Operative Techniques in Otolaryngology (2011) 22, 246-252

ELSEVIER

Operative Techniques in

Otolaryngology

ORIGINAL CONTRIBUTION

Introduction to an office-based sinus surgery technique

Ashley Sikand, MD, FACS

From Ear, Nose, and Throat Consultants of Nevada, Las Vegas, Nevada.

KEYWORDS
Sinus surgery;
Balloon sinus dilation;
Office-based techniques;
Minimally invasive surgery

The advent of balloon catheter dilation of the sinus ostia has advanced the ability of surgeons to manage chronic rhinosinusitis with tissue preservation and less-invasive techniques. This technology has provided the opportunity to perform endoscopic sinus surgery outside of the traditional operating room in a select patient population. This article describes the author's experience with a postmarket study assessing the feasibility of moving select endoscopic sinus surgeries with the use of balloon catheter dilation tools to the office setting. A discussion of anesthesia technique, patient selection, procedure room set-up, and equipment requirements is presented. The safety, tolerability, effectiveness, and cost of performing balloon catheter sinus dilation were evaluated in 10 patients in the author's practice. Effectiveness was assessed with both the sinonasal outcome test (SNOT-20) as well as change in Lund-Mackay computed tomography scan scores. Patient pain perception during the procedure was measured with a visual analogue scale. Patient outcomes were assessed at 1-, 4-, 24-, and 52-week follow-up to determine the durability of the surgical results. At 6 months, SNOT-20 symptom scores were significantly improved (0.89 vs 2.05 baseline), as were Lund-Mackay computed tomography scores, which decreased from a preoperative mean of 7.00 to 0.86. With respect to tolerability, 9 of 10 patients indicated that the procedure was well tolerated.

In the United States alone, an estimated 31 million adults (14% of the adult population) are affected by sinusitis, resulting in approximately 15 million ambulatory care visits per year.[1] Direct annual health care costs are estimated at US$5.8 billion[2] and include approximately 500,000 surgical procedures each year.[3]

Patients who do not respond to maximal medical management of chronic rhinosinusitis (CRS)[4] are considered for surgical treatment.[5,6] Traditionally, endoscopic sinus surgery (ESS) has been performed in either a hospital or ambulatory surgery center-based operating room with the patient under general anesthesia. The economic cost of operating room-based sinus surgery is significantly greater than office-based sinus surgery.[7] In addition, general anesthesia incurs certain risks and morbidity that may be eliminated with local anesthesia as a stand-alone technique. Finally, early return to work and routine activities represent other advantages of moving ESS to an office setting from the traditional operating room.

The advent of tools for performing balloon catheter dilation of the sinus ostia has provided surgeons with a technique that may be ideally suited to office-based surgery. Balloon-based sinus surgery permits ostial enlargement without tissue removal or resection of bone. The objective of this study is to determine the feasibility of performing ESS in the office using balloon sinus dilation (BSD) tools. Specific attention is given to patient selection, safety and effectiveness.

Methods

Office infrastructure

It is essential to establish an adequate office infrastructure before office-based BSD is attempted. In addition to a standard endoscopy tower (including a large monitor with a high-resolution camera), rigid endoscope, and suction ca-

Address reprint requests and correspondence: Ashley Sikand, MD, FACS, Ear, Nose, Throat Consultants of Nevada, 8530 W. Sunset Road, Suite 230, Las Vegas, NV 89113.

E-mail address: asikand1@aol.com.

1043-1810/$ -see front matter © 2011 Elsevier Inc. All rights reserved.
doi:10.1016/j.otot.2011.08.005

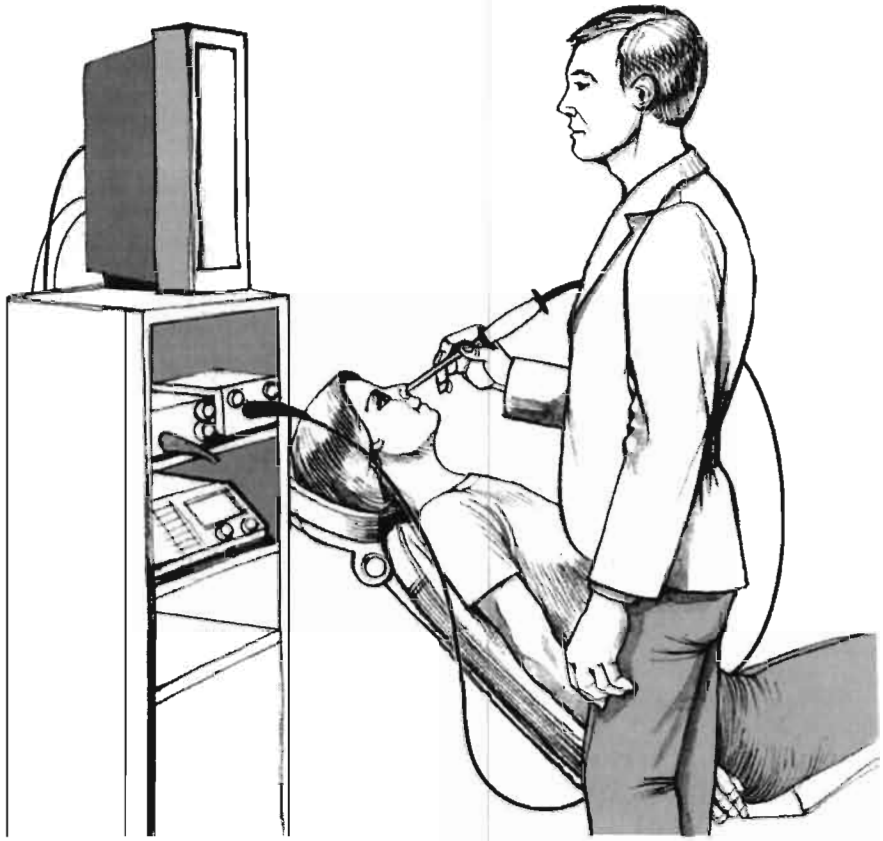

Figure 1 The office layout should emulate the set-up for ESS used in an operating room. The surgeon may be seated or remain standing.

pacity, it is necessary to have 2 light sources (one for the endoscope and another for the Relieva Luma™ Sinus Illumination System; Acclarent, Inc, Menlo Park, CA). A standard light source compatible with GyrusACMI or Wolf adapters is used to enable transcutaneous sinus illumination across targeted nasal and sinus structures. It should be possible to darken the procedure room because ambient light makes it difficult to see the Luma sinus Illumination System's light profile. An adjustable, reclining examination chair or table as well as a height-adjustable workspace ensures comfortable positioning for physician as well as patient (Figure 1). Capacity for a digital image capture is recommended. Instrumentation includes a standard sinus tray and ESS set as well as the required BSD tools (Table 1). A microdebrider may be used in select cases. Additional recommendations are listed in Table 2.

Table 1 The BSD armamentarium

Relieva Flex sinus guide catheter: sizes: S-0, S-30; F-70, F-70C; M-90, M-110, M-110S
Relieva Solo Pro sinus balloon catheter: sizes: 5,6,7 ×16 mm; 5,7 ×24 mm; 2.5 ×12 mm
Relieva Luma sinus illumination system and accessories
Relieva Vortex sinus irrigation catheter
Relieva extension tubing (if needed)
Acclarent balloon inflation device

BSD, balloon sinus dilation.

It is advantageous to have more than one treatment room available for concurrent device and patient preparation. The author used a patient preparation room for the administration of topical anesthesia. Standard staffing for office ESS is required, and most office staff can be easily trained to assist

Table 2 Equipment and supplies

Recommendation for room set-up
Height-adjustable workspace, draped
Multiple 3- to 4-mm rigid endoscopes
Sinus instrument tray
Suction
Office recording and image capture capability
Pulse oximetry monitor
ENT chair
Standard endo-tower with large monitor, high resolution camera
Optional:
Pediatric rod lense scopes
Recommendation for supplies
Drape for patient
20-mL syringes
Multiple light sources
Emesis basin
Saline for balloon inflation and irrigation
Gauze squares
Nasal packing material
Crash cart

ENT, ear-nose-throat.

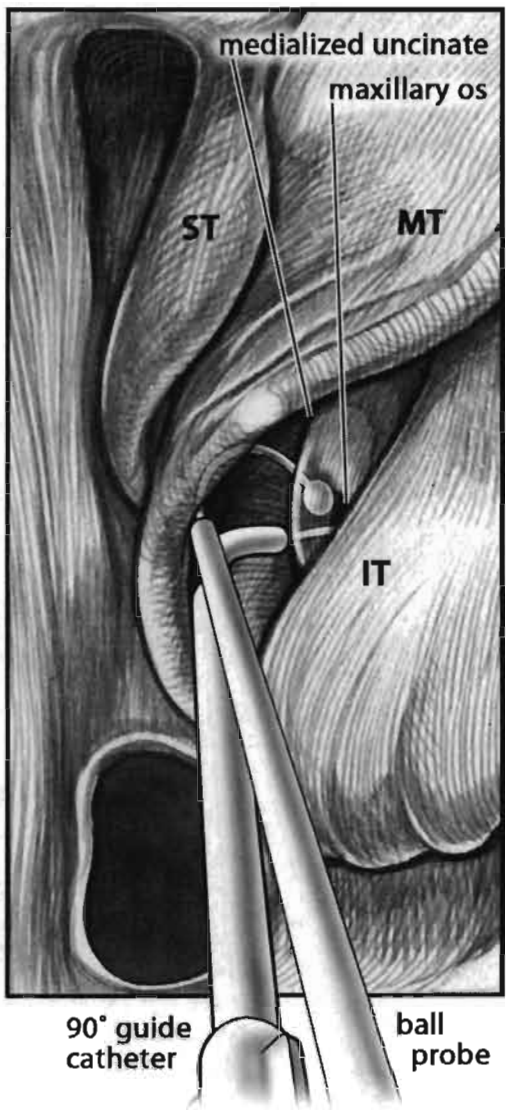

Figure 2 Initial gentle retraction of the uncinate process with a ball-seeker probe permits access to ostia situated superiorly and anteriorly within the infundibular space. Guidewire placement into and through the ostium is achieved in the absence of direct visualization as it is concealed by the uncinate. Surgeons are cautioned to not use the guide catheter as a probe and rather allow the guidewire to find the ostium by using a posterior-to-anterior search pattern.

with the BSD tools and pre- and posttreatment patient orientation and care to optimize surgeon time on the procedure.

Patient selection

Diagnosis of CRS with failure of maximal medical treatment is the indication for a BSD procedure. Selected patients had persistent symptoms for greater than 12 weeks and positive computed tomography (CT) scans. All patients were treated with at least 3 weeks of antibiotics as well as appropriate ancillary medications and were considered treatment failures on the basis of the persistence of clinical symptoms and sinus CT scan abnormalities. The need for certain ancillary procedures (eg, septoplasty) precluded office-based treatment. Patients presenting with cystic fibrosis, Sampter's triad, sinonasal tumors or obstructive lesions, history of facial trauma that distorts sinus anatomy and/or precludes access to the sinus ostium, and ciliary dysfunction were excluded for office-based procedures. Appropriate coagulation studies should be assessed in at-risk patients.

Furthermore, patient personality must be evaluated to ensure suitability for an unsedated office-based sinus procedure. Patients who have difficulty tolerating an endoscopic examination or evidence anxiety during other routine examinations are not good candidates for the office-based sinus procedure under local anesthetic. Beyond this, it is also necessary to set expectations around pain and discomfort and otherwise prepare the patient by explaining the steps involved to achieve adequate analgesia and by describing the anticipated sensations (pressure, popping sensation) and sounds during guidewire insertion, balloon inflation, and irrigation.

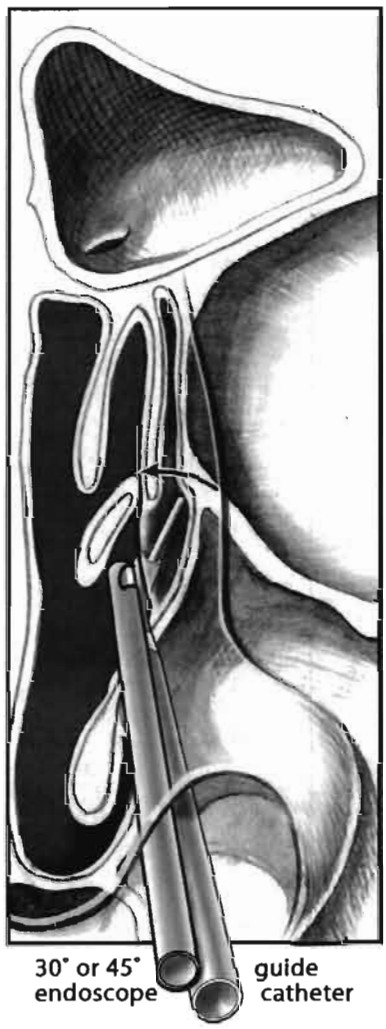

Figure 3 An endoscopic view using a 30° or 45° endoscope to visualize the superior middle meatus anterior to the bulla ethmoidalis. The surgeon places the guide catheter anterior to the bulla and deploys a search pattern that moves anteriorly and from lateral to medial.

Anesthesia

An effective anesthesia technique is critical to successful ESS in the physician's office. In the author's practice this comprised surface anesthesia followed by infiltrative anesthesia. Surface anesthesia is triphasic. In the first phase, atomized lidocaine 4% (50/50 with phenylephrine [Neo-synephrine; Bayer, Morristown, NJ]) is applied twice at 5-minute intervals. This is followed by cotton pledgets immersed in the same lidocaine/Neo-synephrine solution. These are left in place for an additional 5 minutes. Finally, in the third phase, topical epinephrine 1:1000 on a pledget is placed in the middle meatus to maximize vasoconstriction. Epinephrine has been shown to be safe as a surface medication for nasal mucosa and is 20 times more potent as a vasoconstrictor than oxymetazoline.[8]

After waiting approximately 10 minutes, one can move the patient to the procedure room where infiltrative anesthesia is administered. This consists of 1% lidocaine with 1:100,000 epinephrine. Lidocaine maximum dose is 6-7 mg/kg. A safe dose for a noncardiovascular disease patient is 20 mL of the 1% lidocaine with 1:100,000 epinephrine solution. In patients who are American Society of Anesthesia class 3 or 4, caution must be used when infiltrating with solutions containing epinephrine. In these patients, a maximum safe dose of 4 mL of the 1:100,000 epinephrine solution or 8 mL of the 1:200,000 is recommended. It is also the author's practice to monitor heart rate and blood pressure during anesthesia administration for patients diagnosed as American Society of Anesthesia class 3 and 4. Because epinephrine has a half-life of approximately 2 minutes, monitoring after 5 minutes is not required when vital signs have returned to baseline.

Slow, low-pressure injection minimizes discomfort. Consider the addition of sodium bicarbonate in a 10% solution to lower the pH of the injectable thus further decreasing discomfort. Distraction techniques effectively bridge the more anxiety-inducing phases of the procedure. It is difficult to define any minimum or optimum anesthesia that patients require to comfortably tolerate an office BSD procedure. It may be necessary to inject additional anesthesia intraprocedurally if the patient appears to be experiencing more discomfort than anticipated.[8]

Application of balloon sinuplasty dilation tools

The BSD tools used in this procedure include a guidewire, guide catheter, balloon catheter, and irrigation catheter (see Table 1 for a complete listing.) the operator should choose the guide catheter type and balloon catheter size (5, 6, or 7 mm) best suited to the sinus(es) indicated for treatment. Superb visualization of the middle meatus should be achieved before initiating the procedure (Figure 2). The guide catheter is preloaded with the sinus illumination system and the balloon and introduced into the nasal cavity under endoscopic visualization (Figure 3). The guide catheter is placed adjacent to the obstructed maxillary, sphenoid, or frontal ostium or recess (Figure 4). The sinus illumination

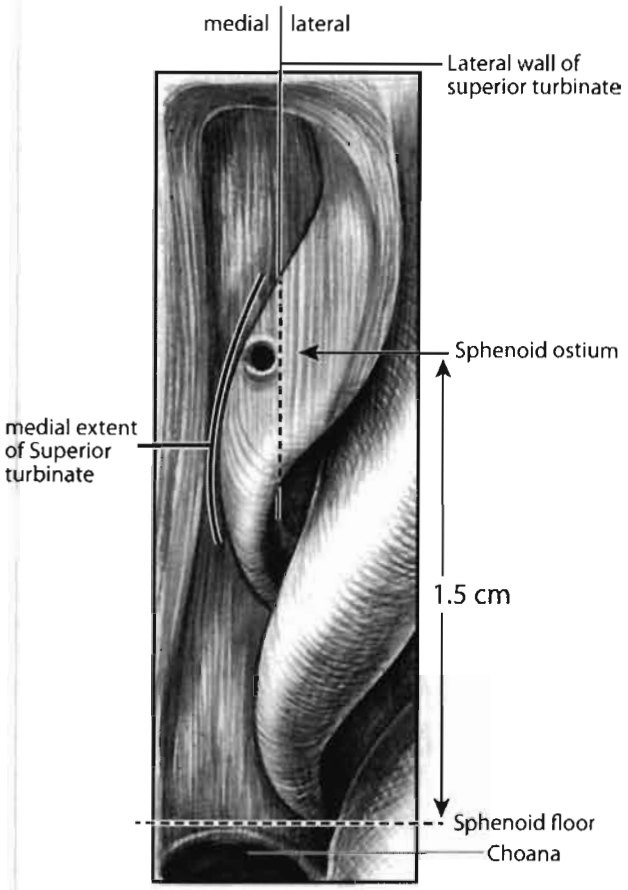

Figure 4 The sphenoid ostium is located 1.5 cm superior to the sinus floor and just medial to the lateral projection of the superior turbinate. The search pattern is initiated superior to the posterior choana and progresses superior and lateral toward the superior turbinate.

system is then advanced into the sinus and used to confirm sinus access before ostial dilation (Figure 5). Thereafter, the balloon catheter is advanced into position over the guidewire. A single inflation to 12 atm is usually sufficient; however, if necessary, multiple inflations are also possible. Multiple sinuses can be treated with each balloon. After dilation, the tissues are inspected endoscopically. If indicated, the sinus is irrigated by retrograde flushing with the sinus lavage catheter (Figure 6). Concomitant suctioning and irrigation is achievable with the current system and usually effectively manages fluids for patient comfort.

The author favors primary frontal sinus treatment if the maxillary sinuses are also to be treated. Take care to assess the anatomic tolerances of the hiatus semilunaris and infundibulum for maxillary dilation. The author has not encountered any difficulty using a 7 × 16-mm balloon, inflated to 12 atm of pressure, in all 3 sinuses (maxillary, sphenoid, and frontal), although a range of additional balloon sizes is available (Table 1). Occasionally, a frontal sinus outflow tract may be so long as to require sequential ballooning.

Patients are sent home on antibiotics, over-the-counter analgesics as needed for pain management, and sinonasal lavage for residual mucus and clot management. They gen-

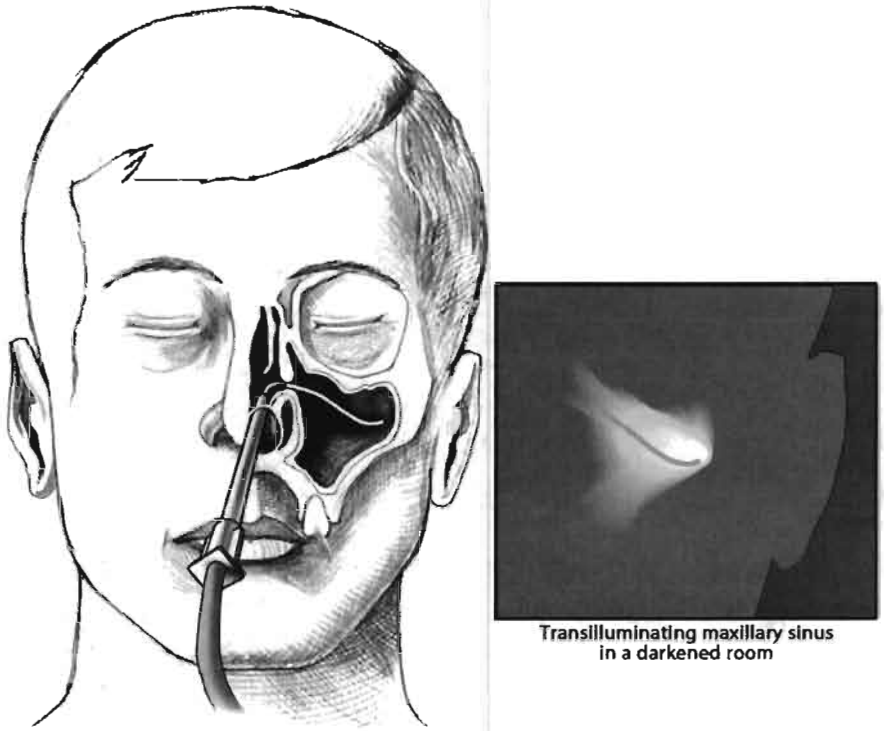

Figure 5 Transillumination provides confirmation of correct entry into the sinus. Rotation of the fiberoptically enabled guidewire may be required to demonstrate this effect.

erally return to normal activities within 24 hours. Patients return for follow-up at 1 and 4 weeks posttreatment. By establishing patent sinus ostia in the fashion described above, the need for repeated postoperative debridements is obviated, as natural mucociliary function will provide the necessary clearance of nasal debris. Initially, it may be advisable to treat isolated disease in one or two sinuses. Experience thus gained will be translated over time into the ability to efficiently treat more than two sinuses per patient.

Results

In this paper, the author is reporting on 10 BSD procedures performed in his practice between October 2008 and January 2009 as part of the ORIOS (ESS Performed in Operating Room versus Clinician's Office) clinical trial. The mean age of the patients was 55 years, and an average of 1.4 sinuses was treated per patient. A breakdown of sinuses treated and the distribution of primary vs revision treatments is provided in Table 3.

Nine of the 10 patients found the procedure tolerable and rated their pain as moderate to little, with the greatest discomfort occurring during balloon inflation. One patient was not able to tolerate the procedure. Wire access to the sinuses could not be achieved because of edema and granulation tissue from multiple previous functional ESS. See Tables 4, 5, and 6 for procedure tolerability, pain rating, and greatest discomfort during procedure.

Outcomes were also evaluated in terms of sinonasal outcome test (SNOT-20) and Lund-Mackay CT scan scores. Results of SNOT-20 baseline scores and postoperative assessments at each of the follow-up intervals (1, 4, 24, and 52 weeks postprocedure) for matched pairs are listed in Table 7. Evaluation of change in Lund-Mackay CT scan scores between baseline and the 24-week follow-up for matched pairs are noted in Table 8. "Matched pairs" refers to patients who have complete data for both the baseline/preprocedure evaluation and the referenced follow-up visits. There are some missing data points for patients who did not complete the required follow-up visit. There were 2 adverse events noted during the course of the study; both concerned infection related to preexisting conditions and were therefore deemed unrelated to procedure or device.

Discussion

The present article represents an initial study of the feasibility of moving ESS to the office setting in a selected patient subset. All procedures were performed in patients receiving local anesthesia without sedation. Regarding patient tolerability, 7 of 10 patients described little or mild pain, and 9 of 10 patients indicated that the procedure was well tolerated. Successful ostial dilation was obtained in 9 of 10 patients. Outcome measures used were the SNOT-20 and Lund-Mackay CT scores before and after surgery. Tables 7 and 8 show statistically significant improvement in both outcome metrics, with SNOT-20 postoperative means demonstrating an improvement of at least −1.16 difference (at the 6-month follow-up interval) with even greater gains in score at other follow-up intervals. The 24-week postoperative Lund-

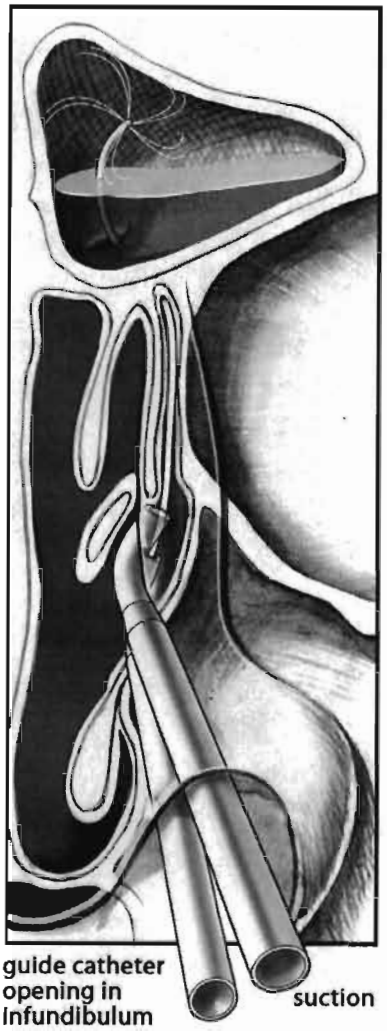

Figure 6 A vortex irrigation catheter is used to evacuate sinus contents. A suction is held adjacent to the ostium to capture all efficient solution and prevent drainage into the nasopharynx. A suction trap is used to collect fluid for culture.

Mackay CT score improved from 7.00 (preoperative) to 0.86, representing a −6.14 point gain in this metric.

Moving selected surgical candidates for ESS to an office setting confers certain distinct advantages (Table 9). First, the cost is less. In results from all 10 sites involved in the ORIOS clinical trial the mean operating room cost was US$13,035 ± 7120 (n = 33 procedures) compared with US$2983 ± 2219 (n = 35 procedures) for the office-based cost.[7] This impacts the patient who is frequently required to absorb the costs of increasing deductibles for facility fees. It also offers a similar decrease in cost outlays for third-party insurers. Second, the elimination of general anesthesia decreases postoperative care and morbidity and may also significantly reduce recovery time before patients can return to work and other routine activities. Finally, the office setting is generally well-accepted by patients and may assist in mitigating anxiety before surgery that can be heightened in the hospital operating room.

The shortcoming in this analysis is the limited number of patients and lack of randomization. However, this study does demonstrate safety, tolerability, effectiveness, and patient satisfaction of office-based ESS using BSD tools. In addition, it has allowed for the development and optimization of anesthesia, infrastructure management and patient selection strategies.

Table 3 Sinus treatment type: Primary vs revision

Sinus type	Primary treatment	Revision treatment	Total
Maxillary	9	1	10
Sphenoid	0	1	1
Frontal	2	1	3
Total	11	3	14

Table 4 Procedure tolerability

0 = not tolerated	10.0% (1/10)
1 = barely tolerable	0.0% (0/10)
2	0.0% (0/10)
3	30.0% (3/10)
4	40.0% (4/10)
5 = highly tolerable	20.0% (2/10)

Procedure tolerability ratings based on a scale of 0–5.

Table 5 Rating of pain experienced

0 = No Pain	0.0% (0/10)
1 = little pain	20.0% (2/10)
2	50.0% (5/10)
3	20.0% (2/10)
4	0.0% (0/10)
5 = intense pain	10.0% (1/10)

Patient pain ratings based on a scale of 0–5.

Table 6 Greatest discomfort during the procedure

Sinus Illumination guidewire insertion	10.0% (1/10)
Balloon insertion	30.0% (3/10)
Balloon inflation	50.0% (5/10)
Not applicable	10.0% (1/10)

Patient discomfort rating, identifying the procedure phase during which greatest discomfort occurred.

Conclusions

It must be emphasized that the author recommends the use of an office-based location only for those patients clinically indicated for ESS who would have been selected for the operating room under the current practice paradigms. The office setting does not change the current treatment protocol

Table 7 SNOT-20 symptom scores

	n	Preoperative Mean [95% CI]	Postoperative Mean [95% CI]	Δ from Baseline [95% CI]	*P* value*
Postoperative week 1	7	2.05 [1.45, 2.65]	0.67 [0.27, 1.07]	−1.38 [−1.94, −0.81]	0.0010
Postoperative week 4	7	2.05 [1.45, 2.65]	0.37 [0.01, 0.74]	−1.68 [−2.43, −0.92]	0.0016
Postoperative week 24	7	2.05 [1.45, 2.65]	0.89 [−0.06, 1.83]	−1.16 [−2.34, 0.01]	0.0515
Postoperative week 52	4	2.21 [1.52, 2.90]	0.40 [−0.21, 1.01]	−1.81 [−2.00, −1.62]	<0.0001

A matched pair comparison of SNOT-20 symptom scores: postoperative visits and baseline.
CI, confidence interval; SNOT-20, sinonasal outcome test.
*Test for significant change from baseline using paired *t*-test.

Table 8 Total Lund-Mackay CT score

N	Preoperative Mean [95% CI]	Postoperative 24-wk Mean [95% CI]	Δ from Baseline [95% CI]	*P* value*
7	7.00 [4.08, 9.92]	0.86 [0.03, 1.69]	−6.14 [−8.67, −3.61]	0.0010

A matched pair comparison of total Lund-Mackay CT Scores: 24 week postoperative visit and baseline.
CI, confidence interval; CT, computed tomography.
*Test for significant change from baseline using paired *t*-test.

Table 9 Potential advantages of office-based BSD sinus surgery

- Cost savings (No PACU or G/A expenses)
- Patient requires no postoperative recovery
- Decreased complication rate (eg, airway)
- Minimization of procedure time
- Unsedated: no intravenous medication
- Less time lost from work and family
- Excellent outcomes, safety, etc.
- Acceptable risk-to-benefit ratio
- Avoidance of exposure to radiation and contrast

A listing of some of the advantages of office-based BSD sinus surgery.
BSD, balloon sinus dilation; PACU, post operative care unit; G/A, general anesthesia.

for management of chronic sinusitis or the criteria for recommending ESS procedures. However, financial considerations, medical issues, and desire to avoid general anesthesia may affect surgery site selection.

Office-based ESS with BSD techniques offers the potential for decreased cost, reduced recovery time, and avoidance of general anesthesia. In addition, the safety and effectiveness of office-based ESS deploying BSD tools were demonstrated. Clearly, a larger multicenter study is necessary to better statistically analyze these trends.

Acknowledgments

The technique described in this article uses Balloon Sinus Dilatation (BSD) tools developed and distributed by Acclarent, Inc., Menlo Park, CA. The ORIOS clinical trial is supported in part by Acclarent, Inc. I would like to thank Sandra Schlachter for her assistance with the drafting of the manuscript. Ms Schlachter is a consultant for Acclarent, Inc., Menlo Park, CA.

References

1. Centers for Disease Control and Prevention: Sinus Conditions. 2009. Available at: http://www.cdc.gov/nchs/fastats/sinuses.htm. Accessed September 7, 2011
2. Ray NF, Baraniuk JN, Thamer M, et al: Healthcare expenditures for sinusitis in 1996: contributions of asthma, rhinitis, and other airway disorders. J Allergy Clin Immunol 103:408-414, 1999
3. National Center for Health Statistics, Division of Data Services Combined Surgery Data: (NHDS and NSAS), Data Highlights, updated 1996. Available at: http://www.cdc.gov/nchs/data/hdasd/13_139t9.pdf. Accessed September 7, 2011
4. Lanza DC, Kennedy DW: Adult rhinosinusitis defined. Otolaryngol Head Neck Surg 117:S1-S7, 1997
5. Devyani L, Scianna JM, Stankiewicz JA: Efficacy of targeted medical therapy in chronic rhinosinusitis, and predictors of failure. Am J Rhinol Allergy 23:396-400, 2009
6. Stewart AE, Vaughan WC: Balloon sinuplasty versus surgical management of chronic rhinosinusitis. Curr Allergy Asthma Rep 10:181-187, 2010
7. Sillers MJ, Albritton FD, Casiano R, et al: Safety, feasibility and cost comparison of endoscopic sinus surgery: in-office balloon versus operating room. Presented October 3, 2009 at the 55th Annual Meeting of the American Rhinologic Society, San Diego, CA
8. Malamed SF: Handbook of Local Anesthesia. St. Louis, MO, Mosby, 2004