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Twelve-Month Outcomes of a Bioabsorbable Implant for In-Office Treatment of Dynamic Nasal Valve Collapse

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Objectives: To examine 12-month outcomes for in-office treatment of dynamic nasal valve collapse (NVC) with a bioabsorbable implant.

Study Design: Prospective, multicenter, nonrandomized study.

Methods: One hundred sixty-six patients with severe-to-extreme class of Nasal Obstruction Symptom Evaluation (NOSE) scores were enrolled at 16 U.S. clinics (November 2016–July 2017). Patients were treated with a bioabsorbable implant (Latera, Spirox Inc., Redwood City, CA) to support the lateral wall, with or without concurrent inferior turbinate reduction (ITR), in an office setting. NOSE scores and Visual Analog Scale (VAS) were measured at baseline and 1, 3, 6, and 12 months postoperatively. The Lateral Wall Insufficiency (LWI) score was determined by independent physicians observing the lateral wall motion video.

Results: One hundred five patients were treated with implant alone, whereas 61 had implant + ITR. Thirty-one patients reported 41 adverse events, all of which resolved with no clinical sequelae. Patients showed significant reduction in NOSE scores throughout 12 months postoperatively (77.4 $\pm$ 13.4 baseline vs. 36.2 $\pm$ 22.7 at 1 month postoperatively, 33.0 $\pm$ 23.4 at 3 months, 32.1 $\pm$ 24.6 at 6 months, and 30.3 $\pm$ 24.3 at 12 months; $P < 0.001$). They also showed significant reduction in VAS scores postoperatively (69.7 $\pm$ 18.1 baseline vs. 31.3 $\pm$ 27.1 at 12 months postoperatively, $P < 0.001$). These results were similar in patients treated with implant alone and those treated with the implant + ITR. Consistent with patient-reported outcomes, postoperative LWI scores were demonstrably lower (1.42 $\pm$ 0.09 and 0.93 $\pm$ 0.08 pre- and postoperatively, $P < 0.001$).

Conclusion: In-office treatment of dynamic NVC with a bioabsorbable implant improves clinical evidence of LWI at 6 months and improves nasal obstructive symptoms in a majority of patients up to 12 months.

Key Words: Nasal valve, nasal implant, lateral wall insufficiency, valve repair, nasal obstruction.

Level of Evidence: 2b

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INTRODUCTION

Nasal airway obstruction (NAO) is an unpleasant condition that impacts patients' daily activities such as breathing and sleeping. NAO can be due to a variety of physiologic or anatomic factors that may present in isolation or as a combination.[1] At times, the presence of physiologic factors can exacerbate NAO symptoms caused by already compromised nasal anatomy.

Treatment strategies for NAO depend on the underlying cause of the symptoms.[2] For NAO patients with physiologic factors such as allergy and sinus inflammation, noninvasive treatments such as topical and systemic therapies are usually applied. For patients with compromised nasal anatomy, more invasive surgical procedures are needed to enlarge the nasal airway and relieve NAO symptoms.

The most common anatomic factors contributing to NAO include septal deviation, inferior turbinate hypertrophy, and nasal valve dysfunction.[3] Septal deviation can be corrected by septoplasty, and inferior turbinate hypertrophy is addressed by inferior turbinate reduction (ITR). Nasal valve dysfunction can have static and dynamic components, both which can be addressed by functional rhinoplasty. The static component in nasal valve dysfunction is commonly treated with spreader grafts and extracorporeal septal reconstruction.[4–7] Dynamic nasal valve collapse (NVC), although as common as septal deviation and inferior turbinate hypertrophy, is often underdiagnosed and left untreated.[8,9] Batten grafts, bone-anchored sutures, and lateral crural strut grafts[5,10–12] are common methods in functional rhinoplasty to address dynamic NVC. With techniques such as radiofrequency or laser ablation, in some instances ITR

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can be performed using local anesthesia in the physicians' office. However, minimally invasive in-office procedures to correct septal deviation or dynamic NVC have been lacking.

Recently, a bioabsorbable implant (Latera, Spirox Inc., Redwood City, CA) comprised of 70:30 copolymer of poly(l-lactide) and poly(d-lactide), which can be placed under local anesthesia in the physician's office or under general anesthesia in the operating room (OR), was used to address dynamic NVC by supporting the nasal lateral wall.[13,14] Animal studies showed that the implant material was biocompatible and was absorbed over 18 to 24 months postoperatively.[15] Combined interim 6-month safety and effectiveness results of two studies using this bioabsorbable implant have been reported in a mix of patients who received the implant in an OR or office setting.[16] This report presents the 12-month safety and effectiveness of the bioabsorbable implant used for NAO patients treated in the office setting with the implant alone or with concurrent ITR.

MATERIALS AND METHODS

Study Design

This was a prospective, multicenter, nonrandomized trial (clinicaltrials.gov NCT02964312). The study was designed to assess mid-term safety and effectiveness of an absorbable nasal implant (Latera, Spirox Inc., Redwood City, CA) with or without concurrent ITR for treating NAO patients in an office setting. All patients provided written informed consent, and approval was obtained from the institutional review board at each center.

The baseline visit included a medical history review, evaluation of symptoms, assessment of NAO, and lateral wall motion video of the internal nasal cavity. The degree of nasal obstruction was rated on a severity scale as mild, moderate, severe, or extreme based on the validated Nasal Obstruction Symptom Evaluation (NOSE) score.[17–19] NAO breathing assessment was also done using a Visual Analog Scale (VAS).

During treatment, Latera absorbable nasal implant(s) were delivered to patients under local anesthesia, with or without concurrent ITR. In addition to local anesthesia, patients may have also received monitored anesthesia care or conscious sedation according to the center's standard-of-care practice. If the treatment plan included ITR, the procedure was performed according to the physician's standard practice before the Latera was placed. The Latera implant and delivery procedure was previously described.[13] Follow-up visits took place at 1, 3, 6, and 12 months postprocedure. During each follow-up visit, internal and external nasal exams were performed, as well as collection of NOSE scores, VAS scores for NAO breathing assessment, physician-derived Lateral Wall Insufficiency (LWI) scores,[20] and adverse event assessment. The endoscopic videos from baseline and 6 months postoperatively were examined by experienced otolaryngologists to determine the LWI score using a standardized, blinded protocol. Physical examinations included an evaluation of nasal skin and nasal mucosa appearance and the presence of any implant extrusions, fractures, or migration. A satisfaction questionnaire was also completed by each patient at follow-up visits to collect information related to patient satisfaction with the implant procedure and patient nose appearance.

Enrollment

Enrollment occurred between December 2016 and July 2017 at 16 institutions across the United States. Eligible patients were adults seeking treatment for NAO due to dynamic NVC (confirmed by positive modified Cottle maneuver). In addition, patients had NOSE scores ≥55 (severe, extreme) and had failed to benefit from—or were unable to tolerate—appropriate maximal medical management (e.g., nasal steroid for at least 4 weeks; antihistamines; oral decongestants; nasal strips, stents, or cones). Eligible patients had appropriate nasal and facial anatomy to receive Latera and were willing to undergo an in-office Latera procedure alone or with an ITR. Appropriate facial anatomy can include several features. One is whether there is sufficient nasal cartilage for the implant to support (because the device is indicated for the support of lateral wall cartilage). Patients who have had multiple reduction rhinoplasties may not have enough cartilage. Secondly, it is necessary to have a stable and reasonably wide nasal bone base to stabilize the Latera device. A patient with over-reduced or aggressively osteotomized and narrowed nasal bones would not be a good candidate for Latera. Thirdly, septal deviation was ruled out as a contributor for nasal obstruction because the procedure was office-based and concurrent septoplasties were not allowed.

Statistical Analysis

For purposes of analysis, we examined the following patient groups: Latera alone (without ITR), Latera + ITR, and all patients. Baseline characteristics were compared across subgroups using the *t* test for continuous variables and the chi-square test or Fisher's exact test for categorical variables. NOSE scores were converted to a 100-point scale by multiplying the total score by 5.[17] A VAS was used to capture patients' perception of their ability to breathe through the nose, allowing patients to indicate the degree of breathing difficulty they are currently experiencing, with 100 indicating maximum imaginable difficulty and 0 indicating no difficulty. This analysis includes the change in NOSE and VAS scores from baseline (preoperative) to 1, 3, 6, and 12 months postoperative follow-up. Paired *t* tests were used to compare the mean baseline value to each of the follow-up time points to determine whether there were significant reductions in NOSE and VAS scores, with P values <0.05 considered statistically significant.

A NOSE score severity classification system was developed by Lipan and Most.[19] Their analysis derived clinically relevant severity classes of NOSE scores: mild (5–25 points), moderate (30–50 points), severe (55–75 points), or extreme (80–100 points). This classification system was used as the prespecified definition of a responder. Responders were defined as patients who had at least one NOSE class improvement or a NOSE score reduction of at least 20% from baseline. For this study, the response rate was calculated at 1, 3, 6, and 12 months postprocedure.

We also included an ad hoc analysis of the change in NOSE scores based on a meta-analysis conducted by Rhee et al.[10] They evaluated NOSE scores pre- and postoperatively in patients who had undergone conventional invasive surgical procedures such as septoplasty, turbinate reduction, and functional rhinoplasty—in combination or alone—for treatment of nasal airway obstruction. They concluded that a reduction of 30 or more points on the NOSE score may be considered a clinically meaningful measure of success.

A mean LWI score was calculated at baseline and 6 months postprocedure. Mixed models for repeated measures with unstructured covariance matrices were used to account for repeated measures (nasal cavity) within patients. The least square means, standard errors, and P values were derived from these mixed models.

Statistical analyses were performed by an independent statistician (April Slee, Axio Research, New Arch Consulting, Seattle, WA) using SAS version 9.4 (SAS Institute, Inc., Cary, NC) and R version 3.2.3.

RESULTS

A total of 166 patients were included in this study. Of those, 105 were treated with Latera alone (i.e., no ITR), and

61 were concomitantly treated with ITR. A total of 27 patients (15 Latera only and 12 treated with Latera + ITR) exited from the study before completing their 12-month follow-up. Of the 15 Latera-only patients, seven were lost to follow-up; five withdrew from the study for reasons other than NAO symptoms; and three required additional NAO surgery. Of the 12 patients treated with Latera + ITR, four were lost to follow-up, three withdrew from the study for reasons other than NAO symptoms, and three required additional NAO surgery. The six patients requiring additional NAO surgery were symptomatic and needed additional intervention. The type of additional surgery was not identified in the patient data collection.

Demographics and relevant clinical history for the overall study population, Latera alone, and Latera + ITR procedures are described in Table I. A majority of patients had prior surgical history for which septoplasty and ITR were the most common procedures (Table I).

A total of 41 procedure- or implant-related adverse events were reported in 31 patients. The majority (82%) of the adverse device events occurred within the first 3 months of the implant procedure. These events included 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). There were 17 implant retrievals in a total of 319 implants (5.3% retrieval rate). The reasons for implant retrievals were patient manipulation (5), patient request (1), bump/pimple (1), and unknown reasons (10). The authors hypothesize that the unknown reasons could be due to poor placement or unknown manipulation of the nose. The investigators presume the implant retrievals were not due to adverse physiologic tissue rejection because there was no evidence of tissue inflammation. Additionally, 16 of the retrievals were unilateral. Only one retrieval was bilateral, and this was requested by the patient because the patient did not like the cosmetic impact. Twelve of the 17 patients were treated with Latera only. All events resolved with no clinical sequelae.

Patients had short- and midterm improvement in nasal obstruction symptoms as measured by NOSE scores. Overall, statistically significant reductions in mean NOSE scores were observed throughout the 12-month follow-up period after the procedure (77.4 ± 13.4 baseline vs. 36.2 ± 22.7 at 1 month postoperatively, 33.0 ± 23.4 at 3 months, 32.1 ± 24.6 at 6 months, and 30.3 ± 24.3 at 12 months; $P < 0.001$ for all). Similarly, patients also showed short- and midterm improvement in nasal obstruction symptoms as measured by VAS scores. Overall, 12-month mean VAS scores (29.7 ± 27.9) were significantly reduced as compared with baseline (68.0 ± 18.0, $P < 0.001$). Changes in the NOSE and VAS scores at all follow-up time points are shown in Table II and III, respectively. The reduction in NOSE and VAS scores throughout the 12-month follow-up period was observed for patients treated with Latera alone and those treated with Latera + ITR.

TABLE I.
Patient Demographics and Relevant Medical History.

Characteristic	All Patients N = 166	Latera Alone N = 105	Latera + ITR N = 61
Age (years)	50.5 ± 14.9	51.2 ± 14.4	49.5 ± 15.4
BMI	27.0 ± 5.0*	26.8 ± 4.8	27.4 ± 5.2
Sex, female	82 (49.4%)	51 (48.6%)	31 (50.8%)
Race			
American Indian or Alaska Native	1 (0.6%)	0 (0.0%)	1 (1.6%)
Asian	3 (1.8%)	2 (1.9%)	1 (1.6%)
Black or African American	3 (1.8%)	2 (1.9%)	1 (1.6%)
Hispanic or Latino	11 (6.6%)	6 (5.7%)	5 (8.2%)
White	143 (86.1%)	93 (88.6%)	50 (82.0%)
Other	4 (2.4%)	2 (1.9%)	2 (3.3%)
Sinus disease	57 (34.3%)	43 (41.0%)	14 (23.0%)
Allergic rhinitis	76 (45.8%)	48 (45.7%)	28 (45.9%)
Previous nasal surgery	98 (59.0%)	75 (71.4%)	23 (37.7%)
Septoplasty	65 (39.2%)	54 (51.4%)	11 (18.0%)
Rhinoplasty	14 (8.4%)	11 (10.5%)	3 (4.9%)
Turbinate reduction	64 (38.5%)	51 (48.6%)	13 (21.3%)
ESS	35 (21.1%)	27 (25.7%)	8 (13.1%)

Results are presented as mean ± SD or n (%).
Latera, Spirox Inc., Redwood City, CA.
*BMI was only available for 162 participants.
BMI = body mass index; ESS = endoscopic sinus surgery; ITR = turbinate reduction; SD = standard deviation.

TABLE II.
Change from Baseline in Mean NOSE Score and Responder Rate at 1, 3, 6, and 12 Months.

Follow-up Period	N	Change in NOSE Score, Mean ± SD	Responder Rate* % (95% CI)	*P* Value†
All patients				
1 month	164	−41.3 ± 24.1	89.6% (83.9%, 93.8%)	<0.001
3 months	156	−44.3 ± 25.1	91.7% (86.2%, 95.5%)	<0.001
6 months	152	−45.1 ± 25.8	89.5% (83.5%, 93.9%)	<0.001
12 months	139	−46.3 ± 25.5	89.2% (82.8%, 93.8%)	<0.001
Latera alone				
1 month	103	−40.7 ± 24.5	90.3% (82.9%, 95.2%)	<0.001
3 months	100	−43.9 ± 25.7	92.0% (84.8%, 96.5%)	<0.001
6 months	95	−45.2 ± 25.3	91.6% (84.1%, 96.3%)	<0.001
12 months	90	−43.6 ± 26.4	87.8% (79.2%, 93.7%)	<0.001
Latera + ITR				
1 month	61	−42.2 ± 23.7	88.5% (77.8%, 95.3%)	<0.001
3 months	56	−44.9 ± 24.2	91.1% (80.4%, 97.0%)	<0.001
6 months	57	−45.0 ± 26.7	86.0% (74.2%, 93.7%)	<0.001
12 months	49	−51.4 ± 23.3	91.8% (80.4%, 97.7%)	<0.001

Latera, Spirox Inc., Redwood City, CA.
*Responders are defined as patients who have at least 1 NOSE class improvement or a NOSE score reduction of at least 20% from baseline.
†*P* values are based on paired *t* tests for change from baseline, with $P < 0.05$ indicating statistical significance.
CI = confidence interval; ITR = turbinate reduction; NOSE = Nasal Obstruction Symptom Evaluation; SD = standard deviation.

TABLE III.
Change from Baseline in Mean VAS Score at 1, 3, 6, and 12 Months.

Follow-up Period	N	Change in VAS score, Mean ± SD	*P* Value*
All patients			
1 month	164	−34.3 ± 27.0	<0.001
3 months	156	−35.5 ± 28.5	<0.001
6 months	151	−36.9 ± 29.0	<0.001
12 months	139	−37.8 ± 29.8	<0.001
Latera alone			
1 month	103	−33.7 ± 28.5	<0.001
3 months	100	−36.6 ± 29.0	<0.001
6 months	94	−36.4 ± 30.2	<0.001
12 months	90	−38.7 ± 30.0	<0.001
Latera + ITR			
1 month	61	−35.3 ± 24.4	<0.001
3 months	56	−33.6 ± 27.7	<0.001
6 months	57	−37.7 ± 27.2	<0.001
12 months	49	−36.2 ± 29.6	<0.001

Latera, Spirox Inc., Redwood City, CA.
*P values are based on paired t tests for change from baseline with $P < 0.05$ indicating statistical significance.
ITR = turbinate reduction; SD = standard deviation; VAS = Visual Analog Scale.

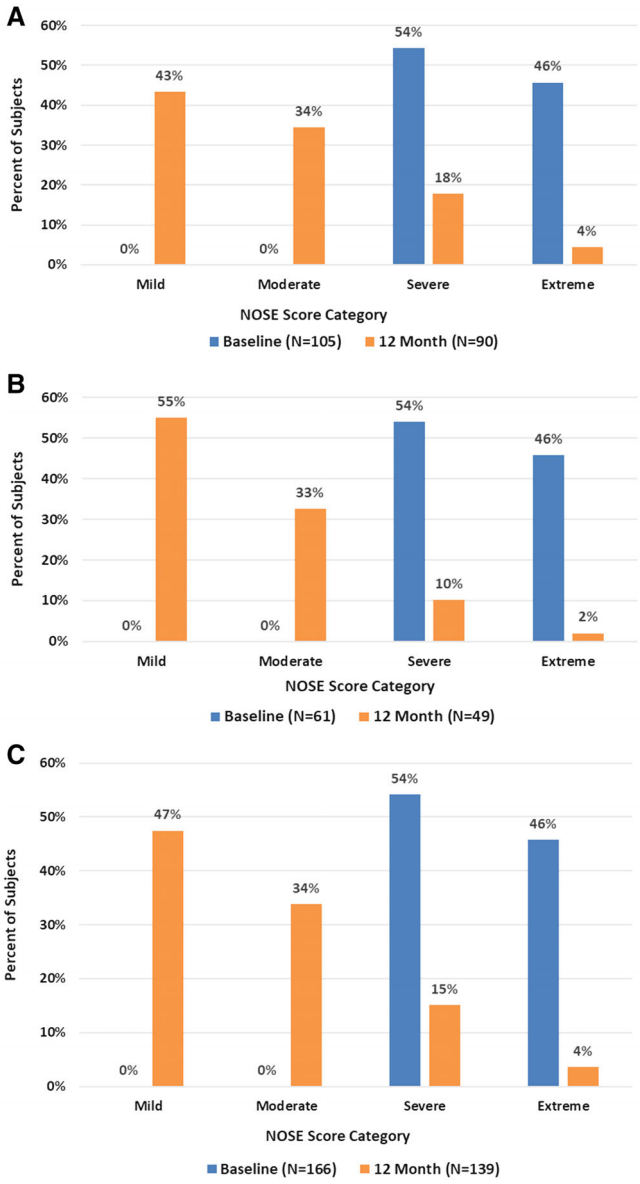

Fig. 1. Changes in NOSE score severity classes at baseline and 12 months after treatment for (A) Latera (Spirox Inc., Redwood City, CA) alone, (B) Latera + ITR, and (C) all patients.ITR = inferior turbinate reduction; NOSE = Nasal Obstruction Symptom Evaluation.

Our ad hoc analysis of NOSE score, based on the clinically meaningful measure of success defined by Rhee et al.,[10] demonstrated that the percentage of patients who achieved ≥30-point NOSE reduction at 12 months was 77% for all patients, 73% for Latera alone, and 83% for Latera + ITR patients.

We examined the NOSE score reduction using our predefined outcome of responder rate of a reduction in clinical severity by at least one category or a 20% reduction in NOSE score. The responder rates ranged from 86.0% to 92.0%. This analysis showed the patients continued to have consistent results at 1, 3, 6, and 12 months after treatment. The percentages are presented in Table II.

We also compared the disease severity category between baseline and 12 months posttreatment. For the majority of patients, their disease severity decreased from "severe" or "extreme" to "mild" or "moderate" at 12 months (Fig. 1). Of the 139 patients who were followed through 12 months, 25 patients (18.0%) improved their clinical symptoms by three categories; 62 patients (44.6%) improved by two categories; and 35 patients (25.2%) improved by one category. Therefore, a total of 122 patients (87.8%) improved by at least one clinical category. Similar trends were observed in Latera alone and Latera + ITR subgroups.

A patient satisfaction survey at the 12-month follow-up was analyzed. Of the 139 patients who completed the survey, only nine patients (6.5%) reported experiencing a cosmetic nose change that was worse than at baseline. The few patients who reported a worse appearance commented on visible bumps and visible Latera forks, and some felt that their nose looked slightly wider. Most of the patients (75%, 104 of 139) indicated that they would recommend the procedure to family or friends. All patients felt the procedure was tolerable (tolerability scale was defined with range 1–4: 1 = very tolerable; 4 = not tolerable).

To objectively measure lateral wall stabilization posttreatment, LWI scores representing the degree of lateral wall motion changes were generated for each nasal cavity separately. Overall, LWI scores were demonstrably lower (less movement) at 6 months postprocedure (1.42 ± 0.09 and 0.93 ± 0.08 pre- and postoperatively, respectively, $P < 0.001$) (Table IV). The improvement in LWI scores was also observed in Latera alone and Latera + ITR subgroups (Latera alone: 1.43 vs. 0.99, $P < 0.001$; Latera + ITR: 1.38 vs. 0.83, $P < 0.001$).

TABLE IV.
Preoperative and 6-Month Postoperative Lateral Wall Insufficiency Scores.

Patient Group	Nasal Cavities	Baseline		6 months		Change		*P* Value*
		LS Mean	SE	LS Mean	SE	LS Mean	SE	
All patients	270	1.42	0.09	0.93	0.08	−0.48	0.08	<0.001
Latera alone	168	1.43	0.11	0.99	0.11	−0.44	0.11	<0.001
Latera + ITR	102	1.38	0.13	0.83	0.13	−0.55	0.12	<0.001

Latera, Spirox Inc., Redwood City, CA.
*P values are based on paired t tests for change from baseline with $P < 0.05$ indicating statistical significance.
ITR = turbinate reduction; LS = least square; SE = standard error.

DISCUSSION

This study demonstrates that in-office treatment of NAO patients using the Latera bioabsorbable nasal implant with or without ITR was effective throughout 12 months after the procedure. Nasal obstruction symptoms, as measured by NOSE scores and NOSE severity categories, were significantly reduced across the 12-month follow-up period. Patients' perception of their ability to breathe through the nose, as evaluated by VAS scores, was significantly improved. Additionally, a patient satisfaction survey showed that very few patients considered the cosmetic changes to their nose to be worse than baseline, and the majority of the patients would recommend the procedure to others. Furthermore, an objective evaluation of lateral wall motion by a blinded physician-derived score demonstrated the physical effect stabilization provided by the implant. Altogether, these different measures show that the in-office procedure with Latera effectively improves the nasal airway in patients with NAO due to dynamic NVC.

The improvement in nasal obstruction symptoms measured by the mean NOSE score reduction in this study is similar to that reported in surgical studies in the OR setting. A meta-analysis by Floyd et al. pooled 16 studies and reported a mean 49-point (95% confidence interval [CI], 39–58) NOSE score reduction at 12+ months after functional rhinoplasty.[21] Similarly, a recent meta-analysis published by Kandathil et al. also reported a 49.0-point (95% CI 35.8–62.1) NOSE score reduction at 6+ months after functional rhinoplasty.[22] In this study, the mean reduction in NOSE score was 46.3 points at 12 months for all patients, 43.6 points for Latera alone patients, and 51.4 points for the Latera + ITR patients, representing a similar effect size as functional rhinoplasty. Additionally, the NOSE score reductions are in line with clinically meaningful measures of success as defined in the Rhee study.[10] All these comparisons consistently demonstrate that for patients with dynamic NVC, an in-office, minimally invasive procedure with Latera can achieve NAO symptom relief comparable to functional rhinoplasty.

The most frequently performed surgeries for NAO patients addressing common anatomic factors include septoplasty, inferior turbinate reduction, and functional rhinoplasty. Most of these procedures are invasive and often require an OR, resulting in longer procedure time, longer recovery, and additional costs associated with anesthesia and OR facility. Our study shows that patients with dynamic NVC can benefit from a minimally invasive in-office procedure with a bioabsorbable implant. Due to its minimal invasiveness, this treatment strategy has the potential to reduce postoperative recovery time and costs associated with anesthesia and OR facility.

Most adverse device events were reported in the early months of treatment and included infection, inflammation, bumps, and skin irritation. It is notable that all these events were resolved within 6 months of the index procedure. The implant retrieval rate (5.3%) is similar to that seen in a previous study.[13]

There are a few limitations of this study. This is a single-arm study comparing pre- and posttreatment measurements of symptoms. A future randomized controlled study should be considered to further examine the device efficacy. Follow-up for this study was limited to 12 months postprocedure. Previously, animal histology studies have shown that an implant of the same composition is absorbed over 18 to 24 months after implantation[15] and that, upon complete absorption, the implant is replaced with nodular bundles of mature collagenized fibrous tissue that may provide mechanical strength at the lateral wall.[15] Therefore, additional follow-up out to 24 months would be beneficial.

CONCLUSION

Using a disease-specific quality-of-life instrument and objective physical examination, our study shows that an in-office, minimally invasive procedure to stabilize the nasal wall with an absorbable implant significantly improves NAO symptoms in patients with dynamic NVC. At 12 months, the Latera implant is safe and efficacious for selected patients in whom dynamic NVC is a main contributor to their NAO. Longer follow-up is needed to determine efficacy beyond 12 months.

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