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TRANSNASAL BALLOON DILATION

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INTRODUCTION

Thirty-seven million Americans suffer from chronic rhinosinusitis (CRS). Treatment begins with medical therapy, and if this fails, endoscopic sinus surgery (ESS) is the mainstay of treatment. Medical treatment should be anywhere from 3 to 4 weeks and sometimes 12 weeks and includes the use of some or all of the following: antibiotics, steroid nasal sprays, oral steroids, antihistamines, leukotrienes, saline, analgesics, steam, and hydration.

The goals of ESS include improving aeration, ventilation, and drainage of the involved sinus or sinuses with removal of inflammatory tissue and/or osteitic bone.

ESS has been enhanced since its inception in the early 1980s. This advance has occurred as a result of better imaging of the sinuses with multiplanar computed tomography (CT) and the introduction of the endoscope. With the advent of powered instrumentation (microdebrider), surgical navigation, and most recently balloon catheter technology (BCT), the techniques and tools utilized in ESS have witnessed significant evolution in the last decade.

The concept of preservation of normal structures while simultaneously promoting drainage and ventilation of the sinuses has been pioneered for the last 35 years first by Messerklinger and Stammberger and then by Kennedy who introduced this into the United States in 1985 and termed this conservative approach “Functional Endoscopic Sinus Surgery.” Instrumentation used to accomplish this goal of preserving tissue while creating outflow drainage included forceps, curettes, and microdebriders.

Stammberger noted that delicate removal of the obstructing cells in the frontal recess allows frontal sinus outflow tract drainage, thereby preserving frontal sinus mucosa. Kennedy noted that following removal of diseased mucosa from a sinus, the regenerated tissue has remarkably diminished ciliary density and therefore recommended that a mucosal sparing technique be used wherever possible.

In an effort to be even more conservative with respect to tissue removal, sinus BCT was introduced into otolaryngology based on recent success observed with its application in cardiology, urology, gastroenterology, and vascular surgery. Balloon use was first reported in 2005 when a cadaveric study demonstrated its safety and feasibility in paranasal sinus dilation. This was followed by Bolger and Brown’s “first-in-man” study in which balloon catheter dilation was successfully performed on 10 patients with CRS.

Balloon technology has provided the surgeon with an additional tool to navigate the frontal sinus, sphenoid sinus, and maxillary sinus ostia. Transnasal balloon dilation, or better now called balloon sinus ostial dilation, allows the surgeon access via the nose into the sinus ostia with dilation of the narrowed ostium through balloon inflation. Particularly with respect to the frontal sinus, which has historically represented the most technically challenging of all the sinuses to access, balloon devices can assist in locating the frontal sinus ostium and its outflow tract with subsequent dilation of the involved sinus. If necessary, one can then perform traditional surgery on the frontal sinus if the balloon alone does not result in an adequate drainage pathway. The balloon device is designed to microfracture and mobilize the bony fragments surrounding the sinus ostia by inflating the catheter balloon to a specific diameter under high pressure.

The technology has been pioneered primarily by two companies: Acclarent, Inc. (Menlo Park, CA, USA), Relieva Spin device (Fig. 11.1), and Entellus Medical, Inc. (Maple Grove, MN, USA), Gen2 Xpress

Fig. 11.1

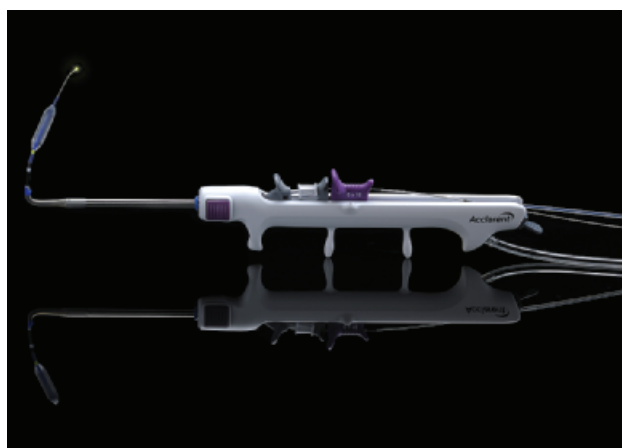


FIGURE 11.1
Relieva Spin device (Courtesy
of Acclarent Inc.).

device (Fig. 11.2). Acclarent began investigating the feasibility of this technology for the sinuses in 2002. Their balloon dilation device was approved by the U.S. Food and Drug Administration (FDA) in 2005 and launched as balloon sinuplasty. With this procedure, a guide catheter is placed into the nasal cavity under endoscopic visualization and a flexible guidewire is then placed into the catheter until it reaches the target sinus. A balloon catheter is then passed over the wire using the Seldinger technique and the sinus ostium dilated. Since that time, more than 6,500 otolaryngologists have been trained in a balloon sinuplasty, and more than 300,000 patients have been operated upon to date, with 30,000 having undergone this procedure in an in-office setting.

Entellus Medical recognized there was a problem gaining access to the maxillary sinus ostium transnasally with the original BCT. Since this was essentially performed as a blind procedure, accessory maxillary sinus ostia were often being cannulated instead of the true natural ostium. Consequently, they developed a transantral approach in which direct access to the maxillary sinus ostium was accomplished via the canine fossa so that there would be no manipulation within the nose. This device was referred to as the Functional INFundibular Endoscopic Sinus System and was approved by the FDA in 2008. Subsequently, Entellus developed the XprESS Multi-Sinus Dilation Tool, a balloon device that consists of a curved sinus seeker with a malleable tip and overlying slideable balloon for transnasal endoscopic cannulation of the sinuses. Unlike the Acclarent balloon, no wire or catheter is necessary.

Balloon use with respect to sinus surgery therefore is threefold:

- A. Stand-alone:** The balloon is used to find and dilate the sinus ostium (e.g., the maxillary sinus) without tissue removal or any additional sinus surgery being performed.
- B. Hybrid procedure:** (a) The balloon is used to identify the ostium (e.g., the frontal sinus) and dilate it, and if need be, a traditional ESS is then done on an unrelated affected sinus. This is one form of hybrid surgery,

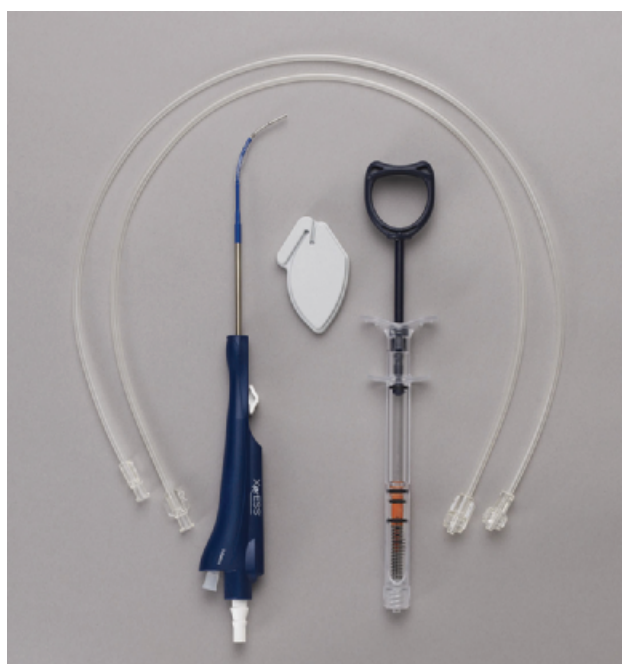


FIGURE 11.2
Gen2 Xpress device
(Reprinted with permission
from Entellus Medical, Inc.).

that is, stand-alone on one sinus and ESS on another sinus. (b) The balloon is used as an ostium seeker, (e.g., frontal sinus ostium) with traditional ESS performed on the same sinus once its ostium has been located and dilated. This is another form of hybrid surgery, that is, balloon dilation and ESS on the same sinus.

HISTORY

- The patient typically has limited disease of the sinuses with or without minimal ethmoid involvement. This may be:
 - An isolated frontal or both frontal sinuses
 - An isolated maxillary or both maxillary sinuses
 - Isolated sphenoid or both sphenoid sinuses
 - A combination of any of the above
- The best uses are for the elderly debilitated individual who cannot undergo an extensive ESS procedure nor have general anesthesia; this can be done in an office or intensive care unit (ICU) setting.
- Patients with a bleeding disorder, where no tissue is to be removed, and the ostium can be dilated to promote drainage.
- As a guide in gaining access to a sinus, in particular the frontal sinus (whereby it can be used as a frontal sinus seeker). This is now used by many surgeons, who over the years have found it difficult to find and navigate the frontal sinus ostium and the nasofrontal recess where the anatomy can be complex and rather confusing.
- Since this is a surgical procedure, albeit conservative, the patient should still always be treated first with appropriate medical therapy including those medications previously discussed and should be tried for a minimum of 3 to 4 weeks.
- If this medical therapy fails, then the patient can undergo ESS, and the balloon would be a reasonable first choice as a stand-alone procedure or part of a hybrid procedure.
- The history should include nasal congestion, postnasal drip, facial pain, headache, fever, anosmia, cough, and general malaise in accordance with the clinical practice guidelines and diagnostic criteria for adult CRS as established by the American Academy of Otolaryngology-Head and Neck Surgery Foundation in 2007.

PHYSICAL EXAMINATION

- After confirming a history consistent with CRS, an endoscopic evaluation of the nose and sinuses must be performed to allow the surgeon to document any anatomical abnormalities that may be present (e.g., deviated septum), evaluate the sinus ostia, and determine if there is any polypoid degeneration or purulent exudate evident in the region of the ostiomeatal complex.
- Nasal endoscopy allows the surgeon to determine the extent of the disease, which sinuses are involved, as well as the status of the ostiomeatal complex and sinus ostia.
- A CT scan examination of the sinuses is indicated if medical therapy has failed and should be obtained prior to any surgical manipulation be it a balloon alone, ESS, or a hybrid procedure.
- The CT scan of the sinuses should always include the ability to use surgical navigation should this be necessary.
- For balloon use alone, one must be able to access the involved sinus. Consequently, if there is a deviated septum, this may have to be corrected first and would preclude balloon dilatation being performed as an in-office procedure.
- Diffuse nasal polyposis and extensive rhinosinusitis may be a contraindication for balloon use as a stand-alone procedure but can be used as a hybrid procedure. Furthermore, if the diffuse disease were present in a sinus (e.g., the frontal sinus), the balloon may be used as a frontal sinus seeker to allow the surgeon to gain access into the frontal sinus, dilate the frontal sinus, and then perform ESS on the nasofrontal recess.
- Ethmoid sinusitis is a contraindication for balloon use, as it is not indicated for access or surgery within the ethmoid sinus.
- Presence of extensive scarring or osteoneogenesis within the frontal recess secondary to prior surgery and long-standing infection can impede cannulation of the frontal sinus outflow tract and preclude the use of the balloon.

INDICATIONS

- Elderly patients
- Debilitated patients
- Localized pathology in one or more sinuses
- Bleeding disorders
- Frontal sinus seeker
- Office-based procedures

- ICU-based procedures
- Revision procedure, especially if in the office

CONTRAINDICATIONS

- Diffuse nasal polyposis
- Complications of sinusitis—orbital or intracranial
- Ethmoid sinusitis
- Possible neoplastic sinus disease
- Markedly deviated septum
- Osteoneogenesis

PREOPERATIVE PLANNING

- A decision needs to be made as to whether the procedure will be performed in the office or the operating room.
- An office-based procedure requires a compliant patient, limited pathology, a septum that is not so deviated that it limits access to the sinus ostia, and appropriate staff and instrumentation.
- A documented history of rhinosinusitis, recurrent, acute, or chronic having failed optimal medical therapy.
- Endoscopic evaluation to confirm the presence of rhinosinusitis.
- CT sinus evaluation—coronal, axial, and sagittal views.
- Surgical navigation if necessary.
- Lengthy discussion with the patient once medical therapy has failed—discussion will include the risks, benefits, and alternatives.
- MRI not necessary unless there is concern about a complication of rhinosinusitis, be it orbital or intracranial, or concern of a neoplasm.
- Evidence of complex frontal sinus anatomy (i.e., Type III frontoethmoidal cells) should be noted to avoid inadvertent cannulation of frontoethmoidal or supraorbital cells instead of the true frontal sinus ostium.

SURGICAL TECHNIQUE

The procedure can be done under local or general anesthesia in an operating room, office setting, or rarely an ICU.

The balloon can be used as a stand-alone procedure whereby no tissue is removed and the natural ostium of the sinus is enlarged, thereby promoting ventilation and drainage of the sinus. This can be performed on one or both frontals, one or both maxillary, one or both sphenoids, and any combination or all of the above as a stand-alone procedure. Balloon dilation cannot be performed in the ethmoid sinuses. Consequently, if ethmoid sinus surgery is necessary, then traditional ESS must be performed.

A stand-alone frontal sinus dilation can be performed in which the guidewire is used to locate a sinus ostium, in particular the frontal sinus, and the balloon is passed over the guidewire into the nasofrontal recess and inflated so as to move aside any bony partitions and thereby enlarge the frontal sinus drainage pathways as described by Bolger et al.

If dilation alone is insufficient to promote drainage and the frontal sinus has been located and the drainage pathway enlarged, traditional ESS on the nasofrontal recess can be performed to further enlarge the drainage pathway of the frontal sinus hybrid procedure on the same sinus. The endoscopic procedure could be carried out using a curette, upbiting through-cutting forceps, or a microdebrider (hybrid procedure). Surgical navigation could be used in conjunction with the endoscopic procedure of the nasofrontal recess if necessary.

Another form of hybrid procedure would be that in which a stand-alone procedure is done on one sinus (e.g., a frontal sinus) and traditional ESS is done on another sinus (such as the ethmoid sinuses), or if the uncinate process needed to be removed, one could utilize endoscopic sinus surgical procedures to remove the uncinate process so that the balloon can gain access into the maxillary sinus.

DESCRIPTION OF TECHNIQUE

Operating Room

If a procedure is performed in the operating room, the patient is placed on the operating table in the supine position and endotracheal anesthesia is established. 4% cocaine is applied topically in the nose. The mucosa is injected with 1% Xylocaine and 1:200,000 epinephrine. Depending on the extent of the surgery, one injects the septum, the inferior turbinates, the middle turbinates, the ostiomeatal complex, the uncinate process, the ethmoid bulla, and the sphenoid area. Usually, 10 to 15 mL of Xylocaine with 1:200,000 epinephrine is injected.

The cocaine pledgets are left in place for 10 minutes while the surgeon scrubs and preps the patient. During this time, the surgeon will review the CT scan in detail one more time. A discussion with the anesthesiologist takes place with respect to placement of the endotracheal tube, which should be to the left and down low so that it does not hamper the surgeon's ability to operate within the nose. Ten to twelve milligrams of dexamethasone is given intravenously. Antibiotics are only administered if there is evidence of acute infection.

Surgical navigation is used if frontal, sphenoid, or posterior ethmoid surgery is contemplated, and then an appropriate headset is applied to the forehead. Surface registration is carried out. Accuracy of the instruments is usually checked and calibrated. At this time, another review of the CT scan is carried out during surface registration.

Instruments to be used throughout the procedure include 0-degree, 30-degree, 45-degree, and 70-degree telescopes. The 0-degree scope is used more than any other scope. A digital video tower is used with the capability to view on the screen, take photographs, and record the procedure on DVD or CD.

Prior to performing surgery, I inspect the nasal cavity for the following:

1. Presence or absence of a septal deviation
2. Presence or absence of nasal polyps
3. Inferior turbinate hypertrophy
4. Anatomy of the ostiomeatal complexes bilaterally, especially the uncinate process and middle turbinate
5. Any presence of purulent exudate exuding from the ostiomeatal complexes

If there is a deviated septum and this is compromising the ability to use the balloon, then I carry out a septoplasty first. Following this, I evaluate the frontal sinuses to be operated upon. Preferably, no manipulation of the ostiomeatal complex is necessary unless the middle turbinate is lateralized or engorged, and then gentle manipulation of the middle turbinate medially is done using a Freer elevator. The middle turbinate can be gently crushed with a noncutting straight forceps to provide more room for the guide catheter. The uncinate process can be gently medialized using an ostium seeker in a superior-to-inferior fashion if the frontal sinus drainage pathway is lateral to the frontal sinus. This allows for the guide catheter to be easily placed under the uncinate process and will allow easier manipulation of the guidewire into the nasofrontal recess (Fig. 11.3).

When working on the frontal sinus, I use the balloon device to act as a frontal sinus seeker. The frontal sinus guide catheter by Acclarent is placed lateral to the uncinate process. The Luma Light guidewire is then passed into the guide catheter gently, and it is slowly advanced by the operating assistant so that the surgeon can see the wire going into the nasofrontal recess. The wire is then gently passed upward in the direction of the nasofrontal recess, and this is viewed endoscopically on the screen. The operating room lights are turned down, and the surgeon observes the wire passing into the frontal sinus as it transilluminates the frontal sinus (Fig. 11.4). I confirm this by rolling the wire in my fingers and visualizing the light moving around in the frontal sinus under the anterior table of the frontal sinus. The guidewire can be inappropriately passed into

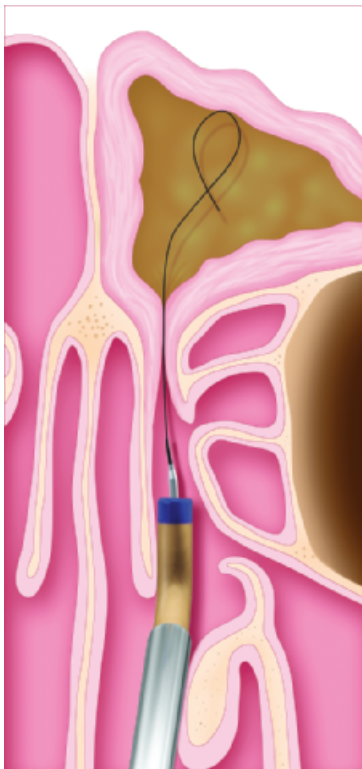


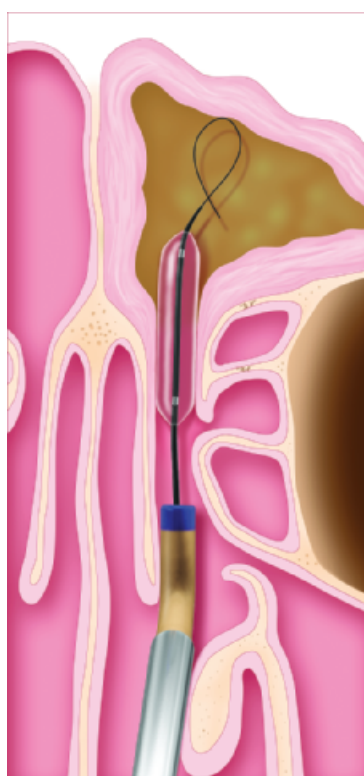
FIGURE 11.3

Placement of the guidewire into the nasofrontal recess (Courtesy of Acclarent Inc.).

**FIGURE 11.4**

The guidewire passing into the frontal sinus, transilluminating the frontal sinus (this is my patient).

a supraorbital cell, and the transillumination will be different, as one will not see the light moving under the anterior table and this indicates that I know that the wire is not in the frontal sinus. If the wire does not pass into the frontal sinus at the first or second attempt, then the guide catheter is realigned more superiorly or laterally until this occurs. It does not always enter the frontal sinus the first time, and sometimes, it does not enter at all, in particular in revision cases, in diffuse polyposis, or if there is significant stenosis or scar tissue in the nasofrontal recess. A few attempts should be tried, and if this is not successful, then a traditional approach to the frontal sinus with or without image guidance may be necessary. Image guidance is not necessary when threading the Luma wire into the frontal sinus. Once there is confirmation of the wire being in the frontal sinus, then the balloon is passed over the wire and inflated (Fig. 11.5). I prefer to use a 5 × 16 mm balloon, but a larger

**FIGURE 11.5**

Passing the balloon over the wire and inflating it (Courtesy of Acclarent Inc.).

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balloon can be used if necessary. The surgical assistant will gently inflate the balloon with the surgeon observing the balloon dilation. The surgical assistant will call out as the balloon is dilated starting with 2 PSI, 4 PSI, 6 PSI, 8 PSI, 10 PSI, and if need be as much as 12 PSI. This is a slow and gentle process. The balloon is left inflated for 10 to 15 seconds. The balloon is then deflated, and the guide catheter, wire, and balloon are removed as one. The balloon can be manipulated within the nasofrontal recess and advanced or withdrawn minimally and reinflated if need be, in particular if the nasofrontal recess is long. If it is medically indicated, the frontal guide catheter is then placed under the opposite uncinate process to dilate the second nasofrontal recess, and the process is repeated in the same manner as for the first frontal sinus.

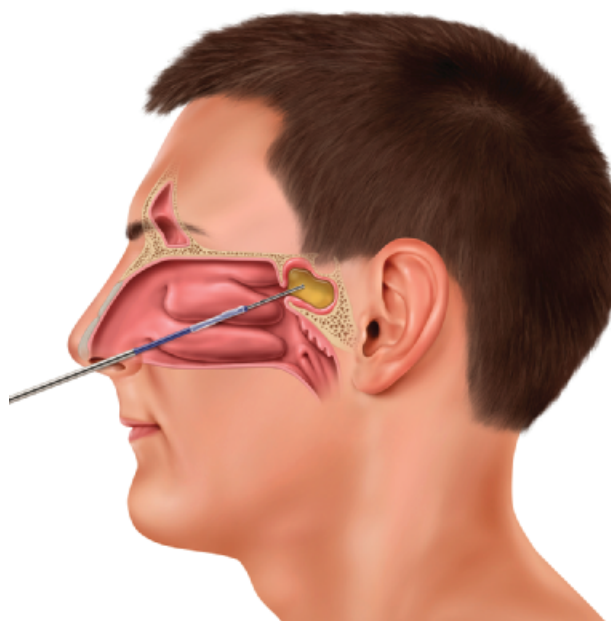
The nasofrontal recess is inspected with a 30-degree, 45-degree, or 70-degree scope to be sure that there will be adequate drainage from the frontal sinus (Fig. 11.6). If visualization of the frontal drainage area is such that there is still concern about ventilation and drainage, then additional surgery may be needed to further enlarge the nasofrontal area should this be necessary. An upbiting through-cutting forceps, curette, or microdebrider can be used. If, on the other hand, the surgeon wishes to use the balloon as a stand-alone and not remove any tissue, then no additional ESS is necessary. If possible, visualization into the frontal sinus should be carried out and further manipulation within the frontal should be performed should the surgeon so wish. I irrigate and flush out the sinus, obtain cultures, and instill medications into the sinus at this time.

If the surgeon uses surgical navigation, then it is not necessary to use the wire to locate the sphenoid sinus ostium. If one prefers to use the balloon rather than surgical navigation, then the natural ostium of the sphenoid sinus can be located medial to the superior turbinate and this can gently be entered with a wire (Fig. 11.7). Transillumination of the sphenoid sinus can be carried out, but it is extremely difficult to confirm that one is within the sinus in this fashion. Once in the sinus, the balloon is passed over the wire and the balloon is dilated once again to about 10 PSI (Fig. 11.8). The sphenoid sinus guide catheter is straight so that it can pass directly into the natural ostium of the sphenoid (Fig. 11.9). If the ostium is not patent, then one can gently manipulate the ostium with a probe or a Cottle elevator without damaging or traumatizing tissue, thereby gently enlarging the ostium. Once I have access into the sphenoid, the guide catheter will be placed up against the sphenoid sinus ostium. I then pass the guidewire into the sphenoid sinus, and then the balloon is passed over the wire and inflated to 10 PSI causing dilation of the ostium.

Each sinus has a different Acclarent guide catheter with a different angulation necessary to enter the appropriate sinus, while Entellus has a single malleable guide catheter that can be appropriately bent to suit the sinus pathway. With respect to the maxillary sinus, I do not dilate the maxillary sinus ostium when performing surgery in the OR, as I prefer to gain access to the maxillary sinus after resecting the uncinate process and enlarging the maxillary sinus ostium with the use of a microdebrider. If one wishes to use the balloon for the maxillary sinus, then one can gently manipulate the uncinate process medially or preferably remove the uncinate process, and this will give good visualization of the maxillary sinus ostium when using a 30- or 45-degree nasal endoscope (Fig. 11.10A–C). There have been many documented studies demonstrating that one may

**FIGURE 11.6**

Inspecting the nasofrontal recess after balloon dilation (Courtesy of Acclarent Inc.).

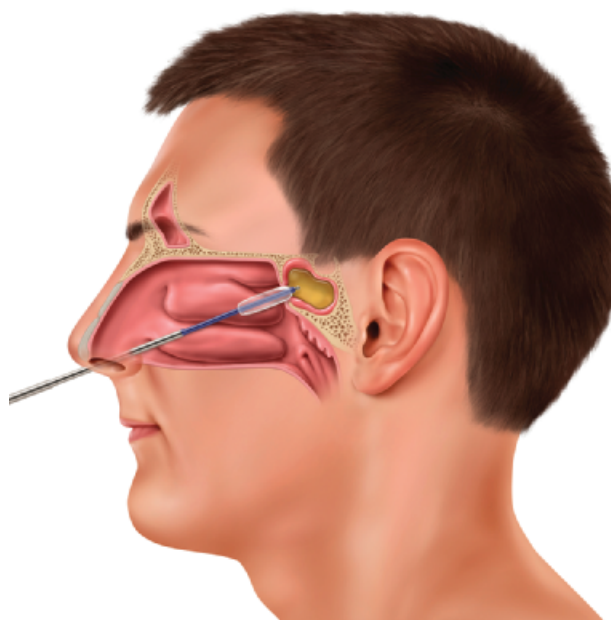
**FIGURE 11.7**

Entering the natural ostium of the sphenoid sinus with a wire (Reprinted with permission from Entellus Medical, Inc.).

enter or create an accessory sinus and then dilate it rather than the natural ostium, thereby preventing adequate drainage from the maxillary sinus. Accordingly, I always remove the tunicate process when doing ethmoid and/or maxillary sinus surgery, and should I wish to enter the maxillary sinus with a balloon, I remove the tunicate process, thereby allowing better visualization of the maxillary sinus ostium.

Following the balloon dilation procedure, I can then proceed with traditional ESS of the ethmoid sinuses if this is necessary. I could perform ESS of the anterior and/or posterior ethmoids on one or both sides and do traditional ESS on the other sinuses that one did not dilate with the balloon. Furthermore, I can perform surgery on a sinus that may have been dilated should I feel that more enlargement of the drainage area is necessary. In this manner, the balloon becomes a tool, one part of the surgical armamentarium of the operating surgeon to be used as necessary.

Following the surgical procedure, hemostasis is obtained. If a septoplasty was carried out, I may consider splinting the septum for 1 week. If any manipulation was carried out on the middle turbinates, one could support the middle turbinates with a spacer. I use compressed MeroGel (Medtronic Inc.) or Gelfoam, and I place it under the middle turbinate and leave it in place for 1 week. No packing is used, but a small cotton ball may be placed in each nostril and left in place overnight, to be removed on the first postoperative day. Following this procedure, the patient is awakened, extubated, and taken to the recovery room. The patient is observed in the recovery room for at least 1 hour and then discharged.

**FIGURE 11.8**

Passing the balloon over the wire and dilating to about 10 PSI (Reprinted with permission from Entellus Medical, Inc.).

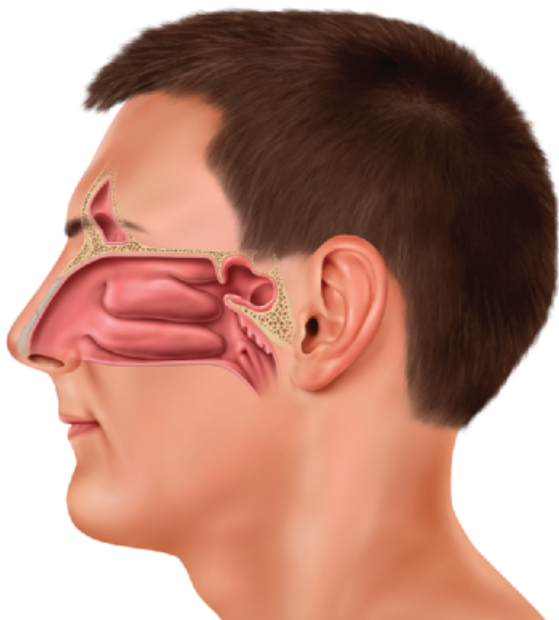


FIGURE 11.9
The natural ostium of the sphenoid (Reprinted with permission from Entellus Medical, Inc.).

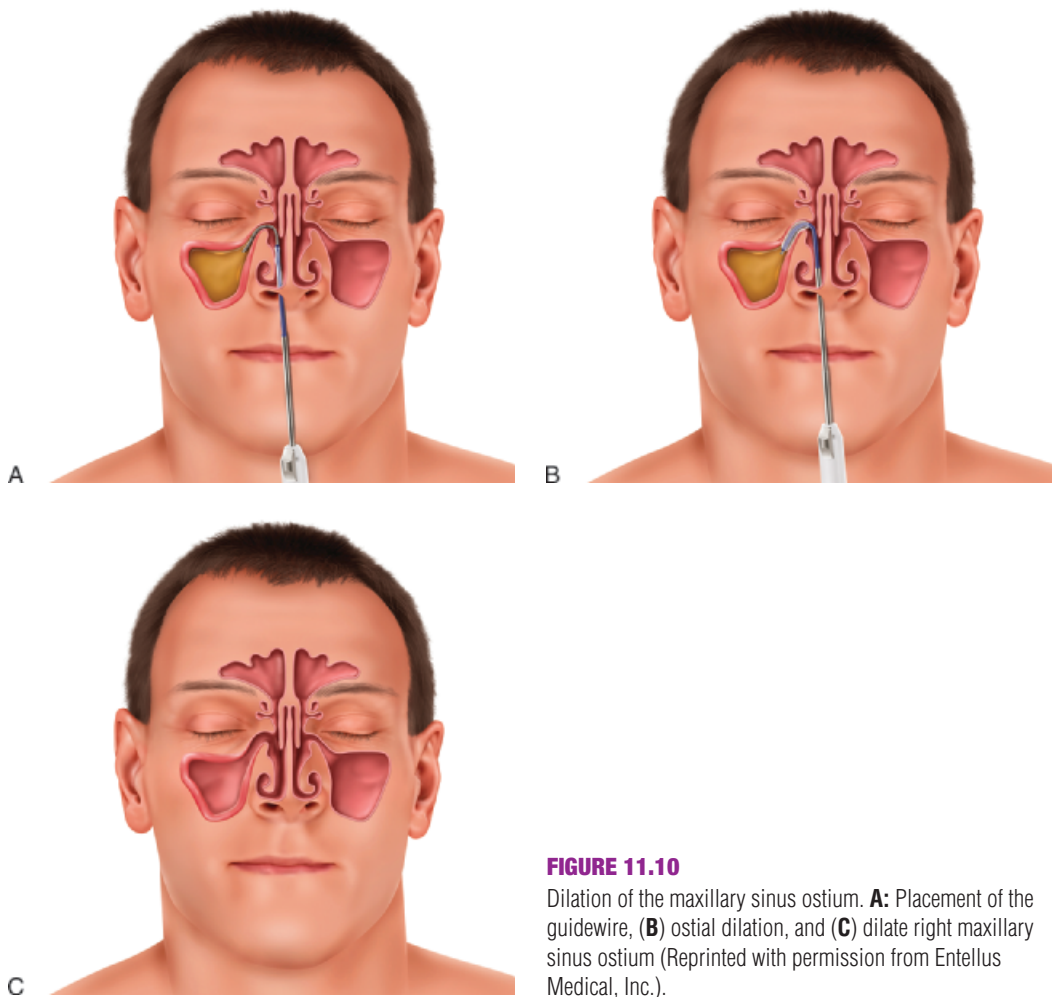


FIGURE 11.10
Dilation of the maxillary sinus ostium. **A:** Placement of the guidewire, **(B)** ostial dilation, and **(C)** dilate right maxillary sinus ostium (Reprinted with permission from Entellus Medical, Inc.).

OFFICE PROCEDURE

In the office setting, an operating chair; a digital tower; 0-degree, 30-degree, and 45-degree telescopes; a well-trained nursing assistant; and the ability to apply adequate topical anesthesia and injection of 1% Xylocaine with 1:200,000 epinephrine are necessary. The team must be prepared for any unexpected medical reactions from the injectable materials and/or the surgical procedure.

The technique itself is the same in the office setting as it is in the operating room. An office procedure can best be performed if there is a markedly deviated septum on the involved side. The procedure can be performed on from one to six sinuses, and one can use either the Acclarent or Entellus dilating equipment.

With the Entellus Express, one can use one balloon device to operate on all six sinuses (namely, the maxillary, sphenoid, and frontal sinuses) unlike the Acclarent device, which needs a different guide catheter depending on the sinus involved. With the Entellus system, the guidewire is malleable and can be manipulated such that it could be straight for the sphenoid, angled minimally for the frontal, and angled more so for the maxillary sinus. It is an all-in-one hand instrument, and the balloon is gently passed over the wire and inflated with a syringe up to 10 PSI. The Acclarent Relieva Spin device allows the surgeon to control the insertion of the Luma guidewire and balloon with one hand, thus making reliance on an assistant less important. The in-office procedure is a cost-saving measure, as it eliminates the facility fee and the general anesthesia fee. Recovery from an in-office procedure is much quicker since there is no general anesthetic and no ethmoid surgery, septoplasty, or turbinectomy.

POSTOPERATIVE MANAGEMENT

- Saline nasal sprays 3 to 10 times per day for the 1st month following surgery.
- Oral steroids, preferably a steroid tapering dose pack for 6 days.
- Antibiotics for 5 days if an infection is noted.
- Nasal steroid sprays for 1 month, especially if allergic or inflammatory.
- Analgesics as necessary.
- First postoperative visit depends on the nature of the surgery. If a hybrid procedure and/or septoplasty was performed, one will see the patient on day 1 or 2 and day 7. On day 1 or 2, cotton balls are removed. There is no packing. On day 7, the nasal splints are removed if a septoplasty was done.
- If extensive surgery is performed, especially on the ethmoid sinuses, even though a balloon was used in the sinuses, then debridement is performed at 7 days if necessary.
- If a stand-alone balloon only is done and no septoplasty or ethmoid surgery, then the patient is seen on the seventh postoperative day. The nose is inspected via endoscope and a gentle debridement carried out if necessary depending on whether or not there were crusts, clots, or scar tissue noted. If none of the above is seen on endoscopy, then no debridement is necessary.
- Debridement is dictated by the nature of the underlying medical problem (e.g., diffuse nasal polyposis or extensive rhinosinusitis or extensive nasal and sinus surgery).
- If minimal surgery (e.g., stand-alone balloon dilation only) in a clinical setting is minor, then no debridement is necessary.
- The patient is seen weekly for 4 weeks after the 1st week.
- The patient is seen every 3 months for the 1st year, at which time nasal endoscopy of the nose is carried out at each visit after the 1st month.
- Continued medical therapy for the nose is dictated by the clinical scenario, in particular significant nasal allergies.

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COMPLICATIONS

Complications from balloon dilation of the sinuses are extremely rare, although the same complications that occur with traditional ESS can occur. When a hybrid procedure is carried out at the time of a stand-alone procedure, there is a greater risk for potential complications due to potential risks of ESS.

RESULTS

These have been extremely good as are evident by the numerous studies in the literature.

A prospective, multicenter clinical trial of 115 patients then ensued, referred to as the clinical evaluation to confirm safety and efficacy of sinuplasty in the paranasal sinuses or CLEAR study. Initially published in 2007, the CLEAR study investigated durability of the sinus ostial dilation, safety profile, and outcomes after 6 months. 1- and 2-year follow-up studies were subsequently published in 2008. Statistically significant decreases in SNOT-20 and Lund-MacKay scores were reported after 2 years, with 85% of patients reporting symptomatic improvement. The safety and effectiveness of this technique was also shown in a large-scale “real-world” registry of 1,036 patients in which 96% experienced symptomatic benefit after an average follow-up of 40 weeks

with no adverse events. It should be acknowledged, however, that the aforementioned studies were single-armed, uncontrolled, nonrandomized, trials sponsored by the device company Acclarent Inc. (Menlo Park, CA, USA).

My personal experience so far has been very positive for the following reasons:

1. Easier access to the frontal sinus both in the office and the operating room
2. Confirmation by transillumination that the tip is in the frontal sinus
3. Ability to perform limited office-based procedures in the elderly or debilitated patient in whom general anesthesia and/or traditional surgery may not have been possible

PEARLS

- Balloon technology helps to locate the frontal sinus drainage pathway area and gain access to the frontal and document being in the frontal sinus by transilluminating the frontal sinus.
- Luma guidewire facilitates confirmation of the frontal sinus.
- Balloon sinuplasty is a tool that assists in identification of the natural ostium of the frontal sinus safely. The guidewire can be used in difficult and obstructive areas to promote drainage from the frontal sinus by manipulating frontal sinus cells, agger nasi cells, supraethmoid cells, and supraorbital cells and pushing these bony partitions aside.
- A review of the axial, coronal, and sagittal CT allows one to better evaluate the nasofrontal recess.
- Radiation exposure from fluoroscopy is avoided with use of the Luma Light guidewire.
- Office procedures are possible and can assist in dilation of a stenotic frontal, maxillary, or sphenoid sinusotomy postoperatively.
- Associated with less pain and discomfort postoperatively.
- Less postoperative follow-up and/or office visits needed.
- Less postoperative debridement necessary.
- Prior medical management before balloon dilation is important.
- Allows for a faster recovery.
- Useful in the elderly debilitated patient.
- Useful in the patient with a bleeding disorder.
- Minimally invasive.
- Minimal if any complications.
- Can be done in an ICU setting.
- A well-trained assistant is critical.

PITFALLS

- Inability to access a sinus if stenosed or polypoid swelling, adhesions, or neoosteogenesis noted.
- Maxillary sinus dilation of an accessory maxillary sinus ostium in error would dilate this accessory ostium and can mislead the surgeon into believing the natural ostium was dilated.
- Image guidance may be required for the sphenoid.
- Cannot be used for the ethmoid sinus.
- Inability to remove osteitic bone in stand-alone procedure.
- Inability to remove polypoid tissue in stand-alone procedure.
- Stand-alone balloon-only procedure does not permit a tissue diagnosis.
- Balloon only may not give as wide an access to the involved sinus as traditional ESS, and this may be important in the postoperative instillation of necessary medications.
- No pathologic confirmation is possible in the stand-alone procedure since no tissue is removed.
- Expensive technology is required for office procedures.
- Significant training is required for office procedures.
- If imaging is required (e.g., C-arm fluoroscopy), the resulting radiation exposure can be hazardous to both patient and surgeon.
- Some insurance carriers do not reimburse stand-alone procedures.
- Coding and reimbursement for stand-alone procedures continue to be a problem with some insurance carriers in spite of the fact that Medicare approves reimbursement.

INSTRUMENTS TO HAVE AVAILABLE

- Nasal speculum
- Nasal endoscopes 0, 30, and 45 degrees
- Ostium seeker

- Cottle or Freer elevator
- Nasal suction
- Nasal polypectomy forceps
- Video tower
- O₂ and pulse monitors if possible
- Balloon equipment
- 1% lidocaine with 1 in 200,000 epinephrine
- 4% topical lidocaine
- Topical neosynephrine
- Appropriate operating facility

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DISCLOSURES

I have nothing to disclose with respect to the subject matter of this chapter, but I am on the Speaker's Bureau for Meda and Teva.

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