Solving the Problem of Post-operative Airway Obstruction in Nasal/Sinus Surgery

A Strategy and New Device to Ensure Patient Safety, Comfort, and Satisfaction

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Sinus surgery, septoplasty—with or without turbinate reduction—and rhinoplasty are among the most common surgical procedures performed by our specialty. In 2006, 600,000 sinus surgeries were performed in the United States.[1] A recent paper reported more than 300,000 rhinoplasties done per year.[1, 2] Septoplasties and ancillary procedures accounted for an additional 489,000 procedures.[1]

NASAL PACKING: NECESSSARY, BUT NOT POPULAR WITH PATIENTS

Nasal and sinus surgery typically require some surgeon-inserted "packing," placed or injected into the nasal fossae, at the conclusion of the operation for a variety of reasons:

- To stabilize manipulated/repositioned/reconstructed elements in the proper and anatomically correct positions
- To prevent synechiae formation
- To reduce the chance of bleeding and prevent hematoma formation
- To act as a substrate for medications, e.g., antibiotics and steroids
- To act as a conduit for topical medications to be instilled after surgery, e.g., nasal decongestant drops to reduce bleeding and/or relieve congestion

In the recent National Interdisciplinary Rhinoplasty Survey, 39% of surgeons reported using packing 81%–100% of the time, with 81% of the surgeons leaving the packing in place for 0–3 days post-operatively.[2]

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The Doctor's Dilemma: Prospective Patients Fear "The Packing"

Today it is common knowledge among the lay public that nasal and sinus surgery require packing. However, and for good reason, nasal packing has had "bad press" for decades.

Patients report that the standard one-to-five-day period of indwelling packing is the most oppressive feature of the entire experience.[4] This is not due to discomfort/pain, which generally is not severe and can be controlled with medication. Rather, it is the packing-induced blocked nasal airway that generates acute anxiety and claustrophobia. "It was as if someone left a clothespin on my nose and walked away," reported one semi-irate patient. Call it "asphyxia anxiety."

Yet the surgeon has sound reasons to employ packing—the benefits of nasal packing far outweigh the risks. The literature notes significant complications and adverse effects: toxic shock syndrome, septal perforation or other tissue necrosis, and even a profound vagal response.[6, 7, 8] But the odds of major problems are low, and thus percentages still favor employing packing.

One issue that needs to be recognized is that even though nasal packing has a limited post-operative tenure, studies have shown that complete, bilateral nasal packing can also cause obstructive sleep apnea and hypoxemia.[5]

Accepting that the positives of packing trump the negatives, today's nasal surgeons have ample choices to serve packings' assorted missions. Modern biotechnology is now delivering a variety of excellent packing products. Designed to prevent infection, accelerate healing, and reduce bleeding, surgeons have the choice of the mesh, clothlike absorbables, gel-liquids, or the non-absorbable, non-adherent, and easily removable varieties. In addition, there are new packing substances on the horizon, as bioscience is learning to impregnate the materials with biologicals that stimulate healing.

Improving Coexistence Between Packing and an Airway Device: The Win-Win for Patient Safety and Comfort

Surgeons, tinkerers by nature, tend to fixate on surgical technique. We embrace novel technology, innovative instrumentation in the pursuit of patient safety, and improved surgical results and operating room efficiency and economy. In the pursuit of more rapid healing and the prevention of post-operative complications, we focus on the benefits of nasal packing while overlooking the importance of concomitantly maintaining an airway. Maybe we have developed tunnel vision as we labor in the nasal tunnels. Are we losing opportunities to provide our patients with successful operations because we have neglected to also focus on patient comfort and satisfaction? Perhaps, particularly because few of us have stood in the patient's shoes; "Every so often, a doctor needs to be a patient. He will then be a better doctor."

Appreciating the face-off between post-operative safety and healing objectives, and comfort, we have examined the products and devices, past and present, that purport to facilitate nasal breathing after nasal/sinus surgery, despite the nose being packed.

Some products, designed for dual packing-airway function, insinuate a pliable airway within a single piece of solid, foam-like packing material that expands when moistened.

Fig. 1. Combination airway and pack.

Fig. 2. Doyle Septal Splints

The veteran and popular "Doyle Septal Splint," rather than a one-piece packing/airway device, is a different variety of airway hybrid: it features pre-shaped and pre-sized soft silicone sheaths that act as septal splints..

Fabricated onto each of the pair of splints are one-half diameter, or "hemi-tubes," designed to allow airflow. The Doyle septal splints are parabolic-shaped, and the attached hemi-tubes are curved to mirror normal airflow through the nose. The splint is 6 cm long; the hemi-tube has a radius of 4mm. Sold as a right-and-left pair, both members are inserted astride the septum and sutured to each other using a mattress suture across the septum. The aim is to stabilize the post-resection septal cartilage, return the previously elevated septal perichondrium against the cartilage, and promote readherence of mucosa to cartilage. To accomplish all this, the device must be secured to the cartilaginous septum through the mucosa, deep within the nasal passages, beyond the nostril opening, beyond the internal nasal valve, and even beyond the membranous septum. Thus, positioning of the splints relegates the anterior openings of the airway members to a position far inside the nasal fossae.

While this combination of a removable septal splint and an attached intranasal airway is conceptually attractive, the functional reality is that the nasal airway in-situ generally quickly becomes inoperative. Early in the post-operative period, the hemi-tubes promptly and irrevocably clog with blood and mucus. The deep-interior location effectively prohibits the patient or caretaker from gaining access to these anterior openings to keep the tubes from blocking. The air passage is now defunct.

The commonality to all deep-seated packing/airway hybrid devices are location-based, post-operative inaccessibility. Other dual-purpose, removable packing devices, as mentioned earlier, are the Pure Pak®, Slik-Pak®, and Venti-Pak®. These products, into whose PVA foam centers are seated a tube to ostensibly carry air, have been somewhat disappointing. Because immediately after surgery the nasal fossae quickly fill with secretions, the relatively narrow airflow tube can become blocked. Plus, their openings are not easily accessible for post-op, home-care maintenance.

We need to recognize that patients (who may be sedated by medications) and/or caregivers are understandably reluctant to explore the nasal interior and reopen blocked tubes and reestablish functionality. They are justifiably intimidated and fearful of causing pain or "ruining" the operation. Realistically, laypeople should not be charged with performing intranasal procedures to reopen an inoperative medical device.

An Independent, Single-purpose Device Is the Better Answer for Post-operative Airway Maintenance

We have studied, evaluated, and analyzed the deficiencies and functional compromises of the dual-mission hybrids: the splint and airway and the packing and airway versions. Perhaps it is better not to merge two disparate missions into a single device. For better performance and patient comfort and satisfaction, perhaps it is wiser to separate the splinting/ packing and airway roles.

Since there is now an ever-increasing variety of packing devices, it seems advantageous to allow the surgeon to choose from among them. For any of these modern packing products, a dedicated, independent, and reliable device to provide the post-operative airway is an ideal teammate.

As a product of the above-mentioned studies, we have developed and fabricated a post-operative nasal airway device: a one-piece, dual-nasal airway appliance that is inserted by the surgeon at the end of the operation, before or after packing and/or optional septal splint placement. This device will provide a corridor for adequate air passage through both nasal passages without compromising splint's or packing's important functions. It is compatible with any current packing product.

The single piece, dual-nasal airway tube is made of soft (25+/-5 durometer), latex-free, medical-grade silicone. Length = 12 cm, with centimeter graduations. Internal diameter = 5 mm; outside diameter = 7.5 mm. The right and left airway tubes are connected by an even softer, highly pliable bridge. This bridge connection to the anterior segments of the tubes prevents posterior slippage into the nasopharynx and assures visible anterior tube openings for easy and safe post-operative home care.

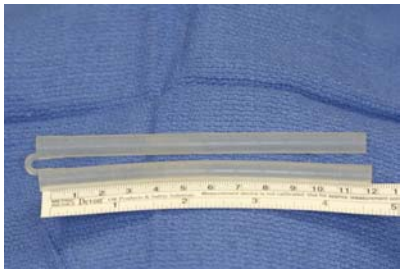


Fig. 3. 12-cm nasal airway device.

Figs. 4 & 5. Close-up of device

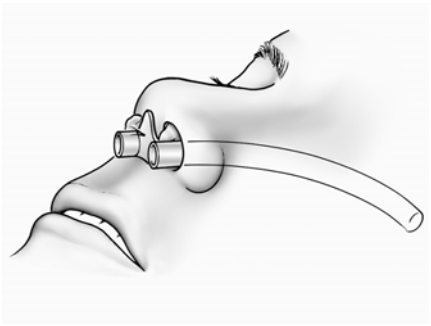


Fig. 6. Illustration of airway device in nasal passages.

A Study of Airflow Through the New Device Versus Through Existing Hybrid Airways

The clinical value of any airway appliance **rests** on the volume of air that passes through the air tube en route to the lungs. Pouiseuille's Law*, which quantitates laminar airflow through a definable and measurable passage governs the analysis of nasal airway devices.

Poiseuille determined that the wider the tube radius, the lower the airflow resistance. More importantly, the change in

radius is not proportional to the change in resistance but yields a four-fold increase in resistance for a given reduction in radius. Therefore, a small change in radius significantly affects either flow rate or pressure drop required to achieve the same flow.[8] If the lumen of the airway becomes obstructed or narrowed, the effective radius of air flow will be significantly reduced, negatively affecting air flow to the patient.

Accepting that small increases in an air tube's diameter increases airflow exponentially, it is possible to scientifically assess, applying Poiseuille's Law, what might be a major difference in airflow through the single-mission new device contrasted with a popular airway-splint hybrid, the Doyle Septal Splint, and an airway-pack hybrid, the Venti-Pak®.

The flow through each member of the Post-operative Nasal Airway is 188.1 cm^3/pa-s (or 376.2 cm^3/pa-s through both tubes) based on a length of 7.5 cm and a radius (internal diameter) of 0.5 cm. Airflow through the Doyle Septal Splint is 14.7 cm^3/pa-s (or 29.6 cm^3/pa-s through both nostrils), based on a length of 6.2cm and radius of 0.5cm. Reflecting the airways' differential diameters and length, the airflow through the new independent airway device is 12.8 times greater than that through the Doyle Septal Splint.

The photo below visually compares the lumena of the Doyle Septal Splint and the new nasal airway device.

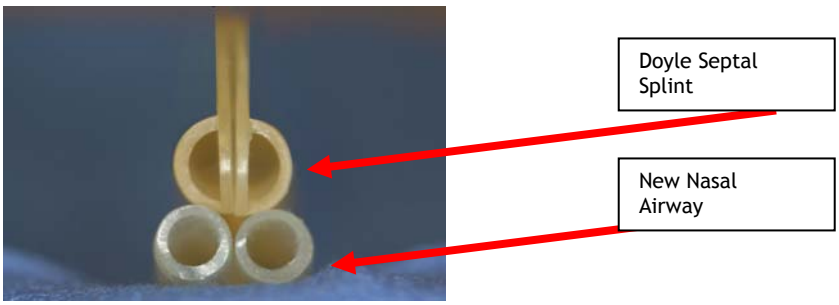


Fig. 7. Comparative view of cross-sectional diameter of Doyle Splint with the Post-operative Nasal Airway.

*Poiseuille's law states that the flow rate Q is dependent on fluid viscosity η, tube length l and the pressure difference between the ends.
Pouiseuille's Law: $V = \Delta P \pi r^4 / 8 \eta l$, where V = air flow, ΔP = the difference in pressure between the two points, r = radius of the tube, η = gas velocity, and l = length of the tube.
Using Poiseuille's Law, assuming negligible change in pressure, the laminar air flow through the Doyle Septal Splint is 14.7 cm_3/pa-s (or 29.6 cm_3/pa-s through both nostrils), based on a length of 6.2cm and radius of 0.5cm. Note that each Doyle airway is a hemi-tube, so the airflow through each of these hemi-tubes, calculated by Poiseuille's Law, was halved. The flow through each side of the post-operative nasal airway is 188.1 cm_3/pa-s (or 376.2 cm_3/pa-s through both tubes) based on a length of 7.5 cm and radius of 0.5 cm.

The Venti-Pak®, a prototypical airway-packing hybrid, has an air tube inside diameter of 4 mm. Using Poiseuille's Law,the calculated airflow through a Venti-Pak® is 82.5 cm^3/pa-s. While delivering greater air flow than thru the Doyle Septal Splint, the Venti-Pak®, also delivers less air to the nasopharynx than the newer device.

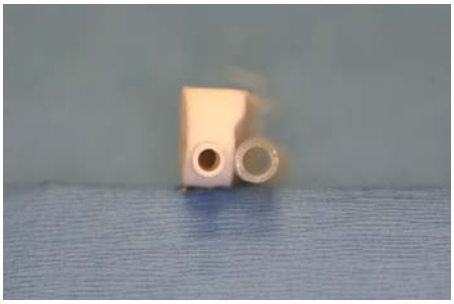


Fig. 8. Comparative view of cross-sectional diameter of Venti-Pak® (left) with the Post-operative Nasal Airway (right).

The Clinical Application of the Post-operative Nasal Airway

Each 12-cm tube can, by amputating a measured portion from the posterior end, be shortened to match the length of the nasal passage.

A simple measuring rod is used to judge the proper length of the airway appliance. A gynecologic fundal probe, with the tip bent to 90 degrees, is passed into either nasal passage. The posterior end of the septum or the hard palate can be palpated, engaged, and therefore the length of the nasal passages calculated by measuring the distance from the engaged posterior end of the septum to the external nostril. That point is marked onto the measuring stick, and the distance from tip crook to the blue line is measured. The desired tube length is then matched along the length of the airway device, which is accordingly shortened (average length has been 7.5 cm).

Fig. 9.The measuring probe determines the proper length of the nasal airway device.

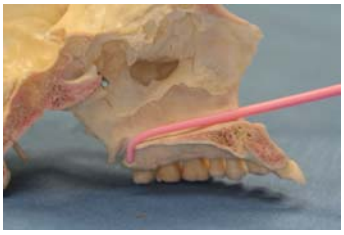
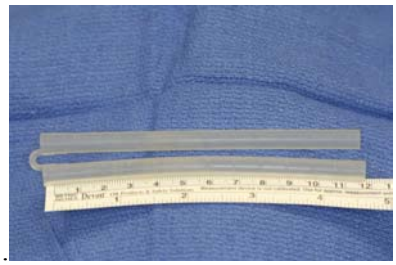
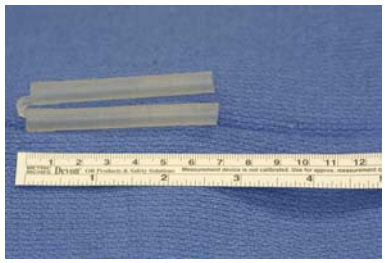


Fig. 10. Probe inserted, posterior edge of septum or hard palate engaged.

Fig. 11. or hard palate engaged. Length of nasal passage ink-marked onto measuring probe.





Figs. 12. & 13. Tubes shortened to match probe-determined length of nasal passage.

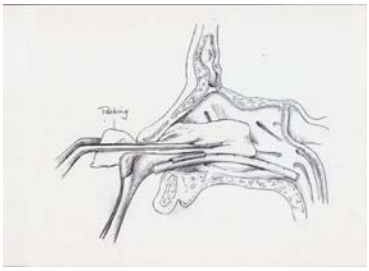
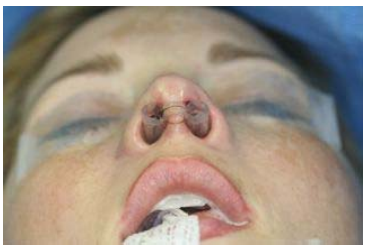


Fig.14. Illustration of pack insertion following seating of nasal airway appliance



Figs. 15. & 16. Airways in place at conclusion of operation. Chromic suture, connecting left and right removable nasal packs, passes over columella below device bridge.

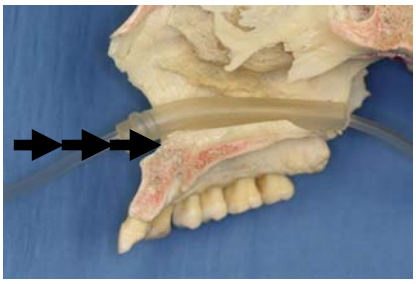


Fig. 17. Tube positioned within nasal fossa. Arrows and nasogastric tube demonstrate airflow into nasopharynx.

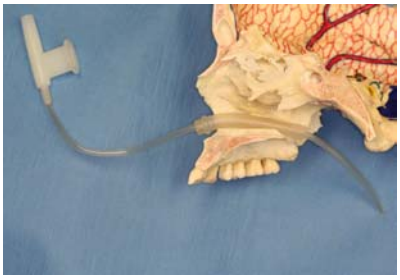


Fig. 18. Depiction of anesthesia specialist's suction catheter access to oropharynx.

Our anesthesia colleagues appreciate and utilize the nasal airway. At the end of the procedure, prior to awakening the patient, a standard 10 fr. plastic suction catheter can be passed easily through each nasal airway tube to suction the oropharynx. Anesthesia specialists prefer such access into the pharynx for suctioning while the patient is still asleep. No need to struggle to perform oral-pharyngeal toilet, as the patient is emerging from anesthesia, using a Yankauer suction tip or the soft suction catheter, either of which requires patient cooperation. Using this device, the pharynx has been cleared of secretions, via the nasal airway pathway, while the patient has been asleep, just prior to emergence.

Fig. 19. Illustration of home irrigation of airway device. The tube's anterior openings are positioned for cleansing and irrigation, to maintain a patent airway.

The Clinical Experience: 78 Patient Case Histories

In the senior author's practice, 78 patients scheduled to undergo reconstructive nasal surgery—nasal septoplasty and bilateral inferior turbinate resection, with or without rhinoplasty—were offered and consented to placement of the bilateral nasal airway.

Of this population, 20 patients had prior nasal surgery and had endured packing with complete nasal blockage. One patient within this subgroup had three failed prior septorhinoplasty procedures.

The airway device was placed at the end of the surgical procedure and prior to the insertion of the packing. Initially, the device was sutured into place, using a single 4-0 nylon suture. The device was affixed either at the columella or internally, through the nasal septum. However, early in our experience with the new device, we recognized that ten patients, all of whom had suture fixation, exhibited some skin irritation of the medial nostrils or face of the columella.

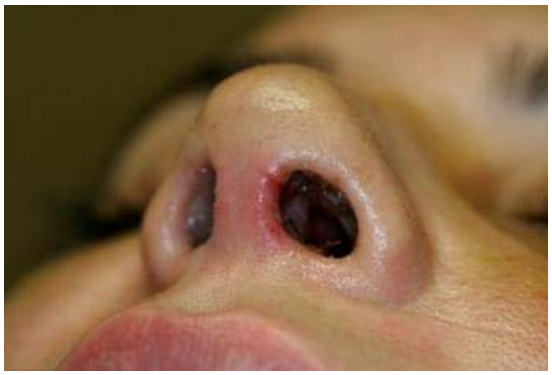


Fig.20. Pressure-induced irritation of columella.
Modification of tube design allowed secure placement
without suture fixation and no irritation presented thereafter.

Abandoning the suture fixation and modifying the bridge's shape and stiffness prevented any further problems. Our experience was that the "fit" between the tube device and the nasal fossae is such that it is not necessary to secure the airway-tube device via suture fixation. In discussions with colleagues who are champions of the external rhinoplasty's horizontal columellar incision, we realized that without suture fixation, undesirable pressure that the tubes and/or the bridge might exert on suture lines at the membranous septum or an external rhinoplasty incision would be avoided.

In all cases, the senior author inserted two different packings: one absorbable and one non-absorbable. The absorbable was a two-ply sheet of either gauzelike Surgicel® or absorbable hemostatic gauze ActCel® draped over the turbinate remnant. The removable pack was a folded (thus two-ply) single sheet of non-adherent Telfa® coated on both sides with tetracycline ointment. As a means to ease insertion of the absorbable packing (which becomes a bit unmanageable when moistened by mucus or blood), the ointment-coated, now surface-sticky Telfa® pad was used to "carry and deliver" the gauze to its home over the medial edge of the turbinate. Through this maneuver, the Telfa® pad was simultaneously placed favorably to fulfill its overall packing mission. A remnant suture from the surgical procedure is secured to the right and left Telfa® pads before insertion. This was tied to its opposite member over the columella **(**see Figs. 19 & 20, photo/illustrations, above) or taped to the adjacent cheek, to anchor and prevent accidental posterior displacement of the Telfa® pad. The suture-string also facilitates the pack's removal.

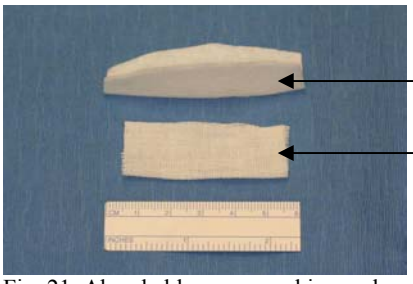


Fig. 21. Absorbable gauze packing and removable, non-adherent, non-absorbable pad


Fig. 22. Non-adherent pad coated with tetracycline ointment to facilitate placement of absorbable packing .


Fig. 23. Absorbable gauze packing and removable' non-adherent, non-absorbable pad trimmed to size

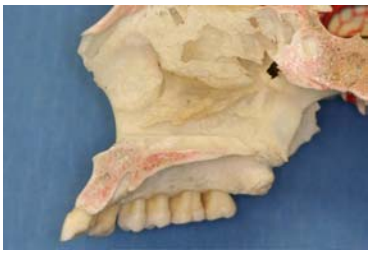


Fig. 24. View of nasal interior demonstrating right inferior turbinate and right lateral nasal wall.

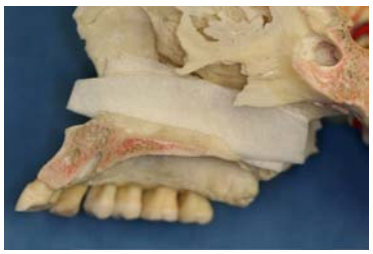


Fig. 25. Absorbable gauze adherent to non-adherent nasal pack for each ease of insertion to cover turbinate.

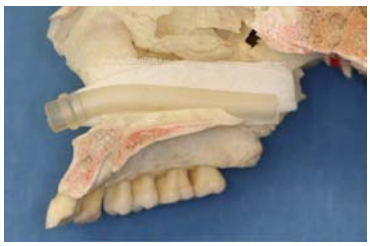


Fig. 26. Absorbable gauze pad positioned pad, fills major portion of nasal cavity. Airway tube aids in stenting both packs.

To prepare the patient for ease of tube and non-absorbable pack removal, five drops of an anesthetic-decongestant solution (equal volumes of oxymetrazolamine and tetracaine 2%), were instilled into the nasal cavities to anesthetize and decongest the mucosa in anticipation of tube and pack removal. The tubes easily slid out of the nasal fossa, and the non-absorbable pads were likewise easily extracted. The absorbable packing was absent, and mucosal surfaces demonstrated early healing. There were no remnant signs of any internal damage from the indwelling tubes in any of the cases. Significantly, there was not a single episode of significant epistaxis at time of tube and pack removal that required intervention of any kind. One patient had a bleeding episode from a posterior turbinate resection site and from the posterior septoplasty site, 11days after surgery that required placement of absorbable packing.

Of the 78 patients, 75 sustained the tube placement for either four or five days. Three patients requested removal because they were not interested in, or capable of, the home irrigation of the tubes necessary to maintain patency and airflow. One patient took it upon himself to remove the tubes after three days. No adverse consequences ensued from any premature removal.

Questionnaires were given to all 78 patients to assess each's experience and satisfaction. 50 of the 78 patients completed the questionnaires. Of the 50 patients, 47 answered "Yes" to the question: "Would you recommend to friends or family members that they have the airway tube in place for nasal or sinus surgery?"

The "Control Group"

The overall aim of the study was to determine if a new, unique and highly-serviceable airway device would provide a better patient experience. But, compared to what? That needed to be answered because a patient's experience is subjective.

At the suggestion of a colleague, we embarked upon structuring a "control" subset of patients having the standard surgical procedure. The most obvious and practical format by which a given patient could himself or herself experience the difference between having and not having a functioning airway in place would be to provide the patient with the standard packing bilaterally and yet plant the airway device on only one side. The "non-airway" side would act as the control.

Twelve additional patients, bringing the total participants in the study to 90, graciously volunteered to enter this final portion of our study. Of that subset of twelve patients, three had had prior nasal airway surgery with bilateral complete packing. The side in which the airway device was placed was randomly chosen by direction of the operating room's circulating RN. Of the twelve patients, all reported perceiving the different in the post-operative experience. When asked the standard study question, "Would you recommend having such an airway device to prospective patients?", all twelve answered
"Yes".

Of the twelve patients, three had prior nasal airway surgery without any airway provided. They, of course, represented the ultimate and ideal judges of the device and method.

Conclusion

Though nasal and sinus surgery is common and widespread, there is no consensus on choice of nasal packing. However, surgeons do agree that nasal packing—in some form—is important to prevent post-operative complications such as synechiae, bleeding, and anatomic destabilization.

Despite their importance and value, contemporary packing materials and devices and airway appliances generate patient dissatisfaction. Nasal obstruction generates anxiety, claustrophobia, and negative public relations. For these routine and generally successful procedures to be rejected by patients because of post-operative dissatisfaction — which need not occur — is unfortunate. There are perhaps tens of thousands of potential patients who would be approaching nasal surgeons requesting the operation had the procedure's bad public image not scared them off.

In an era of biotech-generated improved packing materials, we can offer our patients fewer complications and more rapid healing. Packing can be a vehicle for delivery of medications, including antibiotics, steroids, and even decongestants. However, we need to revisit the issue of how we provide today's technologically improved packing and yet simultaneously deliver a consistent open nasal airway for the post-operative nasal-sinus surgery patient. We should be able to win on both fronts: the packing benefits and the comfort and functionality of an indwelling airway.

To that end, providing improved patient comfort and restoring normal airway physiology, a new, alternative nasal silicone airway tube device — independent of any packing material or packing product — was shown to deliver functionality and patient comfort in 90 patients by providing an ongoing nasal airflow through the immediate post-operative period.

As a result of investigating the issue of patient comfort and safety in the nasal/sinus surgery post-operative period, the new medical device described in this report provides a safe airway that contributes to patient comfort and, ultimately, provides a more satisfactory post-surgical experience.

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9. Johns Hopkins School of Medicine's Interactive Respiratory Physiology.

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