In-Office Balloon Dilation: Procedure Techniques and Outcomes using a Malleable Multi-Sinus Dilation Tool

By James D. Gould, MD FACS

Synergy ENT Specialists • St. Louis, Missouri

636-931-7380 • www.stlsinuscenter.com

BACKGROUND

Balloon devices enlarge narrowed sinus ostia and outflow tracts by remodeling the surrounding bone and paranasal sinus structures. Multiple studies have demonstrated that balloon dilation either as a stand-alone procedure or when combined with ESS (i.e. "hybrid" procedure) can be performed with a high rate of technical success safely in the operating room and yields significant sinus symptom improvement and sustained patency of the ostia and sinus drainage pathways without a high rate of repeat sinus surgery.[1-4] Over the past several years, balloon procedures started to move from the OR to the office as new procedure codes became effective and to avoid the risks of general anesthesia used in hybrid balloon/ESS procedures. This move into the office also provides greater convenience for the patient and physician and reduces the overall cost of the procedure. Several studies have demonstrated that balloon dilation can be safely performed in the office setting with minimal discomfort to the patient and with outcomes similar to those reported from early studies in which balloon procedures were performed in the OR.[5-8] The objective of this small case series was to highlight the techniques used to achieve successful balloon dilation in an office setting using a malleable-tip multi-sinus balloon device and also provide outcomes that were prospectively collected under a protocol that was reviewed and approved by an independent ethics committee (i.e. Institutional Review Board; IRB). This is the first report of the use of a malleable-tip multi-sinus balloon device in a series of patients treated in the physician's office using sinus balloon dilation as a stand-alone technique.

PATIENT SELECTION

Patients who were eligible and selected for balloon dilation were at least 18 years of age with a diagnosis of uncomplicated sinusitis confined to the maxillary sinuses or the maxillary and anterior ethmoid sinuses without adjacent involvement of neurologic, soft tissue, or bony structures. Each patient also had either four or more documented episodes of acute rhinosinusitis (i.e., less than 4 weeks duration) in one year, or chronic sinusitis (i.e., greater than 12 weeks duration) interfering with lifestyle. Additionally, aggressive medical management including antibiotic therapy, nasal steroids, allergy assessment, nasal lavage and decongestants was attempted as indicated by the sinus surgeon prior to treatment, and each patient had a radiological scan (CT) within six months of the procedure. Patients with fungal sinusitis or evidence of significant polypoidal disease were not treated nor were individuals with primary ciliary dysfunction, cystic fibrosis, hemophilia, Samter's Triad, sinonasal tumors or obstructive lesions. Patients who had previously undergone endoscopic sinus surgery or who required sinonasal surgery at the time of the planned balloon dilation procedure were also excluded from participation.

PATIENT DEMOGRAPHICS

A total of 21 patients were treated and followed for six months to assess procedure outcomes and sinus symptom severity through six months after balloon dilation. The average age of the population was 52 ± 18 years. Twelve females and nine males were treated. Over 76% (16) of the patients experienced either year-round or seasonal allergies and 90% (19) of the patients were non-smokers. As indicated by the patient selection criteria, none of the patients had nasal polyps nor had prior sinus surgery. The average Lund-MacKay score of the pre-procedure CT scans was 4.7 ± 3.4.

PROCEDURAL TECHNIQUE

Pre-operative oral anxiolytics were administered at the discretion of the surgeon. Seventy-one percent (15/21) of the patients received an oral sedative and narcotic pain medication prior to the procedure. Local anesthesia was then administered per the recommended regimen that included nasal decongestant spray and anesthesia spray followed by intranasal placement of pledgets soaked with a topical anesthesia and nasal decongestant. After a short wait of up to 10 minutes, the pledgets were removed and topical anesthesia was injected into the uncinate process and root of the middle turbinate. The sphenopalatine region and anterior middle turbinate were also routinely anesthetized.

Balloon dilation of the maxillary sinus ostia and ethmoid infundibula was performed transnasally with the XprESS™ Multi-Sinus Dilation Tool and the PathAssist™ Light Fiber™ (**Figure 1.** Entellus Medical, Plymouth MN). The study device included a 6-mm by 18-mm balloon on a malleable-tipped shaft that was reshaped in the optimal configuration to navigate individual patient anatomy and cannulate the natural ostium with the uncinate intact.

Prior to treating this patient population in the office, each surgeon received training from the device manufacturer. Procedural techniques that were consistent with the manufacturer's training guidelines were applied during treatment of all patients in this case series. These techniques are summarized in **Table 1**.

Figure 1: XprESS Multi-Sinus Dilation Tool with PathAssist Light Fiber

Table 1: Recommended Procedure Technique for Balloon Dilation of the Maxillary Sinus Ostium

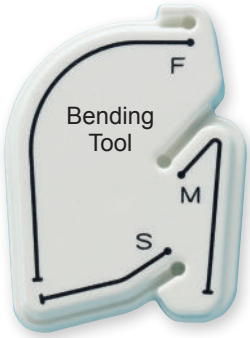
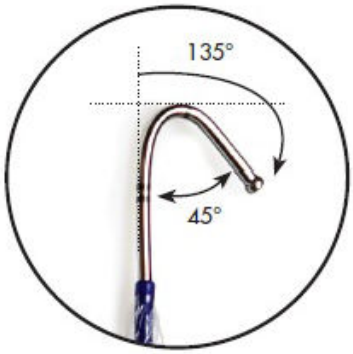
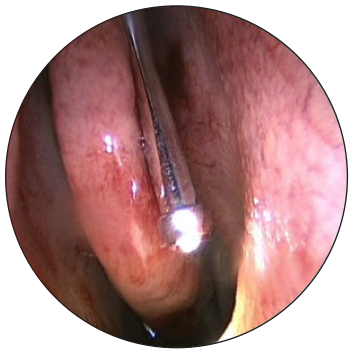
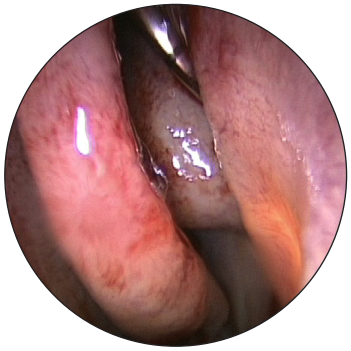
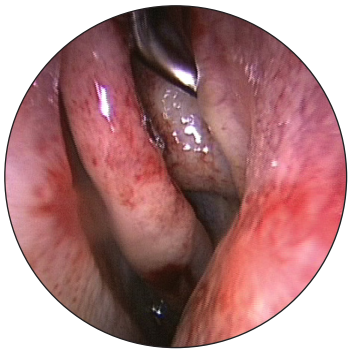
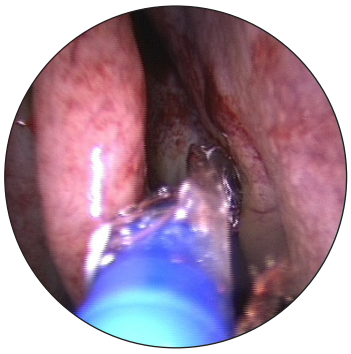
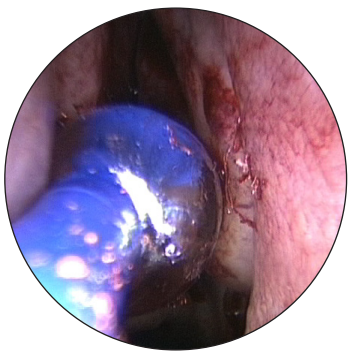
Step	Technique Description
1	Use a maxillary sinus seeker to create clearance between uncinate process and ethmoid bulla.
2	Position a light fiber in the open lumen of the balloon device, secure it at the device tip, and use illumination to help identify the ball tip location throughout procedure.
3	Configure the tip of the balloon device to a bend angle of 135 degrees using a bending tool designed for the device.  
4	With the tip of the device pointing downward, advance the balloon device into the nasal cavity. If the initial attempt to position the tip of the balloon device in the maxillary ostium does not allow the ball tip to be placed behind the posterior margin of the uncinate process, withdraw the device and reshape the tip to a bend angle of approximately 115 to 125 degrees. Alternatively, start with the device positioned with the ball tip pointing upward and engage the free edge of the uncinate process near its inferior attachment (not shown). Additional bend angles no less than 110 degrees may be applied as necessary to facilitate placement of the device tip behind the uncinate process. 

Table 1: Recommended Procedure Technique for Balloon Dilation of the Maxillary Sinus Ostium (Continued)		
5	With the device oriented “tip down”, place the elbow of the device high in middle meatus with its leg adjacent to uncinate process. Rotate the device to place the ball tip behind the uncinate process and observe the ball tip riding along the postero-lateral aspect of the uncinate process as the device tip is gently moved inferiorly to cannulate the natural ostium. As shown in the photo on the right, transillumination of the uncinate can help verify the contact of the ball tip against the uncinate process, thereby avoiding risk of contact with the posterior fontanelle. Alternatively, when the device “tip up” orientation is preferred (not shown), rotate the elbow of the device superior and lateral around the ball tip, maintaining gentle antero-medial pressure on the device until its elbow swings free of the middle turbinate and the tip of the device cannulates the natural ostium.	
6	Position the inside of the device elbow against the free edge of the uncinate while maintaining cannulation of the natural ostium.	
7	Advance balloon while maintaining light anterior pressure to keep the device seated in the ostium.	
8	Dilate the maxillary ostium and ethmoid infundibulum. After dilation, attempt to position the tip of the device more inferior and anterior and repeat dilation. Retract the balloon and gently remove the balloon device from the nasal cavity.	

INTRAOPERATIVE RESULTS

All procedures were performed in the clinic without any additional or adjunctive sinonasal procedures. A total of 42 maxillary ostia in 21 patients were targeted for treatment. In each patient, the ethmoid infundibulum and natural ostium was successfully cannulated and dilated for a technical success rate of 100%. In this study, over half (23/44) of the maxillary cannulations were performed with the bend angle of 135 degrees as configured through the use of the proprietary bending tool while 96% of the ostia were successfully accessed and dilated with a bend angle between 120 and 150 degrees. In 3 patients (6 ostia), the tip of the balloon device was reshaped to an angle of less than or equal to 110 degrees to allow successful access to, and dilation of, the maxillary ostia and ethmoid infundibula.

The average patient self-reported discomfort during the procedure was 1.8 ± 1.8 (0=no pain; 10=severe pain). Patients who were administered oral sedative and narcotic pain medication prior to the procedure reported an average pain score of 1.1 ± 1.1 while those who did not receive any pre-operative medications reported intra-operative pain scores of 3.6 ± 2.0. None of the ostial dilation attempts had to be abandoned due to patient discomfort. The overall average time spent in the clinic per patient, from time of admission into the clinic procedure room until departure from the clinic post-procedure, was approximately one hour (59.9 ± 15.6 minutes). The total procedure time per patient from time of first local anesthetic injection to discharge was 28.4 ± 7.6 minutes while the total time to complete bilateral cannulation and dilation of the maxillary ostia and ethmoid infundibula was 16.7 ± 10.5 minutes. Bleeding after ostial dilation was minimal and no actions, such as the use of hemostatic agents or nasal packing, were required to control post-procedure bleeding. There were no complications reported during the procedure and all devices performed as intended without malfunction.

POSTOPERATIVE RESULTS

After discharge from the clinic, patients returned for follow-up evaluation at one week, one month and six months. During each follow-up, patients underwent a physical exam, nasal endoscopy, and completed the Sino-Nasal Outcome Test 20 (SNOT-20) questionnaire. The SNOT-20 is a validated sinus-specific quality of life survey that rates sino-nasal symptoms form 0 to 5 (0 = "no problem"; 5 = "problem as bad as it can be"). A decrease of 0.8 in the SNOT-20 score is considered clinically meaningful.[9]

Post-discharge, fifteen patients did not take any over-the-counter (OTC) or prescription (Rx) pain medication. For the six patients who used postoperative pain medication, the average duration of use was less than 2 days (OTC 1.9 days, Rx 1.2 days). Nineteen patients (90%) were able to return to normal activity within 24 hours and the average recovery time for all patients was 16.1 ± 17.8 hours.

Table 2 shows the mean SNOT-20 score at baseline and each subsequent follow-up time period through the end of the study. The mean SNOT-20 score at baseline before balloon dilation was 2.3 ± 0.8. The mean SNOT-20 improved significantly ($p<0.0001$) at each post-operative evaluation. This improvement was also clinical meaningful ($\Delta > 0.8$) as evidenced by a 1.5 decrease in mean SNOT-20 score by one month that was sustained over the duration of the follow-up period. Patient compliance to the follow-up visit schedule was excellent as 100% of the patients completed the SNOT-20 survey at one and six months.

During the six-month follow-up period, one patient was hospitalized for treatment of diabetes-related complications that were not related to that patient's sinus disease or balloon procedure. There were no other serious, or major, complications reported and none of the subjects underwent a revision sinus surgery (e.g., balloon or endoscopic sinus surgery) or additional sinonasal procedures over the duration of the study. At the end of the study, all (100%) patients answered that they would recommend the balloon procedure to a friend while 95% (21/22) of the patients indicated that they were satisfied with the outcome of the procedure.

Table 2: Change in Mean SNOT 20 Scores by Follow Up Duration

	All Subjects		Intrapatient Change (matched pairs[1])		
Time Point	**Mean ± SD**	**N**	**Change Δ from Baseline (Mean ± SD)**	**N**	**p-value**
Baseline	2.3 ± 0.8	21	-	-	-
1 Week	1.1 ± 0.7	20	-1.3 ± 0.6	20	<0.0001
1 Month	0.8 ± 0.5	21	-1.5 ± 0.9	21	<0.0001
6 Months	0.8 ± 0.6	21	-1.5 ± 0.9	21	<0.0001

[1]Only includes subjects with both baseline and specified follow-up interval data.

SUMMARY

Balloon dilation, whether used as a tool in "hybrid" procedures or as a stand-alone intervention in the physician office, has been demonstrated to be safe and efficacious. Previous published study results as well as the case series presented here offer consistent evidence that balloon dilation is safe and can be successfully performed under local anesthesia in the clinic office with minimal discomfort to the patient followed by rapid return to normal activities and sustained improvement in sinus symptoms over time.[5,8]

In addition, balloon dilation as a stand-alone treatment offers significant cost savings to both the healthcare system and patients alike when compared to ESS performed in the OR. For example, in 2012, the national average cost to treat a Medicare patient with bilateral maxillary and anterior ethmoid disease using traditional ESS techniques in the ambulatory surgery center (ASC) was $4,046 and the cost to treat in a hospital out-patient facility was $6,296. Treating this same patient with balloon dilation of the maxillary sinus ostia and ethmoid infundibula in the physician office has a cost to Medicare of $3,243. This cost differential would be even greater if it included the postoperative cost of post-procedure debridement which has been shown in studies to be performed more frequently after ESS than after balloon dilation.[8,10] The cost savings related to stand-alone sinus dilation performed in the physician office also extends to patients who are often required to pay a co-pay amount that is a percentage of the procedure cost.

This case series along with other published balloon literature together show that adults with uncomplicated sinus disease in the absence of significant polyposis, fungal disease, and other underlying pathologies that adversely affect the cilia or native mucosa are good candidates for stand-alone balloon dilation performed under local anesthesia in an office-setting. These patients when treated with stand-alone balloon dilation in the office can expect to experience lower out-of-pocket costs, a well-tolerated procedure, clinically meaningful reduction of sinusitis symptoms, a rapid return to normal activities, and a high degree of satisfaction.

References

1. Weiss RL, Church CA, Kuhn FA, Levine HL, Sillers MJ, Vaughn WC. Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. *Otolaryngol Head & Neck Surg*. 2008;139:S38-S46.
2. Levine HL, Sertich II AP, Hoisington DR, Weiss RL, Pritikin J. Multicenter registry of balloon catheter sinusotomy outcomes for 1,036 patients. *Ann Otol Rhinol Laryngol*. 2008 Apr; 117(4):263-270.
3. Plaza G, Eisenberg G, Montojo J, Onrubia T, Urbasos M, O'Connor C. Balloon dilation of the frontal recess: a randomized clinical trial. *Ann Otol Rhinol Laryngol*. 2011; 120:511-518.
4. Stankiewicz J, Truitt T, Atkins J, Winegar B, Cink P, Raviv J, Henderson D, Tami T. Two-year results: transantral balloon dilation of the ethmoid infundibulum. *Int Forum Allergy Rhinol*. 2012; 2:199-206.
5. Cutler J, Truitt T, Atkins J, Winegar B, Lanier B, Schaeffer BT, Raviv J, Henderson D, Duncavage J, Stankiewicz J, Tami T. First clinic experience: patient selection and outcomes for ostial dilation for chronic rhinosinusitis. *Int Forum Allergy Rhinol*. 2011; 1:460–465.
6. Eloy JA, Friedel ME, Eloy JD, Govindaraj S, Folbe AJ. In-office balloon dilation of the failed frontal sinusotomy. *Otolaryngol Head Neck Surg*. 2012; 146:320-322.
7. Albritton FD 4th, Casiano RR, Sillers MJ. Feasibility of in-office endoscopic sinus surgery with balloon sinus dilation. *Am J Rhinol Allergy*. 2012; 26:243-248.
8. Karanfilov B, Silvers S, Pasha R, Sikand A, Shikani A, Sillers M; for the ORIOS2 Study Investigators. Office-based balloon sinus dilation: a prospective, multicenter study of 203 patients. *Int Forum Allergy Rhinol*. 2012; 00:X-XX.
9. Piccirillo, JF; Merritt, MG; Richards, M. Psychometric and clinimetric validity of the 20-Item Sino-Nasal Outcome Test (SNOT 20). *Otolaryngol Head Neck Surg* 2002; 126: 41-47.
10. Kuhn FA, Church CA, Goldberg AN, Levine, HL, Sillers, MJ, Vaughan WC, Weiss, RL. Balloon catheter sinusotomy: one-year follow-up outcomes and role in functional endoscopic sinus surgery. Otolaryngology Head and Neck Surgery 2008; 139:S27-S37.

entellus MEDICAL™

866-620-7615
www.EntellusMedical.com