



## Middle Meatal and Nasal Surgery for Obstructive Sleep Apnea: An Effective New Paradigm for Reducing the Apnea-Hypopnea Index

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### Abstract

**Background:** The curative impact of nasal surgery on patients undergoing septal and turbinate surgery for obstructive sleep apnea (OSA) has been minimal. New models of nasal airflow have shed important light on key functional elements of nasal obstruction, including the middle meatus and swell body. Based on this information, we evaluated middle meatal and nasal surgery targeting areas of maximum nasal airflow as treatment for patients with OSA.

**Methods:** An IRB-approved prospective study included consecutive adult patients with the diagnosis of OSA who underwent nasal surgery by a single rhinologic surgeon during a 36-month period. Surgery included: uncinectomy, anterior ethmoidectomy, reduction of concha bullosa, endoscopic septoplasty, radiofrequency ablation of the inferior turbinate and septal swell body, and nasal valve repair. The primary outcome measure was change in apnea-hypopnea index (AHI). Additional outcome measures included change in Epworth Sleepiness Score (ESS), body mass index and oxygen-saturation (O<sub>2</sub>)-nadir.

**Results:** 43 patients were enrolled with pre- and postoperative polysomnography results. Average preoperative AHI was 31.2; Range 8.3 - 97 to postoperative mean of 16.4; Range 0.3 - 79.2 (n = 42; p < 0.0001). Average ESS was reduced from 12 to 4.2. O<sub>2</sub>-nadir and BMI remained stable ( $\Delta$  O<sub>2</sub>-nadir -0.1;  $\Delta$ BMI 0.2). Absolute cure rate = 37.2%, Surgical cure rate = 46.5%. No surgical complications occurred.

**Conclusion:** Targeted middle meatal surgery, swell body ablation, and nasal valve repair, concurrent with septal and inferior turbinate surgery, further optimizes nasal surgery for OSA. Our surgical protocol demonstrates significant reduction in AHI and ESS for patients with OSA regardless of BMI.

**Keywords:** Obstructive Sleep Apnea; Nasal Airflow Dynamics; Nasal Obstruction; Nasal Surgery; Nasal Valve

### Introduction

Obstructive sleep apnea (OSA) affects up to 7% of men and 5% of women while accounting for more than 400,000 annual adult office visits to otolaryngologists in the United States [1,2] and its prevalence grows alongside the projected rise in obesity [3]. OSA is associated with several medical co-morbidities including hypertension, obesity, cardiovascular and cerebrovascular disease, diabetes, as well as changes in cognition and one's ability to concentrate [4-6]. Despite the significant and well-established sequelae of

untreated OSA, optimal medical and/or surgical treatment remains elusive.

Empiric medical treatment with continuous positive airway pressure (CPAP) is often first-line therapy, with many patients never being evaluated by an otolaryngologist to identify the potential contributing level(s) of upper airway obstruction. Yet many patients are noncompliant with nightly use of CPAP as demonstrated by Hoffstein, et al. who reported compliance rates ranging from 38

- 82% [7]. This high rate of noncompliance with CPAP has led to the pursuit of a durable, effective, minimally invasive surgical option.

Nasal surgery for OSA has been studied extensively during the past two decades demonstrating improvement in CPAP tolerance and quality of life measures [8,9]. However, nasal surgery has largely failed to demonstrate polysomnographic improvement in AHI [8-12]. Meen and Chandra reviewed 17 published studies designed to evaluate the role of the nose in sleep-disordered breathing (SDB), and concluded that “nasal obstruction plays a modulating, but not causative role in SDB” [13]. Previous studies of “nasal surgery” in OSA patients have mostly focused on septal and inferior turbinate surgery alone, with a minority of studies including a few patients undergoing surgery within the middle meatus [13,14]. Recent 3-dimensional computational fluid dynamic (CFD) models have provided new detailed information of the true path of inspired and expired air through the upper airway, advancing our understanding of the physiology of nasal airflow [15]. In particular, these studies emphasize that the majority of inspired air enters the nostril and arcs through the middle meatus before descending through the nasopharynx. They also showed that even a moderate degree of nasal obstruction leads to negative pressure within the nasopharynx, which could collapse the soft palate and Eustachian tube orifices.

Based on this information, we developed a study to evaluate the impact of targeted middle meatal surgery and septal swell body ablation, in conjunction with septal and inferior turbinate surgery, in patients with OSA.

## Methods

An IRB-approved prospective study was performed including adult patients with a diagnosis of OSA who were non-compliant with, or intolerant of CPAP. All patients underwent nasal, septal, inferior turbinate, and middle meatal endoscopic surgery by the senior author during an 36-month period. Obstructive sleep apnea was defined by a baseline in-hospital polysomnogram measuring an Apnea-Hypopnea Index (AHI) greater than 5. Inclusion criteria required patients to complete both baseline and 9-month postoperative polysomnography, ESS questionnaire, and BMI measurement. Patients with pre- or postoperative home sleep study and those having undergone previous sinus surgery were excluded. All patients underwent computerized tomography of their sinuses, as well as a head and neck exam and nasal endoscopy to assess their nasal oropharyngeal airway. Patients with tonsils >3+ and/or an

elongated soft palate were excluded from the study, thereby eliminating obvious causes of oropharyngeal obstruction.

Patient data were collected for the following: demographics, medical comorbidities, Mallampati score, ESS, and body-mass index (BMI). Baseline and 9-month postoperative polysomnography results (AHI and oxygen-saturation nadir) were collected. Lund-MacKay scores were obtained from preoperative sinus computed tomography (CT) imaging. Patients identified with limited occult chronic sinusitis without nasal polyps were included. Those with polyps were excluded as the extent of surgery would not be uniform. All patients received uncinectomy and anterior ethmoidectomy [16] in addition to endoscopic septoplasty, submucosal radiofrequency ablation of the inferior turbinate, and septal swell bodies ablation as described by the senior author [17]. Based on physical exam and CT findings, some patients have also received reduction of a middle turbinate concha bullosa, and nasal valve repair as described by Dolan, *et al.* [18]. A resorbable chitosan sponge was placed in the middle meatus of all patients at the time of surgery, however none of the patients received nasal packing or septal splints [19]. All surgical complications and adverse events were recorded.

All patients began saline sinus irrigations the day following surgery which were continued for 4-weeks. Nasal steroid sprays and CPAP therapy were not permitted during the first 2-weeks postoperatively.

All statistical analyses were performed using GraphPad 6 (2012) and statistical significance was considered to be  $p < 0.05$ . A paired t-test was used to compare preoperative and postoperative polysomnogram outcome measures (BMI, oxygen-saturation, AHI) and ESS.

## Results

43 patients with OSA met inclusion criteria and, in addition to nasal surgery, completed both baseline and 9-month postoperative polysomnograms. Eighty-five percent of study patients were male with an average age of 50 years (Range 29 - 85). Baseline BMI average was 31.3 which remained relatively unchanged postoperatively ( $\Delta 0.2$ ). Baseline average Lund-MacKay score was 5 (Range 2 - 8) (Table 1). All patients underwent middle meatal and nasal surgery as described above (Table 2) and there were no major postoperative surgical complications in the study.

	Range	
Avg Age	50	(29 - 85)
Males	85%	
BMI	31.3	(20.4 - 57)
HTN	51%	
DM	18%	
CAD	8%	
Avg Lund-MacKay	5	(2 - 8)
Avg Epworth	12	(0 - 24)

**Table 1:** Patient characteristics (n = 43).

Baseline BMI	Δ AHI	Δ O <sub>2</sub> -nadir (%)	Surgery
29	49.1	-5	SP, SMR, MIST
32.8	39.2	-19	SP, SMR, MIST, CBR
29.6	19.9	-1	SP, SMR, MIST, SB
29.8	11.1	-4	SMR, MIST, SB
33.1	11	2	SP, SMR, MIST, SB
34.5	7.3	3	SP, SMR, MIST, MTS
26.9	4.3	-5	SP, SMR, MIST, SB
31.3	38.6	-9	SP, SMR, MIST, SB
30.2	3.4	3	SP, SMR, MIST, CBR
26.6	27.4		SP, SMR, MIST, SB
30.1	0.4	9	SP, SMR, MIST, SB
30	3.6	1	SP, SMR, MIST, SB
32.5	-1.5	2.5	SP, SMR, MIST, SB
32.3	-2.5	10	SP, SMR, MIST, SB
38.4	3.1	6	SP, SMR, MIST, SB
29.5	6.8	-6	SP, SMR, MIST, SB
41.6	14.9	-5	SP, SMR, MIST, SB
27.7	12.1	3	SP, SMR, MIST, NVR
23.6	9.8	11	SP, SMR, MIST, NVR
35.1	13.7	8	SP/SMR/MIST, SB
28	-1.3	0	SP/SMR/MIST, SB
31.2	50.9	-8	SP/SMR/MIST, SB
27.26	12.1	-7	SP/SMR/MIST, SB
57	12.1	-2	SP/SMR/MIST, SB/NV
30.9	15.7	0	SP/SMR/MIST, SB
23.4	-1.7	-34.2	SP/SMR/MIST, SB
26	24	-2	SP/SMR/MIST, SB

22.8	43.3	-11	SP/SMR/MIST, SB
27	14.8	-11	SP/SMR/MIST, SB
31	34.8	6	SP/SMR/MIST, SB
27.4	10.7	0	SP/SMR/MIST, SB
37.7	2	5	SP/SMR/MIST, SB
38	-8.7	-7	SP/SMR/MIST, SB
28	5		SP/SMR/MIST, SB
27	-2.3	2	SP/SMR/MIST, SB
26.6	10.2	-1	SP/SMR/MIST, SB
22.5	18	0	SP/SMR/MIST, SB
44	-18	3	SP/SMR/MIST, SB
30.7	59.1	-5	SP/SMR/MIST, SB
25	33.2	-5	SP/SMR/MIST, SB
25	1		SP/SMR/MIST, SB
32	-7.5	1	SP/SMR/MIST, SB

**Table 2:** Patient procedures (n = 43).

SP: Septoplasty; SMR: Submucosal Turbinate Resection; MIST: Minimally-Invasive Sinus Technique; MTS: Middle Turbinate Shave; CBR: Concha Bullosa Resection; SB: Swell Body; NVR: Nasal Valve Repair.

Overall AHI was reduced from a preoperative mean of 31.2 (Range 6.3 - 97) to postoperative mean of 16.4 (Range 0.3 - 79.2) (n = 43; p < 0.0001) (Figure 1). The O<sub>2</sub>-nadir, however, remained relatively stable (preoperative 82%; postoperative 83.8%). BMI demonstrated minimal change from 31.3 preoperatively to 30.9 postoperatively. 16/43 patients (37.2%) achieved an “absolute cure” or AHI < 5; further subgroup analysis shows that an AHI < 5 was obtained in 6/12 (50%) of patients with “mild” apnea, in 5/13 (38.5%) of those with “moderate” apnea, and in 5/18 (28%) of those with severe apnea. The average pre vs post-op AHI for this group (i.e. AHI < 5) is shown in table 3. The average pre-op AHI was reduced from 11.1 to 4.3 in the mild group, from 20.3 to 5 in the moderate group, and from 48.8 to 3.3 in the severe group. Combining patients who had an “absolute cure” (AHI<5) with those who achieved a “surgical cure” (defined as a > 50% reduction in AHI to an AHI < 20) [20], the overall “surgical cure” rate reaches 46.5% (20/43). An additional 3 patients showed a reduction in AHI of > 50%, but did not achieve a final AHI < 20. Average ESS was reduced from a baseline of 12 to 4.2 post-operatively (p < .05).

Evaluation of "Cured" Patients (AHI<6)		
N	Avg Pre-op AHI	Avg Post-op AHI
Overall = 15/42 36%	25.9	3.8
Mild = 16/12 50%	11.1	4.3
Moderate = 4/12 33%	20.3	5.0
Severe = 5/18 28%	48.8	3.3

Table 3: Evaluation of patients with "absolute cure".

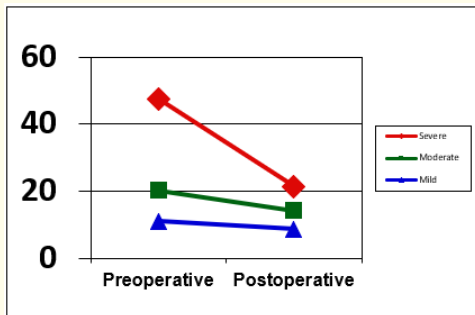


Figure 1: AHI of OSA patients with nasal surgery (n = 43).

Subgroup analysis of change in AHI by severity of OSA revealed no significant difference amongst those with mild OSA (n = 12; p = .2120), which is in significant contrast to those with either moderate (n = 13; p = .0329) or severe OSA (n = 18; p < 0.0004) (Figure 2-4). Only one patient had an increase of greater than ten events per hour in post-op AHI; their baseline AHI was 26. Table 4 details the mean change in pre- versus postoperative AHI according to 4 categories of BMI. A significant reduction (p < 0.05) in AHI was observed in all categories of BMI, regardless of OSA severity.

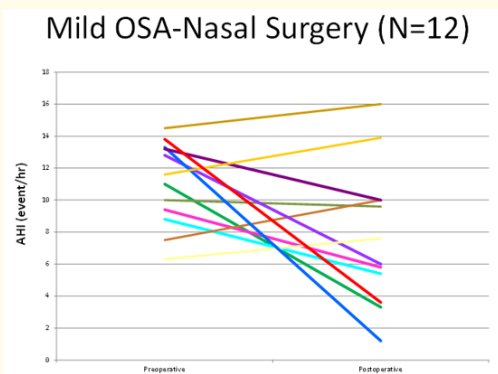


Figure 2: AHI of mild OSA patients with nasal surgery (n = 12).

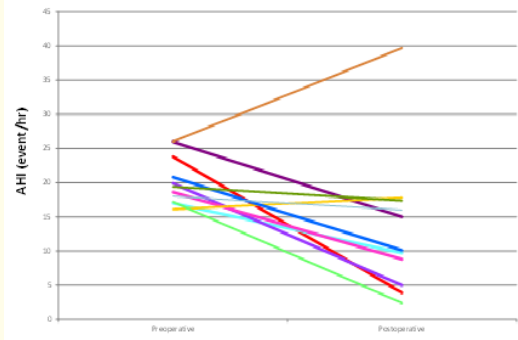


Figure 3: AHI of moderate OSA patients with nasal surgery (n = 13).

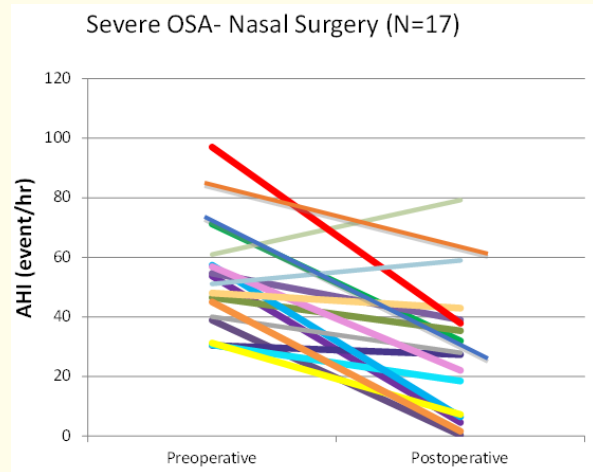


Figure 4: AHI of severe OSA patients with nasal surgery (n = 18).

BMI	N	Preoperative AHI	Postoperative AHI	
<25.0	5	24.425	11.1	p = 0.01
25.0 - 29.9	16	26.7	12.7	p < 0.0009
30.0 - 39.9	18	34.0	20.0	p = 0.02
≥40	4	40.3	24.5	p = 0.04

Table 4: Weight-based reduction in AHI post-nasal surgery (n = 43).

### Discussion

Ever since its introduction, uvulopalatopharyngoplasty (UPPP) has been the workhorse surgical procedure for all patients with OSA despite its limited efficacy (< 50%) and significant morbidity [20]. However, the expansion and improvements in CPAP technologies have made it the primary treatment for patients with OSA. Previous studies that evaluated the effect of nasal surgery in patients

with OSA failed to show any significant reduction in AHI, which in our opinion was because the surgery performed did not address the most relevant anatomic structures along the nasal airflow arc. Our protocol used uncinctomy and anterior ethmoidectomy to address the middle meatus, in combination with septal, turbinate, swell body, and nasal valve surgery to improve nasal airflow by reducing nasal resistance along the arching air path described by Xiong, *et al.* [21] While multi-level upper airway assessment and treatment is the accepted contemporary paradigm, strategically reducing anatomic obstruction along the entire nasal airway in a minimally invasive manner reduces inspiratory nasal obstruction and downstream airway collapse. Our surgical protocol is the first to demonstrate a significant reduction in AHI, especially in patients with moderate and severe OSA, and in all body weight categories. A major advantage of our surgical model compared to others in the literature is the uniformity of surgical steps in a majority of patients and its low morbidity, thereby allowing for reproducibility from patient to patient, and surgeon to surgeon. Thus, in an attempt to standardize the procedure, patients with extensive CRS, with or without nasal polyps, were excluded from the study.

Study of nasal physiology and its role in OSA is largely based on the Starling resistor model predicting negative downstream intraluminal pressure contributing to oro- and hypopharyngeal collapse in patients with nasal obstruction [22]. Resultant mouth - breathing in patients with nasal obstruction contributes further to airway impairment by compensatory lowering of the mandible and flattening of the tongue with subsequent decrease in the retro-glossal space [23]. Nasal obstruction associated with OSA is also believed to blunt the nasal-pulmonary reflex resulting in reduced minute ventilation and reduced concentrations of nitric oxide, thereby exacerbating ventilation-perfusion mismatch. Therefore, correcting upper airway obstruction improves one's respiratory function in many ways.

New models of nasal airflow mechanics, namely computational fluid dynamics (CFD), have shed important light on key functional elements of nasal obstruction. Older tools such as standard rhinomanometry and acoustic rhinometry provide a generalized assessment, however fail to demonstrate the nuances and details of dynamic nasal airflow. Recent developments in CFD studies have provided better simulation models of the human nasal airway, thus allowing measurement of airflow change after nasal surgery. Xiong, *et al.* showed a 13% increase in airflow through the middle meatus after uncinctomy and anterior ethmoidectomy alone [24].

CFD modeling has also allowed 3D rendering of inspiratory airflow, showing a predominance of flow through the middle meatus. This arching trajectory of airflow appears to be a more dominant vector than that through the inferior nasal cavity and is the key reason that middle meatal and swell body surgery is required to improve overall nasal airway patency.

The nasal swell body is perfectly positioned to provide yet another area of resistance to nasal airflow. Similar to the Cottle maneuver, the swell body can easily be compressed with a freer in the office to elicit a subjective response from the patient regarding their nasal breathing. In our recent report on this topic, we showed a significant reduction in NOSE score after radiofrequency treatment of the swell body alone [17]. Over 90% of the patients in the current study required swell body ablation to help improve nasal airflow. Swell body ablation was performed in the office a minimum of 3 months after the primary surgical procedure to avoid the risk of septal perforation [17].

Diagnosis of internal nasal valve collapse was clinically determined by use of the Cottle maneuver. Correction was performed in symptomatic patients with a positive Cottle maneuver via a simple procedure reported by the senior author in 2009 [18]. The procedure removes the caudal aspect of the upper lateral cartilage via a small intranasal incision. This technique avoids the need for open rhinoplasty or cartilage grafts and has been shown to be highly effective for the majority of internal nasal valve deformities. Only 3 of the 43 patients in this study required nasal valve repair; two were bilateral and one was unilateral.

When one reviews the data by severity of OSA, only the mild OSA group failed to achieve significant change in AHI after surgery. We believe the reasons for this are several. Because the mild OSA group has the smallest range of values ( $5 < \text{AHI} < 15$ ), only a small delta (i.e. 10 points) is possible for any given patient. Secondly, there were four patients in this group with an increase in post-op AHI. One possible explanation for the increase in AHI in these 4 patients is the "first night" effect, whereby the baseline PSG results were artificially low due to poor sleep efficiency during the "virgin" study [25]. In fact, each of these four patients had poor baseline PSG sleep efficiency scores of 71%, 66%, 69% and 57%, respectively. It is likely this phenomenon was present in this study to some degree in all AHI groups. Therefore, the results of this study would only be more dramatic than those shown as the true or actual baseline AHI would be higher than those reported herein, making the pre-op vs

post-op AHI delta larger. The “first night” effect is a well-known phenomenon associated with in-lab polysomnograms, which was the only type of PSG used in this study. Perhaps an “at home” PSG would minimize this issue, while at the same time introducing other concerns, such the reliability of the data as there is more chance for error if the patient does not use the equipment properly.

Another very interesting finding in this study relates to outcomes based on BMI (Table 4). While all weight groups show a statistically significant improvement in AHI after surgery, the greatest delta was seen in those of normal weight and the morbidly obese. It has long been thought that patients with a higher BMI have more oropharyngeal collapse during sleep, and therefore require base of tongue support, mandibular advancement, UPPP, or some combination. Our results suggest that significant improvement can be achieved in even the morbidly obese patient with severe OSA with the proper minimally invasive nasal intervention. This does not mean that multi-level surgery is not required in these patients to reach an AHI < 5, however, the ability to achieve a “cure” is significantly enhanced with targeted nasal surgery as described herein. Our results also show a statistically significant reduction in ESS from 12 to 4.2, which is consistent with previous reports of ESS after nasal surgery for OSA.

The results of this study are very promising, and while not reducing AHI to < 5 in all patients, the AHI was reduced to < 5 in 37.2%, and a “surgical cure” was achieved in 46.5%. These results greatly exceed those reported by Verse, and again by Li, which showed a surgical cure rate after nasal surgery of only 16.7% [26,27]. Its importance is not only because of the statistically significant reduction in AHI that was achieved across multiple severities of apnea and BMI, but because it provides new insight into the pathophysiology of SDB. Furthermore, these results provide otolaryngologists with a reliable, effective, minimally invasive surgical procedure to treat patients with OSA that can actually reduce their AHI. In our opinion, patients in this study with residual OSA due to an AHI > 5 require treatment of their tongue base to ultimately cure their OSA as enlarged tonsils and elongated soft palate were not present in this cohort.

Limitations of our study include the inherent risk of selection bias as not all patients had the exact same nasal intervention. We purposely excluded a control arm of patients undergoing septoplasty and inferior turbinoplasty alone because we felt it unethical to subject patients to a surgical intervention that has been shown

to be ineffective [13] and would ultimately require a second surgical intervention to improve their nasal airway. This remains a controversial issue as the equivalent of a surgical “placebo” is difficult to design, as costs and logistics are far greater than that of a placebo pill. We did not use the NOSE score as a metric in this study as the ESS and AHI were our main metrics, representing validated subjective and objective outcome metrics, respectively. In our experience, patients with OSA do not always complain of nasal obstruction for two reasons: they have no appreciation of what proper nasal breathing feels like, and their nasal obstruction may only become clinically significant when they are supine during sleep. When supine, the turbinates and swell body often enlarge due to fluid shifting back into these structures, however, the sleeping patient is unaware of this phenomenon. This has been well described and shown in our report on swell body ablation [17]. Despite these limitations, our study demonstrates strong clinical evidence of improvement in night time airway obstruction for patients with any degree of OSA.

### Conclusion

This study demonstrates that targeted middle meatal surgery, combined with septoplasty, turbinate reduction, swell body ablation, and nasal valve repair, can significantly reduce the AHI and ESS in patients with any degree of OSA and BMI. CFD illustrations of changes between pre and postoperative airflow through the middle meatus support the rationale for our approach.

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