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RESEARCH NOTE

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

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KEYWORDS
long-term follow-up, nasal obstruction, nasal valve, radiofrequency, temperature-controlled

1 | INTRODUCTION

Chronic nasal obstruction is a common condition treated by the otolaryngologist that negatively impacts patients' quality of life.[1] Nasal valve collapse is recognized as a common cause of chronic nasal obstruction that, if left unaddressed, may result in unsuccessful surgical outcomes.[2,3] Temporary treatments depend on daily use, and functional rhinoplasty surgeries are performed in the operating room, involve graft implantation, and require extensive recovery with risks of bleeding, infection, and persistent discomfort.[4–7]

Temperature-controlled radiofrequency (TCRF) treatment is a minimally invasive option to reduce nasal valve–related obstruction through submucosal remodeling to improve nasal airflow. The objective of this study was to assess the long-term durability of TCRF treatment of nasal valve collapse for relief of symptoms of nasal airway obstruction through 48 months in a cohort of patients enrolled in a prospective study with previously reported results.[8,9]

2 | METHODS

2.1 | Study design

Patients in this extended 48-month follow-up study were invited to participate after completing an initial 26-week study with an extension to 24 months.[8,9] The initial study was a prospective, single-arm multicenter study enrolling patients with chronic severe nasal obstruction with nasal valve collapse identified as the primary cause of obstruction.[8,9] Patients with prior nasal valve surgery or other surgical nasal procedures within the past 12 months were excluded. Medication use was not controlled during the study but patients were medically treated before surgery. Patients underwent bilateral treatment with a Vivaer device (Aerin Medical), which maintains treatment

temperature at 60°C. The stylus tip was placed against mucosa underlying the lower edge of the upper lateral cartilage. Three to four nonoverlapping sites on the lateral nasal wall were treated for 12 seconds. No concomitant treatments were allowed. Extended follow-up assessments included use of the validated Nasal Obstruction Symptom Evaluation (NOSE) scale score, completed in person, by telephone, or through mail at 36 and 48 months postprocedure.

2.2 | Data analysis

Statistical comparisons included *t* tests (or Wilcoxon two-sample test) and Fisher exact tests. Longitudinal NOSE scores were analyzed using a repeated-measures linear mixed model with Tukey–Kramer comparisons; severity category distributions were analyzed using generalized linear models with visit comparisons. All available data are reported for each time point without imputation for missing values. Unless otherwise stated, NOSE scale scores are reported as least-square means and range with percentage change relative to baseline. Responders included patients with a decrease of ≥15 points on NOSE score.

3 | RESULTS

Of the 49 patients in the initial study,[8] 39 agreed to participate in follow-up through 24 months.[9] Of these,

TABLE 1 Demographic and baseline characteristics of participant and nonparticipant patients through the 36- and 48-month extended follow-up period

	Participants (n = 29)		Nonparticipants (n = 20)		Statistical test, *p* value
	No.	Value	No.	Value	
Age (years) mean (± SD, range)	29	54.1 (± 11.9, 32.0–78)	20	46.0 (± 12.5, 24-71)	*t* Test, $p = 0.025$
10-year age ranges (%)					Fisher exact, $p = 0.255$
20–29	0	0	2	10.0	
30–39	4	13.8	5	25.0	
40–49	7	24.1	6	30.0	
50–59	8	27.6	5	25.0	
60–69	7	24.1	1	5.0	
70–79	3	10.3	1	5.0	
Sex (%)					Fisher exact, $p = 0.771$
Men	15	51.7	12	60.0	
Women	14	48.3	8	40.0	
Race (%)					Fisher exact, $p = 0.408$
White	29	100.0	19	95.0	
Declined available choices	0	0	1	5.0	
Ethnicity (%)					Fisher exact, $p = 0.162$
Hispanic or Latino	0	0	2	10.0	
Not Hispanic or Latino	29	100.0	18	90.0	
BMI, mean (± SD, range)	29	27.3 (± 4.8, 18.5–36.6)	20	29.5 (± 5.6, 21.6-42.7)	*t* Test, $p = 0.138$
Baseline NOSE score mean (± SD, range)	29	81.0 (± 9.9, 65–100)	20	77.3 (± 11.2, 60-95)	Wilcoxon two-sample test, $p = 0.250$
6-month NOSE Score mean (± SD, range)	29	21.6 (± 18.6, 0–70)	20	29.3 (± 22.4, 0-90)	Wilcoxon two-sample test, $p = 0.191$
6-month NOSE score responders (%)					Fisher exact, $p > 0.999$
Responders (≥15 points)	27	93.1	19	95.0	
Nonresponders	2	6.9	1	5.0	

NOSE, Nasal Obstruction Symptom Evaluation.

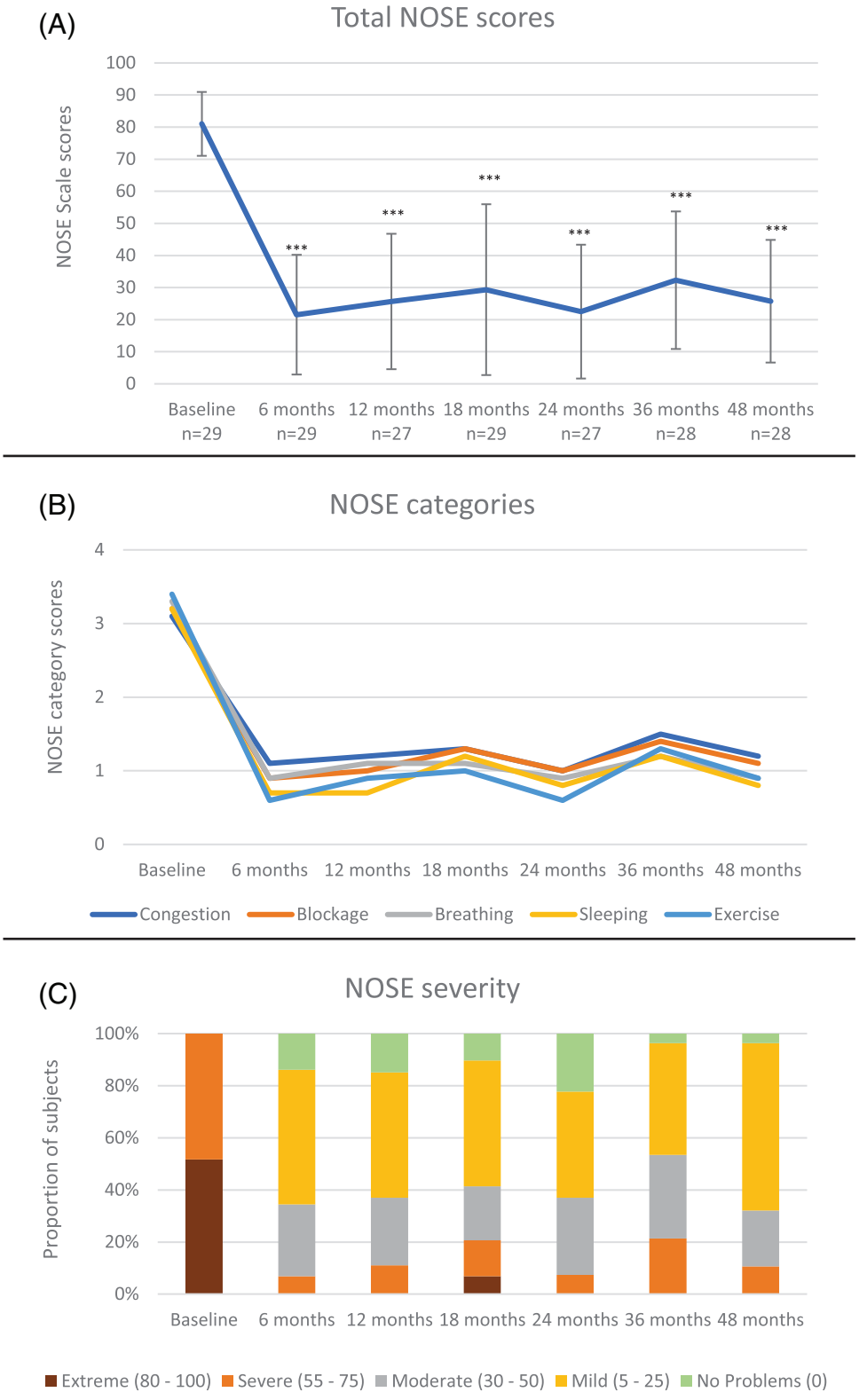

FIGURE 1 (A) Comparison of mean total Nasal Obstruction Symptom Evaluation (NOSE) scale scores at baseline and at 6-, 12-, 18-, 24-, 36-, and 48-month time points. Considerable improvements were noted at all follow-up times, consistent with previous work.[8,9] Markers and error bars indicate means ± standard deviation. *** indicates a statistically significant ($p < 0.001$) difference from baseline. (B) Mean NOSE scale scores by category at baseline and 6-, 12-, 18-, 24-, 36-, and 48-month time points. (C) Proportion of patients by NOSE scale severity at baseline and 6-, 12-, 18-, 24-, 36-, and 48-month time points. At baseline (pretreatment), all patients reported a NOSE scale severity score as either "severe" (48.3%) or "extreme" (51.7%). The proportion of patients in the "severe" category decreased to 10.7% at 48 months with no patients in the "extreme" category at either posttreatment time point. These differences in severity compared with baseline were statistically significant ($p < 0.001$)

29 patients agreed to extended follow-up through 48 months (five declined participation, three did not respond to the invitation, and two had a surgical procedure for nasal airway obstruction and were ineligible to continue). Demographic and baseline characteristics are presented for initial and long-term follow-up cohorts, including those who declined to participate. The baseline mean NOSE score was 81.0 (± 9.9), and at 6 months it was 21.6 (± 18.6) with 93% responders. Except for mean age, participants versus nonparticipants had no significant differences in characteristics. The proportion of 6-month responders among the nonenrolled group was 95%, confirming that early treatment response was unlikely to be associated with participation in extended follow-up (Table 1).

Compared with baseline, mean total NOSE scores significantly improved after treatment and were maintained throughout the 48 months. NOSE scores decreased from 81.0 (±9.9) at baseline to 21.6 (±18.6) after 6 months (73.3% change), 25.6 (±21.1) after 12 months (68.3% change), 29.3 (±26.6) after 18 months (63.8% change), 22.5 (±20.9) after 24 months (72.2% change), 32.3 (±21.4) after 36 months (60.1% change), and 25.7 (±19.1) after 48 months (68.3% change) ($p < 0.001$ for all comparisons).

Mean NOSE domain scores showed sustained improvement through 48 months, including patients with NOSE scores in the "extreme" (score of 80-100) or "severe" (score of 55-75) categories at baseline. At 48 months, 67.9% of patients had severity scores in the "no problems" or "mild" categories, 21.4% were in the "moderate" and 10.7% were in the "severe" categories, and none in the "extreme" category, representing significant changes in the proportion of patients in each category ($p < 0.001$) (Figure 1). Based on a ≥15-point improvement on the NOSE score scale, 93.1% (27 of 29), 96.3% (26 of 27), 96.6% (28 of 29), 100% (27 of 27), 92.9% (26 of 28), and 96.4% (27 of 28) of patients were considered responders at the 6-, 12-, 18-, 24-, 36-, and 48-month follow-up times, respectively.

4 | DISCUSSION

This report of patients treated with TCRF for chronic nasal obstruction attributed to nasal valve collapse provides the longest postprocedure outcome data to date for this technology. The significant postprocedure NOSE score improvements observed through 24 months for this cohort were sustained through 48 months (60.1% and 68.3% improvement from baseline at 36 and 48 months, respectively; $p < 0.001$) and distributed across NOSE score domains. The extent and duration of improvement observed from TCRF treatment over time in this report compares favorably with improvements observed up to 12 months following surgical nasal valve repair and functional rhinoplasty performed to address chronic nasal obstruction.[10]

This study was limited by its use of a single-arm design without randomized control, no control of medication usage, and significant patient attrition relative to the primary study.[8] Two nonparticipants were known to have undergone subsequent surgery for nasal obstruction and it is possible that the effectiveness declined in the extended follow-up nonparticipants, although participants and nonparticipants had similar baseline characteristics and both groups experienced robust NOSE score reductions at 6 months.

In conclusion, in the longest follow-up report to date, significant and sustained improvements in symptoms of nasal airway obstruction were shown through 4 years following treatment of nasal valve collapse via a single TCRF procedure.

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CONFLICT OF INTEREST

Drs Jacobowitz, Ehmer, and Davis are consultants for Aerin Medical, and Dr Ehmer is a speaker for Aerin. Drs Lanier and Scurry have no conflicts of interest to disclose.

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