Office-Based Balloon Sinus Dilation

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Office-Based Balloon Sinus Dilation: 1-Year Follow-up of a Prospective, Multicenter Study

Ashley Sikand, MD, FACS[1], Stacey L. Silvers, MD[2], Raza Pasha, MD[3], Alan Shikani, MD, FACS[4], Boris I. Karanfilov, MD[5], Dan T. Harfe, MSE, MBA[6], and Michael J. Sillers, MD[7]; for the ORIOS 2 Study Investigators

Abstract

Objective: Balloon sinus dilation (BSD) instruments afford the opportunity for office-based sinus procedures in properly selected patients with chronic rhinosinusitis (CRS). This study evaluated patient-reported outcomes 1 year after office-based BSD.

Methods: Adult patients with medically refractory CRS were prospectively enrolled into a multicenter, single-arm study and treated with office-based BSD under local anesthesia. Follow-up on 203 patients was conducted at 2, 8, and 24 weeks postsurgery using validated outcome measures for quality of life (SNOT-20) and computed tomography imaging (Lund-Mackay score). After 24 weeks, patients were re-enrolled for 1-year follow-up to evaluate changes in SNOT-20 scores and revisions.

Results: All patients who re-enrolled (n = 122) completed the study, with an average follow-up of 1.4 years. Neither preoperative SNOT-20 nor Lund-Mackay CT scores were predictive of re-enrollment and return for follow-up. Compared to baseline, improvements in SNOT-20 scores remained statistically significant ($P < .001$) and clinically meaningful (mean decrease ≥ 0.8). In patients followed to 1.4 years, 9 of 122 (7.4%) had revision surgery.

Conclusion: Following office-based BSD, significant improvements in quality of life observed at 24 weeks were maintained 1 year postsurgery. These extended results provide further evidence of office-based BSD as an effective, minimally invasive procedure for appropriately selected patients with CRS.

Keywords

chronic rhinosinusitis, ethmoid disease, endoscopic sinus surgery, balloon sinus dilation, office surgery

Introduction

Patients with chronic rhinosinusitis (CRS) typically require multiple rounds of medical management to achieve adequate disease control and some require surgical treatment. Balloon sinus dilation (BSD) instruments are increasingly used by surgeons in an office setting to treat appropriately selected patients with CRS; however, limited data exist on long-term outcomes. In a recent study, we reported 24-week outcomes for 203 CRS patients recruited from 14 centers in the United States who underwent office-based BSD using transnasal instrumentation under local anesthesia.[1] Frontal, maxillary, and sphenoid sinuses were dilated as required in CRS patients who had failed medical therapy. Effectiveness was demonstrated through statistically and clinically significant improvements in quality of life (QOL) scores (SNOT-20) and statistical improvement in computed tomography (CT) scores. Patients typically returned to normal activities within 2 days of the procedure. A majority of patients consented to participate in a study extension for 1 year. Here, we describe QOL outcomes and revision procedures throughout the 1-year period.

[1]Ear, Nose & Throat Consultants of Nevada, Las Vegas, Nevada, USA
[2]Madison ENT & Facial Plastic Surgery, New York, New York, USA
[3]Pasha Snoring & Sinus Center, Houston, Texas, USA
[4]Maryland Nose and Sinus Center, Baltimore, Maryland, USA
[5]Ohio Sinus Institute, Dublin, Ohio, USA
[6]Acclarent Clinical Research, Menlo Park, California, USA
[7]Alabama Nasal and Sinus Center, Birmingham, Alabama, USA

Corresponding Author:
Ashley Sikand, MD, FACS, Ear, Nose & Throat Consultants of Nevada, 3195 St Rose Parkway, Suite 210, Henderson, NV 89052, USA.
Email: asikand1@aol.com

Methods

Patients and Study Design

The Optimization and Refinement of Technique in In-Office Sinus Dilation 2 (ORIOS 2) study (ClinicalTrials.gov identifier: NCT01107379) was an institutional review board (IRB)-approved, prospective, single-arm, multicenter study of office-based BSD in adult patients (18 years old and older) diagnosed with CRS. The study design and procedures to week 24 have been described previously[1]; this report will focus on follow-up through 1 year. In brief, all patients enrolled in the study were diagnosed with CRS as defined by the American Academy of Otolaryngology–Head Neck Surgery Clinical Practice Guideline,[2] and all patients had planned endoscopic sinus surgery (ESS) prior to being considered as candidates for the study. Prior to enrollment, all patients had previously failed medical management including 3 to 6 weeks of broad spectrum or culture-directed antibiotics and 3 to 6 weeks of intranasal steroid spray and/or oral steroids if polyps or severe inflammation were present. Antihistamines and/or decongestants were prescribed as clinically indicated. Nasal saline irrigation was routinely used throughout the treatment course. The specific regimen of preoperative and postoperative medical therapy was customized to the patient's disease by the physician. Patients having severe polyposis (grade 3) that could prohibit access of BSD tools to the target anatomy (sinus ostia and transition spaces) were excluded from the study. As described in the previous 24-week report,[1] grade 3 was "severe polyposis, large polyps reaching below the lower edge of the inferior turbinate and causing total or almost total obstruction."[3]

In-office BSD using transnasal instrumentation (Acclarent, Inc, Menlo Park, California, USA) was performed under local anesthesia on frontal, maxillary, and sphenoid sinuses requiring treatment. Following the 24-week visit, 13 of the 14 investigators were available to participate in a study extension and IRB approval was granted at the 13 investigational sites for follow-up through 52 weeks. All patients from the 13 sites (n = 197) were contacted for participation in the follow-up visit. As required by the study protocol, a minimum of 3 attempts was made to contact each eligible patient. Patients had to provide written informed consent for inclusion in the extension phase. Some patients had already passed the 52-week time point when the decision to extend the study was made, and so this final visit is notated throughout this report as a 52+ week visit to indicate that the upper bound of the visit was not restricted.

Study Endpoints and Statistical Analysis

The primary endpoint for the study extension was improvement in sinus symptoms as measured by the mean change in Sino-Nasal Outcome Test (SNOT-20)[3] score between preoperative baseline and the 52+ week postoperative visit. The SNOT-20 is a validated sinus-specific (QOL) instrument consisting of 20 questions, each of which is rated from 0 to 5 (0 = no problem, 5 = problem as bad as it can be). A decrease of ≥ 0.8 in the mean SNOT-20 score is considered clinically meaningful.[4] Individual subscores from the SNOT-20 surveys were also analyzed to determine which aspects of QOL were most affected by the BSD procedure. In addition, surgical revisions and the occurrence of any adverse events for all patients followed to 52+ weeks were quantified.

In addition to the primary analysis, a subgroup analysis of patients with ethmoid disease was performed. As reported previously, a subgroup of 31 patients enrolled in ORIOS 2 had been diagnosed with mild to moderate ethmoid disease entering the study (along with their peripheral disease [frontal, maxillary, or sphenoid]), were not treated with an ethmoidectomy, and had baseline and 24-week CTs available.[1] Twenty-four week radiographic and QOL results for this subgroup had shown a reduction in radiographic ethmoid-specific Lund-Mackay (eLMK) CT scores[5] and statistically and clinically meaningful changes in QOL ratings. To address the question of long-term outcomes for patients with mild to moderate ethmoid disease, a subanalysis of the SNOT-20 results was done in patients with and without radiographic evidence of ethmoid disease at baseline.

The sample size rationale and calculations for ORIOS 2 were reported previously.[1] Data in this report are for all patients enrolled in the 52+ week follow-up visit unless otherwise specified. Data are shown with 2-sided 95% confidence intervals. A Bonferroni-corrected significance level was used for evaluating changes in the individual SNOT-20 subscores from baseline. Logistic regression was employed to evaluate the effects of baseline characteristics on (1) the probability to return for the 52+ week follow-up visit, and (2) occurrence of revision procedures within the ethmoid subgroup. All data analyses were performed using SAS version 9.2 (SAS Institute, Cary, North Carolina, USA).

Results

Patient Characteristics and Disposition

Across the 13 clinical sites, 197 patients were invited to participate in the extended study and 122 were re-enrolled (Figure 1). The extended study population of 122 patients included 61 patients who had baseline radiographic evidence of ethmoid disease, 59 patients without ethmoid disease, and 2 patients previously diagnosed with ethmoid disease who underwent in-office ethmoidectomies at the time of their BSD procedures. One patient's ethmoidectomy procedure consisted of a limited, left anterior ethmoidectomy, and in the other patient, total (anterior and posterior) bilateral ethmoidectomies were performed. Both

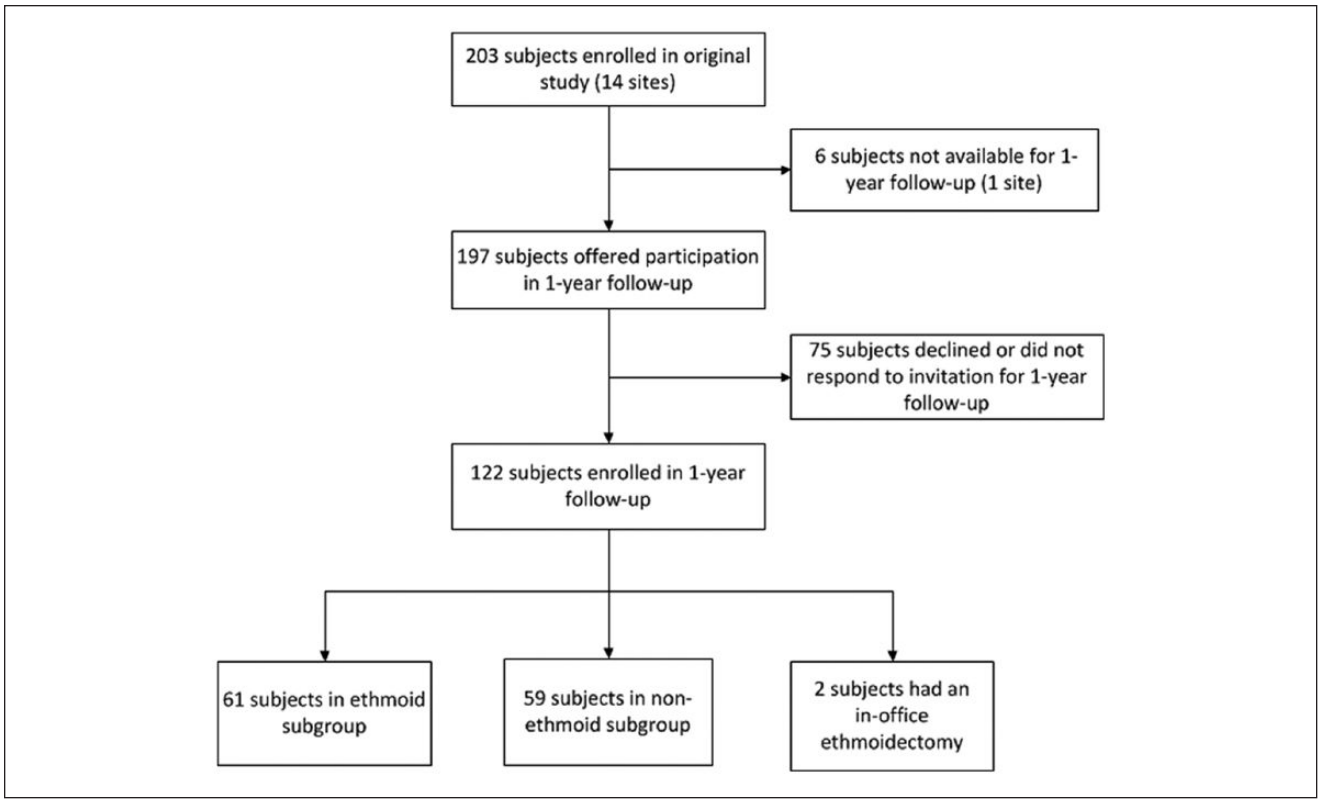

Figure 1. Study profile for patients followed to 52+ weeks.

Table 1. Baseline Demographics and Characteristics of the Population Followed to 52+ Weeks Compared to the Population Who Did Not Participate in the Extended Follow-up.

	Patients Followed to 52+ Weeks (n = 122)	Patients Exited Prior to 52+ Weeks (n = 81)	*P* Value[a]
Preoperative SNOT-20 score, mean (SD)	2.1 (0.8)	2.1 (0.9)	.35
Preoperative LMK score, mean (SD)	6.8 (6.8)	7.2 (3.5)	.28
Prior sinus surgery, %	47.5	24.7	.001
Polyps, %	10.7	4.9	.23
Age, mean (SD)	50.0 (15.8)	46.2 (14.6)	.17
Male, %	40.1	55.6	.02
No. of sinuses dilated, mean (SD)	2.7 (1.4)	2.7 (1.5)	.19

Abbreviations: LMK, Lund-Mackay; SNOT-20, 20-item Sino-Nasal Outcome Test.
[a]*P* value generated from logistic regression model.

in-office ethmoidectomies were performed using standard instruments under local anesthesia. All 122 enrolled patients completed their 52+ week follow-up. The mean time to follow-up was 497 days or 1.4 years. Of the patients followed to 52+ weeks, 58 of 122 (47.5%) had sinus surgery prior to BSD, 13 of 122 (10.7%) had polyps (mild or moderate), and 31 of 122 (25.4%) had irrigation during office-based BSD.

As shown in Table 1, baseline SNOT-20 ($P = .35$) and LMK scores ($P = .28$) were not significant effects in the logistic regression model when comparing patients who were followed to 52+ weeks and those who were not (either did not respond to the invitation or elected not to participate in the study extension). The regression model also accounted for other potential sources of follow-up bias, including prior ESS, presence of polyps, age, sex, and number of sinuses dilated. Although no differences were found in SNOT-20 or LMK scores, we did observe in the model that the 52+ week group had a statistically greater percentage of females ($P = .02$) and a statistically higher percentage of patients who

Table 2. Mean SNOT-20 Scores for all Patients Who Completed SNOT-20 at Baseline and the Specified Time Point.

	All Patients			Intrapatient Change (matched pairs[a])			
	Mean (SD)	No.	95% CI	Change From Baseline, Mean (SD)	No.	95% CI	*P* Value
Baseline	2.1 (0.9)	202	2.0, 2.2	—	—	—	—
2 week	1.1 (0.8)	191	1.0, 1.2	−1.0 (0.9)	189	−1.1, −0.9	< .001
8 week	0.9 (0.8)	178	0.8, 1.0	−1.2 (1.0)	177	−1.3, −1.0	< .001
24 week	0.9 (0.8)	114	0.8, 1.1	−1.2 (1.1)	113	−1.4, −1.0	< .001
52+ week	1.0 (0.9)	122	0.8, 1.1	−1.1 (1.0)	122	−1.3, −0.9	< .001

Abbreviation: SNOT-20, 20-item Sino-Nasal Outcome Test.
[a]Includes only patients with both baseline and specified follow-up interval data. Note that data from 1 patient in the 24-week cohort is newly added in this report, as the data were unavailable at the time of the primary manuscript submission.[1]

Table 3. Individual SNOT-20 Subscores, Ordered by Magnitude of Change.[a]

	Mean Change From Baseline, Mean (SD)	95% CI	No.	*P* Value
Facial pain/pressure	−1.8 (1.5)	−2.1, −1.5	120	< .001
Wake up tired	−1.8 (1.8)	−2.1, −1.5	117	< .001
Fatigue	−1.8 (1.6)	−2.1, −1.5	121	< .001
Lack of a good night's sleep	−1.5 (1.8)	−1.8, −1.2	119	< .001
Reduced productivity	−1.4 (1.6)	−1.7, −1.1	120	< .001
Reduced concentration	−1.4 (1.6)	−1.7, −1.1	121	< .001
Wake up at night	−1.4 (1.7)	−1.7, −1.1	119	< .001
Frustrated	−1.3 (1.7)	−1.6, −1.0	120	< .001
Postnasal discharge	−1.2 (1.6)	−1.5, −0.9	117	< .001
Ear fullness	−1.1 (1.7)	−1.4, −0.8	119	< .001
Difficulty falling asleep	−1.1 (1.6)	−1.4, −0.8	118	< .001
Thick nasal discharge	−1.0 (1.8)	−1.3, −0.7	118	< .001
Cough	−0.9 (1.4)	−1.2, −0.7	120	< .001
Need to blow nose	−0.8 (1.7)	−1.1, −0.5	122	< .001
Runny nose	−0.8 (1.6)	−1.1, −0.5	121	< .001
Dizziness	−0.8 (1.4)	−1.0, −0.5	121	< .001
Embarrassed	−0.7 (1.4)	−1.0, −0.5	121	< .001
Ear pain	−0.6 (1.5)	−0.8, −0.3	117	< .001
Sad	−0.6 (1.3)	−0.8, −0.3	121	< .001
Sneezing	−0.6 (1.3)	−0.8, −0.3	118	< .001

Abbreviation: SNOT-20, 20-item Sino-Nasal Outcome Test.
[a]*P* values are for baseline to 52+ week changes, and a *P* value of .05 / 20 = 0.0025 is considered significant.

had prior ESS ($P < .001$) when compared to the group not followed to 52+ weeks.

Quality of Life Endpoint

Table 2 shows the SNOT-20 results for all evaluable patients at each visit through 52+ weeks, as well as the mean intrapatient change for matched pairs (QOL improvement for patients with data at both baseline and the specified time point). Changes in the primary QOL endpoint were clinically and statistically significant ($P < .001$) with a mean (SD) SNOT-20 reduction from baseline to 52+ weeks of −1.1 (1.0) for the 122 patients with both baseline and 52+ week data available.

Individual SNOT-20 subscore changes for the 122 patients who had baseline and 52+ week data available are shown in Table 3. The number of responses across the subscores ranges from 117 to 122 as each patient did not respond to every question. After accounting for multiplicity by using a Bonferroni-corrected significance level of .0025 (or .05 / 20), all 20 subscores of the SNOT-20 showed a statistically significant mean change from baseline to 52+ week follow-up.

Of the 203 patients enrolled in the ORIOS 2 study, there were 102 patients who had baseline eLMK scores greater

Table 4. Baseline Demographics and Characteristics of the Ethmoid Subgroup Comparing Patients With and Without Revision Procedures.

	Ethmoid Subgroup Without Revision (n = 53)	Ethmoid Subgroup With Revision (n = 8)	*P* Value[a]
SNOT-20, mean (SD)	2.1 (1.0)	1.8 (0.7)	.49
LMK, mean (SD)	9.0 (3.7)	7.9 (2.2)	.31
eLMK, mean (SD)	2.9 (1.6)	2.0 (1.3)	.17
Prior sinus surgery, %	54.7	50.0	.48
Polyps, %	17.3	25.0	.71
Age, mean (SD)	48.5 (16.1)	59.4 (15.1)	.10
Male, %	49.0	37.5	.95
No. of sinuses dilated, mean (SD)	3.0 (1.5)	3.0 (1.9)	.63

Abbreviations: eLMK, ethmoid-specific Lund-Mackay; LMK, Lund-Mackay; SNOT-20, 20-item Sino-Nasal Outcome Test.
[a]*P* value generated from logistic regression model.

than 0, indicating radiographic presence of ethmoid disease entering the study. As shown in Figure 1, 61 of the 102 patients enrolled in the study extension and completed the 52+ week follow-up. It was anticipated that further analysis of outcomes in this ethmoid subgroup of 61 patients may provide insight into the long-term clinical efficacy of office-based BSD for patients who present with mild to moderate ethmoid disease.

The baseline eLMK for the 61 patients with ethmoid disease was 2.8 out of a total possible score of 8 (sum of left and right, anterior and posterior scores). The baseline SNOT-20 score for the ethmoid subgroup was 2.1, compared to a baseline SNOT-20 of 2.0 for the 59 patients with 52+ week follow-up who did not enter the study with ethmoid disease ($P = .77$). At the 52+ week time point, SNOT-20 scores for the ethmoid group declined by 1.0, compared to a SNOT-20 decline of 1.2 for patients without ethmoid disease ($P = .36$).

As described in the primary manuscript, there were 4 patients with clear ethmoid sinuses at baseline who showed an increase in eLMK at 24 weeks.[1] Two of the 4 patients did not enroll in the study extension. One of the 2 patients who did enroll in the study extension had shown a SNOT-20 reduction at 24 weeks (despite their increase in LMK) of −2.7. At 52+ weeks, the patient maintained an overall score reduction from baseline of −2.6. The other patient had also shown a SNOT-20 reduction at 24 weeks of −1.8. At 52+ weeks, the patient maintained an overall score reduction of −1.95.

Revision Procedures

Of the 122 patients followed to 52+ weeks, 9 patients (7.4%) underwent revision procedures due to recurrence of symptoms, with 2 of the 9 patients treated using BSD in the office setting and 7 patients treated using ESS in the operating room (OR). Revision procedures were conducted for frontal (n = 5), maxillary (n = 5), and sphenoid (n = 3) sinuses. There were no device-related or procedure-related adverse events reported between 24 and 52+ weeks.

In the ethmoid subgroup followed to 52+ weeks, revision procedures were performed on 8 of 61 (13%) patients, with an average follow-up of 1.4 years, compared to 1 of 59 (2%) patients in the non-ethmoid group ($P = .03$), with an average follow-up of 1.3 years. To identify any preoperative characteristics that might be predictive of the need for revision, a comparison of baseline characteristics for patients with ethmoid disease who required revision (n = 8) versus those who did not require a revision procedure (n = 53) was performed via logistic regression (Table 4). There were no baseline characteristics predictive of revision procedures in the ethmoid cohort. Of the 8 patients in the ethmoid subgroup who required a revision procedure, 5 showed residual radiographic ethmoid disease at 24 weeks, 2 showed no residual radiographic ethmoid disease, and CTs were unavailable for the 1 remaining patient. An ethmoidectomy was performed during the revision procedure in 4 of the 8 patients; the other 4 revisions were for peripheral sinus disease only.

Discussion

In this extension of a multicenter prospective study, we found that office-based BSD of maxillary, frontal, and sphenoid sinuses remains effective at improving QOL for CRS patients through a minimum of 52 weeks. Quality of life improvement seen as early as 2 weeks after BSD was maintained through an average of 1.4 years. The improvement at 52+ weeks is consistent with 52-week results previously reported for office-based BSD studies,[6,7] as well as OR-based BSD[8] and OR-based traditional ESS at 12 months.[9,10]

Compared to baseline, mean subscores for the SNOT-20 instrument improved significantly at 52+ weeks, with the

largest improvement seen in "facial pain/pressure," "wake up tired," "fatigue," and "lack of a good night's sleep" (Table 3). The substantial improvement in fatigue-related aspects of QOL is consistent with prior studies of the effects of ESS on fatigue-related symptoms and emphasizes the important QOL benefits that patients can achieve with sinus surgery.[11,12]

During the introduction of office-based BSD, it was not known whether surgeons could accomplish the full extent of surgery required to achieve meaningful improvement in QOL. A critical goal of this extended study was to evaluate outcomes to at least 1 year to understand whether patient QOL improvement is compromised by the inherent challenges of office-based surgery (awake patients and limited opportunity for adjunct procedures). Consistent with prior studies of office-based BSD,[1,6,7] OR-based BSD,[8,13] and ESS,[14] the QOL improvement seen at 24 weeks was stable out to 1 year. In addition, QOL improvement has been shown to be stable beyond 1 year as observed at 20 or more months for ESS[13] and OR-based BSD.[15]

In the extended study population, the number of patients who underwent revision surgery (7.4%), with an average follow-up of 1.4 years, is comparable to that seen in OR-based BSD and OR-based ESS.[8,16-18] This is particularly encouraging, as most surgeons were performing their first office-based cases within this study. Revision procedures on 2 patients were performed in an office setting, suggesting that for some recalcitrant patients, repeated office-based procedures may obviate the need for an OR-based procedure.

At the start of the ORIOS 2 study, 102 patients were enrolled with mild to moderate ethmoid disease, as the presence of disease in the ethmoid cavity was not an exclusion criterion. At 24 weeks, an analysis of eLMK scores on a subgroup of 31 patients showed complete radiographic resolution of ethmoid disease (see examples in Figures 2 and 3) in a high percentage of patients (64.5%) with 87.1% (27/31) showing some improvement.[1] However, some patients had residual ethmoid disease, and it was unclear whether the residual disease would lead to recurrence of symptomatic disease and require revision procedures.

The 52+ week ethmoid subgroup of 61 patients was substantially larger than the 24-week cohort (n = 31), as inclusion in the 52-week analysis was not limited by CT availability. For this ethmoid subgroup, there were 8 revision procedures at a mean follow-up of 1.4 years. As anticipated, this was considerably higher than the 1 revision procedure for the group of patients who entered the study without ethmoid disease. Despite the higher number of revisions, it was an encouraging and positive finding that 87% (27/31) of the ethmoid group was able to be successfully treated with a single office-based procedure (without ethmoidectomy), obviating the need for an OR-based procedure under general anesthesia. As noted in the results, only

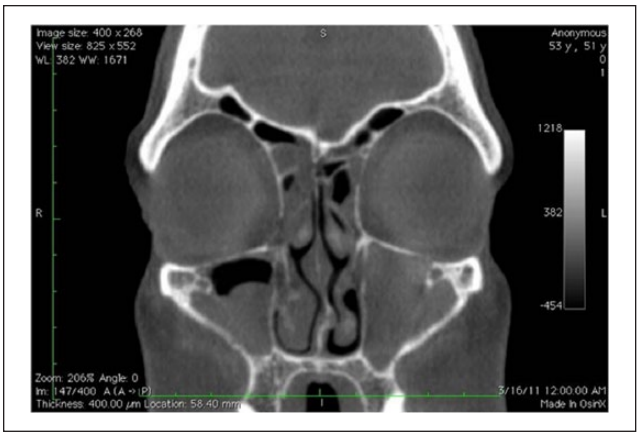

Figure 2. Study patient baseline computed tomography image (coronal section plane) showing maxillary and ethmoid evidence of mucosal disease.

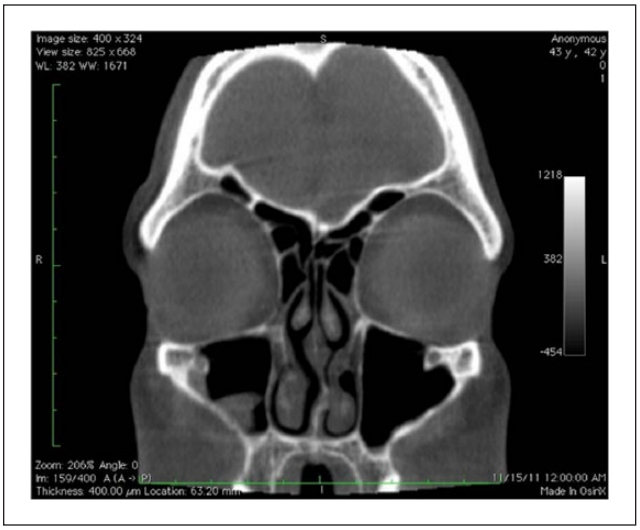

Figure 3. Study patient from Figure 2, 24-week postprocedure computed tomography (CT) image (coronal section plane) showing resolution of ethmoid mucosal disease. Multiple CT images demonstrated mild mucosal thickening and an asymptomatic right maxillary sinus cyst that required no further sinus intervention at 1-year follow-up.

4 of the 8 ethmoid subgroup revisions included an ethmoidectomy, and 2 of the 8 patients had clear ethmoids at the 24-week CT scan, making it difficult to implicate the ethmoid cavity as the primary cause of the revisions in these patients. The heterogeneous nature of CRS confounds definitive conclusions and the ability to attribute residual disease in the ethmoid sinuses as a cause for the revision procedures. An analysis of the ethmoid subgroup to identify baseline characteristics that might predispose a patient to recurrence of disease and requirement for a revision procedure did not yield any definitive conclusions (Table 4).

Further study is warranted to better optimize the selection criteria for office-based BSD for patients with ethmoid disease and to understand the potential benefits related to avoidance of a more extensive procedure in the higher acuity OR setting.

A limitation of the present study extension is that not all ORIOS 2 patients chose to re-enroll for the 52+ week follow-up. This was anticipated given that follow-up visits after 8 weeks were optional for a substantial proportion of the patients. Of the 203 patients who were enrolled in the original study, 89.7% (182/203) completed the protocol-required follow-up to which they consented. The 122 patients who were followed to the 52+ week visit had statistically similar baseline characteristics in terms of radiographic and SNOT-20 scores when compared to the 81 patients who were not followed. Further analysis also showed no significant difference in mean SNOT-20 scores at 24 weeks between patient groups ($P = .15$). However, the followed patients did have a significantly higher rate of previous operations and a higher proportion of female patients. Given that revision patients tend to have more recalcitrant disease that can repeatedly recur, it is believed that including a higher proportion of previously revised patients in the followed population could bias the results conservatively (ie, result in more reported revision procedures and lower QOL change benefits).

A limitation of the overall study is that the preoperative and postoperative medical therapy was not standardized across the sites. Instead, the model reported by the American Rhinologic Society Study Group[19] was applied, in which investigators customized their medical therapy to the particular patient's disease. Similar to all prior studies of ESS that we are aware of, our study design does not allow us to eliminate postoperative medical therapy optimization or spontaneous resolution as contributors to the improvement in patient QOL or other outcome measures including ethmoid improvement, although the medically refractory nature of the patient population lessens this potential confounding factor.

Conclusion

This extended, multicenter study of office-based, transnasal BSD of maxillary, frontal, and sphenoid sinuses demonstrated sustained, significant improvement in QOL at an average of 1.4 years of follow-up. Patients with mild to moderate ethmoid disease can be effectively treated in an office setting with peripheral dilation. Transnasal office-based BSD is a viable option for properly selected CRS patients who have failed medical management and are candidates for ESS.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Dr Boris Karanfilov, Dr Stacey Silvers, and Dr Ashley Sikand are consultants for Acclarent, Inc. Dr Raza Pasha is a consultant for Acclarent, Inc and Medtroni, Inc. Dr Alan Shikani has no conflicts of interest. Dan Harfe is an employee of Acclarent, Inc. Dr Michael Sillers is a consultant and former scientific advisory board member for Acclarent, Inc.

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ORIOS 2 Study Investigators

Neil Brown, MD, Mayo Clinic Health System–Franciscan Healthcare, La Crosse, WI
Brian Heaberlin, MD, HIMG Regional Medical Center, Huntington, WV
Edward Hepworth, MD, Associates of Otolaryngology, Denver, CO
Jacob Johnson, MD, San Francisco Otolaryngology, San Francisco, CA
Boris I. Karanfilov, MD, Ohio Sinus Institute, Dublin, OH
Rom Karin, MD, ENT Clinic of Los Gatos, Los Gatos, CA
Steven Levine, MD, ENT and Allergy Associates, Trumbull, CT
Raza Pasha, MD, Pasha Snoring & Sinus Center, Houston, TX
Alan Shikani, MD, FACS, Maryland Nose and Sinus Center, Baltimore, MD
Ashley Sikand, MD, FACS, Ear, Nose & Throat Consultants of Nevada, Las Vegas, NV
Michael J. Sillers, MD, Alabama Nasal and Sinus Center, Birmingham, AL
Stacey L. Silvers, MD, Madison ENT & Facial Plastic Surgery, New York, NY
Richard Strabbing, DO, Spectrum Health Medical Group, Holland, MI

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