timepoints for the analysis cohort. Bars are the 95% confidence intervals.

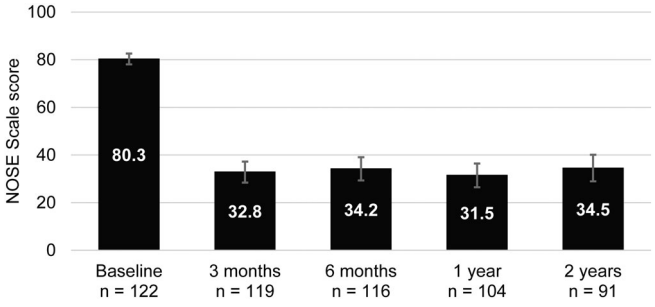

FIGURE 3 Adjusted (least square) mean NOSE Scale scores at baseline and follow-up for the analysis cohort. The significant improvement in score observed at 3 months was sustained through 2 years; $p < .001$, comparing each follow-up timepoint to baseline. Bars are the 95% confidence intervals.

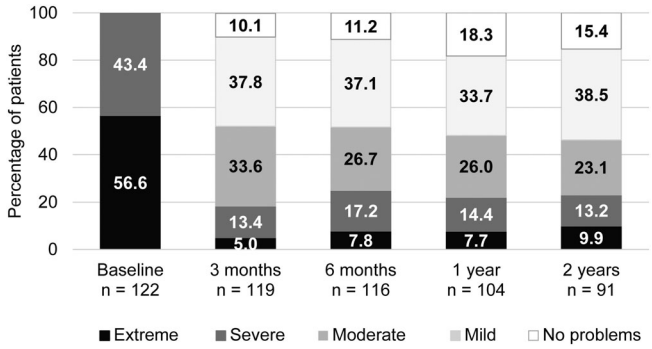

FIGURE 4 The proportion of patients in the analysis cohort exhibiting each NOSE Scale severity class at baseline and follow-up. At each follow-up timepoint, the distribution of the ordered classes was significantly improved from baseline; $p < .001$ comparing each follow-up timepoint to baseline.

severe/extreme baseline NOSE Scale severity class subpopulations (main effect $p = .001$), but the differences were not consistent across visits (across visits $p = .017$); this result is likely driven by the difference

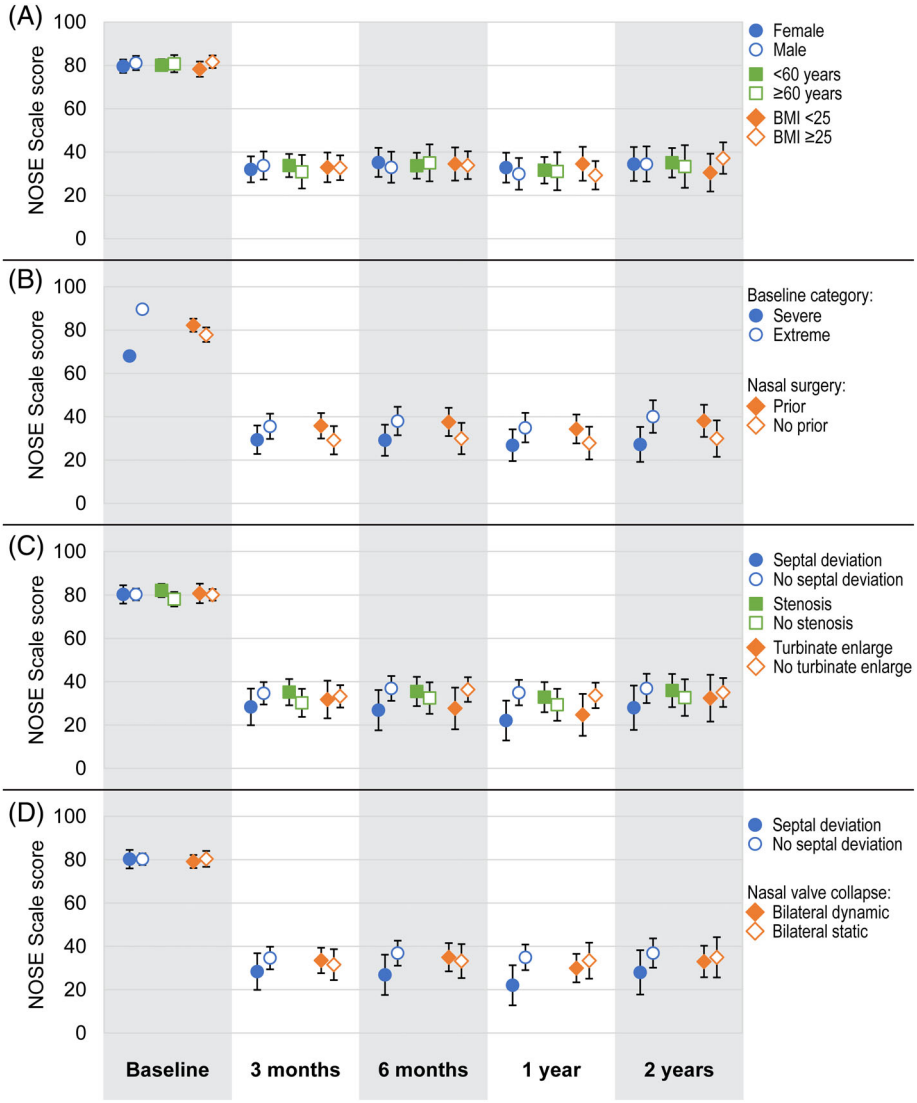

FIGURE 5 Adjusted (least square) mean NOSE Scale scores at baseline and follow-up for subpopulations (univariate analyses). Bars are the 95% confidence intervals. The statistically significant improvements in score observed at 3 months were sustained through 2 years, $p < .001$ comparing each follow-up timepoint to baseline for each subpopulation. BMI = body mass index in kg/m^2. Severe and extreme refer to the baseline NOSE Scale severity class. Stenosis = nasal vestibular stenosis. Turbinate enlarge = turbinate enlargement. The septal deviation/no septal deviation data in panel C are repeated in panel D for visual comparison. Table S3 includes the number of patients in each subpopulation at each timepoint.

TABLE 2 Multivariable regression analysis for a NOSE Scale score of ≤25 at 2 years[a].

Covariable	Comparison	Beta estimate	SE of beta	*p* value	Odds ratio	(95% CI)
Sex	Female versus male	0.147	0.527	.780	1.158	(0.412–3.255)
Age group (years)	<60 versus ≥60	−0.098	0.508	.847	0.907	(0.335–2.453)
BMI (kg/m^2)	<25 versus ≥25	0.186	0.514	.718	1.204	(0.440–3.300)
Severity class[b]	Severe versus extreme	1.009	0.515	.050	2.743	(1.000–7.528)
Prior nasal surgery	Yes versus no	−0.757	0.516	.143	0.469	(0.171–1.290)
Septal deviation	Yes versus no	0.918	0.557	.099	2.503	(0.841–7.454)
Nasal vestibular stenosis	Yes versus no	0.060	0.530	.910	1.062	(0.376–2.998)
Turbinate enlargement	Yes versus no	0.650	0.552	.239	1.915	(0.649–5.651)
Nasal valve collapse	Bilateral dynamic versus bilateral static	−0.501	0.535	.348	0.606	(0.212–1.727)

Abbreviations: BMI, body mass index; CI, confidence interval; NOSE, nasal obstruction symptom evaluation; SE, standard error.
[a]Multivariable logistic regression (full model) with the dependent variable of a NOSE Scale score ≤25 vs. >25 modeling the probability of NOSE Scale score ≤25 at 2 years.
[b]NOSE Scale severity class at baseline.

in baseline score that defines these subpopulations. Differences between both the prior/no prior nasal surgery subpopulations and the septal deviation/no septal deviation subpopulations approached significance, and the differences were consistent across visits (main effects $p = .060$ and $p = .054$, respectively; across visits $p = .958$ and $p = .284$, respectively).

For the multivariable analysis, based on achieving a NOSE Scale score of ≤25 points at 2 years (i.e., a NOSE Scale severity class of mild or no problems), none of the independent variables in the full model, which included all variables, reached statistical significance with all OR 95% CIs including 1 (Table 2). The severe/extreme baseline NOSE Scale severity class subpopulations approached significance; again, likely driven by the difference in baseline condition.

3.4 | Safety

To date, there have been 13 reported adverse events with a relationship to the study device and/or procedure reported in 8 patients (Table S5). Nearly all adverse events were reported within 8 days of treatment with the most common event being nasal crusting. No serious adverse events were reported with any relationship to the study device and/or procedure.

3.5 | Patients with additional nasal procedures

Of 12 patients undergoing additional nasal procedures during 2-year follow-up, 2 patients withdrew and 1 was lost to follow-up, leaving 9 patients with 2-year data. The mean time to the additional procedures was 333 days after the study procedure. Four of 12 patients had additional procedures addressing the nasal valve (1 alar batten graft with auricular cartilage, 1 spreader graft, 1 septoplasty with placement of a bioabsorbable implant, and 1 unspecified nasal valve repair) and the remaining 8 patients had a mix of other procedures, most addressing separate septal or turbinate contributors of NAO (further details in Table S6). Seven of nine patients with 2-year data had improvement in NOSE Scale scores following the study procedure and were responders at the visit prior to the additional procedures, and five of these achieved a further improved 2-year NOSE Scale score after the additional nasal procedures. The two patients that were nonresponders following the study treatment responded to the additional procedures.

4 | DISCUSSION

The results of this study, which contains the largest cohort to date, showed a significant and long-term improvement in the symptom burden of patients with NAO secondary to NVC after TCRF treatment of the internal nasal valve. No serious adverse events reported were reported over the 2-year period. The results are consistent with previous reports in terms of safety, the treatment effect size, and the durability of the effect.[8–13] At 2 years, 90.1% of the patients were responders with a mean NOSE Scale score improvement of 45.8 points. Importantly, as seen in Figures 3 and 4, the improvements in total NOSE Scale score as well as severity classes were maintained from the time of treatment through 2 years. Moreover, a large number of patients achieved a NOSE Scale score of ≤25 following the procedure (47.9%, 57/119) that was maintained at 2 years (53.8%, 49/91). The persistent improvement in the NAO symptoms also led to decreased use of oral medications, nasal sprays, and breathing strips in a substantial number of patients that used them at baseline.

Given the size of this study, multiple analyses were performed on different subpopulations based on sex, age, BMI, baseline NOSE Scale severity class, prior nasal surgery, NVC mechanism, and presence of septal deviation, turbinate enlargement, or nasal vestibular stenosis. Prior nasal surgery and NVC mechanism have also been examined in previous reports.[8,9,14]

Sex was included due to differences in nasal morphology and function, such as those reported for Caucasian males and females.[18] Age was included as there are age-related changes to the nasal structure that may disrupt airflow as well as changes in collagen quality that may affect treatment outcomes.[19,20] Finally, BMI was included as there is a potential relationship with nasal patency.[21] That said, after univariate and multivariable analyses, all patients regardless of sex, age, or BMI had similar degrees of sustained NAO improvements.

When considering prior surgery, interestingly, septoplasty was the most common prior nasal procedure (64.7%, 44/68), followed by inferior turbinate reduction (38.2%, 26/68), yet all had persistent severe/extreme NAO at baseline, highlighting the likely overlooked nature of NVC.[2] Separately, there is also the possibility of occult NVC that was previously masked due to the significant degree of nasal obstruction secondary to turbinate hypertrophy and deviated septum.[4,22,23] The results showing a sustained NAO improvement despite having previous nasal surgery, indicate that TCRF treatment can be considered even in patients who have undergone separate NAO surgery. As the subpopulation analyses also shown sustained significant improvement of NOSE Scale scores despite the presence of a deviated septum or turbinate enlargement, one can consider TCRF treatment as an initial option for patients with septal deviation/turbinate hypertrophy prior to pursuing surgery in the operating room. Overall, TCRF device treatment of the internal nasal valve is minimally invasive and does not preclude subsequent procedures if needed, and therefore can be considered as part of an early and comprehensive approach to treating patients with NAO as well as for patients who have undergone prior surgery but have persistent NAO due to NVC.

At 2 years, relatively few patients (9.8%, 12/122) in the study had additional nasal procedures for NAO despite many of these patients having additional anatomic contributors, such as septal deviation and turbinate enlargement present at baseline. Most of these patients (80.0%, 8/10 with follow-up data) were responders to TCRF device treatment as defined by the study but decided to undergo additional treatment based on perceptions of worsening NAO. Two of these patients underwent TCRF neurolysis of the posterior nasal nerve to treat rhinitis, which is a different indication, but with an obvious overlap in symptom profile. Considering the multiple factors that go into a patient deciding to undergo medical procedures, it is difficult to draw additional conclusions based on the small number of additional procedures in this study.

One limitation of this study is the lack of a control arm. While RCTs result in the highest level of evidence of treatment efficacy, they

are associated with practical constraints such as cost, operational complexity, and randomization to a suitable non-interventional arm, resulting in a smaller sample size, which limits the assessment of long-term safety and effectiveness in a larger population. Therefore, a single-arm trial was conducted to enable the collection of real-world evidence for long-term safety and effectiveness in the largest-to-date interventional cohort from multiple institutions. The large cohort also allowed multivariable analyses to identify patients who may be more or less likely to experience different treatment outcomes. Non-blinded, single-arm studies may contribute bias, however this study employed a before-and-after design using a validated patient reported outcome measure (i.e., NOSE Scale score) rather than physician assessments to assess symptoms before and after treatment to mitigate such bias. To further qualify the results of this largest multiinstitutional study, the improvement in the NOSE Scale scores is comparable to the previously performed RCT[8] as well as other smaller studies evaluating similar patient sets.[9–13]

This study was limited to treatment of the internal nasal valve, even though the TCRF device is indicated for treatment of soft tissues such as inferior turbinates and septal swell bodies, and the results of this present study may not represent the total effect that that may be achievable using TCRF in a comprehensive NAO treatment protocol. Further studies that incorporate more liberal application of TCRF to address multiple NAO contributors are needed to evaluate the full potential of TCRF-based treatment of NAO. The subpopulation analyses were exploratory and future studies focusing on discreet subpopulations may be useful in determining optimal TCRF treatment protocols to address NAO in specific patient populations. Finally, the study population was predominantly White, which limited the analysis of outcomes in patient populations with different races and ethnicities, who may have meaningful differences in nasal anatomy.

5 | CONCLUSIONS

This is the largest to date multiinstitutional cohort study which contributes substantial real-world evidence that minimally-invasive TCRF device treatment of the internal nasal valve for NAO is well tolerated and effective in significantly and sustainably reducing NAO symptom severity through 2 years. The results also served to confirm and add to previously published results on the efficacy of TCRF in a greater number of patients over 2 years. Furthermore, TCRF treatment is effective in patients with either static or dynamic NVC, septal deviation, turbinate enlargement, and prior nasal surgery, all of which are common characteristics of patients who present at clinics seeking relief from their symptomatic NAO.

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CONFLICT OF INTEREST STATEMENT

William C. Yao: Consultant to Aerin Medical, Medtronic Inc, and on the Speaker's Bureau for Optinose. Jordan Pritikin: Consultant to Aerin Medical, 3-D Matrix, Olympus North America, and AIM Specialty. Speaker for Optinose. Michael J. Sillers: Consultant to Aerin Medical and Neurent Medical. Henry P. Barham: Consultant to Aerin Medical.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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