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Evaluation of Safety and Efficacy for an Intranasal Airway Device in Nasal Surgery

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IMPORTANCE Postoperative packing in nasal surgery often results in nasal obstruction and discomfort. Commercially available silicone intranasal airways (IAs) serve as dual-nasal airway tubes aimed at alleviating this process, but the safety and efficacy of these devices are unknown.

OBJECTIVE To evaluate the safety and efficacy of an intraoperatively placed IA device in rhinoplasty and nasal surgery.

DESIGN, SETTING, AND PARTICIPANTS In this retrospective record review, the medical records of patients undergoing nasal surgery with insertion of the IA at a single institution from 2012 to 2017 were reviewed. After review of over 200 patients, a questionnaire was developed to assess device efficacy.

EXPOSURES Use of the IA device. The IA is 12 cm long, anchored across the columella, extends distally along the nasal floor, and has a proximal external portion used for cleaning and maintaining patency. Placed intraoperatively, the device aims to support air flow postoperatively in the face of edema, hemorrhage, and packing.

RESULTS A total of 302 operations in 300 patients were analyzed, including primary and revision septorhinoplasty. A total of 24 (7.9%) patients self-removed or inadvertently dislodged the IA. Minor acute postoperative complications not unique to airway insertion included cellulitis in 4 (1.3%) participants and epistaxis in 6 (2%). Postoperatively, 1 (0.3%) patient developed dehiscence along transcolumellar incisions. A total of 59 patients (100% compliance) completed the efficacy questionnaire. The mean breathing score was between good and average (2.9 of 5), comfort scores between comfortable and average (2.9 of 5), and mean ease of irrigation score was between very easy and easy (1.96 of 5). The device was irrigated on average 3.57 times per day. A total of 43 (76%) particpiants had full patency or only partial obstruction, compared with 13 (24%) patients with total obstruction. In all patients, with or without obstruction, the effect lasted an average of 4 days.

CONCLUSIONS AND RELEVANCE The device is safe and well-tolerated for maintaining patency of the nasal airway in patients undergoing rhinoplasty and nasal reconstruction without increased risk of incisional dehiscence.

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Supplemental content

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Packing and related materials in nasal surgery are used widely to support unstable nasal bones, splint an acutely corrected septal deformity, protect the mucosal flap in septal perforation repair, and control epistaxis.[1-3] Although approaches to nasal packing vary greatly among surgeons with respect to devices, materials, and duration of placement,[4] postoperative packing itself has remained an integral part of both nasal and sinus surgery. Historical approaches using massive amounts of densely packed gauze in the nasal vault are now uncommon, and most contemporary rhinoplasty surgeons use much less material to achieve the same objectives, including devices and materials such as dissolvable polymers, methylcellulose dressings, and various stents or silicone sheets.[4] Edema, secretions, and residual bleeding may contribute to postoperative nasal obstruction independent of the use or nature of the packing material, and the clinician is thus left with a challenge of maintaining nasal airway patency. This airway compromise may result in patients experiencing discomfort, sleep disturbances,[5] or hypoxia.[2] Likewise, loss of airway patency at the time of extubation may lead to patient agitation resulting in bleeding and displacement of materials. Several devices and modifications to commercial packing materials have been developed to ensure patency of the nasal airway postoperatively, and require various techniques to secure the device for proper placement including suturing or vestibular packing abutment.[6-8] The goal of these devices is to ensure airflow through the nasal cavity postoperatively while minimizing patient discomfort.

The Kotler Nasal Airway (Anthony Products Inc) is a silicone dual intranasal-airway (IA) tube designed for placement following nasal surgery (**Figure 1**).[9] The device consists of a 7.5-mm inner diameter external portion used for irrigation, and a 5-mm inner diameter IA that extends posteriorly for a total of 80 mm along the nasal floor. The device is the only commercially available product anchored across the columella. It requires no sutures for fixation, and can be used in conjunction with most postoperative packing materials. This IA has a gentle flexure that approximates the curvature of the nasal sill-pyriform-nasal floor complex.

The objective of the present study was to first evaluate the safety of this device in septorhinoplasty and other nasal operations, specifically whether placement of the device resulted in any transcolumellar incision issues. Second, in the later patients in this series, device efficacy was analyzed using a questionnaire developed at our institution aimed at providing information on duration of airway patency, irrigation frequency, and comfort, which might shed insight on optimal use.

Key Points

Question Is an intranasal airway (IA) safe postoperatively, and does it help patients with comfort and breathing in the immediate postoperative period?

Findings This review of medical records of 302 patients undergoing nasal surgery with insertion of IA and subsequent survey of 59 such patients shows that use of the IA in rhinoplasty and other nasal surgeries does not increase risk of postoperative complications compared with accepted rates in the literature and is overall well tolerated by patients.

Meanings Use of an easily placed IA may help assist patients with breathing postoperatively without increasing postoperative wound breakdown, bleeding, or infection.

Methods

Placement of the IA

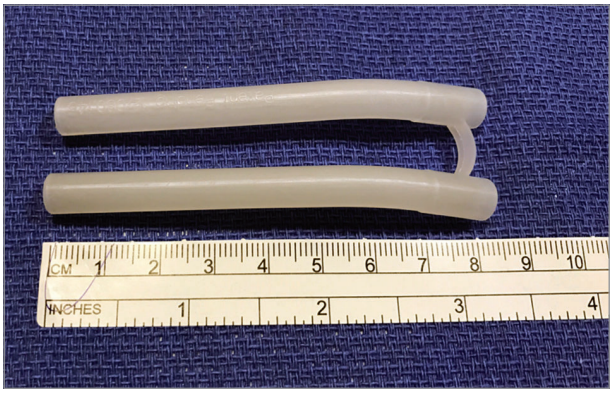
This study was approved through the University of California, Irvine, institutional review board and written informed consent was waived owing to the retrospective nature of the data used. All IA devices were placed intraoperatively after transseptal quilting sutures or septal splints were placed, when indicated. At the conclusion of the operative procedure the IA was placed medial to the inferior turbinates along the nasal floor under direct visualization with use of bayonet forceps and a nasal speculum. Following placement, additional postoperative packing was placed based on the senior author's (B.J.F.W.) preference. For septorhinoplasty, we routinely use a small 20 × 5-mm strip of hylaronic acid gauze (Merogel, Medtronic) to support the internal nasal valve and protect the internal aspect to the soft tissue triangle. Both bacitracin-impregnated cellulose hemostatic dressing (Surgicel, Ethicon) and polyurethane foam (Nasopore, Stryker) are used to support the new nasal contour. We drape a small piece of Xeroform gauze (approximately 15 mm × 7 mm) across the cross bar of the IA to provide a buffer against the transcolumellar incision (**Figure 2**). The nares, cross bar, and xeroform are all coated liberally with bacitracin ointment. In the operating room, the nasal airway is irrigated with normal saline. A tracheal suction is inserted through the IA to remove any blood from the nasopharynx. Postoperatively, patients are instructed to irrigate the IA to maintain patency using sterile water or saline and a syringe and adapter system, which is included with the kit. They are instructed to irrigate the IA 4 to 5 times per day and as needed.

Retrospective Medical Record Review

All medical records of patients undergoing nasal surgery with insertion of the device, Current Procedural Terminology (CPT) code 30999, were reviewed from 2012 to 2017. Accessed records included preoperative visits and consultations, operative reports, postoperative hospitalizations and emergency department (ED) visits prior to the first postoperative follow-up, and postoperative follow-up. If postoperative complications were noted, subsequent follow-up visits were reviewed until there was resolution. When concurrent procedures were performed with the assistance of additional surgeons (ie, concurrent functional endoscopic sinus surgery), postoperative visits for both surgeons were reviewed. Procedures performed at the first postoperative visit were also reviewed.

The primary outcome for safety evaluation was dehiscence or necrosis along transcolumellar incisions or native columella where the device was anchored. A database was generated, and for each patient the following information gathered:

Figure 1. The Intranasal Airway (IA)



The IA consists of a 7.5-mm inner diameter external portion used for irrigation, and a 5-mm inner diameter IA, which extends posteriorly 120 mm along the nasal floor.

Figure 2. Intraoperative Photograph Demonstrating Intranasal Airway in Place, With Xeroform Protector Over Columella

type of nasal surgical procedure, use of autologous rib or conchal cartilage graft, use of synthetic materials, concurrent turbinate reduction, type of concurrent surgical procedure, use of intranasal postoperative splint, osteotomy type and location, duration of IA placement, self-removal of the device by the patient or inadvertent dislodgement of the device, and any wound breakdown. Wound breakdown/dehiscence was based on clinical examination at the first follow-up appointment.

Nasal Airway Stent Assessment Log Survey

Given our evaluation of the device for safety in over 200 patients, we sought to determine the postoperative efficacy. The Nasal Airway Stent Assessment Log (NASAL) survey was developed using the Nasal Obstruction Symptom Evaluation (NOSE)[10] as a guide. The survey assesses device-specific breathing, comfort, obstruction/patency, as well as ease and frequency of irrigation (eFigure in the Supplement), and was provided to the patient immediately following removal of the device at the first in-office postoperative visit. The *t* test and Pearson correlation analysis was used to evaluate association between comfort and breathing, and for all subgroup analysis given that the data sets include unpaired, categorical, nonnormally distributed data. Analyses were performed using SPSS statistical software (version 2.3, IBM).

Results

Surgical Characteristics

The device was used in a total of 302 operations in 300 patients between 2012 and 2017 (eTable in the Supplement). Operations included rhinoplasty (n = 249), which included primary open septorhinoplasty (n = 186), and revision septorhinoplasty (n = 63), repair of vestibular stenosis (n = 5), endonasal septorhinoplasty (n = 3), closed reduction of nasal bone fracture (n = 24), excision of intranasal lesion including the vestibule and nasal sill (n = 5), isolated turbinate reduction (n = 5), isolated septoplasty (n = 4), repair of nasoorbitoethmoid fracture (n = 2), removal of dorsal nasal implant (n = 3), lateral rhinotomy with skin graft (n = 1), and excision of supranumerary tooth (n = 1).

Table 1. Rates of Premature Removal or Inadvertent Dislodgement of the Intranasal Device

	No. (%)	
Surgery	Self-removed	Dislodged
Rhinoplasty	12 (3.9)	10 (3.3)
Nasal fracture reduction	1 (0.3)	NA
Turbinate reduction	NA	1 (0.3)

Abbreviation: NA, not applicable.

A total of 70 patients had concurrent placement of a Doyle-type intranasal splint with the flanking side ports removed (Medtronic) or silicone sheeting (0.5 mm, Medtronic) for septal stabilization and/or splinting. Inferior turbinate reduction was performed concurrently in 185 cases. A total of 30 operations (29 rhinoplasty, 1 nasal fracture reduction) occurred in conjunction with an additional operation including endoscopic sinus surgery (n = 23), repair of septal perforation (n = 2), partial turbinate resection and/or polypectomy (n = 2), endoscopic adenoidectomy (n = 1), fat transfer (n = 1), and orbital fracture repair (n = 1).

Device Removal

The IA remained in place postoperatively on average for 6.7 (range 1-15) days, and was generally removed at the first postoperative follow-up, which was on the following Wednesday of the next week. In total, the device was self-removed by 13 (4.2%) patients (12 rhinoplasty, 1 nasal fracture reduction), and either self-extruded or partially extruded in 11 (3.6%) patients (10 rhinoplasty, 1 turbinate reduction) (**Table 1**). The documented reason for self-removal was patient discomfort. If the device was partially extruded, the patient was instructed to remove it, or presented for postoperative follow-up earlier than scheduled for removal.

Table 2. Rates of Postoperative Complications

Complication	No. (%)
Infection	4 (1.3)
Epistaxis	6 (2)
Columellar breakdown	1 (0.3)

Postoperative Complications and the Transcolumellar Incision

The average duration of placement of the IA was 5.95 days for all patients with postoperative complications (**Table 2**). There were a total of 4 (1.3%) postoperative infections, and a total of 6 (2%) postoperative epistaxis occurrences. Only 1 patient developed breakdown along transcolumellar incisions (1 [0.3%]).

Survey Outcomes

The final 59 patients completed the survey (34 primary rhinoplasty, 19 revision rhinoplasty, 6 other). The IA remained in place for 7.2 (range 2-14) days, consistent with the senior author's acute postoperative surgery clinic experience. Mean scores are reported in **Table 3**. The mean (SD) breathing score fell between good and average (2.9/5 [1-5]), mean (SD) comfort score was between good and average (2.9 [1-5]), and mean (SD) ease of irrigation between very easy and easy (1.96/5 [1-5]). There was no statistical difference between breathing and comfort scores (95% CI, −0.44 to 0.48; P = .47). Of the 56 patients with obstruction data, a total of 14 (25%) patients had no postoperative nasal obstruction, whereas 29 patients (51.8%) had 1 patent side (7 [12.5%]) or overall partial obstruction (22 [39.2%]). A total of 13 (23%) had total obstruction. Breathing and comfort scores were significantly correlated (95% CI, 0.01-0.48; P = .046). There was no significant correlation between duration of device use or number of times irrigating daily with comfort (95% CI, −0.33 to −0.17; P = .52; 95% CI, −0.38 to 0.13; P = .74, respectively), breathing (95% CI, −0.35 to 0.16; P = .45; 95% CI, −0.31 to 0.20; P = .65; respecively), or difficulty irrigating (95% CI, −0.43 to 0.06; P = .13; 95% CI, −0.32 to 0.19; P = .60; respectively) (Table 3).

To assess duration of breathing and comfort, a subgroup analysis was performed, comparing patients scoring between very good and average (1, 2, or 3), and those scoring poor/uncomfortable to very poor/uncomfortable (4 or 5).

For 38 patients who had a breathing rating of very good, good, or average, a score of 1, 2, or 3 was maintained for a mean of 4.2 days. Similarly, 20 patients who had a breathing rating of poor or very poor, had scores that were maintained for 4.1 days. For 38 patients who had a comfort rating of very comfortable, comfortable, or average, a score of 1, 2, or 3 was maintained for 4.2 days. Similarly, for 19 patients who had a comfort rating of uncomfortable and very uncomfortable, a score of 1 or 2 was maintained for 4.0 days.

Table 3. NASAL Survey Results in 56 Participants for Breathing, Comfort, Irrigation, and Obstruction

Variable	Mean (SD)	Interpretation
Breathing, comfort, and irrigation		
Breathing	2.9 (1-5)	Good to average
Comfort	2.9 (1-5)	Easy to average
Difficulty irrigating	1.96 (1-5)	Very easy to easy
Frequency of irrigation	3.56 (1-5)	NA
Obstruction, No. (%)		
Bilateral unobstructed	14 (25)	
One patent side	7 (12.5)	
Partial obstruction	22 (39.2)	
Total	13 (23.2)	

Abbreviations: NASAL, Nasal Airway Stent Assessment Log; NA, not applicable.

Discussion

Use of the IA by the senior author first began with closed reduction of nasal bone fractures to provide a patent nasal airway in circumstances where intranasal packing was used to support a mobile or depressed nasal bone. The benefits appeared obvious, and patients were easily suctioned just prior to extubation and breathed well in the immediate postoperative period. Noting this advantage, we selectively began to apply the device in rhinoplasty patients with cautious optimism over concerns of infection and columellar dehiscence, leading us to perform the present retrospective safety evaluation. After analyzing the device in hundreds of patients, we noted its wide application in nasal surgery with a low rate of columellar breakdown, and continued receiving positive feedback from patients with respect to their ability to breathe postoperatively. Therefore, our survey was developed to (1) delineate operational factors ("how long does the device stay open" and "how often is it irrigated?"), (2) justify a time point for removal, and (3) quantify comfort and breathing.

The IA device does not result in risk of columellar breakdown greater than rates currently reported in the available literature,[11-13] even among all open rhinoplasty patients with transcolumellar incisions. We identified only 1 patient with this complication. This patient had concomitant use of polydioxanone (PDS) plate in conjunction with cartilage grafts, which may have been a predisposing factor for this complication. In this patient, columellar incision breakdown continued laterally toward the marginal incisions near PDS plate placement. Closure of this lateral columellar incision was under some tension, which also may have contributed to this complication. Fortunately, the patient healed well with antibiotics, local wound care, and observation without need for further intervention. Although controversial,[14,15] thicker PDS plates are thought to obstruct nutrient supply to the mucoperichondrial flap.[16] Several studies have confirmed the safety of open rhinoplasty with respect to blood flow to the nasal tip and columella given the rich subdermal anastomotic network,[17,18] and therefore we believe this complication to be the result of motion, excess tension, and foreign material, and not the result of the IA alone. In our practice we protect the columella with a thin strip of Xeroform gauze before stabilizing the transcolumellar portion of the device, which may be protective, and liberal application of bacitracin ointment at the end of surgery. In addition, postoperative cellulitis, which may or may not be

attributed to the device, was 1.3%, which is below the rate currently accepted in the literature.[19] All cases of cellulitis resolved with local wound care and antibiotic regimen change. Similarly, our rates of epistaxis were lower than the accepted historical rates,[20] and all patients were treated conservatively without need for operative control of hemorrhage.

Our survey demonstrated the device efficacy in providing acute airway patency for patients with reasonable comfort and ease of irrigation. When grouped together, most patients had complete patency or only partial occlusion compared with total occlusion. Patency and comfort parameters both were sustained for approximately 4 days, which may argue for removal of this device at an earlier time point than what we employed. As expected, there was no statistical difference between breathing and comfort scores, which may indicate crossover in patient response. Lastly, given that the longest time point measured was 5 or more days for both comfort and breathing, the actual duration may in fact be longer. This is a potential limitation of the survey.

Common sense would suggest that the IA device offers several advantages over traditional splints, which do not specifically facilitate postoperative nasal airflow. Placement of the IA does not require suture fixation, allowing for both ease of placement, and more comfortable in-office removal. The distal IA protrudes from the nares, unlike most silicone intranasal devices. This offers several advantages: (1) if absorbable material is needed to eliminate potential dead space intraoperatively, packing within the vestibule can still be achieved without compromising patency of the device, and (2) postoperatively, this portion also allows for easier access for self-irrigation. In addition, by the Poiseuille law, airflow through the intranasal device with a 7.5-cm length and 0.5-cm internal diameter is greater than that of other commercially available intranasal splints (188.1 cm^3/Pa-s/tube compared with 14.7 cm^3/Pa-s/tube for Doyle Splints).[19] Several modifications to commercially available packing attempt to provide an adequate postoperative airway in the setting of intranasal packing, for example, through introduction of an infusion tube through a Doyle intranasal splint[8] or silastic suction cathether through a modified Merocel pack (Medtronic Xomed).[7] These modifications essentially mimic the idea of the IA device in form and function, but require time-consuming or more tedious adaptation techniques.

The device also has inherent limitations. Although the external portion is useful for irrigation, it may contribute to patient discomfort, and is conspicuous compared with intranasal splints. Although easier to place and remove by the surgeon, without a fixation suture the device may self-dislodge, although only 22 (7.2%) patients removed or inadvertently dislodged their device. In addition, the device will remain patent so long as patients are diligent with postoperative irrigation. The manufacturer suggests irrigating every 4 hours during the day of surgery and once the first night, followed by 2 to 3 times per day thereafter. We advised patients to irrigate at least that many times, but strongly encourage frequent irrigation to clear secretions and blood. Naturally, noncompliance may contribute to patient discomfort, obstruction, and encourage self-removal. Lastly, inventory for the device results in incurred cost to the surgical center and patient, though some modest degree of third-party reimbursement is common, typically more than covering the cost of the device.

Limitations

Our survey has inherent limitations. Confounders such as postoperative pain make delineation of classic operative discomfort vs device-associated discomfort difficult. In addition, patients were surveyed at their first postoperative visit after device removal and nasal suctioning, which may further introduce response bias because patients are much more likely to breathe well with all intranasal material removed than with their device once edema and increased secretions have decreased. As with any survey, there are issues of recall bias, especially with respect to side of obstruction and frequency of irrigation. Nevertheless, to our knowledge, there is no currently available survey that assesses device-associated postoperative nasal obstruction, and as such, we developed our own.

Our study has other inherent limitations. We did not have a comparison cohort of patients without use of the IA for either safety or efficacy groups because this device is now used in most of the senior author's patients. Although our low complication rate may have precluded meaningful statistical comparison for safety, a control group of other nasal surgeries (ie, isolated septoplasty, or functional endoscopic sinus surgery) where different intranasal airway devices or packing techniques are used may provide a good comparison for future postoperative obstruction analysis. Last, rates of columellar dehiscence and infection are underreported in the rhinoplasty literature, and although our rates are low and can be interpreted as safe compared with previous studies,[13,21] it is a challenge to compare this rate to that at other institutions.

There is a high variability with respect to postoperative packing among rhinoplasty surgeons nationwide, with a shift from classic intranasal packing toward use of septal splints for stabilization or surgeon-fashioned splints along the alar lobule or midvault for lateral wall stability.[4] The use of the IA does not preclude the use of any postoperative packing,[9] splint, or intranasal stabilization. Although not analyzed herein, we still use a variety of intranasal packing materials after rhinoplasty procedures based on need for soft tissue stabilization and hemostasis, especially in the setting of concurrent surgeries. These include Surgicel (Ethicon), Merogel (Medtronic), and Nasopore (Stryker). Placement, maintenance, and removal of this packing was not problematic in the current study when used in conjunction with the IA device.

Conclusions

Following a variety of nasal surgeries including primary and revision rhinoplasty, the IA is a safe device for maintaining patency of the nasal airway, and can be used in conjunction with a variety of commercially available packing materials. The device comfortably maintains airway patency in the early postoperative period for most patients. Our sample indicates no significant risk of columellar breakdown with use of this device.

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