

07.01.83 Treatment of Nasal Valve Collapse

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Related Policies:

- [07.01.31 Balloon Ostial Dilation for Treatment of Chronic and Recurrent Rhinosinusitis](#)
- [07.01.82 Steroid-Eluting Sinus Stents and Implants](#)

Summary

Description

Nasal valve collapse (NVC) is a readily identifiable cause of nasal obstruction. Specifically, the internal nasal valve represents the narrowest portion of the nasal airway with the upper lateral nasal cartilages present as supporting structures. The external nasal valve is an area of potential dynamic collapse that is supported by the lower lateral cartilages. Damaged or weakened cartilage will further decrease airway capacity and increase airflow resistance and may be associated with symptoms of obstruction. Individuals with NVC may be treated with nonsurgical interventions in an attempt to increase the airway capacity but severe symptoms and anatomic distortion are treated with surgical cartilage graft procedures.

- The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction. The concept is that the implant may provide support to the lateral nasal wall prior to resorption and then stiffen the wall with scarring as it is resorbed.
- The application of radiofrequency volumetric tissue reduction for nasal obstruction has been proposed as a less invasive means to treat nasal obstruction due to internal NVC. By utilizing RF energy, the treatment aims to provide relief with reduced recovery times and fewer complications compared to traditional surgical methods.

Summary of Evidence

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse (NVC) who receive an absorbable lateral nasal valve implant (Latera®), the evidence includes one randomized controlled trial (RCT) with a 24-month uncontrolled follow-up phase and 3 nonrandomized prospective, single-cohort studies. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life (QOL). Overall, improvements in a nasal obstruction score have been demonstrated in study reports. Follow-up at 3 months in the RCT showed a statistically significant improvement in response with the implant compared to the sham group, although over half of the control group were also considered responders. Twenty-four-month follow-up has been reported in the 3 multicenter cohort studies and the uncontrolled crossover phase of the RCT. Loss to follow-up was high, although sensitivity analysis with a worst-case scenario supported an improvement in symptoms at 24 months. As reported, adverse events appeared to be mild in severity and self-limiting, but still common. In the larger cohorts, device retrievals or extrusions occurred in 4% of patients. The need for device retrievals appears to occur early in the course of follow-up (1 month); suggesting technical experience limitations on the part of the operator or inappropriate patient selection. No studies have been identified that compared insertion of an implant with inferior turbinate reduction and/or septoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse who receive radiofrequency volumetric tissue reduction (RFVTR), the evidence includes systematic reviews and a randomized controlled trial (RCT) with 12-month and 24-month uncontrolled follow-up phases. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life. Systematic reviews have generally shown improvements in nasal obstruction scores. In the RCT, follow-up at 3 months revealed a statistically significant improvement in response with the RFVTR procedure compared to the sham group. However, these results are limited by the small study size, lack of diversity, short duration, and failure to control for confounding factors such as medication or nasal dilator use. Moreover, the trial's results may not fully represent the potential effect of RFVTR since treatment was limited to lateral nasal wall repair, not addressing soft tissues like septal swell bodies and inferior turbinates. A significant and durable effect on nasal obstruction post-RFVTR treatment was reported up to 24 months during the uncontrolled crossover phase of the trial. Additional RCTs with extended follow-up periods, larger and more diverse populations, and comparisons of RFVTR to other treatments (medications, nasal dilators, and rhinoplasty) are necessary to confirm the procedure's efficacy for nasal obstruction. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

Not applicable.

OBJECTIVE

The objective of this review is to determine whether the insertion of an absorbable lateral nasal implant or radiofrequency volumetric tissue reduction of the nasal valve (VivAer® device) for the treatment of symptomatic nasal valve collapse improves net health outcomes.

PRIOR APPROVAL

Not applicable.

POLICY

The insertion of absorbable nasal implant(s) (e.g., Latera®) for the treatment of symptomatic nasal valve collapse is considered **investigational** because the evidence is insufficient to determine the effects of the technology on health outcomes.

The use of radiofrequency volumetric tissue reduction (e.g., VivAer®, VivAer® ARC Stylus) of the nasal valve for the treatment of nasal airway obstruction is considered **investigational** because the evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY GUIDELINES

Coding

See the [Codes table](#) for details.

BACKGROUND

Nasal Obstruction

Nasal obstruction is defined clinically as a patient symptom that presents as a sensation of reduced or insufficient airflow through the nose. Commonly, individuals will feel that they have nasal congestion or stuffiness. In adults, clinicians focus the evaluation of important features of the history provided by the individuals such as whether symptoms are unilateral or bilateral. Unilateral symptoms are more suggestive of structural causes of nasal obstruction. A history of trauma or previous nasal surgery, especially septoplasty or rhinoplasty, is also important. Diurnal or seasonal variation in symptoms is associated with allergic conditions.

Nasal valve collapse (NVC) is a readily identifiable cause of nasal obstruction. The internal nasal valve is the narrowest part of the nasal passage and is supported by the upper lateral nasal cartilages (see pathophysiology below). On the other hand, the external nasal valve, also known as the nasal entrance, is prone to dynamic collapse and is supported by the lower lateral cartilages. When cartilage is damaged or weakened, it can reduce airway capacity, increase airflow resistance, and lead to symptoms of obstruction. While nonsurgical treatments aim to enhance airway capacity in patients with NVC, severe symptoms and significant anatomical distortion typically require surgical cartilage graft procedures.

Etiology

Nasal obstruction associated with the external nasal valve is commonly associated with post-rhinoplasty or traumatic sequelae and may require functional rhinoplasty procedures. A common cause of internal nasal valve collapse is a septal deviation. Prior nasal surgery, nasal trauma, and congenital anomaly are additional causes.

Pathophysiology

The internal nasal valve, bordered by the collapsible soft tissue between the upper and lower lateral cartilages, the anterior end of the inferior turbinate, and the nasal septum, forms the narrowest part of the nasal airway. During inspiration, the lateral wall cartilage is dynamic and draws inward toward the septum and the internal nasal valve narrows providing protection to the upper airways. The angle at the junction between the septum and upper lateral cartilage is normally 10° to 15° in white populations. Given that the internal nasal valve accounts for at least half of the nasal airway resistance; even minor further narrowing of this area can lead to symptomatic obstruction for a patient. Damaged or weakened lateral nasal cartilage will further decrease airway capacity of the internal nasal valve area, increasing airflow resistance and symptoms of congestion.

Physical Examination

A thorough physical examination of the nose, nasal cavity, and nasopharynx is generally sufficient to identify the most likely etiology for the nasal obstruction. Both the external and internal nasal valve areas should be examined. The external nasal valve is at the level of the internal nostril. It is formed by the caudal portion of the lower lateral cartilage, surrounding soft tissue and the membranous septum.

The Cottle maneuver is an examination in which the cheek on the symptomatic side is gently pulled laterally with 1 to 2 fingers. If the patient is less symptomatic with inspiration during the maneuver, the assumption is that the nasal valve has been widened from a collapsed state or dynamic nasal valve collapse. An individual can perform the maneuver on oneself, and it is subjective. A clinician performs the modified Cottle maneuver. A cotton swab or curette is inserted into the nasal cavity to support the nasal cartilage and the individual reports whether there is an improvement in the symptoms with inspiration. In both instances, a change in the external contour of the lateral nose may be apparent to both the individual and the examiner.

According to American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS, 2023):

- "The diagnosis of symptomatic nasal valve dysfunction is a clinical diagnosis, made by patient history and physical exam. These diagnoses are made by a qualified Otolaryngologist as a part of a thorough physical examination of the nose...Subjective improvement in nasal breathing with the Cottle or modified Cottle maneuver confirms the diagnosis of nasal valve collapse."

Treatment

Treatment of symptomatic nasal valve collapse includes the use of non-surgical interventions such as the adhesive strips applied externally across the nose or use of nasal dilators, cones, or other devices that support the lateral nasal wall internally that support the lateral nasal wall internally applying the principle of the modified Cottle maneuver.

Severe cases of obstruction resulting from nasal valve deformities are treated with surgical grafting to widen and/or strengthen the valve. Common materials include cartilaginous autografts and allografts, as well as permanent synthetic grafts. Cartilage grafts are most commonly harvested from the individual's nasal septum or ear.

Nasal Implants

The placement of an absorbable implant to support the lateral nasal cartilages has been proposed as an alternative to more invasive grafting procedures in individuals with severe nasal obstruction.

Radiofrequency Volumetric Tissue Reduction

The application of low-dose radiofrequency (RF) energy has been proposed as an alternative technique for reshaping nasal tissue to address NVC. This method has been suggested as a viable alternative to more invasive grafting procedures, particularly for patients experiencing severe nasal obstruction. By utilizing RF energy, the treatment aims to provide relief with reduced recovery times and fewer complications compared to traditional surgical methods.

Regulatory Status

In May 2016, LATERA® (Entellus Medical/Stryker ENT, previously Spirox) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. LATERA® is the only commercially available absorbable nasal implant for the treatment of nasal valve collapse. It is a class II device, and regulatory details are summarized in Table 1.

Table 1. Absorbable Nasal Implant Cleared by the U.S. Food and Drug Administration

Product	Manufacturer	Date Cleared	510(k) No.	Product Code	Indication
LATERA® absorbable nasal implant	Spirox (part of Stryker)	2016	K161191	NHB	Supporting nasal upper and lower lateral cartilage

In April 2020, the VivAer® Stylus (Aerin Medical) was cleared for use in otorhinolaryngology (ENT) surgery by the FDA through the 510(k) process as a tool to treat nasal obstruction (K200300). Clearance was based on equivalence in design and intended use of a predicate device, the Vivaer® ARC Stylus (K172529). The VivAer® Stylus is functionally unchanged from the predicate in design and intended use to generate and deliver bipolar RF energy to treat tissue in otorhinolaryngology (ENT) procedures. As per the FDA 510K summary, the VivAer® Stylus is indicated for use in 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.

The VivAer® Stylus is distinct from the RhinAer® device (Aerin Medical) currently reviewed in evidence review 7.01.168 (Cryoablation, Radiofrequency Ablation, and Laser Ablation for Treatment of Chronic Rhinitis) as it targets nasal tissue for remodeling to improve airflow as opposed to disrupting the posterior nasal nerve in rhinitis.

RATIONALE

This evidence review was created in April 2018 and updated periodically with a search of the PubMed database. The most recent literature update was performed through November 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Absorbable Lateral Nasal Valve Implant

Clinical Context and Therapy Purpose

The purpose of insertion of an absorbable nasal valve implant in individuals who have symptomatic nasal valve obstruction due to nasal valve collapse (NVC) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is adults who have severe symptomatic nasal obstruction symptoms due to the internal (also known as zone 1) NVC. NVC is one of the recognized structural causes of obstructed breathing and congestion, and the diagnosis is primarily clinical. NVC may be unilateral or bilateral and is typically constant with each inspiration. The condition may occur in association with prior trauma or rhinonasal surgery. The evaluation consists of a clinical history to elicit alternative causes or co-occurring conditions such as obstructive sleep apnea or medication use. In addition to examination of the head and neck, the Cottle maneuver or modified Cottle maneuver (previously described) is used to rule-in NVC. Anterior rhinoscopy and nasal endoscopy are used to rule out structural abnormalities such as septal deviation or mucosal conditions such as enlarged turbinates. Radiographic studies are not generally indicated.

Interventions

The therapy being considered is a unilateral or bilateral insertion of an absorbable nasal implant into the lateral nasal wall. The product is predominantly cylindrical in shape with a diameter of 1 mm and an overall length of 24 mm with a forked distal end for anchoring into the maxillary periosteum. It is composed of poly (L-lactide-co-D-L-lactide) 70:30 copolymer, which is absorbed in the body over approximately 18 months. It is packaged with a 16-gauge insertion device. The available product information describes the integrity of the implant to be maintained for 12 months after implantation while a

fibrous capsule forms around the device. A remodeling phase where collagen replaces the implant within the capsule persists through 24 months and is the purported mechanism of support for the lateral nasal wall support.

Comparators

The following therapies and practices are currently being used to treat NVC: nonsurgical treatments include the use of externally applied adhesive strips or intranasal insertion of nasal cones. The basic mechanism of action of these treatments is to widen the nasal valve and permit increased airflow. Surgical grafting using either autologous cartilage (typically from the nasal septum, ear, or homologous irradiated rib cartilage) or a permanent synthetic implant may be performed to provide structural support to the lateral wall support defect.

Outcomes

The general outcomes of interest are a change in symptoms and disease status, treatment-related morbidity, functional status, and change in the quality of life (QOL). The Nasal Obstruction Symptom Evaluation (NOSE) score is an accepted symptom questionnaire for research purposes. The score can also be stratified to indicate the degree of severity of the nasal obstruction symptoms. The insertion of the absorbable implant is performed under local anesthesia and the adverse event profile includes mild pain, irritation, bruising and inflammation, awareness of the presence of the implant, infection, and the need for device retrieval prior to complete absorption.

Stewart et al (2004) proposed the NOSE as a validated sinonasal-specific health status instrument that is used to assess the impact of nasal obstruction on the QOL of affected persons.⁵ It is a 5-item questionnaire on breathing problems: nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through the nose, trouble sleeping, and inability to get enough air through the nose during exercise or exertion. The responses are made on a Likert-type scale ranging from 0 (not a problem) to 4 (severe problem). The range of raw scores is 0 to 20. The score is then scaled to a potential total score of 0 to 100 by multiplying the raw score by 5. A score of 100 means the worst possible problem with nasal obstruction.

The NOSE scale-based nasal obstruction severity classification system is proposed as a means to classify patients for clinical management as well as to better define study populations and describe treatment or intervention responses (Table 2).

Table 2. NOSE Severity Classification

Severity Class	NOSE Score Range
Mild	5 to 25
Moderate	30 to 50
Severe	55 to 75
Extreme	80 to 100

NOSE: Nasal Obstruction Symptom Evaluation.

The duration of follow-up to assess early procedural outcomes is 1 month and at least 24 months would be required to evaluate the durability of symptom improvement as well as to confirm the association with the purported device mechanism of action.

Study Selection Criteria

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs;
- In the absence of such trials, we sought comparative observational studies, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, we also sought single-arm studies that capture longer periods of follow-up and/or larger populations;
- Within each category of study design, prefer larger sample size studies and longer duration studies;
- We excluded studies with duplicative or overlapping populations.

Review of Evidence

Randomized Controlled Trial

One sham-controlled randomized trial with 3-month follow-up has been identified (Table 3). Stolovitzky et al (2019) randomized 137 patients with severe to extreme NOSE scores to an office-based nasal implant or sham control procedure. Follow-up at 3 months showed a significant improvement in responder rate, change in NOSE score, and visual analog scale compared to the sham group, although over half of the control group also were considered responders (Table 4). Six patients (8.6% of 70) had the implant removed by 3 months and analysis was not intent-to-treat (see Tables 5 and 6). Adverse events included pain (n=4), foreign body sensation (n=3), localized swelling (n=2), inflammation (n=1), skin puncture (n=1), and vasovagal response (n=2).

Table 3. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Stolovitzky et al (2019) NCT03400787	US	10	2017-2018	137 patients with severe to extreme NOSE scores after 4 weeks of medical management	Nasal implant (n=70)	Sham control with a cannula inserted into the nasal lateral wall (n=67)

NOSE: Nasal Obstruction Symptom Evaluation; RCT: randomized controlled trial.

Table 4. Summary of Key RCT Results at 3 Months

Study	NOSE Responder Rate at 3 mo % ¹	Change in NOSE Score at 3 mo (SD)	Change in VAS at 3 mo (SD)	Implant Removal
Stolovitzky et al (2019) NCT03400787	N=127	N=127		
Nasal Implant	82.5	-42.4 (23.4)	-39.0 (29.7)	6/70 (8.6%)
Sham Implant	54.7	-22.7 (27.9)	-13.3 (30.0)	
p-value	.001	<.001	<.001	

NOSE: Nasal Obstruction Symptom Evaluation; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analog scale.

¹ 20% decrease or decrease in 1 category on the NOSE score.

Bikhazi et al (2021) reported results from a 24-month uncontrolled follow-up phase of the RCT. Participants randomized to the control group were given the option to crossover to the treatment group following the 3-month randomized phase. Table 5 shows the disposition of participants and Table 6 summarizes outcomes at 24 months for the treatment and crossover participants.

Table 5. Disposition of Participants in Uncontrolled 24-Month Follow-up Phase of RCT

Total enrolled in randomized cohort	137 (71 treatment, 66 sham)
Sham participants undergoing crossover procedure	40 (61.0%)
Total enrolled in long-term follow-up phase	111 (71 treatment, 40 sham)
Total completing 12-month visit	90
Total completing 18-month visit	75
Total completing 24-month visit	70

RCT: randomized controlled trial.

Table 6. Summary of Key RCT Results – 24 Months Uncontrolled Crossover Phase

	NOSE Responder Rate¹	Mean Change (SD) from Baseline in NOSE Score	Mean Change from Baseline in Nasal Obstruction VAS	Mean Change (SD) from Baseline in Epworth Sleepiness Scale	Device Migration/extrusion/retrieval	Total Adverse Events
Number analyzed	60	68	NR (reported in figure)	69	111	111
	88.2% (78.1%, 94.8%)	-38.4 (25.8); p<.001	≥29.7; p<.001 at all time points	-2.6 (4.1); p<.001 Among 26 participants with abnormal baseline score (> 10): -4.9 (4.1); p<.001	10 events in 10 participants (4.5% of total implants; 9% of participants)	34 events in 26 participants

NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analog scale.

¹ 20% decrease or decrease in 1 category on the NOSE score.

Tables 7 and 8 summarize the limitations of the RCT and its uncontrolled follow-up phase. Study limitations include the lack of long-term follow-up of the control arm, significant loss of study participants to follow-up at 18 and 24 months (Table 5), and a lack of objective assessment of NVC.

Table 7. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Stolovitzky et al (2019)				6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 8. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Stolovitzky et al (2019)		3. Nasal examination was performed by the treating physician (patients were blinded) Longer-term follow-up data not blinded	In randomized phase, patients who had the implant removed were excluded from analysis.	6. Not intent-to-treat. Six patients who had implant removal were not analyzed. High loss to follow-up in longer-term phase		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important differences.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

No studies have compared insertion of an implant with inferior turbinate reduction and/or septoplasty. A comparative observational study of 90 individuals with nasal obstruction published in 2021 compared nasal implants to a variety of open functional rhinoplasty techniques in individuals who had also undergone septoplasty and inferior turbinate reduction. However, this study was not included because of its retrospective design, follow-up of only 3 months, and heterogeneity in the indications for the interventions and the surgical techniques used.

Three prospective, single-arm cohort studies in a total of 307 individuals receiving nasal implants have evaluated outcomes at 24 months. The characteristics and results of these studies are summarized in Tables 9, 10, and 11.

Sidle et al (2019, 2021) reported outcomes from 2 post-marketing studies that enrolled a total of 277 patients with severe-to-extreme NOSE scores at 19 U.S. clinics between September 2016 and July 2017. One of the trials (NCT02964312) was conducted in an office setting and enrolled 166 participants. The second study (NCT02952313) implanted the device in the operating room and included 113 participants. Concomitant procedures (septoplasty and/or inferior turbinate reduction) were at the discretion of the investigators. The most recent publication from these studies included data from 177 patients who were followed for 24 months under a protocol extension. NOSE scores through 24 months were reported separately for patients who received an implant alone (n = 69, NOSE = 30.4 [24.6 standard deviation {SD}]), implant plus inferior turbinate reduction (n=39, NOSE = 27.6 [23.1 SD]), or an implant combined with septoplasty and inferior turbinate reduction (n=69, NOSE = 16.0 [20.7 SD]). The data presented by Sidle et al (2021) is described in the tables below. The mean change from baseline for the 177 patients with 24-month data was -53.6 (95% confidence interval [CI], -57.0 to -50.1), with a responder rate of around 90%. Loss to follow-up in these cohorts was high, with 100 of 277 participants discontinuing the study before 24 months (44 were lost to follow-up, 17 withdrew due to lack of response, 38 withdrew or did not consent to the extension study, and 2 died). Sensitivity analysis, performed with a worst-case scenario with all missing 24-month data assigned no change from baseline, showed a mean change from baseline in the NOSE score of -34.2 (95% CI, -38.1 to -30.2), representing an improvement of one class.

San Nicolo et al (2017, 2018) reported 24-month outcomes for 30 patients who were treated at 3 clinical sites in Germany. In this study, 13.3% of patients had the implant removed.

The improvement in symptoms was consistent across the 3 studies, with a mean change of over 40 points from baseline on the NOSE score. The 24-month outcomes are the most relevant, because resorption and remodeling are expected to occur within that time frame.

Table 9. Summary of Prospective, Single-Arm Study Characteristics

Study	Study Type	Country	Dates	Participants ^a	Treatment, n	Follow-Up
Sidle et al (2021) NCT02952313 NCT02964312	Two prospective single-arm cohorts	U.S. (19 clinical sites)	2016-2019	277 patients with severe to extreme nasal obstruction (NOSE score ≥ 55) and a positive Cottle maneuver	· Insertion of implant^b alone (n=109) · Insertion of implant^b plus inferior turbinate reduction (n=67) · Insertion of implant^b plus septoplasty plus inferior turbinate reduction (n=101)	24 mo
San Nicoló et al (2017, 2018)	Prospective single-arm cohort	Germany (3 clinical sites)	NR	30	Insertion of 56 lateral wall implant ^b : · Bilateral: 26 · Unilateral: 4	1 wk and 1, 3, 6, 12, 24 mo

NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported.

^a Baseline inclusion criteria: NOSE score ≥ 55 . Baseline exclusion criteria: septoplasty or turbinate reduction within 6 mo, rhinoplasty within 12 mo, recurrent nasal infection, intranasal steroids, permanent nasal implants or dilators, precancerous or cancerous lesions, radiation or chemotherapy within 24 mo.

^b Absorbable polylactide implant marketed in the U.S. as Latera.

Table 10. Summary of Prospective, Single-Arm Study NOSE Score Results

Study	1 Month	3 Months	6 Months	12 Months	18 Months	24 Months
Sidle et al (2021)						
N or n	276	267	258	232	185	177
Baseline (SD)	77.8 (13.6)	77.7 (13.5)	77.6 (13.6)	77.0 (13.5)	77.6 (13.2)	78.0 (13.1)
Mean NOSE score (SD) ^a	33.7 (23.0)	27.8 (23.4)	27.5 (24.0)	26.0 (23.9)	25.4 (24.0)	24.2 (23.6)
Mean change from baseline (95% CI)	-43.9 (-46.7 to 41.2)	-49.9 (-52.7 to -47.1)	-50.2 (-53.0 to -47.3)	-51.5 (-54.5 to -48.4)	-52.2 (-55.6 to -48.8)	-53.6 (-57.0 to -50.1)
Responder rate ^b	90.9%	93.3%	91.9%	91.4%	93.5%	93.2%
Responder rate ^b for implant alone group	90.8% (99/109)	92.5% (98/106)	92.0% (92/100)	88.3% (83/94)	94.5% (69/73)	89.9% (62/69)
San Nicoló et al (2017, 2018)	Baseline		3 Months	6 Months	12 Months	24 Months
N or n	30		29	30	29	25
Mean score (SD)	76.7 (14.8)	NR	28.4	33.3	35.2	32.0 (29.3)
Mean change from baseline (SD)			-48.4 (26.9)	-43.3 (29.7)	-40.9 (29.2)	-44.0 (31.1)
p			<.001	<.001	<.001	
N or n		NR	29	30	29	
Response rate, n (%) ^b			25 (86.2)	24 (80)	22 (75.9)	

CI: confidence interval; NOSE: Nasal Obstruction Symptom Evaluation; NR: not reported; SD: standard deviation.

^a Paired tests were used to compare the mean baseline value with each of the follow-up time points to determine whether there was evidence of significant reductions in NOSE scores. All follow-up points were significant at p<.001.

^b Response rate was defined as an improvement of at least 1 NOSE score category or a 20% reduction in NOSE score.

Table 11. Summary of Prospective, Single-Arm Study Safety and Adverse Event Results

Study	1 Month	3 Months	6 Months	12 Months	24 Months
Sidle et al (2019, 2021)					
Device related ^a				41 events in 31 patients	54 events in 45 patients
Device removals				17 out of 319 implants (5.3%)	22 out of 543 implants (4.0%)
San Nicoló et al (2017, 2018)					
N or n	30	29	30	29	25 ^b
Device tolerability, % (n)					
None/mild pain	30 (100)	29 (100)	29 (96.7)	29 (100)	24 (96.0)
Not assessed			1 (3.3)		
No cosmetic changes ^c	26 (86.7)	27 (93.1)	27 (90.0)	26 (89.7)	17 (89.5)
Device-related adverse events ^d	5	0	0	0	0

^a Foreign body sensation (6), sinus infection (1), mucous production (2), loss of smell/taste (1), skin irritation (1), hematoma (1), infection (4), pain (3), bumps (5), and implant retrievals (17).

^b 4 patients had an additional procedure and 1 was lost to follow-up.

^c Photographic review.

^d 3 device retrievals, 1 hematoma, and 1 inflammation.

Study limitations are summarized in Tables 12 and 13. The lack of a comparator group inherent to the study design is a major limitation. Additionally, the indication for the nasal implant varied within the study populations or was not adequately described.

Table 12. Prospective, Single-Arm Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-Up ^e
Sidle et al (2019, 2021)	1. Patient population varied in important clinical characteristics and types and rates of prior rhinologic surgery 2. Clinical context for patient selection for absorbable implant versus implant plus adjunctive surgery not described		No comparator	6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	
San Nicoló et al (2017, 2018)	2. Clinical context for patient selection for absorbable implant versus alternative surgery not described 3. Study population is heterogenous: 68% had prior rhinonasal surgery		No comparator	6. Clinically significant difference not supported. A positive responder could still have severe symptoms.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Not CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant differences not supported.

^e Follow-Up key: 1. Not sufficient duration for benefits; 2. Not sufficient duration for harms.

Table 13. Prospective, Single-Arm Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Sidle et al (2019, 2021)		1. No control and not blinded to treatment assignment		1. Data incomplete for populations assessed for various outcomes 2. Missing data for patients who had device retrievals		
San Nicoló et al (2017, 2018)		1. No control and not blinded to treatment assignment		2. Missing data for patients who had device retrievals		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Absorbable Lateral Nasal Valve Implant

For individuals with symptomatic nasal obstruction due to internal nasal valve collapse (NVC) who receive an absorbable lateral nasal valve implant, the evidence includes one randomized controlled trial (RCT) with a 24-month uncontrolled follow-up phase and 3 nonrandomized prospective, single-cohort studies. Relevant outcomes are symptoms, change in disease status, treatment-related morbidity, functional outcomes, and quality of life (QOL). Overall, improvements in nasal obstruction score have been demonstrated in study reports. Follow-up at 3 months in the RCT showed a statistically significant improvement in response with the implant compared to the sham group, although over half of the control group were also considered responders. Twenty-four month follow-up has been reported in the 3 multicenter cohort studies and the uncontrolled crossover phase of the RCT. Loss to follow-up was high, although sensitivity analysis with a worst-case scenario supported an improvement in symptoms at 24 months. As reported, adverse events appeared to be mild in severity and self-limiting, but still common. In the larger cohorts, device retrievals or extrusions occurred in 4% of patients. The need for device retrievals appears to occur early in the course of follow-up (1 month); suggesting technical experience limitations on the part of the operator or inappropriate patient selection. No studies have been identified that compared insertion of an implant with inferior turbinate reduction and/or septoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Radiofrequency Volumetric Tissue Reduction

Clinical Context and Therapy Purpose

The purpose of radiofrequency volumetric tissue reduction in individuals who have symptomatic nasal valve obstruction due to nasal valve collapse (NVC) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is adults who have severe symptomatic nasal obstruction symptoms due to the internal NVC. NVC is one of the recognized structural causes of obstructed breathing and congestion, and the diagnosis is primarily clinical. NVC may be unilateral or bilateral and is typically constant with each inspiration. The condition may occur in association with prior trauma or rhinonasal surgery. The evaluation consists of a clinical history to elicit alternative causes or co-occurring conditions such as obstructive sleep apnea or medication use. In addition to examination of the head and neck, the Cottle maneuver or modified Cottle maneuver (previously described) is used to rule-in NVC. Anterior rhinoscopy and nasal endoscopy are used to rule out structural abnormalities such as septal deviation or mucosal conditions such as enlarged turbinates. Radiographic studies are not generally indicated.

Interventions

The therapy being considered is the VivAer® Stylus (VivAer) which is a disposable, handheld device capable of delivering bipolar radiofrequency energy to tissue. The stylus consists of an array of bipolar electrodes positioned on a non-conductive tip which is attached to a handle via a non-conductive shaft. A temperature sensor is located on the tip to monitor tissue temperature during treatment. VivAer improves nasal breathing by modifying the soft tissues of the nasal airway through the use of low doses of

radiofrequency energy. The low-power radiofrequency generates heat within the submucosal tissue, creating a coagulation lesion. As the lesion heals, the tissue retracts and stiffens. This decreases the nasal airflow resistance thereby improving inflow of air through the nose.

Comparators

The following therapies and practices are currently being used to treat NVC: nonsurgical treatments include the use of externally applied adhesive strips or intranasal insertion of nasal cones. The basic mechanism of action of these treatments is to widen the nasal valve and permit increased airflow. Surgical grafting using either autologous cartilage (typically from the nasal septum, ear, or homologous irradiated rib cartilage) or a permanent synthetic implant may be performed to provide structural support to the lateral wall support defect.

Outcomes

The general outcomes of interest are a change in symptoms and disease status, treatment-related morbidity, functional status, and change in the QOL. The Nasal Obstruction Symptom Evaluation (NOSE) score is an accepted symptom questionnaire for research purposes. The score can also be stratified to indicate the degree of severity of the nasal obstruction symptoms. The insertion of the absorbable implant is performed under local anesthesia and the adverse event profile includes mild pain, irritation, bruising and inflammation, awareness of the presence of the implant, infection, and the need for device retrieval prior to complete absorption.

Stewart et al (2004) proposed the NOSE as a validated sinonasal-specific health status instrument that is used to assess the impact of nasal obstruction on the QOL of affected persons. It is a 5-item questionnaire on breathing problems: nasal congestion or stuffiness, nasal blockage or obstruction, trouble breathing through the nose, trouble sleeping, and inability to get enough air through the nose during exercise or exertion. The responses are made on a Likert-type scale ranging from 0 (not a problem) to 4 (severe problem). The range of raw scores is 0 to 20. The score is then scaled to a potential total score of 0 to 100 by multiplying the raw score by 5. A score of 100 means the worst possible problem with nasal obstruction.

The NOSE scale-based nasal obstruction severity classification system is proposed as a means to classify patients for clinical management as well as to better define study populations and describe treatment or intervention responses (Table 14).

Table 14. NOSE Severity Classification

Severity Class	NOSE Score Range
Mild	5 to 25
Moderate	30 to 50
Severe	55 to 75
Extreme	80 to 100

NOSE: Nasal Obstruction Symptom Evaluation.

The duration of follow-up to assess early procedural outcomes is 1 month and at least 24 months would be required to evaluate the durability of symptom improvement as well as to confirm the association with the purported device mechanism of action.

Study Selection Criteria

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs;
- In the absence of such trials, we sought comparative observational studies, with a preference for prospective studies;
- To assess long-term outcomes and adverse effects, we also sought single-arm studies that capture longer periods of follow-up and/or larger populations;
- Within each category of study design, prefer larger sample size studies and longer duration studies;
- We excluded studies with duplicative or overlapping populations.

Review of Evidence

Systematic Reviews

The efficacy of radiofrequency volumetric tissue reduction (RFVTR) to treat nasal obstruction has been assessed through several systematic reviews. Trials included in these systematic reviews can be compared in Appendix Table A1.

Casale et al (2023) performed a systematic review and meta-analysis to evaluate the effectiveness of VivAer for treating nasal obstruction. The review included prospective and retrospective studies involving participants with nasal obstruction due to NVC and high NOSE scores (>55). Five studies (N=297 participants), published through December 2021, met the criteria and involved bilateral treatment of the nasal valve regions. Participants were excluded if they had undergone additional procedures such as septoplasty, turbinate, rhinoplasty, or orthognathic surgery. Studies that did not report quantifiable outcomes or lacked extractable data were also excluded. The primary outcome measured was the NOSE questionnaire scores, which reflect the disease-specific quality of life. Comparisons were made between pre-treatment and post-treatment values, and between post-treatment and control (sham) outcomes over a 3-month follow-up period. Minor adverse events were reported, but none of the studies mentioned changes in the external appearance of the nose. Three months post-treatment, NOSE scores significantly decreased (pre-treatment: 76.16 ± 6.39 ; post-treatment: 31.20 ± 2.73 ; Mean Difference (MD): 46.13; 95% confidence interval [CI] 43.28 to 48.99), with moderate heterogeneity ($I^2 = 70\%$, $p < 0.01$). In the only RCT by Silvers et al. (2021), the active group showed significantly better results than the sham-control group 3 months after treatment (see below). The review authors cautioned that due to moderate heterogeneity and the limited number of small population studies with short follow-up periods, these results should be interpreted with caution. They also noted a risk of bias ranging from moderate to serious. The authors concluded that VivAer could be effective for treating NVC and substantially improved subjective breathing symptom scores. However, they emphasized that additional large-scale studies are necessary to confirm these findings.

Han et al (2024) conducted a systematic review and meta-analysis to compare the treatment effect sizes of RFVTR using VivAer on the internal nasal valve alone, against functional rhinoplasty surgery. Given that functional rhinoplasty for nasal valve dysfunction is often accompanied by septoplasty, turbinate treatment, and cosmetic techniques, they performed analyses to compare RFVTR with (i) rhinoplasty focused solely on the nasal valve, (ii) rhinoplasty excluding turbinate procedures, and (iii) all types of rhinoplasty surgery. The treatment effect was measured using NOSE scale scores at pre-procedural baseline and at 3, 6, and 12 months post-procedure. A pre-procedural NOSE score cutoff of 45 or higher was used to include participants with moderate to severe nasal airway obstruction and to exclude those focused solely on cosmetic outcomes. Five studies on RFVTR and 63 studies on functional rhinoplasty,

published through December 2022, were included in the analysis. Pooled effect sizes for RFVTR and all forms of rhinoplasty were comparable. At 12 months, weighted mean difference (WMD) was -48.8 (95%CI, -56.9 to -40.7), $I^2=68\%$ for RFVTR treatment and WMD, -47.7 (95%CI, -51.1 to -44.4), $I^2=90.0\%$ for functional rhinoplasty. The study concluded that RFVTR of the internal nasal valve has lasting effects comparable to functional rhinoplasty, whether focused on the nasal valve alone or not including turbinate treatment, as well as all rhinoplasty procedures. The study had some limitations, including a follow-up period limited to 12 months to increase the quantity of evaluable data, as studies with longer follow-ups were fewer. It was noted that some datasets might include participants with less than moderate NAO, but the cutoff of 45 ensured most participants had at least moderate nasal airway obstruction. The quality of the included studies varied, with many traditional procedure studies being of moderate to poor quality and showing high heterogeneity.

In a systematic review and meta-analysis, Kang et al (2024) examined the efficacy of RFVTR in mitigating nasal obstruction by addressing NVC. The analysis included studies that assessed QOL and NOSE scores before and after RFVTR with VivAer, and also evaluated sham-controlled studies. Eight studies (N=451 participants) met the inclusion criteria. Participants who underwent RFVTR reported a significantly improved QOL 24 months post-treatment compared to pre-treatment scores. The rates of clinically improved states and positive responses regarding QOL post-treatment were 82% and 91%, respectively. Furthermore, the disease-specific QOL, as measured by the NOSE score, showed significant improvement: At 24 months, MD, 56.35 (95% CI, 50.29 to 62.41, $I^2=0.0\%$). The authors concluded that RFVTR may be beneficial in alleviating nasal obstruction symptoms; however, further RCTs with larger sample sizes are necessary to confirm the effectiveness of RFVTR in enhancing nasal valve function.

Randomized and Noncontrolled Randomized Controlled Trials

A sham-controlled randomized trial with a 3-month follow-up was identified, and its 12-month and 24-month outcomes have been published.

Silvers et al. (2021) presented findings from a prospective, multicenter, single-blinded, industry-funded RCT, which evaluated the safety and efficacy of RFVTR with VivAer for NVC in patients with nasal obstruction (The Vivaer® Procedure for Treatment of Nasal Airway Obstruction: A Prospective, Multicenter Randomized Controlled Trial Comparing Vivaer to Sham Control (VATRAC)). Participants were divided into two groups: (A) received bilateral RFVTR of the nasal valve (n=77), and (B) underwent a sham procedure (n=40). During the sham treatment, participants were prepped for surgery, anesthetized, and VivAer was inserted into their nostrils without transferring RF energy to the target tissue. The device was applied to the mucosa over the lower lateral cartilage of the lateral nasal wall. The primary endpoint was the responder rate at 3 months, defined as a 20% or greater reduction in the NOSE scale score or at least a 1-point reduction in clinical severity category. At baseline, participants exhibited a mean NOSE-scale score of 76.7 (95% CI, 73.8 to 79.5) in the active treatment group and 78.8 (95% CI, 74.2 to 83.3) (p=.424) in the sham-control group. After 3 months, the responder rate was significantly higher in the active treatment group (see Table 15). Moreover, the active treatment group showed a significantly greater improvement in the NOSE-scale score. Three adverse events were considered at least possibly related to the device and/or procedure. In the active treatment group, one participant experienced a vasovagal reaction and another had intermittent nasal bleeding with mucus, both of which resolved. In the sham-control group, one individual experienced intermittent headache, which also resolved. It is important to note that the results of this study may not be generalizable to broader populations. This trial did not control for or analyze possible differences in oral or topical medication use during the trial. Although the study was blinded, the perception of the presence or absence of local effects of RFVTR could have provided participants with an indication of their study group. The authors did not investigate whether participants were aware of their study group.

Studies by Han et al (2022) and Slivers et al (2024) have reported on the 12-month and 24-month results of the VATRAC trial, respectively. After the 3-month visit, which served as the primary endpoint, participants in the VATRAC trial were unblinded. Patients in the index sham-control group who remained eligible and consented to continue in the trial were given crossover treatment. For the follow-up period extending from 3 to 24 months, all participants who received active treatment, including both initial active treatment patients and those who crossed over from the sham-control arm, were combined into a single analysis cohort.

Han et al (2022) published results of the VATRAC trial through 12 months of follow-up. Following evaluation of the primary endpoint at 3 months, eligible participants in the sham control arm crossed over to active treatment (n=31; 77% of the sham control cohort). The mean baseline NOSE Scale score of the combined group of participants who received treatment (N=108) was 76.3 (95% CI, 73.6 to 79.1). At 12 months (81% of those treated were available for analysis; n=88), the rate of participants who were defined as 'responders' by meeting the primary endpoint was 89.8% (95% CI, 81.7% to 94.5%) and the median NOSE Scale score improved from baseline (mean change, -44.9, 95% CI, -52.1 to -37.7). No device nor procedure-related serious adverse events were reported. The high attrition rate and cross-over at 3 months render conclusions regarding this study's outcomes subject to serious bias.

Silvers et al. (2024) presented the two-year results of the VATRAC trial, which aimed to evaluate the long-term effects of RFVTR and changes in the usage of medication and nasal dilators over the study period. At the 24-month mark, the responder rate was 90% (N=108 participants), with a NOSE score treatment effect of -41.7, indicating a 55% improvement. Among participants who used medications or nasal dilators at the beginning of the study, 79% had reduced or stopped use in at least one class. No new adverse events related to the RFVTR procedure were reported during the study period. The authors concluded that RFVTR treatment for nasal valve dysfunction led to significant and sustained improvements in nasal airway obstruction symptoms and a notable reduction in the use of medications or nasal dilators. They also noted that conditions such as turbinate enlargement, septal deviation, or septal swell body did not significantly affect the likelihood of achieving a NOSE score of ≤ 25 at two years. However, there were several study limitations: the long-term follow-up consisted of a single group, despite the trial originally being an RCT with a primary endpoint at three months. Additionally, because the NOSE score is a subjective, patient-reported measure, future studies could benefit from including objective measures such as acoustic rhinometry or rhinomanometry. Furthermore, the study population was predominantly Caucasian, limiting the analysis of outcomes in non-Caucasian populations who might have meaningful differences in nasal anatomy.

Table 15. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Silvers et al (2021); VATRAC ¹² .	US	16	August 2020 -December 2020	N=119^a Baseline patient characteristics: Age 18 to 85 years - The mean (SD) age of patients was 48.5 years (12.3) years 66 (61%) were women. - All seeking treatment for nasal obstruction Baseline NOSE scale score ≥ 55 - Mean score of 77 (95% CI, 74 to 79) and 79 (95% CI, 74 to 83) ($p=.42$) in the active treatment and sham-control arms, respectively. Nasal valve collapse as the primary or a significant contributor to the nasal obstruction Positive response to a temporary nasal dilation measure, such as the modified Cottle maneuver Patient dissatisfaction with medical management.	VivAer; n=77	Sham; n=40

RCT: randomized controlled trial; SD: standard deviation.

^a Of 119 participants, 1 patient in ViAer arm withdrew consent before treatment, and 1 patient in the sham-control arm was lost to follow-up before the 3-month visit (primary endpoint).

Table 16. Summary of Key RCT Results at 3 months

Study	NOSE Responder Rate at 3 mo % (95% CI) ¹	Change in NOSE Score at 3 mo (95% CI)	Mean change in VAS at 3 mo (95% CI)	Adverse events n (%)
Silvers et al (2021); VATRAC ¹² .	N=117	N=117	N=117	N=117
VivAer	88.3 (79.2 to 93.7)	-42.3 (-47.6 to -37.1)	-31.4 (-38.5 to -24.2)	3 (4)

Sham	42.5 (28.5 to 57.8)	-16.8 (-26.3 to -7.2)	-16.1 (-26.3 to -6.0)	1 (2.5)
p value	<.001	<.001	.015	

NOSE: Nasal Obstruction Symptom Evaluation; CI: confidence interval; RCT: randomized controlled trial; VAS: visual analog scale.

¹ Defined as a $\geq 20\%$ reduction in NOSE-scale score or ≥ 1 reduction in clinical severity category.

Tables 16 and 17 summarize the limitations of the RCT.

Table 17. Study Relevance Limitations

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Duration of Follow-up ^e
Silvers et al (2021); VATRAC ¹² .	4. Only 10% participants in each group were from diverse racial/ethnic backgrounds		2. Lack of comparison to other treatments for nasal obstruction (medications, nasal dilators and rhinoplasty)	1. NOSE score is a subjective, patient-reported measure, future studies could benefit from including objective measures such as acoustic rhinometry or rhinomanometry 6. Clinically significant difference not supported. A positive responder could still have severe symptoms	1, 2: Follow-up limited to 3 months

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 18. Study Design and Conduct Limitations

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Data Completeness ^d	Power ^e	Statistical ^f
Silvers et al (2021); VATRAC ¹² .	5. Potential for participants to discern their treatment group due to the nature of the sham procedure	1. Physicians were not blinded to treatment-arm assignment		6. Not intent-to-treat. 7. Lack of control for confounding medication or nasal dilator use		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

^b Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

^d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

^f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Yao et al. (2021) conducted a prospective, single-arm, open-label, multi-institutional study to evaluate the effectiveness of a low-power temperature-controlled radiofrequency procedure to treat the nasal valve and measure symptomatic improvement in patients diagnosed with nasal airway obstruction due to nasal valve collapse. Inclusions criteria included: age 18 years or older; NOSE Scale score ≥ 60 ; nasal valve was a primary or significant contributor to the patient's nasal obstruction as determined by the study investigator (based on clinical presentation, physical examination, nasal endoscopy); positive response to external nasal dilator strips (e.g., Breathe Right Strips), Q-Tip test (manual intranasal lateralization), use of nasal stents, or Cottle's Maneuver (manual lateral retraction of the cheek). Key exclusion criteria included: Prior surgical treatment of the nasal valve within six months; rhinoplasty, septoplasty, inferior turbinate reduction or other surgical nasal procedures within three months prior; anatomy that required an adjunctive surgical nasal procedure on the same day or three months after the study procedure; medical conditions which, in the opinion of the treating physician, would predispose the patient to poor wound healing or increased surgical risk. One hundred twenty-two patients underwent radiofrequency procedure with stylus was placed on the lateral wall of the nasal valve and treatment was applied to the mucosal tissue near the caudal end of the upper lateral cartilage at nonoverlapping loci. NOSE scale total scores at three months post-procedure were significantly improved relative to baseline, from 80.3 (± 12.6 ; range: 60-100) to 32.9 (± 24.2 ; range: 0-100), $P < 0.001$. At baseline, 100% of patients' total NOSE scale scores were in the 'extreme' (score of 80-100) or 'severe' (55-75) categories; at three months post-procedure this decreased to 18.5%. At the three-month visit, 91.6% of the patients had either a 20% improvement in NOSE scale total score relative to baseline or at least one severity category improvement. Ten adverse events that were considered related to the device or study procedure occurred, and all resolved during the study period. The study is limited due to lack of control group and short follow-up time period.

Ephrat et al. (2021) conducted a study to determine whether the results achieved with radiofrequency treatment at six months would be sustained through 24 months (follow-up to the below study [Jacobowitz, et al., 2019]). The study included 39 patients from original cohort of 49 patients with severe to extreme Nasal Obstruction Symptom Evaluation (NOSE) Scale scores and dynamic or static internal nasal valve obstruction as the primary or significant contributor to obstruction were studied. Patients received intranasal bilateral radiofrequency treatment in a clinical study with a follow-up to six months, and were prospectively evaluated at 12, 18, and 24 months. The patient-reported NOSE Scale score and 21 QOL questions were assessed. Clinically significant improvement from baseline in NOSE Scale score change demonstrated at six months (mean, 55.9; standard deviation [SD], 23.6; $p < 0.0001$) was maintained through 24 months (mean, 53.5; SD, 24.6; $p < 0.0001$). Responders (≥ 15 -point improvement) consisted of 92.3% of participants at six months and 97.2% at 24 months. Responses to the QOL questions also showed improvement in patients' QOL. The authors note that it will be necessary to confirm the results of

this study in additional patients as part of a planned randomized, controlled trial that may help determine the relative true treatment effect vs potential placebo effects.

Jacobowitz et al. (2019) reported on a prospective, nonrandomized, multicenter case series to assess the safety and effectiveness of in-office bipolar radiofrequency treatment of nasal valve obstruction. The study included 50 patients with a Nasal Obstruction Symptom Evaluation scale (NOSE) score ≥ 60 and clinically diagnosed with dynamic or static internal nasal valve obstruction as primary or significant contributor to obstruction and were required to have a positive response to nasal mechanical dilators or lateralization maneuvers. Bilateral radiofrequency treatment was applied intranasally using a novel device (Aerin Medical's Vivaer Stylus), under local anesthesia in a single session. Safety and tolerance were assessed by event reporting, inspection and Visual Analogue Scale (VAS) for pain. Efficacy was determined using the NOSE score and patient-reported satisfaction survey at 26 weeks. No device or procedure-related serious adverse events occurred. Soreness, edema and crusting resolved by one month. The mean baseline NOSE score was 79.9 (SD 10.8, range 60-100), and all had severe or extreme obstruction. At 26 weeks, mean NOSE score was 69% lower at 24.7 ($P < .0001$) with 95% two-sided confidence intervals 48.5 to 61.1 for decrease. The decrease in NOSE score did not differ significantly between patients who did or did not have prior nasal surgery. Patient satisfaction mean by survey was 8.2 of 10. The study is limited by the small number of patients, lack of randomization, uncontrolled and lack of comparator, and relatively short-term follow-up.

Brehmer et al. (2019) conducted a prospective, nonrandomized study to evaluate the safety and efficacy of the Vivaer system for the treatment of narrowed nasal valves and to measure changes in the symptoms of nasal obstruction and snoring. The study involved 31 patients presenting with symptoms of nasal obstruction and snoring. Thirty days after the treatment, patients completed two questionnaires measuring nasal obstruction and snoring (NOSE, Snore Outcomes Survey [SOS]). The patients' satisfaction with the treatment was assessed 90 days after the intervention by means of a 10-point Likert scale (1 = completely dissatisfied; 10 = very satisfied). In all patients, an improvement was observed in nasal breathing measured by NOSE score, sleep quality by SOS questionnaire and quality of life as measured by EQ-5D and SNOT-22. The study is limited by the small number of participants, the lack of randomization, control group and comparator, and by the short follow-up time period.

Noncomparative, Single-Arm Studies

Simmons et al (2024) performed a single-center retrospective chart review on 37 patients with a history of rhinoplasty or nasal valve repair who underwent VivAer radiofrequency (RF) treatment due to nasal valve collapse (NVC). The treatment outcomes were assessed utilizing the Nasal Obstruction Symptom Evaluation (NOSE) scale (5-30 mild, 30-50 moderate, 51-80 severe, 81-100 extreme). The primary outcome was defined as a decrease in NOSE score by at least one severity category or a 20% reduction in total NOSE score. Of the 37-patient cohort, 21 (56.8 %) patients showed response to treatment defined as a reduction in a NOSE score severity category or 20% reduction in NOSE score, while 16 (43.2 %) patients did not demonstrate response to treatment. The 21 patients in the responder group demonstrated a mean absolute NOSE score reduction of 34.7 points or 55.6 %, dropping two NOSE severity categories from "severe" (pre-treatment NOSE mean = 61.2) to "mild" (post-treatment NOSE mean = 27.6). Repeat RF in non-responders resulted in 50% response rate. One complication, nasal vestibule abscess was reported and was successfully treated with incision and drainage. The authors concluded "Our study demonstrates the effectiveness of temperature-controlled RF treatment of NVC in patients with a prior rhinoplasty or nasal valve surgery. In this patient population over half (54.3%) were successfully treated and were able to avoid the need for revisions nasal surgery. RF treatment represents a very appealing option for patients with persistent nasal obstruction after prior surgery who are reluctant to undergo additional surgery. Further investigations ideally randomized controlled trials are needed to validate these findings and cement the role of RF in the management of these complex patients."

Section Summary: Radiofrequency Volumetric Tissue Reduction

The current evidence regarding individuals with nasal valve obstruction symptoms due to internal nasal valve collapse (NVC) who receive radiofrequency volumetric tissue reduction (RFVTR) procedure (VivAer®) for remodeling the nasal valve area includes 1 RCT, two prospective and one retrospective single-arm study and two systematic reviews which was evaluated by Hayes Inc. through an Evolving Evidence Review (February 2025). The systematic reviews confirmed the findings summarized above from the single RCT (Silvers 2021) that, compared to sham, VivAer significantly improved nasal symptoms during shorter term follow-up (12 months), without any consequent serious treatment-related adverse events. However, Hayes Inc Evolving Evidence Review concluded that the overall body of evidence suggests a “minimal” level of support for use of VivAer to treat nasal obstruction due to important limitations including the paucity of studies with comparison groups to placebo, sham, or active treatments (n=1 RCT) and the poor to very-poor quality nature of the noncomparative evidence due to small sample sizes and high attrition at the longer-term follow-up points.. Additional well-designed comparative RCTs are needed to assess the effectiveness, safety and durability of VivAer® and determine how VivAer® compares to other active treatments for nasal airway obstruction associated with nasal valve collapse.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

In 2023, the American Academy of Otolaryngology-Head Neck Surgery (AAO-HNS) issued a position statement on nasal valve repair stating that treatment options of nasal valve dysfunction may include implants aimed at stabilizing the nasal valve. No specific recommendations were made for nasal implants. The AAO-HNS recognizes surgical repair of the nasal valve as a distinct surgical procedure that can alleviate nasal obstruction symptoms for patients who have nasal valve collapse and are suitable candidates for intervention.

In 2010, the AAO-HNS released a clinical consensus statement for the diagnosis and management of nasal valve compromise (NVC). No more recent guidelines were identified. Table 19 summarizes the key consensus statements relevant to this review. The statement also indicated that nasal endoscopy and nasal photography were both deemed useful but not routinely required:

Table 19. Consensus Agreement: Diagnosis and Treatment of Nasal Valve Compromise

Item	Statement	Level of Consensus
Definition	Nasal valve compromise is a distinct clinical entity separate from other anatomic reasons for nasal obstruction	Agreement/strong agreement
History and physical	Main symptom of nasal valve compromise is decreased airflow as reported by the patient	Strong agreement
	Anterior rhinoscopy can be adequate for an intranasal evaluation of the nasal valve, weak or malformed nasal cartilages	Agreement/strong agreement
	Inspiratory collapse of the lateral nasal wall or alar rim is consistent with nasal valve compromise	Agreement/strong agreement
	Increased nasal obstruction associated with deep inspiration is consistent with nasal valve compromise	Agreement/strong agreement
Adjunctive tests	Criterion standard test to diagnose nasal valve compromise exists	Strong disagreement
Outcome measures	Various patient-reported outcomes (eg, visual analog scales, satisfaction measures, quality of life scales) are valid indicators of successful intervention	General agreement
Management	Nasal strips, stents, or cones can be used to treat some patients	Strong agreement
	A surgical procedure that is intended to support the lateral nasal wall/alar rim is a distinct entity from procedures that correct a deviated nasal septum or hypertrophied turbinate	Strong agreement

With regards to surgical repair of the nasal valve, the AAO-HNS states:

- "The treatment of nasal valve dysfunction may involve techniques that include cartilage grafting and open surgical repair, suture suspension techniques, and implants or radiofrequency treatment aimed at stabilizing the nasal valve...The nasal valve may be stabilized using office-based treatments, such as implants or radiofrequency treatment. For patients who require anatomic widening and definitive stabilization of the nasal valve, surgical treatment of nasal valve collapse, along with treatment of other possible causes of nasal airway obstruction, is required to optimize patient outcomes. Failure to perform nasal valve repair, when indicated, is a common cause of incomplete symptom resolution for patients with nasal obstruction and nasal valve dysfunction."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) (<i>Latera Absorbable Nasal Implant</i>)
	30469	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling
	30999	Unlisted procedures, nose (<i>May be utilized for Latera Absorbable Nasal Implant</i>)
HCPCS		
	None	
Type of Service	Surgery	
Place of Service	Outpatient	

POLICY HISTORY

Date	Action	Action
November 2025	Interim Review	Policy Renewed
May 2025	Annual Review	Policy Renewed
May 2024	Annual Review	Policy Renewed

April 2023	Annual Review	Policy Revised
October 2022	Annual Review	Policy Renewed
March 2022	Interim Review	Policy Revised
October 2021	Annual Review	New Medical Policy: Content Moved and Revised

Appendix

Appendix 1:

Table A1. Comparison of Studies Included in Systematic Reviews & Meta-analyses

Study	Casale et al (2023)	Han et al (2024)	Kang et al (2024)
Brehmer et al. (2019)	●	●	●
Jacobowitz et al. (2019)	●		●
Wu et al. (2021)	●	●	●
Silvers et al. (2021)	●		●
Yao et al. (2021)	●	●	●
Han et al (2022)		●	●
Ephrat et al (2021)		●	●
Weissman et al (2015)			●

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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Medical Policy Analyst
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