Transantral, endoscopically guided balloon dilatation of the ostiomeatal complex for chronic rhinosinusitis under local anesthesia

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ABSTRACT

Background: *A multicenter study (BREATHE I - Entellus Medical, Inc.) was performed to assess the safety and outcomes of a new, less invasive system that uses direct endoscopic visualization to facilitate balloon dilation of the maxillary sinus ostia and ethmoid infundibulum. General anesthesia was avoided in most subjects to assess feasibility of performing transantral ostial dilatation in an office setting.*

Methods: *Subjects with chronic rhinosinusitis of the maxillary sinuses alone or maxillary and anterior ethmoid sinuses underwent baseline evaluation including CT imaging and symptom assessment using the Sino-Nasal Outcome Test (SNOT 20). Subjects underwent transantral balloon dilation and follow-up evaluation at 1 week, 3 months, and 6 months post-procedure.*

Results: *Thirty subjects were treated at three centers. Fifty-five of 58 maxillary ostia were successfully treated for a procedural completion rate of 94.8%. Ninety-seven percent of the procedures were completed under local anesthesia with or without minimal intravenous sedation. There were no device-related serious adverse events or unanticipated adverse device effects. The mean overall SNOT 20 score at baseline was 2.9 ± 1.0. Mean overall SNOT 20 scores at 1-week, 3-month, and 6-month follow-up were 0.8 ± 0.8, 0.7 ± 0.8, and 0.8 ± 0.9 respectively. Patency at 3-months as confirmed by CT imaging was 95.8%.*

Conclusion: *These results indicate that transantral balloon dilation of the ostiomeatal complex under local anesthesia appears to be a safe technique for managing isolated maxillary or maxillary and anterior ethmoid sinusitis and can potentially be performed safely in an office setting.*

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Key words: Anterior ethmoid sinuses, balloon dilation, chronic rhinosinusitis, endoscopic visualization, less invasive, local anesthesia, maxillary sinuses, ostiomeatal complex, transantral

Functional endoscopic sinus surgery (FESS) evolved from sinus procedures aimed at removing diseased tissue from the affected sinuses and reestablishing drainage. It remains the treatment of choice in most cases of medically refractory chronic rhinosinusitis (CRS). The pathophysiology of sinusitis led to this less invasive approach to improve drainage through the natural ostia.[1] FESS involves removing tissue from the natural sinus outflow pathways often under general anesthesia and has greatly improved the efficacy and recovery from sinus surgery since introduced in the United States around 1985.[2] Recent feasibility studies have shown that balloon catheters can be successfully guided into the sphenoid, frontal, and maxillary sinuses and may offer an alternative FESS tool for the treatment of sinus disease.[3,4]

Subsequent to the emergence of balloon catheter technology in 2005, clinical data have been published to further support the concept that transnasal dilation to open and remodel sinus ostia while preserving mucosa and minimizing trauma to adjacent intranasal structures is an effective technique for the treatment of obstructed sinus ostia and may also be helpful in protecting nasal physiology that is often scarred by FESS.[5] However, intranasal anatomic variants, angle of the infundibulum, the need for middle turbinate medialization, and nasal inflammation often present technical challenges to transnasal balloon dilation in the conscious patient. Therefore, a majority of FESS procedures with balloon dilation have been performed under general anesthesia.

If surgeons can take full advantage of a less invasive technology to dilate sinus ostia safely and effectively under local anesthesia, there may be a subset of CRS patients who do not need general anesthesia for their procedure. This population may include patients with maxillary and anterior ethmoid disease because both sinuses drain into or near the ethmoid infundibulum. Because the ethmoid infundibulum is often as small as 1 mm in diameter in normal subjects, for those patients with an obstructed or narrow infundibulum, small diameter changes may result in long-term improvements without the removal of tissue and creation of a large antrostomy.[6] Another recent study has shown that a small maxillary antrostomy with less tissue removal might be as effective as a large one.[7] These concepts suggest balloon catheter dilation of this pathway without tissue removal may sufficiently improve drainage. If dilation can be performed under local anesthesia, it may be a viable office-based treatment option for patients with more anterior disease.

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Potential Conflicts of Interest: James Stankiewicz, M.D. and Thomas Tami, M.D. are Paid Consultants for Entellus Medical, Inc. (Co-National PI, Scientific Advisory Board); Theodore Truitt, M.D., and James Atkins, M.D., are Paid Consultants and stock shareholders for Entellus Medical, Inc. (Scientific Advisory Board); Douglas Liepert, M.D., and Bradford Winegar, M.D., have no conflicts of interest

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A catheter-based system has been developed in an effort to treat CRS under local anesthesia by preserving tissue while altering the drainage pathway.[8] This system uses a transantral approach to visualize, access, and dilate the maxillary sinus ostia and ethmoid infundibulum. Under this approach, potential intranasal obstacles are avoided, possible scarring due to intranasal instrumentation is eliminated, and blood loss is reduced. This study evaluates the clinical feasibility and safety of transantral, endoscopically guided balloon catheter dilation of the infundibulum and maxillary sinus ostium in the conscious patient and presents early outcomes data through 6 months of follow-up.

METHODS

The prospective, multicenter Balloon Remodeling Antrostomy Therapy (BREATHE I) study was designed to evaluate the feasibility and safety of a system (FinESS; Entellus Medical, Inc., Maple Grove, MN) to treat patients with CRS of the maxillary or maxillary and anterior ethmoid sinuses. The multicenter study was initiated after review and approval by a central Institutional Review Board, and it was conducted according to good clinical practices and applicable FDA requirements.

To be included in the study, subjects had to be at least 18 years of age with a diagnosis of CRS of the maxillary or maxillary and anterior ethmoid sinuses. In addition, radiographic evaluation by computed tomography (CT) imaging after medical therapy was required to show either evidence of an air/fluid level within the maxillary antrum or narrowing of the outflow tract of either the maxillary sinus ostium or the infundibulum with ≥2 mm of mucosal thickening in the maxillary sinus antrum. Subjects were excluded from the study if there was evidence of chronic posterior ethmoid, sphenoid or frontal sinusitis, or presence of any features consistent with fungal sinusitis. All subjects were required to provide voluntary consent before undergoing nonstandard of care screening evaluations and study treatment.

Before enrollment, all subjects received medical therapy followed by the acquisition of a baseline CT scan to assess eligibility. Preenrollment medical therapy consisted of a minimum of 3 weeks of consecutive antibiotics in 14 subjects (47%) and 14 subjects (47%) received consecutive antibiotic therapy from 1 to 3 weeks. The remaining 2 subjects received antibiotic therapy as verified from each subject's primary care physician, but the precise duration of the antibiotic therapy could not be confirmed. Twenty-five (80%) subjects also received either a topical or a systemic steroid. The average time between the start of preenrollment antibiotic therapy and the study procedure was ~9 weeks.

Before study treatment, each subject underwent a physical exam with nasal endoscopy and completed a series of validated questionnaires including the Sino-Nasal Outcome Test (SNOT 20),[9] the Wong-Baker FACES Pain Rating Scale,[10] and several other quality-of-life instruments. All procedures in the current cohort were performed in an ambulatory surgery center under local or general anesthesia. Local anesthesia was preferred, but the final anesthesia plan—including oral, i.v., or no sedation—was at the discretion of the investigator.

The FinESS system was used for access and treatment of the involved sinuses (Fig. 1). To guide the location for access into the maxillary antrum, external landmarks were used as described by Robinson *et al.*[11] to minimize the likelihood of sensory nerve damage. A flexible 0.5-mm endoscope (Karl Storz Endoscopy America, Culver City, CA) and proprietary dual-lumen cannula were used to locate the ostia before balloon insertion (Fig. 2). Under direct, endoscopic visualization, a 5- or 7-mm balloon dilation catheter was advanced into the maxillary sinus ostium and ethmoid infundibulum, inflated to 12 standard atmospheres of pressure, deflated, and removed. Irrigation or suction was permitted during the procedure, but no other concomitant sinonasal procedures were performed. No closure or treatment was required at the sublabial access site. Actual endoscopic images of the natural ostium before treatment, during balloon insertion, and after dilation are shown in Fig. 3, *A*, *B*, and *C*, respectively.

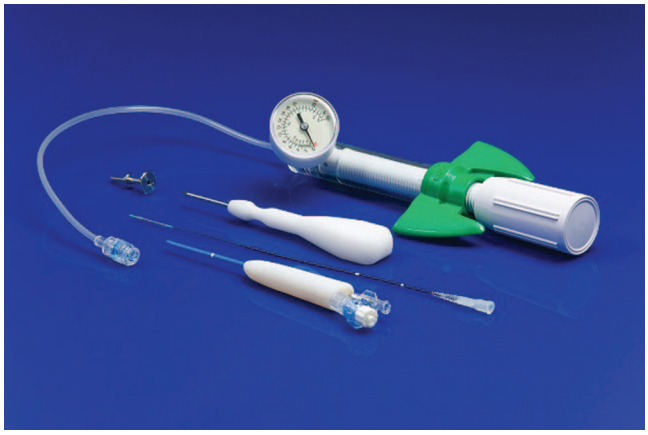

Figure 1. *FinESS system (Entellus Medical, Inc., Maple Grove, MN).*

Figure 2. *Dual-Lumen cannula with 0.5-mm flexible endoscope.*

Postprocedure medical management from discharge through 1 week of follow-up, including antibiotic and steroid therapy, was at the discretion of the investigator. Subjects returned for in-office follow-up at 1 week and 3 months and underwent a physical examination and nasal endoscopy. A postoperative CT at 3 months was also required to evaluate the patency of the ostium and ethmoid infundibulum. Subjects completed the quality-of-life questionnaires at 1 week and 3, 6, and 12 months. Unscheduled follow-up visits and all

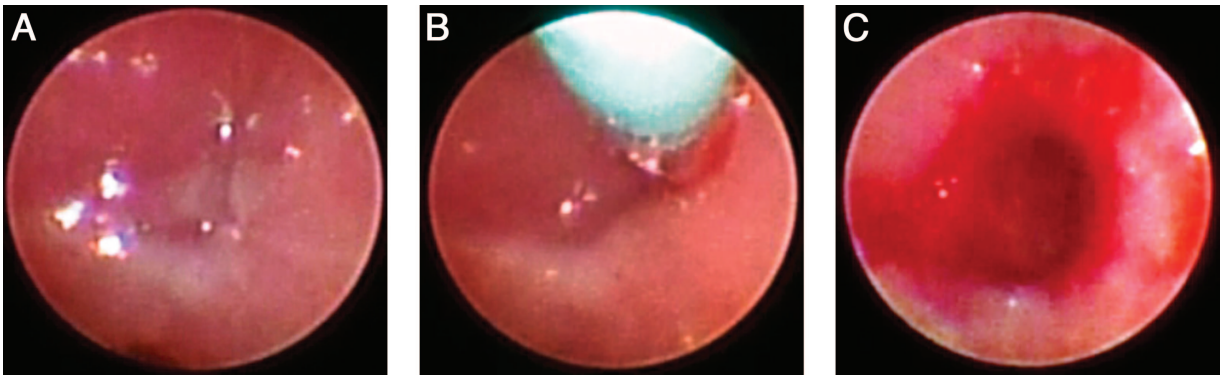

Figure 3. (A) Pretreatment transantral view of a maxillary sinus ostium. (B) Balloon catheter crossing a maxillary sinus ostium. (C) Posttreatment transantral view of maxillary sinus ostium.

Table 1 **Baseline characteristics**

Characteristic	*n*	% (*n*/*N*)	Mean ± SD
Age at treatment (yr)	30		47.6 ± 12.7
Gender (male)	10	33.3 (10/30)	
Ethnicity			
Caucasian	28	93.3 (28/30)	
Hispanic	2	6.7 (2/30)	
Smoking habit			
Current smoker	3	10.0 (3/30)	
Former smoker	10	33.3 (10/30)	
Never smoked	17	56.7 (17/30)	
Respiratory allergies			
All year long	14	46.7 (14/30)	
Seasonal	5	16.7 (5/30)	
Medical history			
Previous nasal surgery	3	10.0 (3/30)	
Asthma/bronchitis	8	26.7 (8/30)	
CRS location			
Maxillary and anterior ethmoid	12	40.0 (12/30)	
Maxillary only	18	60.0 (18/30)	

adverse events (AEs) were also documented and safety surveillance *via* AE reporting will continue through 12 months.

RESULTS

A total of 30 subjects were enrolled at three U.S. clinical sites between September 2007 and March 2008. All subjects have completed study requirements through 6 months for a protocol compliance of 100%. No subjects have withdrawn or have been lost to follow-up. Twenty-eight bilateral and 2 unilateral index procedures were scheduled for a total of 58 planned ostial dilations. The average age at treatment was 47.6 years (range, 24.2–77.9 years). Sixty percent of the subjects presented with maxillary disease and 40% presented with maxillary and anterior ethmoid disease, and all subjects were refractory to medical therapy before enrollment. A summary of the baseline characteristics of this population are shown in Table 1.

Procedural completion rate, as defined by the number of attempted ostial dilations successfully completed, was 94.8% (55/58). In three subjects, bilateral treatment was planned but only one side was successfully treated. Two of these unsuccessful attempts resulted from an inability to locate the primary ostia. In the first subject, the access site was suspected to be too inferior and in the second subject, review of a postprocedure CT showed that access was too superior to the optimal access location. In the third failed attempt, postprocedure review of the baseline CT confirmed that the balloon catheter was unable to advance beyond a native Haller cell. After review of the CT, a second attempt was successfully performed approximately 1 week later. The procedural completion rate, when including second attempts, was 96.6% (56/58). There have been zero device malfunctions reported and no subjects were converted to FESS during any study procedures.

Twenty-two of 30 subjects (73.3%) received local anesthesia with i.v. sedation and 7 of 30 (23.3%) received local anesthesia

Table 2 **Posttreatment recovery time**

Characteristic	Total No. of Subjects Treated (n) = 30	
	n	% (n/N)
Overall recovery time		
Immediately postdischarge	4	13.3(4/30)
Less than 24 hr postdischarge	10	33.3(10/30)
24–48 hr postdischarge	13	43.3(13/30)
4 days	1	3.3(1/30)
6 days	2	6.7(2/30)

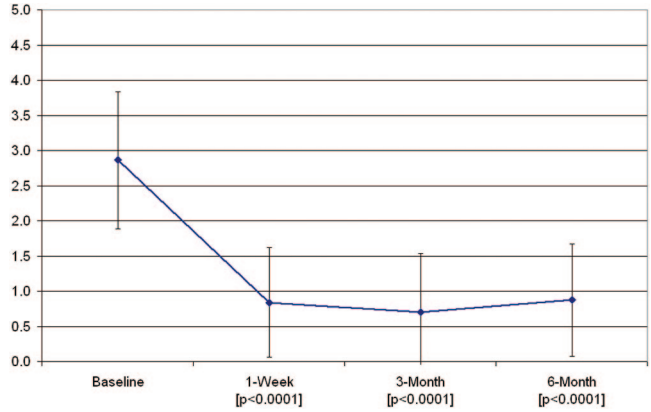

Figure 4. *Mean overall Sino-Nasal Outcome test (SNOT 20) scores.*

without i.v. sedation. One of 30 subjects (3.3%) was treated under general anesthesia during the initial procedure, and 1 subject underwent a second attempt under general anesthesia. For patients treated under local anesthesia with or without i.v. sedation, the intraoperative procedure pain was recorded using the Wong-Baker FACES Pain Scale. On a scale from 0 (no hurt) to 10 (hurts worst), the average pain score during the procedure was 2.4 ± 2.6 (range, 0.0–8.0).

The recovery time, defined as time from discharge to the time when subjects felt like they were able to resume pretreatment activity, was also reported for the study population. As shown in Table 2, ~47% of the subjects recovered within 24 hours of the procedure and ~43% recovered within 24–48 hours postprocedure. Two subjects reported a recovery time of 6 days; one subject was an athlete who was unable to return to strenuous exercise until postprocedure day 6 and the other subject experienced some facial pain and dental numbness prompting a delayed recovery time.

Postoperative bleeding was not a significant problem during this study. Twenty-five of 30 subjects (83.3%) did not experience any bleeding postdischarge. Bleeding resolved within 6 hours in 4 of 30 subjects (13.3%) and only 1 subject noted mild intermittent bleeding through 48 hours postdischarge. No patients required nasal packing at or after discharge. The average duration of posttreatment pain medication was 1.4 ± 1.3 days (range, 0.0–6.0).

The safety profile of the device and procedure was evaluated based on the review of AEs. AEs were classified by severity level and relatedness to the device or procedure. Classification was performed by the investigator. There have been zero unanticipated adverse device effects (UADEs) and zero serious device-related AEs (SAEs). Two unrelated SAEs were reported, including one bowel obstruction and one admission for epigastric pain after eating that occurred 4 months after the study procedure and was diagnosed as a spontaneous pneumomediastinum. Neither event was related to the study device or the procedure. One procedure-related, mild AE was reported because of a rash that developed as a result of an allergic reaction to a postprocedural antibiotic. Three device-related AEs have been reported: two for tooth numbness and one for facial numbness. The severity of each device-related AE was classified as mild. One of the three events has resolved and two remain ongoing. Two revision surgeries were performed. One subject had FESS and balloon sinuplasty for recurring sphenoid disease and one subject underwent a maxillary antrostomy to treat fungal sinusitis, which was not recognized on enrollment into the study. There were no mucosal wound infections related to the puncture site including oral antral fistula or abscess formation. Posttreatment symptomatic improvement was assessed by reduction in SNOT 20 scores from baseline through 6 months and review of the 3-month CT scans was performed to assess patency of the treated area. Figure 4 shows the mean overall SNOT 20 scores for the study population. In addition, SNOT 20 scores for the 18-subject cohort with maxillary disease and the 12-subject cohort with both maxillary and anterior ethmoid disease have also been calculated and are shown in Table 3. These scores also show a statistically significant reduction in SNOT 20 score from baseline through each follow-up visit.

Radiographic imaging at 3 months was also required to assess patency of each maxillary sinus ostium and ethmoid infundibulum treated by balloon dilation. Patency as assessed by the investigator at 3-month follow-up imaging was 95.8% (46/48 ostia). Figure 5, *A* and *B*, show the preprocedure and 3-month postprocedure coronal images from approximately the same anterior slice orientation of the CT scanner for one study subject. Early in the study, radiographic imaging at 1 month was required. When performed, a repeat CT at 3 months was not required. CT imaging at 1 month was completed on 4 subjects (8 ostia) and thus not included in the patency analysis.

Discussion and Conclusions

Endoscopic sinus surgery is directed at improving sinus ventilation and outflow and is the current standard of care for the surgical treatment of CRS. Although less invasive than its predecessors, FESS typically uses general anesthesia and may result in scarring or adhesions within the ostiomeatal unit. Recent data, including the results from a large registry study, suggest that balloon dilation alone or in conjunction with FESS also results in symptomatic improvement in subjects diagnosed with medically refractory CRS.[12,13] However, balloon catheter procedures from these earlier studies routinely required the use of general anesthesia and fluoroscopy to navigate the balloon catheter to the treatment site. In an attempt to reduce the perioperative comorbidities associated with tissue removal under general anesthesia as well as improve the prolonged recovery times often experienced after

Table 3 **Mean overall SNOT 20 scores**

Category	Statistics	Baseline	1-Week Follow-Up	3-Month Follow-Up	6-Month Follow-Up
All subjects	Mean ± SD	2.9 ± 1.0	0.8 ± 0.8	0.7 ± 0.8	0.8 ± 0.9
(n = 30)	Range	0.7–4.4	0.1–3.8	0.0–3.0	0.0–3.7
	p-value	N/A	<0.0001	<0.0001	<0.0001
Maxillary only disease	Mean ± SD	2.9 ± 0.9	0.8 ± 0.9	0.7 ± 0.8	0.7 ± 0.8
(n = 18)	Range	0.9–4.4	0.1–3.8	0.0–3.0	0.0–2.6
	p-value	N/A	<0.0001	<0.0001	<0.0001
Maxillary and anterior ethmoid disease	Mean ± SD	2.9 ± 1.1	0.9 ± 0.7	0.7 ± 0.9	1.0 ± 1.1
(n = 12)	Range	0.7–4.2	0.1–1.9	0.1–2.5	0.0–3.7
	p-value	N/A	0.0001	<0.0001	0.0002

SNOT 20 = Sino-nasal Outcome Test.

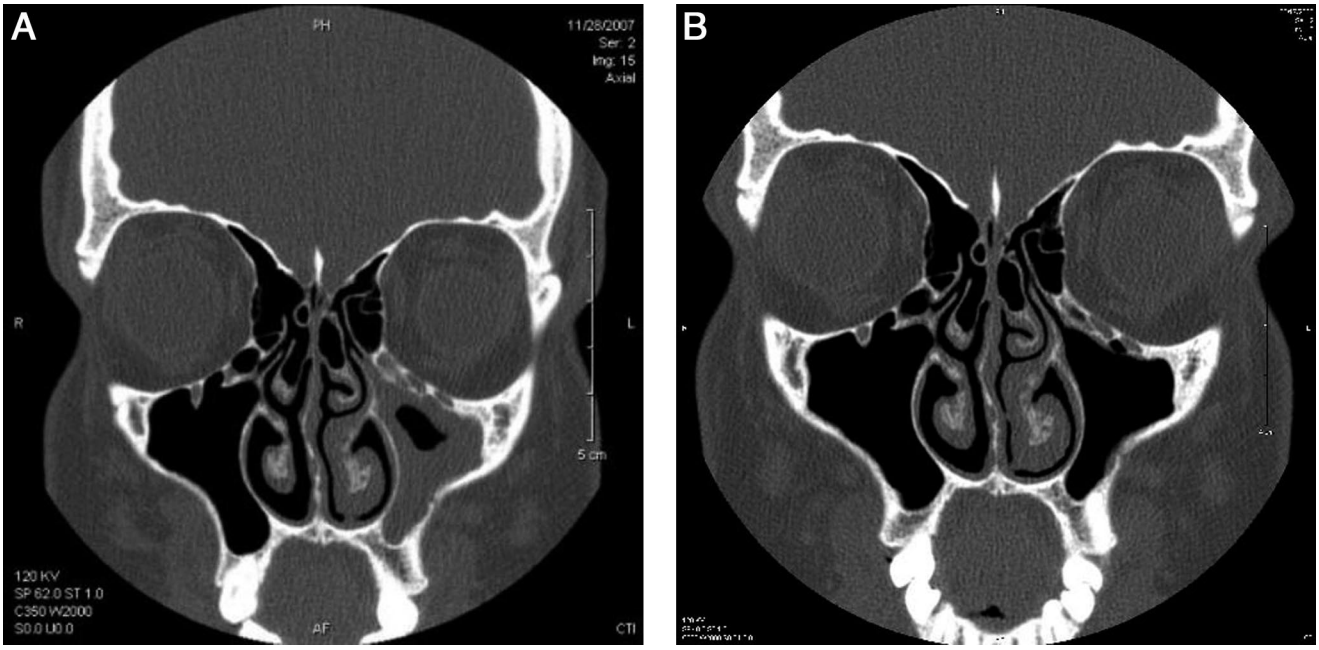

Figure 5. *(A) Preprocedure coronal computed tomography (CT). (B) Three-month postprocedure coronal CT.*

FESS, a new balloon catheter system (FinESS) has been developed to treat CRS of the maxillary sinuses alone or in conjunction with anterior ethmoid disease.

Although canine fossa puncture for access to the maxillary sinus is not as commonly performed today as it was in the pre-FESS era, most otolaryngologists remain proficient and comfortable with this technique. A recent study by Robinson *et al.* describes clear anatomic landmarks for performing this access with minimal risk to the sensory nerves of the face. By identifying the intersection of two lines, a vertical line through the middle of the pupil of the eye and a horizontal line at the bottom of the nose, physicians can be trained to locate these landmarks and use them in all procedures.

As previously discussed, one of the key potential benefits of a transcanine approach is to enable balloon dilation of the maxillary ostia and ethmoid infundibulum under local anesthesia in the office. To show the feasibility of transferring the procedure safely from an ambulatory surgery center or hospital outpatient department to the office, this study evaluated subject comfort while conscious during treatment. Experience in the BREATHE I study to date suggests a thorough blanching of the lateral nasal wall adjacent to the maxillary ostium/uncinate process and of the middle turbinate is adequate to control subject discomfort during treatment.

Safety of transantral maxillary antrostomy has been carefully monitored throughout the duration of this study. There have been previous studies that report facial numbness and dental numbness as potential complications when entering the maxillary antrum through the canine fossa. Singhal *et al.*, using a 5-mm drill/trocar with 4-mm microdebrider insertion, reported the frequency of facial tingling, facial numbness, and teeth numbness as 11, 20, and 16%, respectively, through a mean assessment period of 12.6 months after surgery. Approximately 75% of the complications resolved within 1 month after surgery, and only 3% (2/63) of the

patients reported ongoing symptoms at the time of assessment. None of the events required additional treatment.[14]

In the BREATHE I study, a microtrocar ~3 mm in diameter was used to achieve access and there was minimal manipulation of the soft tissue overlying the canine fossa during the procedure. This, coupled with the use of anatomic landmarks mentioned earlier, should reduce the likelihood of damage to the two sensory nerves of the face (anterior superior alveolar nerve and middle superior alveolar nerve). At the time of this report, two subjects (6.7%) continue to report ongoing mild facial and/or dental numbness. Review of postoperative CT scans in one subject confirmed access was too superior. In the second subject with ongoing paresthesia, access location appeared to be optimum relative to the external landmarks. Other potential complications with FESS, including bleeding requiring overnight packing, cerebrospinal fluid leak, and intraorbital complications, were not seen in this study.

This study uses the validated SNOT 20 quality-of-life survey to quantify improvement in these patients. In their validation of the SNOT 20 quality-of-life assessment survey, Piccirillo *et al.* established that a magnitude of change in SNOT 20 score of >0.8 is considered clinically meaningful. Therefore, both clinical and statistical relevance of the outcomes were assessed in this study.

Three-month data for the first 30 subjects showed a change in average SNOT 20 score from baseline to 3-month follow-up of -2.2 ($p < 0.0001$) while the change from baseline to 6-month follow-up was -2.1 ($p < 0.0001$). As previously described, preoperative and postoperative medical management was not uniform, but all enrolled subjects were determined by the investigator to have CRS after failing medical therapy. At discharge, 53% of the subjects (16/30) received ~1–2 weeks of antibiotics and ~27% (8/30) also received a topical steroid. Fourteen[14] subjects did not receive any medication at discharge. Furthermore, 17 of the 30 subjects (57%) did not receive any antibiotic therapy posttreatment.

To determine whether symptomatic improvement and treatment effects were masked by nonuniform medical management, the study population was stratified into two groups. Group A ($n = 14$) included all subjects who received ≥3 weeks of consecutive antibiotics before balloon dilation and group B ($n = 16$) included all subjects who received <3 weeks of consecutive antibiotics before study treatment. The baseline average SNOT 20 scores for groups A and group B recorded after medical therapy were 2.8 and 3.0, respectively. For group A, the changes in average SNOT 20 score from baseline to 3- and 6-month follow-up were -2.2 ($p < 0.0001$) and -1.9 ($p < 0.0001$), respectively. The changes in average SNOT 20 score from baseline to 3- and 6-month follow-up for group B were -2.2 ($p < 0.0001$) and -2.3 ($p < 0.0001$), respectively.

This subgroup analysis suggests that the treatment effect was not biased by nonuniform medical management. The severity of pretreatment symptoms was essentially the same for groups A and group B, regardless of the preenrollment medical therapy as determined by each group's average SNOT 20 scores. All subjects received robust, albeit nonuniform, medical management and remained highly symptomatic before treatment as confirmed by the overall average SNOT 20 score at baseline of 2.9. This, coupled with the observation that improvement in SNOT 20 scores for the entire study population and each subgroup through 6-month follow-up, showed clinical and statistical significance of approximately the same magnitude in the absence of more aggressive or accelerated medical therapy after treatment further support the supposition that symptomatic improvement was not biased by variations in preoperative and postoperative care. Therefore, it is reasonable to conclude that symptomatic improvement may be attributed to balloon dilation.

These results show a similar decrease in baseline SNOT 20 scores when compared with the 6-month treatment results from balloon sinuplasty in conjunction with FESS (-1.4; $n = 48$) and a greater reduction in SNOT 20 scores in the cohort treated with balloon sinuplasty alone (-0.87; $n = 36$) as reported by Bolger *et al.* The results reported in the BREATHE I study also compare favorably to FESS.[15]

Because mucosal thickening does not always resolve after FESS even in the presence of improvement in CRS symptoms, changes in Lund-MacKay scoring between baseline and follow-up were not considered as an end point for this study.[16] In addition, Lund-MacKay scores do not account for variations in inflammation for grade I disease. Because subjects enrolled in BREATHE I had less advanced sinus disease confined to the maxillary and anterior ethmoid sinuses with or without obstruction of the ostiomeatal complex, and none of the subjects included in the study had complete opacification of any sinuses (maximum score of 4 or less per side), the information gained from analyses of pre- and postoperative scores would be limited and therefore staging of the disease using Lund-MacKay scoring was not performed.

The least invasive surgical approach to sinus treatment would involve removing as little tissue as possible and still achieve an adequate drainage pathway with resolution of CRS symptoms. There are a number of unanswered questions within rhinology including middle turbinate preservation, large versus small ostia, uncinate process preservation, and the need for tissue removal with balloon sinuplasty. Because mucosal tissue and the uncinate process are preserved during balloon catheter dilation, this approach may be a less invasive alternative to FESS in patients with ostiomeatal unit and infundibular obstructive patterns. Success has been shown with balloon sinuplasty due to the displacement and remodeling of bone along the sinus outflow tract. The transantral technique of remodeling the infundibulum enables selective treatment of the drainage pathway in the conscious patient without collateral trauma to the middle turbinate and other structures near the drainage pathway.

The transantral approach may also be more desirable from an office-based standpoint. Obstacles that stand in the way of predictable transnasal treatment include septal deviation, concha bullosa, mucous membrane edema, local anesthetic delivery, patient tolerance, and need for middle turbinate medialization. The advantages of the transantral approach include ease of anesthetization, patient acceptance of an intraoral versus a transnasal approach, predictable location of the primary ostium, avoidance of scar tissue formation, and preservation of the intranasal anatomy. In addition, sinus procedures that use fluoroscopy are not easily adopted into an otolaryngologist's office. Because delivery of and treatment with the FinESS system is performed *via* endoscopic visualization, the need for fluoroscopy with its in-office logistical difficulties and resulting radiation exposure to the patient and clinical staff is eliminated.

The results of this study show that this new balloon system can be used as a tool to safely dilate the maxillary sinus ostia and ethmoid infundibulum in conscious subjects and confirm that access through the canine fossa is well-tolerated with minimal discomfort and can be completed with a high degree of procedural success. Additionally, these outcomes show a statistically significant improvement in subject symptoms after treatment of the maxillary ostia and ethmoid infundibulum *via* transantral balloon dilation at 3 and 6 months based on the changes in SNOT 20 scores after treatment. Data from continued enrollment and surveillance of the BREATHE I study will be presented when available. (The BREATHE I ClinicalTrials.gov identifier is NCT00645762).

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