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## Concurrent Septoplasty during Endoscopic Sinus Surgery for Chronic Rhinosinusitis: Does it Confound Outcomes Assessment?

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### Abstract

**Objective**—To determine if chronic rhinosinusitis (CRS)-specific health-related quality-of-life (HRQoL) outcomes are affected by concurrent septoplasty performed during endoscopic sinus surgery (ESS) for medically refractory CRS.

**Study Design**—Prospective, multi-center cohort study.

**Methods**—A total of 221 patients with medically refractory CRS without nasal polyposis who elected primary ESS were included in this study. Patients were dichotomized into two cohorts: concurrent septoplasty (n=108) or no septoplasty (n=113) during ESS. Main outcomes of interest included two CRS-specific HRQoL instruments: the Rhinosinusitis Disability Index (RSDI) and the Chronic Sinusitis Survey (CSS). Symptom presentation was assessed using eight sinonasal visual analog scale (VAS) symptom scores.

**Results**—There were no differences in CRS-specific HRQoL improvements on all RSDI and CSS measures following ESS between cohorts with or without septoplasty (all  $p > 0.05$ ). In patients with medically refractory CRS, the presence of septal deviation did not result in a different CRS-specific symptom presentation compared to patients without septal deviation (all baseline VAS symptom score comparisons  $p > 0.295$ ).

**Conclusions**—To optimize nasal patency and improve surgical access, septoplasty is commonly performed during ESS. Based on the results of this study, concurrent septoplasty does not appear to affect CRS-specific HRQoL or symptom outcomes and does not function as a confounding factor in HRQoL improvement.

**Level of evidence**—2c

### Keywords

Septoplasty; quality of life; endoscopic; surgery; chronic rhinosinusitis; sinusitis

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The Institutional Review Board at Oregon Health & Science University provided approval and oversight for all investigational protocols and annual review.

**Conflict of Interest:** None

## INTRODUCTION

Septal deviation is a common clinical finding and is often present in patients reporting nasal obstruction. Septal deviation has also been implicated as a contributing factor in the development of rhinosinusitis<sup>1</sup>, contact point headaches<sup>2</sup>, and may impair visualization during endoscopic sinus surgery (ESS). As a result, surgical correction through septoplasty remains one of the most common rhinologic surgical procedures with an estimated 340,000 procedures performed in the US every year.<sup>3</sup>

In 2004, a prospective, multi-institutional study by Stewart et al. evaluated the role of septoplasty in patients with a septal deviation presenting with nasal obstruction using a validated instrument called the Nasal Obstruction Symptom Evaluation (NOSE) questionnaire. The results demonstrated that septoplasty significantly improved nasal obstruction-related quality of life (QoL).<sup>4</sup> This study excluded patients with CRS to prevent confounding in the assessment of septoplasty-specific outcomes. However, some patients present with both septal deviation and CRS and since patients with CRS commonly describe symptoms of nasal congestion and obstruction, it is challenging to differentiate the degree of nasal obstruction, which is related to the septal deviation relative to the chronic mucosal inflammatory disease. In a large prospective, multi-center study by Smith et al, 27% of ESS cases included concurrent septoplasty.<sup>5</sup> The impact of concurrent septoplasty during ESS on CRS-related QoL outcomes has not been specifically evaluated and may be a potential confounding variable in CRS clinical outcomes research.

Rudmik, et al. recently reported that patients with low-stage computed tomography (CT) CRS, presenting with a Lund-MacKay score = 3, experienced similar health-related QoL (HRQoL) improvements compared to patients with high-stage CT CRS (Lund-MacKay score = 4) following ESS.<sup>6</sup> In response to this article, an important question was raised in a letter to the editor, as to whether the HRQoL improvements in the low-stage CT CRS group could be attributed to the concurrent septoplasty, rather than to the ESS.<sup>7</sup>

The primary objective of this study is to evaluate the impact of concurrent septoplasty on CRS-specific HRQoL outcomes following ESS for medically refractory CRS. The secondary objective was to evaluate the impact of septal deviation on the symptom presentation of medically refractory CRS. We hypothesize that concurrent septoplasty during ESS for medically refractory CRS will not affect CRS-specific HRQoL outcomes, and thus does not function as a confounding variable.

## MATERIALS and METHODS

### Patient Recruitment and Data Collection

Adult patients were recruited between July, 2001 and April, 2009 to participate in a prospective, multi-institutional cohort study at three centers. Overall results of this study have been reported elsewhere.<sup>5, 8</sup> Inclusion criteria for this study included: 1) CRS defined by Task Force criteria<sup>9</sup>, 2) ≥ 18 years of age, 3) persistent symptoms despite medical management including, but not limited to, three or more weeks of broad-spectrum or culture-directed antibiotics and at least one trial of systemic corticosteroids, and 4) ability to complete all study materials in English. Exclusion criteria included patients with: 1) sinonasal polyposis, 2) history of ESS, and 3) less than 6 (± 1) months of follow-up data. Study subjects were asked to complete postoperative follow-up at three time points after surgery (6, 12, and 18 months), while the latest postoperative data was utilized for this analysis.<sup>10</sup>

Patients were then dichotomized into two groups based on whether or not they underwent concurrent septoplasty during the ESS procedure. The indication for concomitant septoplasty was the presence of a septal deviation which resulted in impaired access to the middle meatus, and/or a symptomatic nasal obstruction. The Institutional Review Board at each enrollment site provided approval for all research protocols.

### Quality of Life and Symptom Assessments

The Rhinosinusitis Disability Index (RSDI) is a validated 30-item Likert scale instrument containing three subscales that assess the impact of sinusitis on physical, functional, and emotion domains (range: 0–120).<sup>11</sup> Higher total and subscale RSDI scores represent a worse impact of sinus disease. The duration-based Chronic Sinusitis Survey (CSS) is a validated, 6-item instrument designed to measure symptom and medication utilization within the 8-weeks preceding study enrollment (transformed range: 0–100).<sup>12</sup> Lower total and subscale CSS scores represent worse impact of sinus disease. All study patients completed these CRS-specific HRQoL instruments preoperatively, at the initial enrollment meeting. Study patients were asked to complete postoperative HRQoL evaluations during regular follow-up visitations. The clinician investigator at each performance site was blinded to all HRQoL responses for the duration of the study.

A subset of study patients were asked to quantify a degree of sinonasal symptom severity using visual analog scales (VAS) pre- and postoperatively. Completion of VAS involves choosing a point along a 10 cm line that best represents the current severity of: facial pain/pressure, nasal congestion, sinus congestion, nasal discharge, headache, fatigue, change in sense of smell, and upper teeth ache/pain, ranging from 0 cm (no symptom) to 10 cm (most severe symptom imaginable).

### Olfactory Evaluations

A subset of patients also completed the Smell Identification Test (SIT, Sensonics Inc., Haddon Heights, NJ) pre- and postoperatively as an efficient measure of olfactory function. The SIT is a validated, self-administered, forced choice test utilizing microencapsulated odorant strips (range: 0–40).<sup>13</sup> All study patients with preoperative SIT scores  $\leq 5$  were considered unreliable and eliminated from the final analysis due to possible malingering.

### Statistical Analysis

Statistical analyses were conducted using commercially available statistical software (SPSS v.19, SPSS Inc., Chicago, IL). Patient characteristics were described with summary statistics to compare patient groups with and without concurrent septoplasty (main independent variable). Differences in the prevalence of comorbid conditions between groups was assessed using a Pearson  $\chi^2$  test for discrete variables while all continuous variables were compared using two-sample t-tests. Non-parametric or exact test equivalents were substituted when appropriate. Paired t-tests and Wilcoxon signed-rank tests were used to evaluate improvement in QoL and VAS scores over time where appropriate. Postoperative changes in QoL and VAS were the main outcome of interest (postoperative score minus preoperative score).

## RESULTS

### Baseline Characteristics

A total of 221 patients with medically refractory CRS without nasal polyposis were included in this study. There were no baseline differences between the two groups (Table 1).

### Preoperative CRS Symptom Comparison

There were no differences in the mean presenting CRS VAS symptom scores between those with concurrent septal deviation and those without septal deviation (Table 2). Only one institution collected symptom data, therefore, the final VAS cohort sizes were substantially lower than the multi-institutional HRQoL cohort sizes.

### Postoperative Change in CRS Symptoms - Septoplasty vs. No Septoplasty

When comparing the postoperative change in the eight CRS VAS symptom scores, there was no difference between patients who underwent concurrent septoplasty during ESS and those that did not (Table 3).

### HRQoL Outcomes – Septoplasty vs. No Septoplasty

When evaluating the CRS-specific HRQoL scores between the concurrent septoplasty and no septoplasty groups, there were no statistically significant differences in the baseline and postoperative RSDI or CSS total and subscale scores (Table 4).

Patients in both cohorts experienced improvement in mean CRS-specific HRQoL outcomes following ESS. When comparing the mean improvement in RSDI and CSS scores between groups, there were no statistically significant differences (Table 5). This suggests that concurrent septoplasty does not alter CRS-specific HRQoL outcomes following ESS. When evaluating postoperative olfactory outcomes, there was no difference in mean improvement between cohorts (all  $p > 0.582$ ).

## DISCUSSION

Septoplasty is commonly performed during ESS and some might question whether ESS outcomes, even CRS-specific outcomes, are the result of the ESS, the septoplasty, or some combination of the two. In this study, we demonstrated that concurrent septoplasty during primary ESS does not affect CRS-specific HRQoL outcomes in patients with medically refractory CRS without polyps. Additionally, our study demonstrates that patients with CRS and septal deviation have a similar CRS-specific symptom presentation to patients with CRS without septal deviation. Although septoplasty is commonly performed during ESS to optimize nasal airflow and surgical access, the postoperative CRS-specific HRQoL improvements appear to be primarily attributed to the ESS rather than the concurrent septoplasty. Since this study utilized CRS-specific HRQoL instruments, we cannot make conclusions regarding the impact of septoplasty on nasal obstruction outcomes more specifically.

Septoplasty is a common rhinologic procedure which was traditionally performed using a head-light and nasal speculum, however, the endoscopic approach has gained popularity over the last decade as it may improve visualization and optimize surgical teaching.<sup>14,15</sup> A recent randomized, single-blinded controlled study by Paradis et al. compared the traditional and endoscopic septoplasty approaches. The results demonstrated no difference in subjective nasal obstruction outcomes, however, the endoscopic approach resulted in reduced operative time and lower intra-operative complication rates.<sup>16</sup>

For the surgical indication of septal deviation, several studies have demonstrated that septoplasty can improve objective nasal patency testing<sup>17</sup>, however, objective testing is poorly correlated with the subjective symptoms of nasal obstruction.<sup>18</sup> As a result, it is commonly accepted that the most clinically relevant outcomes following septoplasty are patient-based measures, such as symptom scores or HRQoL. In 2004, Stewart et al. performed a prospective, multi-institutional study, which evaluated patients undergoing an

isolated septoplasty for nasal obstruction and utilized the NOSE questionnaire.<sup>4</sup> The results from this study demonstrated that septoplasty can provide a significant improvement in nasal obstruction-specific HRQoL. The NOSE questionnaire is a validated, HRQoL instrument designed to specifically assess nasal obstruction's impact on QoL. Therefore, it cannot be assumed that septoplasty will have similar effects on CRS disease-specific HRQoL outcomes. Furthermore, the study by Stewart et al. evaluated the effect of an isolated septoplasty procedure, therefore, the results cannot be applied to combined surgeries such as septorhinoplasty or endoscopic sinus surgery with septoplasty.

In a recent prospective, multi-institutional study by Smith et al., concurrent septoplasty was performed in 27% of ESS procedures for medically refractory CRS.<sup>5</sup> In this study, the indication to perform concurrent septoplasty during ESS was the presence of a septal deviation that impaired surgical access to the middle meatus and/or symptomatic nasal obstruction. Since the chronic mucosal inflammation associated with CRS induces mucosal edema and a narrowed nasal cavity, it is challenging to determine the degree of nasal congestion that specifically relates to concurrent septal deviation. Failure to correct deviated septum during ESS may result in incomplete surgery, reduced postoperative endoscopic visualization, and persistent postoperative nasal obstruction. However, if correction of a deviated septum were to confer CRS-specific HRQoL improvements, then septoplasty could be considered a confounding variable and would need to be controlled for in CRS related clinical outcomes research. The results from this study demonstrated that a concurrent septoplasty during ESS does not appear to alter CRS-specific HRQoL outcomes and thus does not function as a confounding variable.

It must be emphasized that this study did not evaluate the impact of a concurrent septoplasty on *nasal obstruction*-specific QoL and conclusions regarding its impact on nasal obstruction cannot be provided. We postulate that the CRS-specific HRQoL instruments (such as the RSDI and CSS) are not sensitive to detect the improvement in nasal obstruction associated with concurrent septoplasty.

## CONCLUSION

Since concurrent septoplasty is commonly performed during ESS, it is important to determine if septoplasty results in a confounding effect on CRS-specific outcomes. The results from this study suggest that concurrent septoplasty does not affect CRS-specific HRQoL or symptom outcomes. Therefore, patients undergoing concurrent septoplasty need not be excluded from clinical trials evaluating the impact of ESS on the CRS-specific HRQoL outcomes evaluated herein.

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Table 1

Demographic comparison between patients with CRS who underwent ESS with septoplasty vs. no septoplasty vs.

Characteristics:	Septoplasty (n=108)			No septoplasty (n= 113)			p-value
	Mean(SD)	[range]	n(%)	Mean(SD)	[range]	n(%)	
Age (years)	43.9 (12.5)	[18 – 71]		45.5 (14.0)	[18 – 78]		0.385
Gender (male/female)			50(46.3)/58(53.7)			38(33.6)/75(66.4)	0.054
Follow-up duration (mo.)	18.3 (8.4)	[5 – 52]		17.1 (6.9)	[5 – 35]		0.473
Asthma			28 (25.9)			28 (24.8)	0.845
ASA sensitivity			2 (1.9)			4 (3.5)	0.684
Allergy			28 (25.9)			33 (29.2)	0.586
Current smokers			10 (9.3)			15 (13.3)	0.346
LM - CT score	9.2 (5.7)	[0 – 23]		7.9 (5.5)	[0 – 23]		0.080
Olfactory (SIT) score	31.7 (7.5)	[6 – 39]		31.1 (7.5)	[9 – 39]		0.583

CRS; chronic rhinosinusitis, ESS; endoscopic sinus surgery, SD; standard deviation, mo.; months, ASA; acetyl/salicylic acid, LM-CT; Lund-Mackay Computed Tomography, SIT; Smell Identification Test

**Table 2**

Comparison of presenting visual analog scale symptoms in patients with CRS who underwent ESS with septoplasty versus no septoplasty

Symptoms:	Septoplasty (n=23)	No Septoplasty (n=55)	p-value
	Mean (SD)	Mean (SD)	
Facial pain/pressure	5.5 (3.0)	5.8 (2.6)	0.655
Nasal congestion	6.0 (3.0)	6.8 (2.6)	0.295
Sinus congestion	6.7 (2.7)	7.2 (2.2)	0.570
Nasal discharge	6.0 (3.2)	5.5 (3.0)	0.411
Headache	6.0 (3.1)	6.6 (2.8)	0.353
Fatigue	6.1 (3.2)	6.7 (2.6)	0.443
Change in sense of smell	4.4 (3.6)	4.8 (3.5)	0.728

VAS; visual analog scales, CRS; chronic rhinosinusitis, ESS; endoscopic sinus surgery, SD; standard deviation



**Table 3**

Comparison of postoperative changes in visual analog scale symptom scores between patients who underwent ESS with and without septoplasty

Symptoms:	Septoplasty (n=15)	No Septoplasty (n=38)	p-value
	Mean (SD)	Mean (SD)	
Facial pain/pressure	-2.7 (3.8)	-2.9 (2.9)	0.937
Nasal congestion	-1.7 (2.8)	-2.3 (3.9)	0.399
Sinus congestion	-2.4 (3.7)	-3.3 (3.0)	0.532
Nasal discharge	-1.1 (2.7)	-2.4 (3.8)	0.168
Headache	-2.7 (2.4)	-3.1 (3.2)	0.873
Fatigue	-2.1 (3.9)	-3.7 (3.1)	0.246
Change in sense of smell	-1.7 (4.2)	-1.4 (3.5)	0.984

VAS; visual analog scales, ESS; endoscopic sinus surgery, SD; standard deviation

Table 4

Baseline and postoperative mean HRQoL scores between patients with CRS who underwent ESS with and without septoplasty

Outcome measure:	Septoplasty		No septoplasty		t	p-value
	Mean (SD)	[range]	Mean (SD)	[range]		
<b>Baseline:</b>	<b>(n=108)</b>		<b>(n=113)</b>			
RSDI physical	18.6 (6.9)	[4 – 37]	19.2 (8.3)	[0 – 44]	-0.641	0.521
RSDI functional	14.7 (7.1)	[0 – 34]	15.2 (7.1)	[0 – 36]	-0.609	0.543
RSDI emotional	12.2 (7.4)	[0 – 34]	12.8 (7.9)	[0 – 40]	-0.558	0.577
RSDI total	45.4 (19.0)	[8 – 105]	47.2 (20.7)	[1 – 115]	-0.678	0.498
CSS symptom	28.2 (26.4)	[0 – 100]	26.2 (25.0)	[0 – 100]	0.574	0.567
CSS medication	47.0 (28.4)	[0 – 100]	47.6 (27.8)	[0 – 100]	-0.152	0.879
CSS total	37.6 (21.7)	[0 – 100]	36.9 (21.3)	[0 – 92]	0.243	0.808
<b>Postoperative:</b>	<b>(n=76)</b>		<b>(n=77)</b>			
RSDI physical	10.6 (7.1)	[0 – 29]	10.9 (8.5)	[0 – 33]	-0.229	0.819
RSDI functional	7.6 (6.7)	[0 – 29]	7.8 (7.5)	[0 – 35]	-0.218	0.827
RSDI emotional	6.9 (7.1)	[0 – 25]	7.2 (8.0)	[0 – 38]	-0.213	0.831
RSDI total	25.1 (19.1)	[0 – 69]	25.9 (22.5)	[0 – 106]	-0.238	0.812
CSS symptom	58.1 (27.0)	[0 – 100]	60.2 (27.4)	[0 – 100]	-0.468	0.640
CSS medication	61.3 (25.4)	[0 – 100]	61.8 (26.4)	[0 – 100]	-0.120	0.905
CSS total	59.7 (21.9)	[0 – 100]	60.9 (19.2)	[12 – 96]	-0.385	0.701

HRQoL, health-related quality of life, CRS; chronic rhinosinusitis, ESS; endoscopic sinus surgery, SD; standard deviation, RSDI; Rhinosinusitis Disability Index, CSS; Chronic Sinusitis Survey

**Table 5**

Mean improvements in HRQoL scores between patients with CRS who underwent ESS with and without septoplasty

Outcomes measures:	Septoplasty		No septoplasty		t	p-value
	Mean (SD)	[range: LL, UL]	Mean (SD)	[range: LL, UL]		
	(n=76)		(n=77)			
RSDI physical	-8.3 (7.7)	[-24, 12]	-8.7 (8.9)	[-27, 19]	0.325	0.745
RSDI functional	-7.6 (7.3)	[-30, 13]	-7.8 (7.9)	[-27, 17]	0.130	0.896
RSDI emotional	-5.7 (7.4)	[-27, 13]	-6.1 (7.3)	[-22, 14]	0.320	0.750
RSDI total	-21.5 (20.2)	[-78, 33]	-22.5 (21.3)	[-72, 31]	0.292	0.771
CSS symptom	31.5 (33.2)	[-75, 100]	36.4 (33.7)	[-67, 92]	-0.904	0.367
CSS medication	20.5 (28.7)	[-41, 100]	15.8 (32.7)	[-50, 100]	0.946	0.346
CSS total	26.0 (25.1)	[-50, 96]	26.1 (26.7)	[-42, 88]	-0.023	0.982

HRQoL: health-related quality of life, CRS: chronic rhinosinusitis, ESS: endoscopic sinus surgery, SD: standard deviation, LL: lower limit of range, UL: upper limit of range, RSDI: Rhinosinusitis Disability Index, CSS: Chronic Sinusitis Survey