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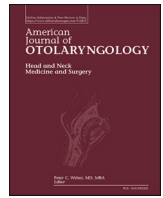
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Effect of alar nasal valve stent on nasal breathing

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ABSTRACT

Purpose: Lateral nasal wall insufficiency has previously been a surgical challenge. In 2018, the Alar Nasal Valve Stent (Medtronic) was taken into use at Helsinki University Hospital. The alar cartilages are repositioned and locked into position with the Alar Nasal Valve Stent on the mucosa. The stent gives support and widens the alar valve while cartilages scar into their new position presumably facilitating breathing after removal of the stent. The aim of this prospective, observational study was to investigate whether the Alar Nasal Valve Stent has an effect on nasal breathing in patients with lateral nasal wall insufficiency.

Materials and methods: Symptom questionnaires (Sino-Nasal Outcome Test-22, Nasal Obstruction Symptom Evaluation, five-step symptom score) were analyzed preoperatively and at 3, 6, and 12 months postoperatively. Acoustic rhinometry, rhinomanometry, and peak nasal inspiratory flow were analyzed preoperatively and 3 months postoperatively. The patients performed a stress ergometry preoperatively and 3 months postoperatively, with their noses being photographed and filmed.

Results: In a series of 18 patients, a significant positive difference was seen in subjective symptom scores preoperatively versus postoperatively. The difference remained stable throughout the follow-up. No difference in objective symptom measurements was observed.

Conclusions: Patients suffering from lateral nasal wall insufficiency experience a significant subjective improvement in nasal breathing after Alar Nasal Valve Stent surgery.

1. Introduction

The nasal valvula, i.e. the internal and external nasal valves, is the gatekeeper of nasal airflow [1–8]. The valvula is situated in the nose rim and is limited by the septum, the inferior bottom of the nasal cavity, and laterally by the upper lateral cartilage (ULC). The lower lateral cartilages (LLC) of the lateral wall act as a supporting structure to the nasal alae. Even a small dysfunction of these structures can impair the nasal breathing markedly [1,9]. If the cartilages are suboptimally positioned or are too weak, the nasal alae collapse during inspiration, i.e. the patient suffers from lateral nasal wall insufficiency (LNWI).

Nonsurgical treatment methods of LNWI include nasal spreaders or tapes [8–10]. Exercise of the nasal muscles has also been mentioned in the literature [11]. If these methods are insufficient, operative treatment is considered. Various surgical methods have been described, including repositioning of the cartilages using different grafts, suspension sutures, and implants to support the lateral wall of the external nasal valve [2,5,8,9,12–16]. The aim of these techniques is to stabilize the lateral

valves and/or widen the nasal opening [5]. As valvula surgery is often challenging, time-consuming, and has a long learning curve, new, more practical methods are welcome. In 2013, a silicon plate (Alar Nasal Valve Stent, Medtronic) was launched on the European market and two years later on the Finnish market (Fig. 1). It was taken into use at Helsinki University Hospital in 2018.

The surgery is performed through an intercartilaginous incision, along the caudal end of the ULC. Through the incision, the soft tissue over the ULC is dissected in a dorsal direction, and the mucosa over the LLC is dissected on the medial side. Thus, the caudal end of the ULC and the cranial end of the LLC are freed to be repositioned. A 4.0 polyester suture, with the Alar Nasal Valve Stent (0.5 mm × 15 mm × 19 mm) fastened to the end of the suture, is then passed through both cartilages starting from the inside of the nasal cavity passing through the ULC, then continuing through the LLC from the lateral side of the cartilage. The Alar Nasal Valve Stent is then folded into shape, and the needle is inserted through a hole in the Alar Nasal Valve Stent. By tightening the suture, the stent is placed on the mucosa of the lateral nasal wall. The

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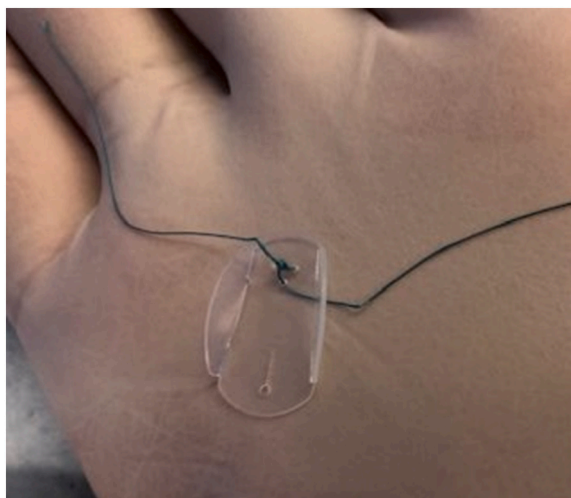


Fig. 1. Alar nasal valve stent.

stent is then further pressed laterally to the nasal wall, which widens the internal nasal valve and slightly everts it. When the stent is in an optimal position, the suture is pulled into the slit in the center of the stent, causing the LLC to glide upwards along the ULC and locking the cartilages and the stent into place. The two ends of the sutures are loosely tied together. The locking mechanism enables the reposition of the cartilages while the stent's purpose is to work as a spring, widening the valve during healing. The stent and the suture are removed after 7–10 days. The new, wide position and the doubled, more stable cartilages scarring together should facilitate nasal breathing.

There are no previous studies on Alar Nasal Valve Stent. The aim of this prospective, observational study was to investigate whether the Alar Nasal Valve Stent has an effect on nasal breathing and nasal obstruction in patients with LNWI.

2. Materials and methods

2.1. Study design

The study was conducted at the Helsinki University Hospital Department of Otorhinolaryngology – Head and Neck Surgery during 2018–2021. All patients diagnosed with nasal obstruction caused by LNWI and scheduled for the Alar Nasal Valve Stent operation were offered the opportunity to participate in the study. Diagnosis was made by ML by inspection, Cottle maneuver, modified Cottle maneuver, cotton ball test, inspection of nasal breathing at rest, and forced breathing test [17]. Rhinoscopy and nasal endoscopy were used for differential diagnosis and to exclude other nasal conditions. The exclusion criteria were pregnancy or planned pregnancy within a year, breast-feeding, coronary artery disease, musculoskeletal problems preventing stress ergometry, previous surgery on the valvular cartilages, and any surgery

of the nose or sinuses within the last year.

Because of the lack of previous studies on Alar Nasal Valve Stent, no power analysis could be calculated. Based on the available resources, the initial aim was to recruit a minimum of 17 patients to this pilot study.

A flow chart of the study is presented in Fig. 2. Peak nasal inspiratory flow value (PNIF), acoustic rhinometry (ARM), and rhinomanometry (RMM) were measured in a sitting position. The highest PNIF value of three attempts was recorded. Of the ARM results, we analyzed the minimum cross-sectional area (MCA) without decongestion, separately on both sides and combining both sides. Of the RMM results, we analyzed the inspiratory mean resistance without decongestion, separately on both sides and combining both sides. Subjective symptom scoring was measured with a five-step symptom score (Likert scale, 1 = no symptoms, 5 = continuous symptoms), Sino-Nasal Outcome Test-22 (SNOT-22), and Nasal Obstruction Symptom Evaluation (NOSE). NOSE score was analyzed by multiplying the total points by five (maximum score 100). A SNOT-22 score difference of 8.9 points was considered clinically relevant, that is, the smallest change in SNOT-22 score that the patient may perceive as an improvement in symptoms [18]. A NOSE score difference of 24.4 points was considered clinically relevant [19]. The patient reported outcome measures, that is, SNOT-22 and NOSE were considered as primary endpoints.

Patients' noses were photographed from below during normal inspiration preoperatively and three months postoperatively. A stress ergometry on a stationary bicycle was performed to evaluate valvular function during exercise and to measure patients' oxygen uptake. Women started the ergometry with a resistance of 40 W, and the resistance was increased by 40 W every 3 min, whereas the corresponding resistances for men were 50 W. While riding the bicycle, patients' noses were filmed from ahead. The patients continued the stress ergometry for as long as they could, and the total time was noted.

After all patients had had their last follow-up visit, an experienced rhinologist (SHM) reviewed the patients' pre- and postoperative videos and photographs in a randomized order, estimating whether the video/ photograph was pre- or postoperative. The aims of this procedure were to evaluate whether the alar stent visibly changes the appearance of the nose and whether an objective difference exists in alar collapse, which increases during exercise because of higher airflow.

All surgeries were performed by the same surgeon (ML) between October 2018 and January 2020. The surgery was standardized and performed as described above. All surgeries were performed as a day surgery and under local anesthesia. Postoperatively, the patients were advised not to touch or blow the nose, and to use saline spray regularly and analgesics if needed. The stent and suture were removed after 7–10 days, after which no foreign objects were left in the nose. Thus, the stent was used as a support for the cartilage during the healing process, after the cartilage had been surgically repositioned.

The study followed the STROBE reporting guidelines.

2.2. Statistics

The material was analyzed using NCSS 12 Statistical Software (2018,

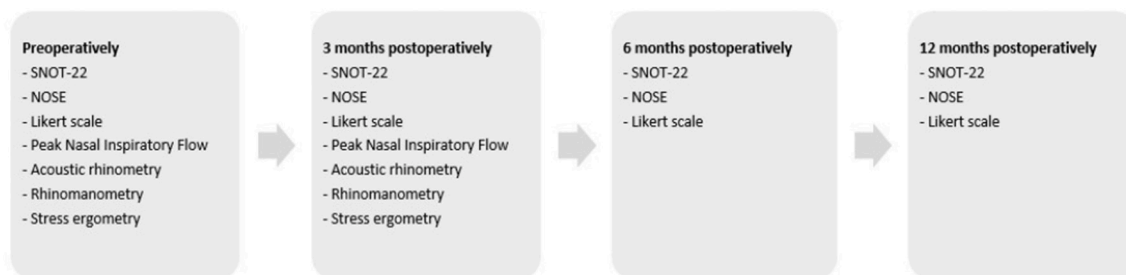


Fig. 2. Flow chart of the study.

NCSS, LLC, Kaysville, UT, USA, ncss.com/software/ncss), applying the Wilcoxon Signed-Rank Test when the values were not normally distributed or the values were order scale variables, and Paired-Sample *t*-test when the values followed normal distribution. A *p*-value <0.05 was considered statistically significant.

2.3. Ethical considerations

The study protocol was approved by the Helsinki University Ethics Review Board (HUS/1684/2018), and all patients gave written informed consent.

3. Results

3.1. Population

We recruited 20 patients to the study. Two were excluded: one because of unexpected pregnancy and one dropped out of follow-up. Three patients failed to attend postoperative stress ergometry and participated only with questionnaires. Two patients failed to return questionnaires: one preoperative SNOT-22 and one postoperative follow-up at three months. All 18 patients returned the follow-up questionnaires at 12 months postoperatively. Due to COVID-19 pandemic regulations, six patients did not attend ARM and RMM.

The mean age of patients was 51.4 (range 25–76) years. Patients' background data are presented in Table 1. As seven patients were symptomatic on only one side of the nose, they had unilateral surgery, while 11 patients had bilateral surgery.

3.2. Symptom questionnaires

Preoperative SNOT-22, NOSE, and Likert scale scores were compared with the scores at 3, 6, and 12 months postoperatively. We found a significant symptom reduction in all symptom questionnaires at every follow-up point (Table 2). Fig. 3 shows the absolute changes in SNOT-22 scores preoperatively versus three months postoperatively. A clinically relevant change of 8.9 points in SNOT-22 score was reached in 13/16 patients (81.3%), whereas 10/17 patients (58.8%) attained a clinically relevant change in NOSE score. Symptom scores remained stable from three to six and 12 months postoperatively.

3.3. PNIF, ARM, and RMM

We analyzed 15 patients' pre- and postoperative PNIF values. Preoperatively, the mean PNIF value was 86.0, while postoperatively it was 102.7 (*p* = 0.08).

We analyzed 12 patients' ARMs and RMMs. No significant difference was seen between preoperative and postoperative MCA values or in inspiratory mean resistances (Table 3).

Table 1
Background data of patients with lateral nasal wall insufficiency.

		Total number n (%)
Sex	Men	9 (50.0)
	Women	9 (50.0)
Smoking status	Yes	1 (5.6)
	No	11 (61.1)
	Ex-smoker	6 (33.3)
Previous nasal surgery	Yes	10 (55.6)
	No	8 (44.4)
	Septoplasty	3 (16.7)
	Septocolumelloplasty	4 (22.2)
	ESS	1 (5.6)
	RFA	8 (44.4)

ESS = endoscopic sinus surgery, RFA = radiofrequency ablation.

Table 2

Preoperative vs. 3-, 6-, and 12-month postoperative symptom questionnaires in patients who underwent Alar Nasal Valve Stent surgery because of lateral nasal wall insufficiency.

	Preop (min-max)	3 months postop (min-max)	P-value
SNOT-22 (n = 16)	47.6 (20–77)	28.8 (7–63)	<0.001
NOSE (n = 17)	70.0 (30–95)	39.4 (5–80)	<0.001
Likert scale (n = 17)	4.71 (4–5)	3.29 (2–5)	<0.001

	Preop	6 months postop	P-value
SNOT-22 (n = 17)	46.8 (20–77)	29.1 (7–70)	<0.001
NOSE (n = 18)	70.3 (30–95)	41.7 (10–90)	<0.001
Likert scale (n = 18)	4.72 (4–5)	3.06 (1–5)	<0.001

	Preop	12 months postop	P-value
SNOT-22 (n = 17)	46.8 (20–77)	32.1 (4–74)	<0.001
NOSE (n = 18)	70.3 (30–95)	42.5 (5–100)	<0.001
Likert scale (n = 18)	4.72 (4–5)	3.28 (1–5)	<0.001

3.4. Bike ergometry

We reviewed 15 patients' stress ergometries. Preoperatively, the mean total time was 526 s, while postoperatively it was 533 s (*p* = 0.63).

3.5. Photographs and videos

We reviewed 15 patients' preoperative and three-month postoperative photographs and videos. Of the preoperative photographs, 13/15 (86.7%) were evaluated correctly as preoperative, while 11/15 postoperative photographs (73.3%) were evaluated correctly as postoperative. Of the preoperative videos, 9/15 (60.0%) were evaluated correctly as preoperative, while 12/15 postoperative videos (80.0%) were evaluated correctly as postoperative. As the photographs and videos were evaluated in randomized order, the sum of evaluated pre- and postoperative photographs and videos does not match.

3.6. Complications

One patient had a mild postoperative infection, which was treated with peroral cephalexin. One patient had a postoperative abscess, which was treated with abscess drainage and intravenous cefuroxime and metronidazole. After these events, patients (*n* = 10, 55.6%) were administered a prophylactic, preoperative dose of 1.5 g cefuroxime intravenously, and no further infections were seen.

One stent did not settle correctly during the surgery and did not stiffen the valvular area sufficiently. The patient underwent a successful alar stent re-surgery 13 months later (not included in the study).

4. Discussion

Alar Nasal Valve Stent surgery in patients with clinical LNWI improves postoperative symptom scores, indicating that the Alar Nasal Valve Stent is an effective treatment for this patient group. Postoperative symptom scores at 3, 6, and 12 months were similar, thus, improvement in nasal breathing is evident within 3 months of surgery and the improvement remains stable. Most of the patients reached a clinically significant change in both SNOT-22 and NOSE scores at three months postoperatively. Interestingly, the three patients who had an increased SNOT-22 score postoperatively (Fig. 3) were not the same patients as those with infections or re-surgery. A common factor for the patients having an increased postoperative SNOT-22 score was a previous nasal surgery, and thus, their SNOT-22 result might be explained by the patients having nasal congestion not only caused by LNWI but also other

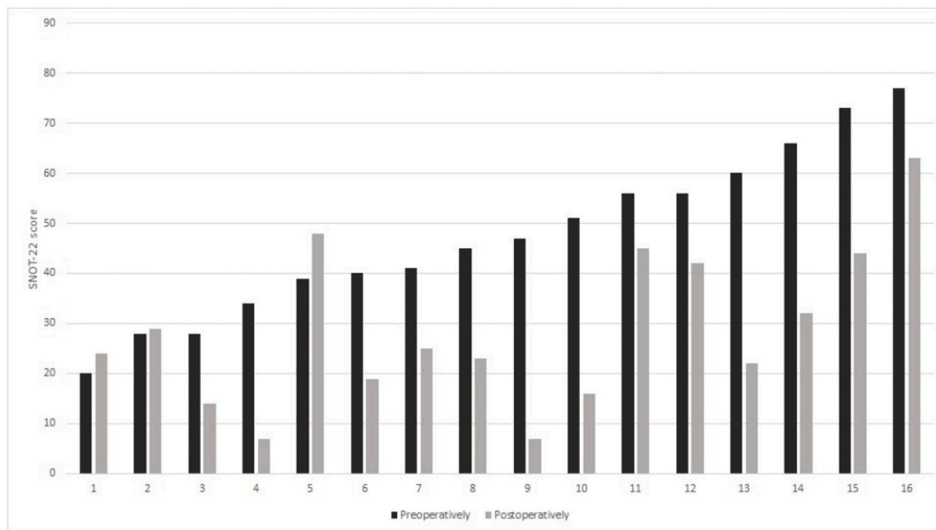


Fig. 3. Absolute changes in SNOT-22 score preoperatively vs. three months postoperatively.

Table 3

Preoperative vs. postoperative ARM and RMM results.

	Preop	3 months postop	P-value
RMM R (Pa/[ml/s])	1.320	0.339	0.13 (NS)
RMM L (Pa/[ml/s])	0.620	0.606	0.85 (NS)
RMM total (Pa/[ml/s])	0.313	0.199	0.17 (NS)
MCA R (cm ²)	0.545	0.511	0.40 (NS)
MCA L (cm ²)	0.548	0.523	0.41 (NS)
MCA R + L (cm ²)	1.093	1.043	0.44 (NS)

R = right, L = left, ARM = acoustic rhinometry, RMM = rhinomanometry (mean inspiratory resistance), MCA = minimum cross-sectional area.

etiologies. There was no significant improvement in patients' PNIF values, although the postoperative PNIF change of 16.7 L/min nearly reached the clinically significant change of 20 L/min suggested by Mo et al. [20]. However, we found no improvement in ARM or RMM, which might be because of the small number of patients (n = 12). It is also possible that the measurement gear stabilizes the alar area, thus not reflecting reality. Furthermore, MCA measures a static situation, whereas alar collapse is dynamic. Our preoperative RMM and MCA values indicate that despite clinical LNWI our patients did not necessarily have poor MCA and RMM values preoperatively.

When blindly evaluating pre- and postoperative photographs and videos, over 50% of both preoperative and postoperative photographs and videos were evaluated correctly. This could be interpreted as the Alar Nasal Valve Stent changing the appearance of the nose during inspiration when viewed from below, and further, the Alar Nasal Valve Stent keeping the nose more open during exercise.

In our relatively small material, we found two postoperative infections, both treated with antibiotics, and one additionally treated with abscess drainage. When Alar Nasal Valve Stent was first taken into use at our clinic, the patients were not given any prophylactic antibiotics. After the abscess, all patients were preoperatively administered a prophylactic dose of cefuroxime 1.5 g intravenously (10 patients, 55.6%), and within the group who received prophylactic antibiotics no postoperative complications occurred.

There were no other complications in our subjects. One patient did not, however, gain sufficient improvement in her nasal congestion and had to undergo a re-operation. The patient was one of the first ones to have an alar stent at our clinic, and therefore, the result might be explained by the surgeon's lack of experience with the method.

In 2019, Ansari et al. treated 60 patients with internal nasal valve dysfunction with conventional septorhinoplasty including spreader

grafts. They found a significant improvement in MCA, SNOT-22, NOSE, and visual analogue scale at 3 months postoperatively, but no significant difference in postoperative RMM, however. A possible explanation to our lack of postoperative MCA improvement is that the AVNS only affects the valvular area, whereas Ansari et al. also performed a septoplasty on their patients [21].

In 2015, Menger et al. performed a systematic review of studies on functional septorhinoplasties. In the included studies, both internal and external nasal valves were operated on with conventional methods. In accordance with our study, they showed a significant, stable improvement in NOSE score postoperatively [22].

This is, to our knowledge, the first study on the effectiveness of the Alar Nasal Valve Stent (Medtronic). In 2011, Stupak published an article about endonasal repositioning of the ULC, an approach very similar to the Alar Nasal Valve Stent [7]. In his study, he repositioned the ULC endonasally, similarly to the method described when using the Alar Nasal Valve Stent, and then placed a supporting suture plate onto the lateral nasal wall. He showed an improvement in the proportion of ULC collapse. Although Stupak's study included 50 patients, also patients with simultaneous nasal or paranasal surgeries with ULC repositioning were included, which might have affected the results. His follow-up time varied from one to 18 months.

Another fairly new minimally invasive technique in treating LNWI is the Latera absorbable implant, which is inserted submucosally to support the lateral cartilages [9]. It has been shown to significantly improve the patients' NOSE scores, with the longest follow-up time being 24 months [13]. It also reduces lateral wall medialization during inspiration [14]. The implant absorbs within 24 months, follow-up beyond that is yet to be published. Unlike Alar Nasal Valve Stent, the Latera implant is a foreign object left in the nose. Thus, possible complications include inflammation, infection, and extrusion of the implant [15,16].

In this study, we did not compare the Alar Nasal Valve Stent to other surgical methods. However, a major advantage of the Alar Nasal Valve Stent is the minimal invasiveness. The surgical technique is easy, and the learning curve is shallow. Unlike open rhinoplasty, there is no need for general anesthesia or overnight stay in hospital. Neither is there a need for cartilage grafts nor foreign body grafts. The cost of Alar Nasal Valve Stent is around \$100. Compared to other operative methods, as mentioned above, there is no need for general anesthesia, the amount of instrumentation needed is modest, the operating time is shorter, and the number of operating room personnel is low, thus reducing the overall costs of using the Alar Nasal Valve Stent.

In 2009, Spielmann et al. published a systematic review on surgical

techniques in treatment of LNWI [5]. They concluded that even though most of the reviewed techniques had a high success rate, it is essential to treat the cause of LNWI and choose the surgical technique individually [5]. We agree, and our convincing results for subjective symptom scores demonstrate a successful patient selection.

The one-year follow up is a strength of this study. The effect of the Alar Nasal Valve Stent is based on the formation of scar tissue in the nasal valves. A year is thus a reasonable follow-up time, as it allows the scar tissue to form and stabilize. The study also has some weaknesses. As in all pilot studies, the patient population was relatively small. Furthermore, because of the COVID-19 pandemic, we were unable to collect all the planned data on all patients. Another weakness of this study was the inclusion of patients with previous nasal surgeries, which might bias the results. Patients who had had any surgery specifically on the valvular area were, however, excluded, as were patients with any surgery on the nose or sinuses during the past year. Further, randomized studies comparing methods are warranted.

5. Conclusion

In this prospective, observational pilot study on the use of Alar Nasal Valve Stent for nasal congestion in patients with LNWI, we found a significant, stable improvement in symptoms reported on questionnaires from three to 12 months. Patients suffering from LNWI thus experienced a subjective improvement in breathing after the minimally invasive Alar Nasal Valve Stent surgery.

CRedit authorship contribution statement

Sara Sainio: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data Curation, Writing – Original Draft, Visualization, Project administration, Funding acquisition **Marie Lundberg:** Conceptualization, Methodology, Validation, Resources, Writing – Review & Editing, Visualization, Supervision, Project administration, Funding acquisition **Sari Hammarén-Malmi:** Conceptualization, Validation, Writing – Review & Editing **Petra Pietarinen:** Conceptualization, Validation, Writing – Review & Editing **Karin Blomgren:** Conceptualization, Methodology, Validation, Resources, Writing – Review & Editing, Visualization, Supervision, Project Administration, Funding acquisition.

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