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UNIVERSITY OF CALIFORNIA,
IRVINE

Comparison of Nasal Obstruction Symptom Evaluation Scale with a Septoplasty Deformity
Grading System for the Evaluation of Nasal Obstruction

THESIS

Submitted in partial satisfaction of the requirements
for the degree of

MASTER OF SCIENCE

in Biomedical and Translational Science

By

Jeffrey Tan Gu

Thesis Committee:
Professor Brian J.F. Wong, Chair
Professor Sherrie Kaplan
Professor Sheldon Greenfield

2017

DEDICATION

To

Mom, Dad, and Melody

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Finally, I thank my parents and fiancé. Their belief in me has kept me afloat throughout this journey, and their wisdom has enriched my life beyond measure.

ABSTRACT OF THE THESIS

Comparison of Nasal Obstruction Symptom Evaluation Scale with a Septoplasty Deformity Grading System for the Evaluation of Nasal Obstruction

By

Jeffrey Tan Gu

Master of Science in Biomedical and Translational Science

University of California, Irvine, 2017

Dr. Brian J.F. Wong, Chair

Background: Nasal airway obstruction (NAO) is among the most common chronic complaints of patients seen in otolaryngology practices. The evaluation of NAO consists of a combination of objective and subjective assessments. Among the subjective assessments, the Nasal Obstruction Severity Evaluation (NOSE) survey has become among the most widely used measures of symptom severity. A variety of objective measures have been studied, however there is much controversy preventing wider adoption of objective measures for NAO due to lack of correlation with subjective measures. Among the current septal deformity classification systems, there is a lack of precision in anatomic localization of defects and grading of deformities.

Aims: This study seeks to develop and validate a septal deformity grading system (SDG) that accounts for anatomic location and grading of deformity severity.

Methods: Retrospective cohort study of patients with nasal obstruction presenting to the UCIMC. Subjects were given pre- and post-operative NOSE questionnaires and were evaluated by a facial plastic surgeon using our SDG system. Validity and reliability analyses were conducted on the SDG results. Statistical analyses were conducted on SDG and NOSE data to assess and compare instruments. A composite SDG score was created by weighting each variable by its factor loading from PCA. SDG, and NOSE scores were divided into high and low groups using the 75th and 25th percentiles respectively.

Results: 95 patients met inclusion criteria. 52 patients had a complete set of pre- and post-operative NOSE, and SDG questionnaires. Four constructs were identified on the SDG questionnaire using PCA. Cronbach's α coefficient was ≥ 0.7 for SDG and pre- and post-operative NOSE scores within our study population. There was a significant difference in pre- and post-op NOSE scores (Z score -6.88, $p < 0.001$). Correlations between NOSE and SDG scores were not statistically significant, and convergent construct validity was not achieved. Subgroup analyses determined a significant difference in primary vs revision operations ($p < 0.001$), history vs no history of nasal trauma and nasal/septal surgery ($p = 0.025$, and 0.003 respectively) between composite score groups. A series of univariate logistic regression models determined the odds of having revision operation to be 72.4% higher given a high composite SDG score than low composite SDG score ($p = 0.018$). The odds of having a history of nasal trauma were 8 times higher for high SDG scores than low SDG scores ($p = 0.014$), and odds of having a history of nasal/septal surgery were 94.4% higher for low composite SDG scores than high composite SDG scores. Comparisons between SDG, pre- and post-operative NOSE scores determined significant differences between primary and revision operations, as well as between patients with and without a history of nasal trauma, and prior nasal/septal surgery.

Conclusions: We have developed a septal deformity grading system that improves upon currently available septal deformity classification systems by addressing the challenge of providing a reliable and consistent method for surgeons to characterize septal deviations for preoperative or postoperative evaluation. Our septal deformity grading scores provide anatomic information on the severity of nasal septal deformities, and may be valuable when used in conjunction with subjective data gathered from the NOSE questionnaire.

CHAPTER 1: INTRODUCTION

Nasal airway obstruction (NAO) is one of the most common clinical indications for otolaryngology referral and carries an estimated economic burden of greater than \$5 billion annually.¹ Numerous studies have sought to improve diagnosis of this condition, however NAO remains a diagnostic challenge due to discrepancies between subjective symptoms and objective findings, whether on physical exam, rhinomanometry, peak nasal inspiratory flow, acoustic rhinometry, or radiographic findings.¹⁻⁶ With the current limitations in identifying specific anatomical sites of obstruction, the diagnosis of nasal obstruction, decision to proceed to surgery, and selection of structures to modify largely depend on surgeon intuition. Nonetheless, among the causes of nasal obstruction, deviation of the nasal septum remains a very common cause.⁷⁻⁹ Definitive correction of nasal septal deformities is through surgical interventions such as functional rhinoplasty or septoplasty. Currently, there is limited evidence to document whether such interventions are effective in improving symptoms of nasal obstruction.¹⁰

There has been a trend in assessment of nasal obstruction towards the use of patient reported outcome measures, specifically in the form of the Nasal Obstruction Symptom Evaluation scale, or NOSE scale.¹¹ Due to the inconsistencies between objective measures and subjective evaluations of nasal obstruction, the consensus has shifted towards weighing subjective evaluations more heavily, since ultimately it is the severity of the subjective symptom of nasal obstruction that determines treatment success. The NOSE questionnaire therefore, has become widely used in the assessment of disease-specific quality of life (QOL) following functional rhinoplasty or septoplasty. The World Health

Organization defines QOL as a multi-dimensional construct that consists of an individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.¹² Within the evaluation of health, or disease-specific quality of life, such as by the NOSE questionnaire, it must be noted that QOL covers a large variety of dimensions. Additionally, it must be noted that the nature of a subjective measure is that such assessments may vary considerably, even among individuals with otherwise equal disease severity.¹³ Altogether, these factors may compound the difficulty of validating clinical measures using patient reported health status measures.

To improve the diagnosis and surgical management of nasal obstruction, this study outlines the development and validation of a standardized nasal septum grading system that will address the challenges of anatomic localization and grading of the severity of nasal septum deformities. The primary objective of the present study was to develop and validate such a septal deformity grading (SDG) system. Additionally, there are several research questions that will be addressed. Following development and validation of our SDG system, study data will be used to explore subjective differences in NOSE scores between high and low SDG scores. We will also evaluate the effect of confounding variables, such as type of operation (primary vs revision), gender, and presence or absence of allergic rhinitis, chronic rhinitis, chronic sinusitis, nasal trauma, and history of previous sino-nasal surgery. Finally, the SDG system will be compared with pre-and post-operative NOSE scores to determine the utility of each instrument for different patient characteristics.

This thesis is organized into the following four chapters. Chapter 2 includes as a

general overview of nasal obstruction, the NOSE scale, septal deformities, and our septal deformity grading and classification system, as well as a review of the recent literature. Chapter 3 provides a summary of methodology and statistical analyses conducted. Chapter 4 provides the results of my analysis. Chapter 5 includes a discussion of my findings, strengths and limitations of this thesis, and areas of future research.

CHAPTER 2: BACKGROUND

Although many physicians consider nasal obstruction to imply an objective blockage within the nasal cavities, it is most commonly defined as the patient's subjective sensation of insufficient airflow through the nose.¹⁴ A patent nasal airway is critical for maintaining proper functioning of vocalization, humidification, filtration and heating of air, and adequate ventilation. Nasal airway obstruction (NAO) can lead to subjective complaints while awake, as well as impairment while asleep, and with chronic progression, it has the potential to cause further sequelae such as reduced mentation, arrhythmia, and cor pulmonale. Air flow through the upper airway can be approximated by Poiseuille's law, which states that flow is proportional to the fourth power of the radius of the tube, therefore a small decrease in airway diameter leads to a relatively large decrease in air flow. Similarly, Bernoulli's principle may be used to explain the phenomenon of dynamic nasal obstruction upon forced inspiration, where there is collapse of the internal or external nasal valves—the flow of air is fastest through the narrowest portion, and causes a negative pressure that leads to nasal valve collapse and thus obstruction.

Nasal Obstruction: Etiology & Brief Overview

The etiologies of nasal obstruction may be classified as inflammatory or non-inflammatory, and anatomical. Excluding the common cold, the most common cause of nasal obstruction is allergic rhinitis, an inflammatory etiology. Allergic rhinitis is common, and affects 10-30% of children and adults in the United States and other industrialized countries.^{15,16} Non-allergic, non-infectious rhinitis includes rhinitis of both known and

unknown origins. Of the many etiologies, certain decongestants may lead to rhinitis medicamentosa, and pregnancy may cause hormone-induced nasal congestion. Most pertinent to the study at hand are anatomical causes of nasal obstruction, which are either present at birth, or acquired. Septal deviations are very common, and those acquired later in life are often of traumatic origin. A large Korean study found the prevalence of nasal septal deformity to be 22% overall (24% in males, and 20% in females), although only 2.8% of the series complained of nasal obstruction. Of the nasal septal deformities, 56% were left-sided, 39% right-sided, and 5% S-shaped (crooked in multiple directions). There was also an increased incidence of nasal septal deformity with increasing age.¹⁷ A Swedish study estimated the annual incidence of nasal obstruction due to septal deviation to be approximately 0.04%, with a prevalence near 1%.¹⁴ Another Swedish study estimated that nasal obstruction attributable to nasal septal deviation affects roughly 2-3% of the population.¹⁸

A considerable difficulty and important factor when considering the evaluation of nasal obstruction is its subjective nature. The variability in the prevalence and incidence data may be partially explained by individual variation in patient perception of nasal obstruction. Therefore, in the assessment of the subjective perception of nasal obstruction it is important to consider a time factor, laterality, the nasal cycle, stage of surgery (primary or revision) and comorbidities. Another important distinction is the discrepancy between objective and subjective nasal patency. It has been shown that although spraying the nose with menthol increases the subjective sensation of nasal patency, there is no objective change in nasal airway resistance. The proposed mechanism of the effect of menthol on nasal sensation of airflow is likely due to action on trigeminal thermoreceptors in the

squamous epithelium of the nasal vestibule which respond to the cooling action of inspired air.¹⁹ In fact, the application of local anesthetic to the nasal vestibule has been shown to correlate with subjective sensation of nasal obstruction.²⁰ It has also been shown that subjective nasal patency has a stronger correlation with unilateral rather than bilateral objective measures, and that subjective nasal patency has a stronger correlation with unilateral measures in the most obstructed side than with measures in the least obstructed side.^{2,21}


The NOSE Scale

The Nasal Obstructive Symptoms Evaluation, or NOSE scale is a brief, disease-specific quality of life (QOL) instrument designed for use in evaluating an adult patient's subjective perception of nasal obstruction following septoplasty and functional rhinoplasty (**Figure 1**). It has been tested for reliability and validity in multiple patient groups and in multiple clinical settings.^{10,13,22-24} The designers of the NOSE scale have demonstrated its validity for use in comparing disease-specific health status between groups of patients before and after treatment, to compare the effects of different treatments, and for assessing differences in outcome when different surgical techniques are used.¹⁰ It is a five item survey that evaluates subjective severity of the following items over the past 1 month: 1) nasal congestion or stuffiness, 2) nasal blockage or obstruction, 3) trouble breathing through my nose, 4) trouble sleeping, and 5) unable to get enough air through my nose during exercise or exertion. These 5 items are graded on a 5-point Likert scale from 0-4 with 0 being "not a problem", 1 "very mild problem", 2 "moderate problem", 3 "fairly bad


problem”, and 4 “severe problem”. The instrument is then scaled to a total score of 0 to 100 by multiplying the raw score by 5.

Of the currently available subjective measures of nasal obstruction, the NOSE scale has been most extensively studied in the context of septoplasty.^{13,25-30,23} Due to the current lack of a gold standard objective measure of nasal patency, and since ultimately for nasal obstruction the measure of success is in the patient’s subjective perception, the NOSE scale has emerged as one of the most clinically meaningful assessment tools to quantify treatment success. Multiple studies have attempted to correlate objective measurements or imaging (e.g. computed tomography scans) and subjective sensation of nasal patency, with no strong correlations found thus far.^{2,31} To improve the clinical applicability of the NOSE scale, it was important to distinguish between the utility of a statistically significant change in score, and a clinically important change in score, since a statistically significant change in score can still be too small to be clinically important. To this end, Stewart et al. calculated a minimal clinically important difference in NOSE score change, and defined this as 0.2-0.3 times the standard deviation of the baseline distribution.³² In a following study, Rhee et al. reviewed the literature and determined that a clinically meaningful measure of surgical success may be considered as a change of at least 30 points for NOSE scores.³³ It was also important to improve the detail of the survey results, and to develop a severity classification system to categorize NOSE scores. Lipan et al. conducted receiver operating characteristic (ROC) curve analysis on NOSE scores from patients with and without nasal obstruction to determine a cutoff point to best distinguish between the two groups. The threshold was determined to be a NOSE score of 30 (sensitivity 93.7%, 95% CI 89.9-96.3%, and specificity 90.3%, 95% CI 82.4-95.5%).³⁴ Studies that report outcomes using the NOSE

scale often demonstrate improvement after surgery, however with a severity based classification scheme, additional context may be provided to supplement NOSE scores.



**Nasal Obstruction Symptom Evaluation (NOSE)
Instrument**



→ **To the Patient:** Please help us to better understand the impact of nasal obstruction on your quality of life by completing the following survey. Thank You!

Over the past 1 month, how much of a problem were the following conditions for you?

Please circle the most correct response

	<i>Not a problem</i>	<i>very mild problem</i>	<i>moderate problem</i>	<i>fairly bad problem</i>	<i>severe problem</i>
1. Nasal congestion or stuffiness	0	1	2	3	4
2. Nasal blockage or obstruction	0	1	2	3	4
3. Trouble breathing through my nose	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Unable to get enough air through my nose during exercise or exertion	0	1	2	3	4

Figure 1. Nasal Obstruction Symptom Evaluation (NOSE) Instrument

State of the Art: Septoplasty Classification Systems

While the NOSE scale has great utility as a patient reported outcome measure, surgical decisions are based on both anatomic findings on physical examination and the presence of patient symptoms. The nasal septum is the key midline support structure of the nose and is composed of the quadrangular cartilage, perpendicular plate of the ethmoid bone, palatine bone, and vomer. Septal deformities are quite common, and are determined

by genetic, cultural, and environmental factors. Although the very first attempts to systematize septal distortions were made by Cottle³⁵, the septal deformity system proposed by Mladina⁷ was the first to become widely adopted, and has since been modified by numerous groups.^{9,36-38} Mladina's system proposed seven classes of nasal septal deviation (**Figure 2**). Type I is classified as mild septal deviation in the vertical plane (no contact with anterior nasal valve). Type II is classified as moderate anterior vertical deviation of the cartilaginous septum in close contact with the limen nasi (i.e. part of the anterior nasal valve). Type III ('C' or reverse 'C'-shaped septum) is classified as posterior vertical deviation at the borderline between quadrangular lamina and perpendicular lamina at the level of the middle turbinate. Type IV is classified as an 'S'-shaped, posterior deviation to one side, and anterior deviation to the other (i.e. Type II on one side and Type II on the contralateral side). Type V is classified as presence of a horizontal, slightly ascending septal spur that may or may not touch the lateral nasal wall. Type VI is classified as presence of a prominent maxillary crest contralateral to the deviation with a septal crest on the deviated side. Type VII (Passali deformity) is classified as a combination of deformities from the previous types (Types I-IV are vertical, and Types V and VI are horizontal deformities). In a following study of 2589 subjects, Mladina noted the general incidence of septal deformity to be 89.2% (males 92.5%, females 84.6%), with Type III as the most frequent type (20.4%), Types I and II with nearly equal frequency (16.4% vs 16.2% respectively), Type V nearly as frequent (14.0%), and Types VI, IV, and VII less frequently seen (9.4%, 8.7%, and 4.1% respectively).⁷

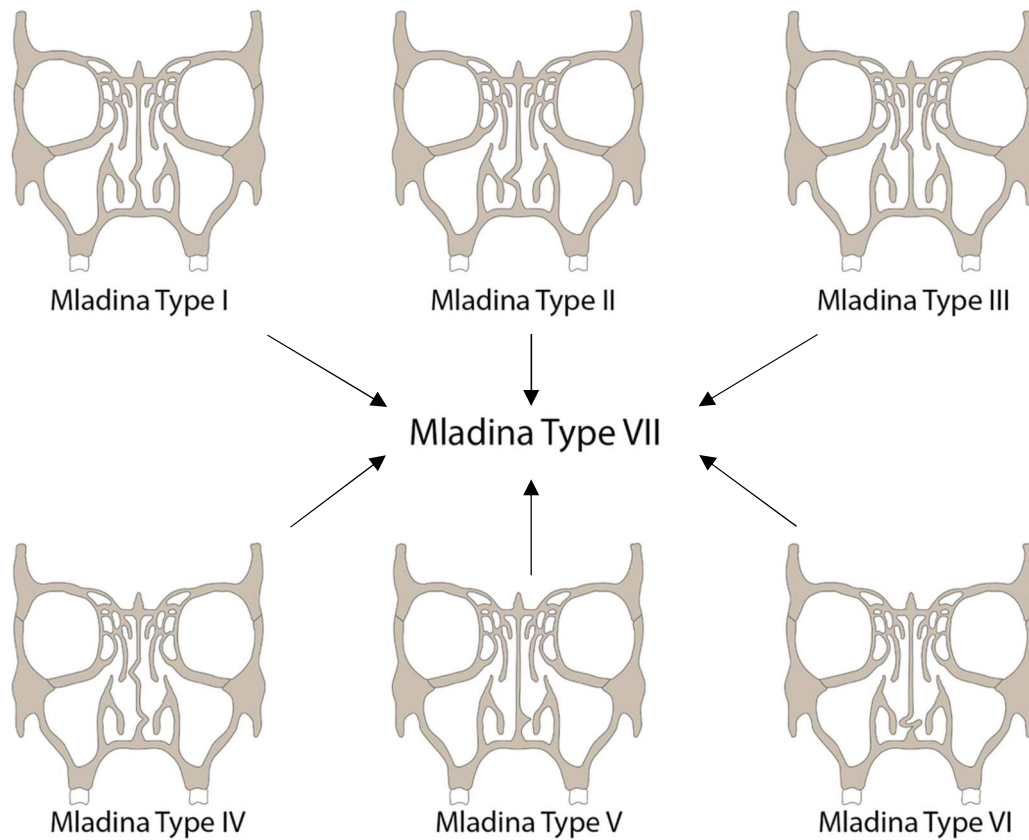


Figure 2. Mladina septal deformity classification system.

Although Mladina³⁶, and subsequent investigators, including Rao⁹, Guyuron³⁷, Jin³⁸, Baumann¹³, and others³⁹ have all proposed modifications of the septal deformity classification system, there remains a lack of consensus regarding how to best examine the nasal septum and how to grade the severity of deformities. A challenge common to all classification methods created thus far is the ability to precisely localize areas of deformity. Additionally, CT imaging does not correlate well with physical exam findings of the nasal septum.³¹ Lin et al. proposed a method to quantify the curvature, extent of deviation, and complex shape of the nasal septum using CT scans and image processing software.⁴⁰ In this study, it was shown that the regions of the septum near the perpendicular plate-vomer

(PPV) junction, the anterior nasal spine, and the crista galli were the areas with the greatest deviations. At the anterior septal angle (ASA), caudal septal deviations and deviations through Little's area were frequently observed. Caudal septal deviation of even 1 mm can impair airflow, although these small deviations would be difficult to measure given the limited resolution of CT.

Proposed Septoplasty Deformity Grading System

In order to address the current limitations in precisely localizing and grading septal deformities, Wong et al. generated contour plots of the septum from CT images, and seven specific septal regions were selected on the basis of detailed analysis of multiple images with highly experienced senior head and neck surgeons and clinical faculty.⁴⁰ These regions included the perpendicular plate of the ethmoid bone and vomer bone junction, nasal spine, nasal bone, crista galli, and mid-distance between the perpendicular plate-vomer (PPV) junction and nasal spine. These selected regions focus on bony landmarks which can be easily identified on virtually any CT scan.

For this thesis, a septal deformity grading system was designed with the seven landmarks identified by Wong et al⁴⁰. Each of the seven regions is further stratified by laterality (left or right), and on a 4-point Likert scale to grade severity of the deformity from 0-3, with 0 indicating lack of deformity, and 3 the greatest extent of deformity. These seven regions and their severity grading are as follows (**Figure 3**). For the sake of brevity, the score of 0 will not be further described since it indicates absence of deformity for all seven regions. 1) Spur, where a score of 1 is "mild, may not require treatment", 2 is "intermediate", and 3 "touches turbinate". 2) Caudal deviation, where a score of 1 indicates

“within columellar footprint”, 2 is “slightly deviates columella”, and 3 “resides in nares”. 3) Dorsal curvature mid-vault C shape, where 1 is “non-surgical”, 2 “requires spreader graft”, 3 is “adjacent/touches the upper lateral cartilages”. 4) Dorsal deviation off angle, where 1 is “non-surgical”, 2 “requires spreader graft”, and 3 is “adjacent/touches the upper lateral cartilages”. 5) Perpendicular plate-vomer-quadrangular cartilage junction, where 1 is “non-surgical”, 2 is “obstructive”, 3 “touches turbinate”. 6) posterior septal angle (PSA), where 1 is “within columellar footprint”, 2 “slightly deviates columella”, and 3 “resides in nares”. 7) Anterior septal angle (ASA), where 1 is “slight deviation of tip”, 2 is “moderate deviation of tip”, and 3 is “severe deviation of tip”. Total counts of scores equal to 1, 2, and 3 are filled in the sum row. The grand total is the sum of the grades given for each side of each of the seven regions for a range from 0-42.

Septal Deformity Grading	name	date				surgeon
		0	1	2	3	
Spur		none	mild, may not require treatment	Intermediate	touches turbinate	
	Left					
	Right					
Caudal Deviation		none	within columellar footprint	slightly deviates columella	resides in nares	
	To Right					
	To Left					
Dorsal Curvature Mid Vault- C SHAPE		none	non surgical	Requires Spreader Graft	Adjacent/ touches the ULC	
	Concave Right					
	Concave Left					
Dorsal Deviation off Angle		none	non surgical	Requires Spreader Graft	Adjacent/ touches the ULC	
	Straight to Right					
	Straight to Left					
PP-Vomer- QC junction		none	non surgical	obstructive	touches turbinates	
	obstruction Right					
	Obstruction Left					
PSA		none	within columellar footprint	slightly deviates columella	resides in nares	
	To Right					
	To Left					
ASA		none	slight deviation of tip	moderate deviation of tip	severe deviation of tip	
	To Right					
	To Left					
Sum						
Grand Total						

Figure 3. Septal deformity grading sheet.

CHAPTER 3: METHODS

Study Population and Research Design

This study was conducted under the review and approval by the Institutional Review Board of the University of California, Irvine, in accordance with their guidelines, and all participants were provided written informed consent to the study. Patient recruitment for this study occurred between November 2014 to April 2017 at a single tertiary medical center. Inclusion criteria were patients 16 years of age or older undergoing septoplasty or rhinoplasty. Patients with and without nasal obstruction were recruited. Exclusion criteria included inadequate command of the English language, and inability to give informed consent.

Once enrolled, all patients underwent a detailed nasal examination by a board-certified facial plastic surgeon and otolaryngology resident. Anterior rhinoscopy was performed evaluate inferior turbinate hypertrophy, and the internal nasal valve (INV) on inspiration and at rest. The degree of external nasal valve (ENV) obstruction was also determined on inspiration and at rest. Each side of the nose was examined by closing the patient's opposite nares with digital compression during nasal inspiration, and both Cottle and modified Cottle maneuvers were performed. Using our septal deformity grading sheet (**Figure 3**), septal deformities were characterized and graded from information gathered on physical exam, imaging (head and neck CT scan), and from direct intraoperative visualization of the anatomy (**Figure 4**). Additional patient information collected included history of nasal obstruction, allergic rhinitis, chronic sinusitis, chronic rhinitis, nasal trauma, previous nasal surgery, age, sex, and BMI. Following surgery (septoplasty or

rhinoplasty), patients were given a second NOSE questionnaire to complete at the follow-up visit.

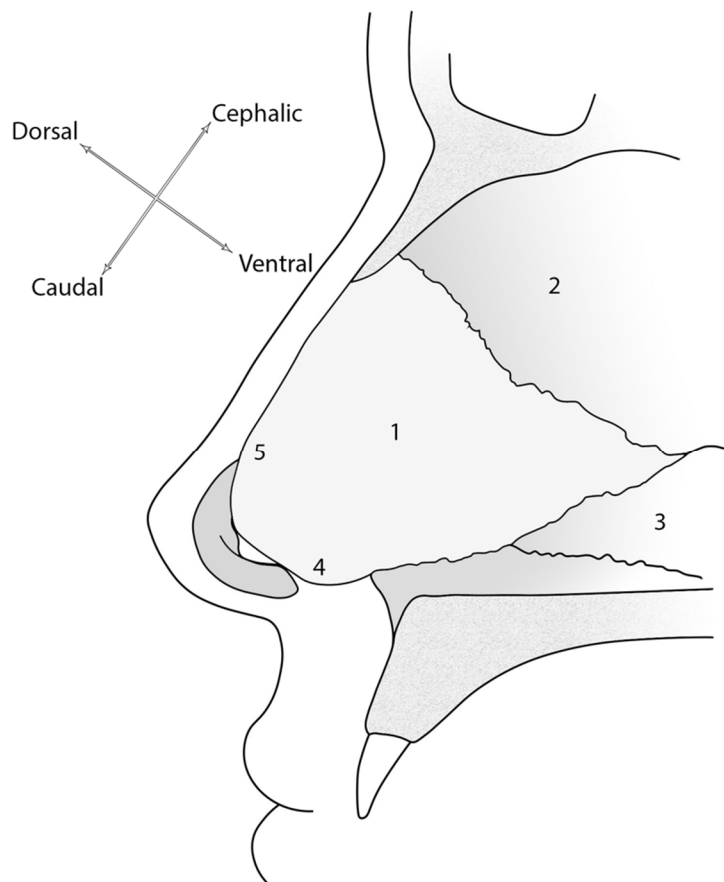


Figure 4. Anatomical landmarks assessed for grading and classification of septal deformity. **1:** Quadrangular cartilage (QC); **2:** Perpendicular plate of the ethmoid bone (PP); **3:** Vomer; **4:** Posterior septal angle (PSA); **5:** Anterior septal angle (ASA). The region where 1, 2, and 3 interact is the PP-Vomer-QC junction. Axes indicate orientation (e.g. caudal vs cephalic, dorsal vs ventral). *Not shown: septal spur, dorsal curvature (C-shaped mid-vault), or dorsal deviation off angle.*

Development and Validation of the Septal Deformity Grading Sheet

The septal deformity grading system was designed with the seven landmarks identified by Wong et al⁴⁰. These seven regions pertain to anatomical landmarks that have been previously shown to be highly deviated from normal in patients with septal

deformities. Each of the seven regions is further stratified by laterality (left or right), and on a 4-point Likert scale to grade severity of the deformity from 0-3, with 0 indicating lack of deformity, and 3 the greatest extent of deformity. The alpha-version instrument included seven constructs that correspond to the seven landmarks assessed.

Content validity was ensured during design of the instrument through review by a board-certified facial plastic surgeon, and medical students. Confirmatory analyses were performed using principle components analysis (PCA) on all items with orthogonal varimax rotation of factors to confirm the hypothesized factor loadings of the septal deformity items by their respective constructs. All factors with an eigenvalue of greater than 1 were retained for potential inclusion in the final rotated factor solution. Internal consistency reliability for each of the constructs was assessed through determination of the Cronbach's α coefficient, and noting item-total correlations of each construct of the septoplasty grading sheet. Internal consistency reliability was considered adequate if $\alpha \geq 0.70$. Items that did not contribute to the overall internal consistency of the instrument were marked for possible elimination. Convergent construct validity analysis was conducted through a series of linear regression models, discussed in greater detail below.

The NOSE questionnaire has been extensively studied and validated in previous investigations. To confirm internal consistency reliability of the NOSE questionnaires within our study population, Cronbach's α was calculated. Again, $\alpha \geq 0.70$ was used as the threshold for adequate internal consistency reliability.

Statistical Analysis

To measure disease-specific (nasal obstruction) change in quality of life in patients undergoing rhinoplasty or septoplasty, a nonparametric analysis (Wilcoxon signed-rank test) was used to compare preoperative and postoperative follow-up NOSE scores. P values less than 0.05 were considered statistically significant. To identify variables from the septoplasty deformity grading sheet that are significantly associated with NOSE scores, a series of univariate linear regression analyses were performed to evaluate the association between preoperative and postoperative NOSE scores, and the septoplasty grading score. β coefficients were determined to assess significant relationships between these variables. Since there are multiple comparisons, a Bonferroni corrected p-value of less than 0.0022 (for 23 comparisons, $p < 0.05/23$) was considered statistically significant for evaluating the univariate linear regression results. A p-value of <0.05 was used to evaluate univariate linear regression models comparing individual NOSE scale items with septoplasty deformity grading scores. SPSS 21.0 software (IBM Inc., Armonk, NY) was used for all statistical analyses.

To examine the effect of possible confounding variables, a nonparametric analysis (Mann-Whitney U) was used to compare between groups with and without the following: allergic rhinitis, chronic rhinitis, chronic sinusitis, nasal trauma, previous nasal surgery. These variables were chosen as potential confounding variables as they have been identified as potential contributors to nasal obstruction by numerous studies.^{15,41-43} Mann-Whitney U was also used to compare between primary operation and revision operation groups, male and female groups, and high and low NOSE score groups (threshold of 30).

CHAPTER 4: RESULTS

We identified 95 patients who met the inclusion criteria. Of these 95 patients, 3 did not have any completed forms and were excluded from analysis. In the remaining 92 patients, 82 had completed preoperative NOSE questionnaires, 71 had completed post-operative NOSE surveys, and 61 had completed septoplasty deformity grading sheets. A total of 52 patients had a complete set of pre- and post-operative NOSE surveys, and septoplasty deformity grading sheets. There were 56 women (58.9%), and 39 men (41.1%), with a mean age of 37.9 years (range, 16-71 years). The mean BMI of the cohort was 25.1 kg/m² (range, 15.9-38.3 kg/m², SD, 4.88 kg/m²). There were 53 primary operations (55.8%), and 42 revision operations (44.2%). Additionally, all included patients had a history of nasal obstruction, 20 patients had a history of allergic rhinitis (21.1%), 18 patients had a history of chronic sinusitis (18.9%), 16 patients had a history of chronic rhinitis (16.8%), 49 patients had a history of nasal trauma (51.6%), and 42 patients had a history of previous nasal or septal surgery (45.6%). Mean scores for pre- and post-operative NOSE surveys, and septoplasty deformity grading scores were 69.45, 24.44, and 25.20 respectively (**Table 1**).

Characteristic	Overall No./No. (%)
Age, mean (SD), y	37.9 (14.9)
Gender	
Female	56/95 (58.9)
Male	39/95 (41.1)
BMI, mean (range)	25.1 (15.9-38.3)
Primary operation	53/95 (55.8)
Revision operation	42/95 (44.2)
History	
Nasal obstruction	92/92 (100)
Allergic rhinitis	20/92 (21.1)
Chronic sinusitis	18/92 (18.9)
Chronic rhinitis	16/92 (16.8)
Nasal trauma	49/92 (51.6)
Previous nasal or septal surgery	42/92 (45.6)
Pre-op NOSE Total Score, mean (SD)	69.45 (23.84)
Post-op NOSE Total Score, mean (SD)	24.44 (26.17)
SDG Total Score, mean (SD)	25.20 (17.46)
Composite SDG Score, mean (SD)	4.99 (2.99)

Table 1. Baseline characteristics and patient demographics.

Dimensionality Analysis: Septal Deformity Grading System

The factor structure of the items of the septoplasty deformity grading system were scored in the same direction on a 0 to 3 scale, where higher scores represent higher levels of deformity. The theoretical minimum and maximum total scores were 0 and 42 respectively, and is a unit-less and dimensionless measure. A visual inspection of Eigenvalues was performed after generating a scree plot from which four components are indicated (**Figure 5**).

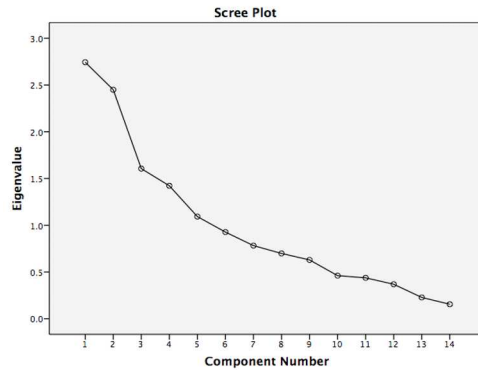


Figure 5. Visual inspection of Eigenvalues of the SDG system through scree plot.

Rotated Component Matrix^a

	Component			
	1	2	3	4
Spur on Left	-.238		.565	.205
Spur on Right	.105	.259	.113	.769
Caudal Deviation to Right	.629	-.104	.143	-.252
Caudal Deviation to Left		.604	.453	.316
Dorsal Curvature Mid-vault C shape concave Right	.132		.790	
Dorsal Curvature Mid-vault C shape concave Left	.742			
Dorsal Deviation off angle straight to the Right	.471	-.187	-.153	.304
Dorsal Deviation off angle straight to the Left	-.148	.869		.198
PP-Vomer-QC Junction Obstruction Right	.519		-.172	.486
PP-Vomer-QC Junction Obstruction Left	-.218		.591	-.267
PSA to Right	.423	.626	-.211	-.285
PSA to Left	-.255			.607
ASA to Right	.753		-.243	
ASA to Left	-.218	.857	-.137	

Extraction Method: Principal Component Analysis.
 Rotation Method: Varimax with Kaiser Normalization.
 a. Rotation converged in 8 iterations.

Table 2. Orthogonal varimax rotation of SDG factors for principal components analysis.

Principal components analysis (PCA) was run on fourteen factors of the septoplasty deformity grading system. Four distinct constructs were observed, with each of the fourteen factors loading correctly, strongly, and uniquely onto each construct (**Table 2**). The overall factor structure of the items differs the hypothesized scales as delineated by our septal deformity grading sheet (**Figure 3**). Caudal deviation to the right, dorsal curvature to the left, dorsal deviation to the right, perpendicular plate-vomer-quadrangular cartilage junction obstruction to the right, and anterior septal angle obstruction to the right load strongly on the first component. Caudal deviation to the left, dorsal deviation to the left, posterior septal angle obstruction to the right, and anterior septal angle to the left load strongly on the second component. Spur obstructing the left, dorsal curvature to the right, and perpendicular plate-vomer-quadrangular cartilage junction obstruction to the left load on the third component. Lastly, spur obstructing the right, and posterior septal angle obstruction to the left load strongly onto the fourth component. Values for each variable were multiplied by their factor loadings and summed to produce a weighted composite SDG score.

Reliability Analysis: Septal Deformity Grading System and NOSE scale

Cronbach’s α coefficients were calculated for the septal deformity grading system, and determined to be 0.756. Cronbach’s α coefficients for preoperative NOSE questionnaires, postoperative NOSE questionnaires were calculated as well, and were 0.848 and 0.920 respectively (**Table 3**).

Construct	Cronbach's α coefficient
SDG	0.756
Pre-op NOSE	0.848
Post-op NOSE	0.920

Table 3. Analysis of internal consistency reliability of individual constructs of the SDG system. A threshold of $\alpha \geq 0.7$ was set to meet adequate reliability.

Pre- vs. Post-operative NOSE Scores

Pre-operative NOSE scores ranged from 15 to 100 (n=82; mean, 69.45; SD, 23.84), and post-operative NOSE scores ranged from 0 to 90 (n= 71; mean 24.44; SD, 26.17). Wilcoxon signed-rank test comparing pre- and post-operative NOSE scores resulted in a Z- score of -6.88 (p<0.001).

Convergent Construct Validity Analysis: Correlations between NOSE Scale and SDG System

A series of univariate linear regression analyses were performed to compare preoperative and postoperative NOSE scores with each of the components of the SDG scores as well as composite totals for each SDG category. SDG scores were converted to a percentage for the percentile SDG score variable. After adjusting for multiple comparisons (p<0.0022), dorsal concavity total (the sum of left and right scores) was found to have a β of 0.456 (p=0.001), however none of the other univariate linear regressions achieved statistical significance (**Table 4**).

Variable	Pre-operative NOSE vs. SDG		Post-operative NOSE vs. SDG	
	β	p-value	β	p-value
Spur R	-0.148	0.276	-0.157	0.265
Spur L	-0.311	0.020	-0.141	0.319
Caudal dev R	0.221	0.102	0.114	0.419
Caudal dev L	-0.137	0.314	-0.141	0.320
Dorsal Concave R	0.040	0.770	0.368	0.007
Dorsal Concave L	0.237	0.082	0.368	0.008
Dorsal Straight R	0.098	0.474	0.027	0.852
Dorsal Straight L	-0.225	0.095	-0.184	0.191
PPVQC Obstruction R	0.136	0.322	0.128	0.370
PPVQC Obstruction L	-0.610	0.654	-0.039	0.781
PSA R	0.035	0.797	-0.100	0.481
PSA L	0.117	0.391	-0.137	0.334
ASA R	0.154	0.262	0.069	0.630
ASA L	-0.206	0.128	-0.218	0.121
Spur Total	-0.297	0.026	-0.194	0.169
Caudal Dev Total	0.105	0.441	-0.130	0.357
Dorsal Concave Total	0.168	0.217	0.456	0.001*
Dorsal Straight Total	-0.068	0.620	-0.214	0.128
PPVQC Obstruction Total	0.083	0.545	0.154	0.277
PSA Total	0.115	0.400	-0.218	0.120
ASA Total	-0.047	0.732	-0.132	0.350
Total SDG Score	-0.026	0.849	-0.095	0.504
Percentile SDG Score	-0.070	0.605	-0.086	0.546
Composite SDG Score	0.012	0.930	0.035	0.805

Table 4. Linear regression models of pre- and post-operative NOSE scores with SDG components. A Bonferroni corrected p <0.0022 was considered statistically significant (*).

Subgroup analysis was performed using independent samples t-test for continuous variables and Fisher’s exact test for dichotomous variables to determine potential relationships in the data between high and low septal deformity grading score groups. Septal deformity scores were recoded into high or low septal score groups using the 75th and 25th percentiles respectively as threshold values. Pre- and post-operative NOSE scores were also recoded into high or low score groups using the 75th and 25th percentiles respectively as threshold values. Groups were compared using exploratory analyses to determine any statistically significant differences. There was a statistically significant difference between primary and revision operations between high and low SDG score groups ($p<0.001$), between history and lack of history of nasal trauma and previous nasal/septal surgery ($p=0.025$ and 0.003 respectively). For the remaining variables, I found no statistically significant differences between high and low septal deformity grading scores (**Table 5**).

Variable	High SDG Score (n=15)	Low SDG Score (n=15)	p-value
High Preop NOSE Score	12 (85.7%)	11 (73.3%)	0.651
High Postop NOSE Score	6 (42.9%)	5 (38.5%)	1.000
Male	8 (53.3%)	4 (26.7%)	0.264
Primary	14 (93.3%)	3 (20.0%)	<0.001*
Hx of Allergic rhinitis	6 (40.0%)	1 (6.7%)	0.080
Hx of Chronic sinusitis	3 (20.0%)	3 (20.0%)	1.000
Hx of Chronic rhinitis	1 (6.7%)	4 (26.7%)	0.330
Hx of Nasal Trauma	12 (80.0%)	5 (33.3%)	0.025*
Hx of Previous Nasal/septal surgery	2 (13.3%)	11 (73.3%)	0.003*

* p-values computed using independent samples t-test for continuous variables and Fisher's exact test for dichotomous variables

**Table entries are counts (percentage)

Table 5. Subgroup analysis between high and low SDG scores, and covariates.

Bivariate logistic regression using high septal deformity grading scores against the covariates of high pre- and post-operative NOSE score, male gender, primary operation,

and history of allergic rhinitis, chronic sinusitis, chronic rhinitis, nasal trauma, and previous nasal or septal surgery were performed to determine if there is a difference in odds. Each of the above variables were inputted as dichotomous variables (i.e. male or female coded as 0 or 1 respectively) for logistic regression. Multivariate logistic regression using a high septal deformity grading scale and the above covariates was performed to determine an adjusted odds ratio (i.e. given a high SDG score, what are the odds of finding each covariate). From the univariate logistic regression model comparing type of operation (primary vs revision) with SDG score (high vs low), the odds of having a revision operation were 72.4% higher for high SDG scores than low SDG scores (p=0.018). The odds of having a history of nasal trauma were 8 times higher for high SDG scores than low SDG scores (p=0.014), and the odds of having a history of nasal/septal surgery were 94.4% higher for low SDG scores than high SDG scores. However, after adjustment the above observations did not reach statistical significance. None of the remaining variables in either the bivariate or multivariate logistic regression models reached statistical significance (**Table 6**).

Variable	Unadjusted Odds Ratio	p-value	Adjusted Odds Ratio (95% CI)	p-value
High Pre-op NOSE Score	2.182	0.417	0.714 (0.04-11.94)	0.815
High Post-op NOSE Score	1.200	0.816	0.698 (0.15-3.24)	0.645
Male	3.143	0.142	2.129 (0.45-10.1)	0.341
Primary	0.018	0.001*	0.220 (0.02-2.52)	0.173
Hx of Allergic rhinitis	9.333	0.054	3.233 (0.51-20.55)	0.214
Hx of Chronic sinusitis	1.000	1.000	0.294 (0.04-2.51)	0.263
Hx of Chronic rhinitis	0.196	0.171	5.383 (0.51-56.89)	0.162
Hx of Nasal Trauma	8.000	0.014*	2.571 (0.56-11.87)	0.226
Hx of Previous Nasal/Septal surgery	0.056	0.003*	1.579 (0.12-20.48)	0.727

*Predictive model was determined using logistic regression analysis.

Table 6. Bivariate and multivariate logistic regression results using high SDG score as a dependent variable against each listed covariate was used to determine unadjusted and adjusted odds ratios

Comparison of SDG, Pre- and Post-Operative NOSE Results

A series of non-parametric Mann-Whitney U tests were performed between SDG scores, pre- and post-operative NOSE scores, and the following groups of variables: male vs female, primary vs revision, and history vs no history of: allergic rhinitis, chronic sinusitis, chronic rhinitis, nasal trauma, and nasal/septal surgery (**Table 7**). There were statistically significant differences in mean composite SDG scores between primary (6.22, SD 3.10) and revision operations (3.34, SD 1.85), $p < 0.001$, for history of nasal trauma (3.88, SD 2.19) and no history of nasal trauma (3.89, SD 2.92), $p = 0.012$, as well as for history of nasal/septal surgery (3.39, SD 2.14) and no history of nasal/septal surgery (6.03, SD 3.03), $p < 0.001$. For mean pre-operative NOSE scores, there were statistically significant differences between primary (67.59, SD 21.86), and revision operations (75.22, SD 26.22), $p = 0.031$, and between history of chronic sinusitis (87.86, SD 23.07), and no history of chronic sinusitis (68.33, SD 23.23), $p = 0.046$. There were no statistically significant differences detected in mean SDG, pre-, or post-operative NOSE scores between remaining group comparisons.

Variable	Composite SDG Mean (SD)	p- value	Pre-op NOSE Mean (SD)	p- value	Post-op NOSE Mean (SD)	p- value
Male	5.87 (3.15)	0.029*	69.81 (24.32)	0.558	22.41 (23.91)	0.471
Female	4.20 (2.65)		72.20 (23.98)		24.20 (26.72)	
Primary	6.22 (3.10)	<0.001*	67.59 (21.86)	0.031*	21.38 (24.53)	0.209
Revision	3.34 (1.85)		75.22 (26.22)		25.65 (26.08)	
Hx of allergic rhinitis	6.27 (2.76)	0.081	76.36 (23.46)	0.800	35.45 (30.29)	0.413
No Hx of allergic rhinitis	4.64 (2.98)		69.51 (24.16)		20.00 (22.80)	
Hx of chronic sinusitis	4.71 (2.99)	0.762	87.86 (23.07)	0.046*	26.43 (16.00)	0.146
No Hx of chronic sinusitis	5.04 (3.02)		68.33 (23.23)		22.78 (26.30)	
Hx of chronic rhinitis	3.88 (2.19)	0.232	62.00 (15.65)	0.376	14.00 (18.17)	0.411
No Hx of chronic rhinitis	5.18 (3.09)		71.91 (24.60)		24.26 (25.64)	
Hx of nasal trauma	5.81(2.81)	0.012*	70.86 (25.00)	0.745	27.24 (27.40)	0.373
No Hx of nasal trauma	3.89(2.92)		71.09 (23.11)		18.26 (19.58)	
Hx of nasal/septal surgery	3.39 (2.14)	<0.001*	74.76 (26.81)	0.165	26.67 (27.22)	0.377
No Hx of nasal/septal surgery	6.03 (3.03)		68.39 (21.89)		20.97 (23.68)	

Table 7. Results of Mann-Whitney U test to compare within groups of variables for SDG, pre- and post-operative NOSE scores.

CHAPTER 5: DISCUSSION

Advancement of Septal Deformity Assessment & Evaluation of Nasal Obstruction

Current septal deformity classification systems are limited in their ability to provide discriminatory information regarding both the anatomic location of the deformity and the degree of deformity. The ability to correctly localize and grade the severity of septal deformities has the potential to greatly augment decision-making in formulating the optimal treatment strategy for nasal obstruction, to justify proposed treatments to payers, and to streamline communication of findings between providers.

Nasal obstruction is primarily a symptom and not a diagnosis, and its evaluation has both objective and subjective measures. The ideal gold standard objective measure would be quantifiable, reproducible, and have a strong correlation with subjective measures of nasal airflow. However, such an exam has not been developed to date. The finding of nasal obstruction is complicated by the lack of objective measures (physical exam, imaging findings, rhinometry, and nasal airflow) that are well correlated to subjective measures of symptom severity.^{2,3,6,31} This problem is further compounded by the current lack of a gold standard in testing for nasal obstruction, whether the cause is static or dynamic. Precise anatomic assessment of the problematic area is critical to guiding the surgeon in treatment planning, both in selection of the optimal procedure for correction, and to predict which patients may benefit most from rhinoplasty or septoplasty.

There has been a trend in medicine toward evaluating quality of life (QOL) in the assessment of disease processes and efficacy of treatment.⁴⁴ The NOSE questionnaire, a patient reported outcome measure (PROM) has become the most relevant structurally based disease-specific quality of life instrument developed for the assessment of nasal

obstruction, and has a body of evidence to support its validity, reliability, and sensitivity.^{10,13,23,22,24} The American Academy of Otolaryngology-Head and Neck Surgery's consensus statement in 2010 concluded that patient oriented outcomes are more important than objective outcomes, recognizing the ambiguities and disparities that exist in the objective evaluation of nasal obstruction.^{45,11} It has also been proposed that the different objective assessments may be capturing different aspects of the nasal airway, and may provide complementary information.⁶ Therefore, the ideal approach for the evaluation of nasal obstruction may be a combination of testing methods with both subjective and objective components.

Summary of Study Findings

The primary goal of this study was to develop and validate our septal deformity grading system, which seeks to address the current need for an integrated system to address location and severity of septal deformities simultaneously. Our septal deformity grading system has demonstrated adequate content validity and internal consistency reliability, and the NOSE questionnaires demonstrated adequate internal consistency reliability within this population as well. Pre- and post-operative NOSE scores were shown to be statistically significantly different following rhinoplasty (Wilcoxon Z-score -6.88, $p < 0.001$). In order to demonstrate adequate convergent construct validity, and to meet the criteria for an objective gold standard, there must be a statistically significant correlation between our SDG system and pre- or post-operative NOSE scores. Our results from linear regression models comparing our SDG scores with pre- and post-operative NOSE scores did not reach statistical significance, and therefore we were not able

to demonstrate adequate convergent construct validity. A composite SDG score was created by weighting each variable by its factor loading from the PCA analysis. SDG scores were then divided into high and low groups, and subgroup analyses determined a statistically significant difference in primary vs revision operations ($p < 0.001$), history vs no history of nasal trauma and nasal/septal surgery ($p = 0.025$ and 0.003 respectively), between composite SDG score groups. There were no statistically significant differences in the distributions of any of the remaining variables between high and low composite SDG score groups. From a series of univariate logistic regression model, the odds of having a revision operation were 72.4% higher for high composite SDG scores than low composite SDG scores ($p = 0.018$). The odds of having a history of nasal trauma were 8 times higher for high SDG scores than low SDG scores ($p = 0.014$), and the odds of having a history of nasal/septal surgery were 94.4% higher for low SDG scores than high SDG scores. However statistical significance was lost after adjusting for confounding variables. Comparisons between SDG, pre-, and post-operative NOSE scores demonstrated that there were statistically significant differences in mean SDG scores between primary and revision operations, as well as between patients with and without a history of nasal or septal surgery. There were also statistically significant differences in mean pre-operative NOSE scores between primary and revision operations, as well as in patients with and without a history of chronic sinusitis.

Although we were not able to demonstrate adequate convergent construct validity, we have demonstrated sufficient internal consistency reliability and content validity. Convergent construct validity is dependent on the demonstration of statistically significant correlations between our objective SDG scores and the subjective pre- and post-operative

NOSE scores. This finding is similar to the evidence from previous studies examining the relationship between objective and subjective measures of nasal obstruction, and therefore should come as no surprise.^{3,4,6,31,46,47} Nonetheless, this may also indicate that our SDG system and the NOSE questionnaire evaluate non-overlapping aspects of nasal obstruction, and therefore may provide a more complete evaluation of nasal obstruction when used together.

The differences in mean composite SDG scores between primary and revision operations as well as between patients with or without a history of nasal trauma, and nasal or septal surgery may be potentially explained by the fact that these variables each reflect significant anatomical changes. The remaining variables included in the analysis, such as history of allergic rhinitis, chronic rhinitis, etc. may or may not have a significant anatomical component, and thus would not likely be assessed by our SDG system. The statistically significant differences in composite SDG scores between patients with and without a history of nasal trauma, and with and without a history of nasal or septal surgery suggests that our SDG composite scores are sensitive to anatomical changes. For nasal traumas, the actual incidence may even be higher than reflected in this study, due to under reporting. Nasal traumas often develop at birth, from direct nasal trauma, or due to abnormal intrauterine posture and difficulties during delivery, and thus may go unnoted throughout life.⁴⁸ Grymer and Melsen suggested that anterior lesions may be due to an external cause whereas posterior lesions may be due to genetic factors, such as the growth of a nasomaxillary complex.⁴⁹ Nonetheless, our SDG composite score is still able to distinguish between patients with and without a history of nasal trauma. The anatomic discrimination by the SDG system, in conjunction with the subjective information provided

by the NOSE survey lends additional support for the concurrent use of objective and subjective evaluations for nasal obstruction.

Limitations of this study

Although the gold standard of evidence in medicine is the randomized controlled trial, this was not possible in this study due to the ethical and practical problems of randomizing patients to different surgical or non-surgical procedures in a blinded fashion. Our outcomes relied on retrospective data, and the current validation has provided guidance to improve our methods. Additionally, although the data used for this study was largely retrospective in nature, our patient recruitment to the study is ongoing, and as our sample size increases, we expect the quality of the data to increase proportionally.

There were however, a number of limitations to our methodology in this study. First, there are numerous contributing factors to nasal obstruction, and the differential diagnosis is quite broad. One such example is the variation in each patient's nasal cycle--the natural, alternating swelling of the inferior turbinate. This is one of many factors that are difficult to control for, and one that has potential confounding effects on the subjective assessment of nasal patency.⁵⁰ Secondly, although precise anatomic localization of septal deformities is critical for treatment planning and the success of surgical interventions, it does not account for dynamic sources of nasal obstruction. Nasal obstruction due to internal or external nasal valve collapse is a dynamic process, whereas anatomic grading and classification is almost by definition a static, snapshot in time assessment. Another limitation was the lack of post-operative septal deformity grading, which would have at least provided objective data to quantify our surgical outcomes, although the main reason

for the removal of this step from our methodology is that we expected that all identified deformities would be completely corrected through the surgical intervention. Finally, this study was limited in the lack of inter-rater or intra-rater reliability in the assessment of septal deformity grading scores, as the assessment of intra-rater reliability would require the 95 patients of the study population to be examined by 4 clinicians on 4 separate times within a short time interval. Inter-rater reliability will certainly be among the additions to the methodology for our ongoing assessments.

Advancement of Science

The development of a systematic, anatomic grading system for the evaluation of septal deformities is a valuable contribution towards improving the diagnosis and surgical management of nasal obstruction. Currently, there are only a few classification systems developed for this purpose in the literature, including the Mladina classification system (**Figure 2**), and modifications by Guyuron³⁷, Bauman³⁶ and others⁹. Although each of these septal deformity classification systems defines anatomic variations in the shape of the nasal septum, they are each limited in the ability to precisely localize areas of deformity, and provided scant information on the degree of deviation at each anatomic location. Our septal deformity grading system seeks to address the challenge of providing a reliable and consistent method for surgeons to characterize septal deviations for preoperative or postoperative evaluation.

Future Directions

This study is ongoing and continually improving. With time and patient accrual, we will overcome any issues due to small sample size. Our findings will require additional evaluation and validation with a larger cohort. Methodologically, there are many additions we will make. We will include the results of our evaluations of dynamic nasal obstruction as a measure to capture additional information that is currently lacking in our grading system. We will also assess inter-rater reliability by asking additional available physicians who are trained in the evaluation of nasal septum deformities, and also obtain post-operative SDG scores from each patient to provide data to quantify our surgical interventions. Obtaining post-operative SDG scores, in conjunction with the NOSE questionnaire results may also allow for the determination of a minimally clinically significant change in septal deformity grading score.

Conclusions

We have developed a septal deformity grading system that improves upon currently available septal deformity classification systems by addressing the challenge of providing a reliable and consistent method for surgeons to characterize septal deviations for preoperative or postoperative evaluation. Our septal deformity grading scores provide anatomic information on the severity of nasal septal deformities, and may be valuable when used in conjunction with subjective data gathered from the NOSE questionnaire.

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