New Paradigms in the Treatment of Nasal Airway Obstruction:

Perspectives from a Rhinologist and a Facial Plastic and Reconstructive Surgeon

More than 20 million Americans[i] have trouble breathing through their nose due to nasal airway obstruction (NAO), and one of the most common causes of NAO is nasal valve collapse (NVC), which occurs as a result of weak lateral nasal cartilage collapsing inward at baseline or when a person inhales. NVC is as prevalent as septal deviation and turbinate hypertrophy among NAO patients.[ii] The sale of 300 million nasal strips annually in the US[iii] underscores the clear need for lateral nasal wall support.

Based on this identified problem, **Dr. Anthony Del Signore**, a fellowship-trained rhinologist, and **Dr. Taha Shipchandler**, a fellowship-trained facial plastic and reconstructive surgeon, convened to discuss existing treatment options, as well as the evolving treatment landscape for NAO due to NVC from two different physician perspectives.

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1. Is NAO due to NVC common within both of your patient populations?

DR. DEL SIGNORE:
Until recently, I didn't fully appreciate the prevalence of NVC within my patient population. That changed when I participated in a national program with 50 fellow otolaryngologists to survey a consecutive series of sino-nasal patients in our practices for NAO contributors. We evaluated over 1,900 total patients, supplementing common diagnostic methods for evaluating septal deviation and turbinate hypertrophy with the Modified Cottle Maneuver to ensure that clinically relevant NVC contributions weren't missed.

Results of this national market research program showed that in a subset of the patients with severe / extreme symptoms (based on NOSE scores) had NVC rates (73%) similar to the established prevalence of septal deviation (80%) and turbinate hypertrophy (77%).[ii] In the past, I only considered the lateral wall as a cause of symptoms in patients with really overt cases of NVC. My participation in the research gave me an appreciation for the prevalence and severity of NVC among my patients. We've also incorporated changes to our intake process with modifications to assess patients' use of Breathe Right strips, activity levels, and NOSE scores. To minimize inefficiencies with the examination, I have included a cerumen loop to be available in exam rooms, which helps to perform a Modified Cottle Maneuver to further determine the involvement of the lateral wall in the complaints.

DR. SHIPCHANDLER:
In my practice, I see NAO patients with NVC almost as often as with septal deviation and/or turbinate hypertrophy. In fact, recent nationwide market research data showed that NVC is as prevalent as septal deviation and turbinate hypertrophy.[ii] For this reason, I evaluate the lateral wall on every NAO patient using the Modified Cottle Maneuver, which is performed using a cerumen loop or curette to gently support the lateral wall cartilage on each side of the nose while the patient inhales through his or her nose. If the patient experiences significant improvement in breathing on inspiration, the test is indicative of NVC being a contributing factor to their NAO. I have my patients breathe gently at first, and then ask them to mimic their breathing as if they were exercising. I find that by lateralizing the nasal wall during this type of breathing provides valuable insights about the dynamic collapse they may experience during exertion.

2. How do you typically treat NAO due to NVC in your respective fields?

DR. DEL SIGNORE:
Despite being a rhinologist and working within the nasal cavity through an endoscope, I had very little experience with managing the lateral wall. I found treatment options such as over-the-counter vasoconstrictive and/or anti-inflammatory nasal sprays did not relieve nasal obstruction completely as NVC was not addressed. Furthermore, most of the traditional NVC procedures, which are highly invasive, are outside the scope of my practice – leading me to forgo treating NVC all together and referring these patients to my facial plastic colleagues for treatment.

DR. SHIPCHANDLER:
As a facial plastic surgeon, I often perform a variety of grafting techniques, including batten, spreader, rim and various suspension techniques, on patients with NAO due to NVC. However, these traditional techniques, specifically batten grafts, risk cosmetic changes in patients with thin skin. In addition, in some patients, it isn't always feasible to place the graft in what would be the optimal location for addressing NVC symptoms. Also, some of these techniques are more complicated and difficult for physicians to perform without significant rhinoplasty experience. NVC, therefore, is often untreated.

3. What was your perception of LATERA® when you first heard about it?

DR. DEL SIGNORE:
Initially what intrigued me about LATERA was the prospect of addressing NVC, which was something that I didn't commonly focus on in the past. I really had an interest in LATERA potentially being a tool to improve patient outcomes. LATERA is an absorbable nasal implant that supports upper and lower lateral nasal cartilage, which may reduce NAO symptoms and help increase nasal airflow. Through a minimally invasive procedure, which can be done in the OR or office setting, a polymer implant is placed precisely in the lateral wall. The implant creates an exoskeleton connecting the upper and lower lateral cartilage and achieves cantilever support from the bone of the frontal process of the maxilla. Formation of a fibrous capsule around the implant helps to maintain its integrity, and further encapsulation promotes acute implant stability.

With LATERA, I can now address an anatomical contributor of NAO that I typically abstained from – the lateral nasal wall. Based on my own experience, I believe that with LATERA, the ability to address the symptoms of NVC is accessible to more patients and physicians through a minimally invasive, safe and predictable procedure.

DR. SHIPCHANDLER:
I am usually very skeptical when it comes to adopting new technologies. I take a "wait-and-see" approach and only offer new techniques to my patients once there is a broad body of real-world clinical experience that allows me to understand the risks and benefits in different types of patients. I initially took this wait-and-see approach when I first learned of LATERA. That changed after I spoke with a number of colleagues in the facial plastic surgery community. They reported that they and their patients have been very satisfied with LATERA and have found it to be an intuitive and durable option for addressing the symptoms of NVC with minimal cosmetic risk.

In addition to these positive clinical experiences, I was particularly interested in evaluating LATERA for my own patients because it's an absorbable product, as I prefer not to use any type of implant that isn't readily absorbed. LATERA is an implant made from poly-L-lactic acid, or PLA – this material has been used in a variety of implants and sutures for decades, giving it a favorable risk profile. Typically, the implant has been replaced by collagen by 18 months post procedure. No major adverse events have been reported with LATERA, and the implant retrieval rate is below 1%.[iv] Taken together, these data made a compelling case for offering LATERA to my own patients.

4. Is there a specific type of patient profile that you consider when offering LATERA?

DR. DEL SIGNORE:
I initially used LATERA in patients with relatively thick skin around the nose, which provided a bit more leeway in the event the implant wasn't perfectly deployed within the plane. Once I had completed several procedures, my comfort level with the technique increased, including the initial piercing to find the plane and transitioning to the parallel direction along the sidewall. My technique for placing the implant continues to evolve after every procedure as a result of adapting to inter-patient differences in laterality, depth and tissue thickness. The learning curve is quick and the feedback I received from my first ten patients who received the implant solidified my decision to offer this innovative approach to patients with NVC. By their four week follow-up visit, these patients all reported feeling great with very little swelling and were satisfied with their breathing and their cosmetic outcome. Over the past year and a half of use, patients have experienced favorable results with minimal added discomfort downtime.

DR. SHIPCHANDLER:
When I first began using LATERA, I was somewhat cautious in my choice of patients. My first patient had medium to thick skin on her nose and had a prior history of other procedures that hadn't provided relief for NAO. I believed that LATERA could provide good clinical and cosmetic outcomes for this patient, and she experienced a profound improvement in her NOSE scores, with a decrease from a baseline score of 75 to a score of 10 just six weeks after the procedure. As I've gained experience with LATERA, I've become more comfortable using the implant in a much broader population of patients, including those with thinner skin, though I inform them of the risk of temporarily seeing the contour of the implant. For patients with unresolved NAO symptoms, I believe that LATERA offers a favorable risk-benefit profile.

5. Has clinical and in-practice data been a major driver of your adoption of LATERA?

DR. DEL SIGNORE:
Aside from my own positive patient outcomes, clinical data show durable results within the range of other traditional, more invasive techniques[v,vi], reinforcing LATERA as a safe and effective option for my patients with NVC-related NAO. Patients in a recent multi-center study demonstrated reduced nasal congestions, less trouble breathing through their nose, reduced nasal blockage or obstruction, and less trouble sleeping. Moreover, these patients saw sustained symptom relief at two years. Given these findings and the favorable risk-benefit profile, LATERA is an important advance for patients suffering with NVC.

DR. SHIPCHANDLER:
Perhaps not surprisingly, patients frequently have concerns about any potential cosmetic effects of LATERA, especially about whether the implant will be visible. The results of clinical trials conducted in Germany demonstrate that LATERA has minimal side effects with minimal cosmetic risk. Recent 18- and 24-month data were presented at the 2017 Annual Meeting of the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS) demonstrating durable relief of NAO symptoms with LATERA with minimal cosmetic changes.[vi] I tell my patients that we consider the approach a success if there's nothing obviously visible within a few weeks after the procedure.

Case Studies Anthony Del Signore, MD

PATIENT 1
64-year-old female with a small nose and medium to thick skin had a prior history of rhinoplasty and balloon sinuplasty and was maintained on nasal irrigation and nasal sprays. Despite these multiple approaches, she continued to experience NAO symptoms. I recommended turbinate reduction, concha bullosa resection along with LATERA because I expected that the NVC component of her NAO would become more prominent once the turbinates had been addressed. After performing the procedure in the operating room, she experienced an 87% reduction in her NOSE scores, from 75 at baseline to 10 at six weeks following the procedures.

PATIENT 2
29-year-old male with a large nose and thick skin had continued NAO symptoms following two prior septoplasty. Thorough internal and external evaluation of his nose indicated that he still had a fair amount of NAO. I recommended LATERA because I believed his nasal anatomy was favorable for a successful outcome with the implant. I performed the procedure in the operating room. His NOSE scores improved from 80 at baseline to 25 at the six-week follow-up visit, a 65% decrease. Prior to the development of LATERA, it would have been a challenge for me to recommend a course of action that I could have performed to improve his breathing.

PATIENT 3
61-year-old female with a normal nose and medium to thick skin presented with a fair amount of NAO, including moderate-to-severe NVC and some inferior turbinate hypertrophy. She indicated that she preferred a treatment option that would not require procedures that had to be conducted in the operating room. I performed bilateral LATERA placement as well as bilateral turbinate coblation in the office under local injection and topical spray. She tolerated both procedures well with minimal discomfort. She had a baseline NOSE score of 85 and saw an improvement to 40 at six weeks, a 60% decrease.

Case Studies Taha Shipchandler, MD

PATIENT 1

26-year-old man with a normal nose and skin had previously undergone septoplasty, turbinate reduction and alar rim grafts. While these procedures had helped address his NAO symptoms, he indicated subsequently that the improvement wasn't quite as good as he had hoped and wanted to explore additional options. I thought LATERA would be a good option for him and performed the procedure in the office. He reported great improvement in his breathing immediately after the procedure, which was very gratifying. At a follow-up visit eight weeks after the procedure, he noted further improvement once the swelling had resolved. His NOSE scores improved from 50 at baseline to 20, a 60% decrease.

PATIENT 2

33-year-old woman with a small nose and thin skin, especially around the bony vault, had previously undergone septoplasty and turbinate reduction by another physician and she was still suffering with NAO symptoms. Placement of batten grafts at a location that would have provided optimal treatment for her NAO symptoms was a challenge - they would have been visible due to the thinness of her skin. LATERA had potential to improve her symptoms with a better cosmetic result. I performed her LATERA implant procedure in the OR because I simultaneously performed a revision septoplasty and turbinate reduction. The cosmetic results were quite good and she has also had significant improvement in her breathing. Her NOSE scores improved from 70 at baseline to 20, a 71% decrease.

PATIENT 3

31-year-old woman with a normal nose and thin skin presented with septal deviation, moderate turbinate hypertrophy and obvious NVC. Initially I recommended septoplasty, but as a surgical resident she had a very busy schedule and was concerned about taking time off, so we decided to use LATERA in order to minimize her downtime. She was able to provide real-time feedback during the procedure and told me that she felt that she could breathe better as soon as the implants had been placed. She had some bruising on the sides of her nose that resolved within 10 days, but she was able to leave for a vacation the day after the procedure and reported that it didn't interfere with her physical activity. Her NOSE scores improved from 70 at baseline to 40, a 43% decrease.

BASELINE

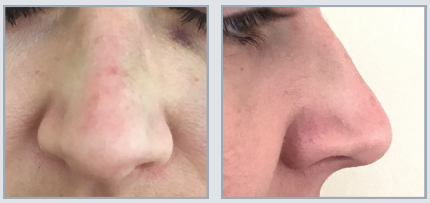
1 WEEK

BASELINE

1 WEEK

BASELINE

1 WEEK



[i] Value calculated based on 2014 US population estimate from US Census and World Bank data in conjunction with incidence numbers cited in: Stewart M, Ferguson BJ, Fromer L. Epidemiology and burden of nasal congestion. Intl J Gen Med. 2010;3:37-45.

[ii] Senior B, et al., Nasal airway obstruction: Prevalence and anatomic contributors. Ear Nose Throat J. 2018 June;97(6):173-176

[iii] Johnsen M. Cough-Cold Report 2016. Drug Store News. February 2016.

[iv] Based on retrievals per implants delivered, and infections per cases completed. Causes are consistent with previously identified risks related to the LATERA implant.

[v] San Nicolo, et. al. 2017. Absorbable Implant to Treat Nasal Valve Collapse. Facial Plast Surg, 32:233-240.

[vi] San Nicolo M, Stelter K, Sadick H, Bas M, Berghaus A. Long term safety and effectiveness of a novel absorbable implant in patients with nasal valve collapse. In: Annual Meeting of the American Academy of Facial Plastic and Reconstructive Surgery. Phoenix, AZ; 2017.

Indications for Use: The LATERA Absorbable Nasal Implant is indicated for supporting upper and lower lateral nasal cartilage.

Disclosures: Anthony Del Signore, MD and Taha Shipchandler, MD are consultants for Spirox. Physician experience and individual patient results may vary.