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MINIMALLY INVASIVE TECHNIQUES

Functional endoscopic dilatation of the sinuses (FEDS): Patient selection and surgical technique

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Current treatment options for patients with chronic rhinosinusitis, defined by Benninger et al as a group of disorders characterized by inflammation of the mucosa of the nose and paranasal sinuses of at least 12 consecutive weeks' duration, range from medical therapy to surgical intervention in the form of functional endoscopic sinus surgery (FESS). While the potential causes of chronic rhinosinusitis are diverse, an underlying mechanism is inflammation of the mucosa that leads to edema and occlusion of the sinus ostia, which causes ineffective mucociliary clearance, mucus accumulation, and subsequent infection. Those patients without an anatomic cause for obstruction (such as polyps), who have failed medical therapy, could benefit from a procedure less invasive than FESS. Sinuplasty, a new technique of sinus ostia balloon dilatation, is specifically aimed at restoring ostium patency without removing tissue, and is performed with the patient under local anesthesia, thus decreasing the morbidity associated with FESS. In this article, we present the patient selection criteria and technical aspects of sinuplasty.

Chronic rhinosinusitis (CRS) affects approximately 31 million Americans.[1] The costs associated with medical expenditures as well as the impact on work efficiency are enormous, which makes this problem a significant priority in terms of the search for better treatment strategies supported by clinical evidence.[2] Treatment options include medical therapy, allergic management, and surgical intervention. Obviously, surgery is reserved for those patients who do not respond to medical therapy and is usually for those who have endoscopic or computerized tomography (CT) evidence of significant mechanical obstruction of the sinus ostia in the form of polyps or inflamed mucosa.[3] The goal of surgery is to reopen the sinus ostium and allow the return of ciliary function. Many patients with recurrent acute rhinosinusitis respond well to medical therapy, but sinusitis frequently recurs after treatment.

In many cases, patients have no obvious underlying mechanical obstruction affecting the ostia, or they may have mild mucosal thickening in between episodes of infection. Often, some of these patients are not considered surgical candidates because their CT findings may not justify the morbidity and risk associated with endoscopic sinus surgery. On the other hand, many are considered candidates because of the failure to control disease, but they decline surgery because of the morbidity and risks involved. Of the 37 million Americans affected by sinusitis each year (both acute and chronic),[4] approximately 31 million are affected by chronic symptoms, and approximately 330,000 undergo sinus surgery annually.[5] Thus, more than 30 million Americans continue to suffer symptoms and their associated effects on their quality of life. Some of these patients may be candidates for a minimally invasive technique to improve sinus health. Many patients who currently undergo functional endoscopic sinus surgery (FESS) may benefit from the less invasive sinus ostia balloon dilatation technique, which may be a valuable tool in conjunction with classical FESS, to cannulate the frontal sinus in difficult situations, such as revision surgery.

A Food and Drug Administration-cleared balloon catheter system has recently been introduced as a potential min-

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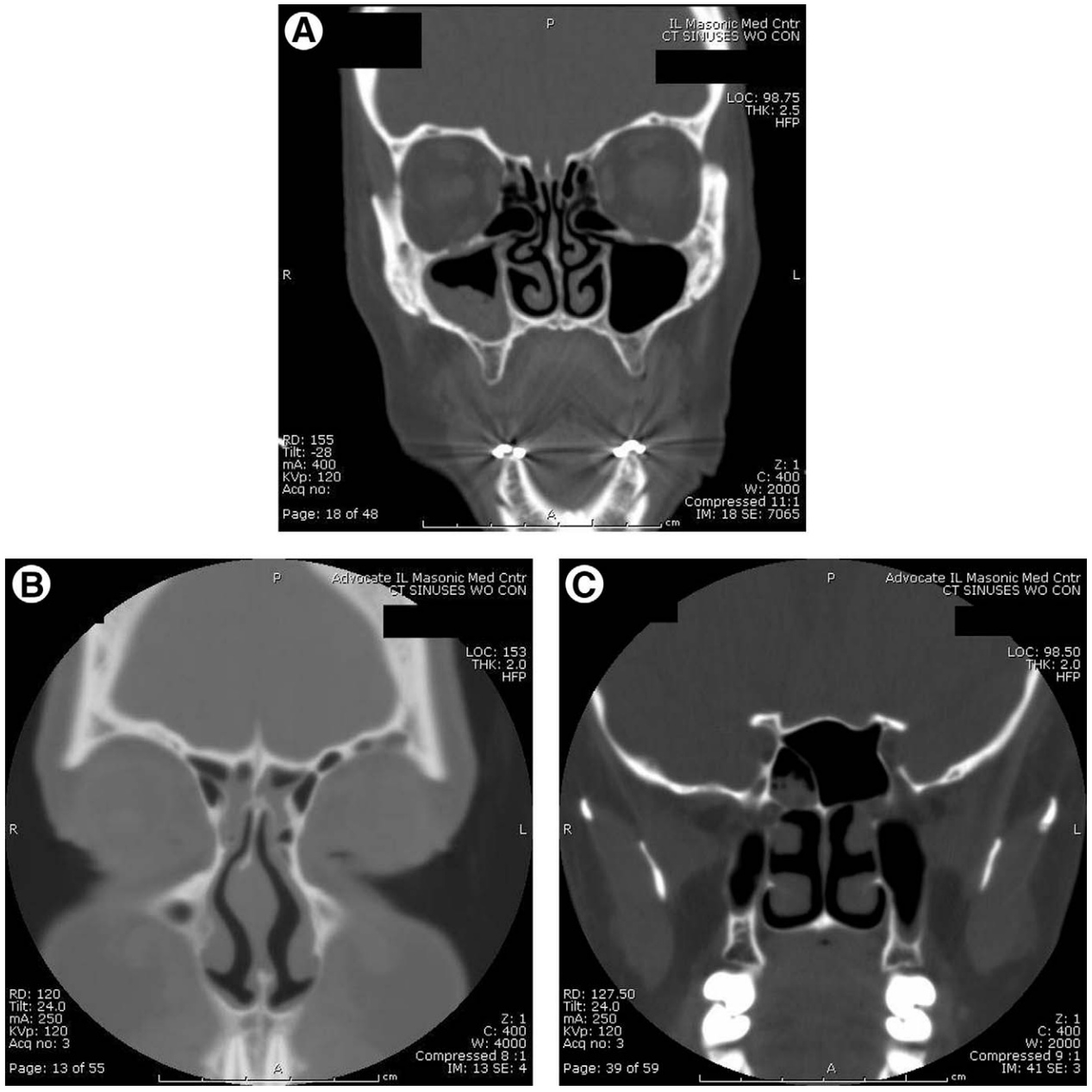

Figure 1 Noncontrast CT of the sinuses showing sinusitis of the right maxillary sinus (A), sinusitis of the bilateral frontal sinuses (B), and sinusitis of the right sphenoid sinus (C).

imally invasive, ambulatory strategy for the treatment of CRS. The system follows the principles of over-the-wire, catheter-based balloon dilatation, commonly used in vascular and urologic surgery, as well as in interventional cardiology. What this system accomplishes specifically for CRS is the dilatation of the sinus ostia by advancing balloon catheters under fluoroscopic guidance to the narrowed segment and inflating them with high pressure. This system is designed for the insertion of special catheters for sinus lavage, drainage, and antibiotic irrigation as well. The dilatation of the ostium also allows for biopsies in situations in which intrasinus masses may represent a neoplasm.

Sinuplasty provides a new set of tools, designed to dilate the natural ostia without tissue removal but with some possible tissue injury. It is not a substitute for FESS but may be an attractive option in select patients.[6] This article describes patient selection and operative technique for functional endoscopic dilatation of the sinuses (FEDS). Obviously, only long-term studies will be able to determine its efficacy and establish its ultimate place in the treatment scheme of CRS. We describe the technique for fluoroscopic-guided sinuplasty with the Relieva™ Sinus Balloon Catheter System (Acclarent, Inc, Menlo Park, CA).

Patient selection

Patient selection, as with any other surgical intervention, is an essential starting point in testing the efficacy of new surgical devices. Inclusion criteria for sinuplasty include history of recurrent rhinosinusitis, despite antibiotics, topi-

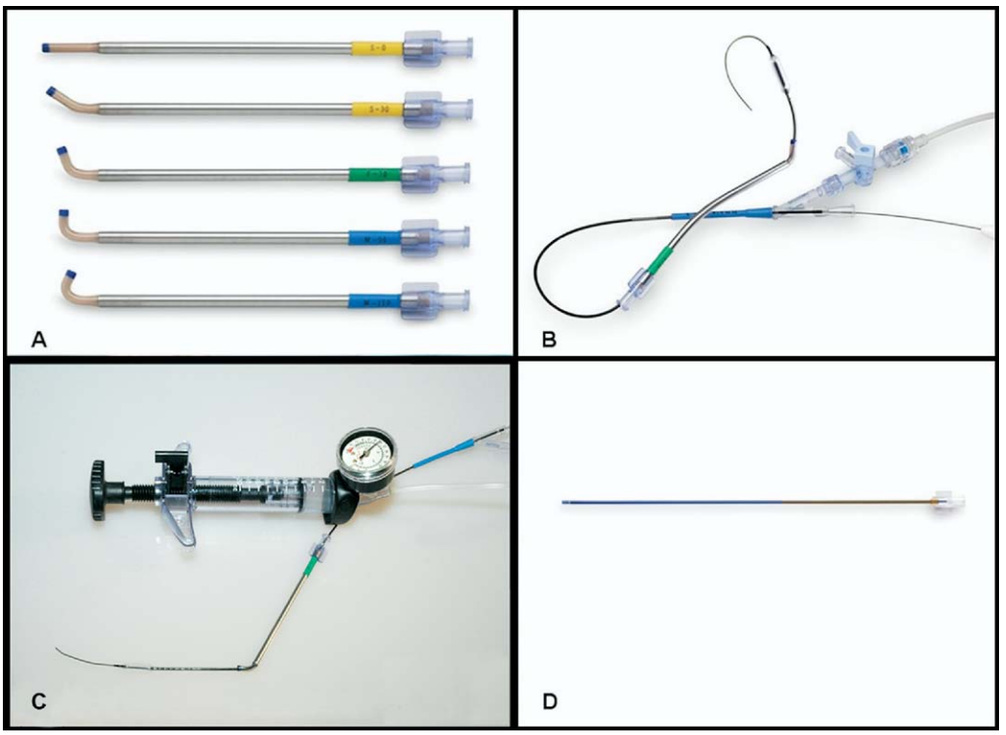

Figure 2 Balloon Sinuplasty equipment (Acclarent, Inc). Sinus guiding catheters (A). From top to bottom: 0°, 30°, 70°, 90°, and 110°. Sinus balloon catheter, passed over a guidewire into the sinus guiding catheter (B). Inflation device, consisting of a high-pressure piston syringe and a manometer (C). Figure shows device attached to balloon catheter. Sinus lavage catheter (D). (Image courtesy of Acclarent, Inc.)

cal steroids, and allergic management. In addition, the patient may have either a persistently abnormal CT after at least 4 continuous weeks on antibiotic treatment or an abnormal CT during treatment with post-treatment normalization, with 3 or more recurrences per year (Figure 1). Patients with these indications for the use of sinuplasty devices are probably the best candidates to undergo balloon dilatation of the sinus ostia under local anesthesia, as described in the "Technique" section.

In addition to its potential value in the treatment of CRS, sinuplasty has been found, in our experience, to have 2 other applications. Frequently, intubated patients with multi-organ disease, or trauma patients in the intensive care unit, are febrile. When work-up points to the sinuses as a potential source of infection, otolaryngologists are often consulted to obtain direct sinus cultures in these patients. Access to the sinuses, and direct cultures by sinus irrigation, can be performed with the assistance of sinuplasty devices. In addition, patients sometimes have sphenoid sinus opacification that requires biopsies and/or cultures. The sphenoid ostium is easily dilated with sinuplasty so that access to the sinus with a 4-mm endoscope can be performed. The frontal and

Figure 3 Sinus balloons. From top to bottom: 7, 5, and 3 mm. (Image courtesy of Acclarent, Inc.)

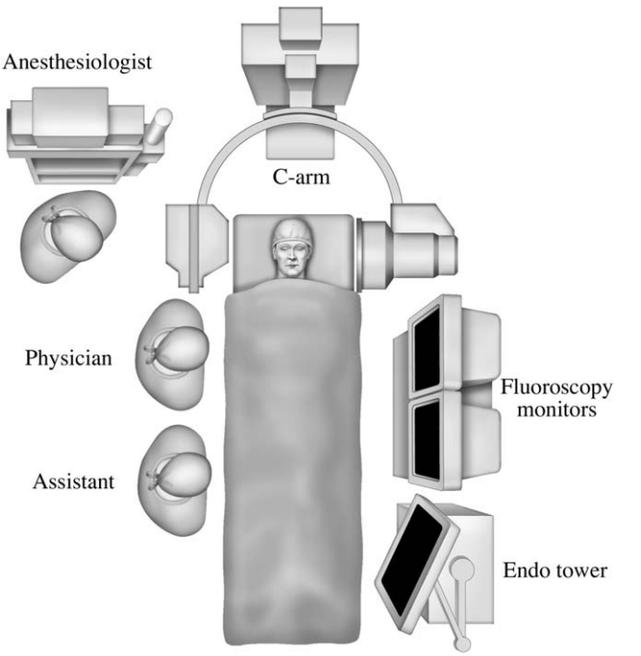

Figure 4 Room setup.

Table 1 Guiding catheters and fluoroscopic views for the cannulation of each group of sinuses

Involved sinus	Guiding catheter	Fluoroscopic views	Comments
Sphenoid	0°	Lateral	Sella turcica and anterior wall of sphenoid bone guide balloon placement
	30°		
Frontal	70°	Anteroposterior and/or lateral	Outflow tract may require 2 overlapping dilatations at different levels
Maxillary	90°	Anteroposterior	Curvature of the balloon indicates position across natural ostium
	110°		

maxillary ostia can be dilated so that fluoroscopic-guided biopsies of sinus neoplasms are also possible.

Patients are not appropriate candidates for primary sinuplasty if they present with a history of previous sinus surgery, significant ethmoid disease, presence of sinonasal polyps, mucocele or pyocele, allergic fungal rhinosinusitis, sinonasal osteoneogenesis, cystic fibrosis, ciliary dysfunction, sinonasal tumors, or obstructive lesions. A history of facial trauma that distorts sinus anatomy, and/or complete opacification of the frontal or maxillary sinuses are relative contraindications if the devices are not used in conjunction with FESS. In our experience, we have used FEDS devices in patients with Lund-McKay scores <10. Patients with severe disease nonresponsive to extended antibiotic therapy often have polyps or fungal debris that require more aggressive tools, such as standard FESS instruments. The devices are not designed to address the ethmoid sinus, hence, they have a significant limitation in this respect. It should be mentioned, however, that complete opacification of the sphenoid sinus is not a contraindication.

Sinuplasty devices can be used in combination with classical FESS with the patient under general anesthesia in the operating room, particularly in cases of difficult revision surgery, and in more extensive endoscopic procedures, even in the setting of distorted postoperative anatomy. Fluoroscopically-guided cannulation of a frontal sinus with a guidewire can be very helpful in revision frontal sinus surgery.

Instruments, equipment, and preparation

Standard endoscopic sinus instruments, including 0°, 30°, and 45° endoscopes, are used in the procedure. Additionally, sinus balloon dilatation requires sinus guiding catheters, flexible sinus guidewires, sinus balloon catheters, sinus lavage catheters, and a sinus balloon inflation device with a manometer (Figure 2). The sinus balloon inflation device and the sinus catheters are prepared following the manufacturer's instructions. The inflation device consists of a high-pressure syringe barrel with a piston handle, and a gauge used to monitor the pressure inside the balloon at the tip of the catheter (Figure 2C). The solution used for injection into the balloon consists of iodine contrast media, diluted in sterile saline or water at a concentration of approximately 150-180 mg/mL. Contrast is used so that the sinus balloon can be visualized fluoroscopically as it is inflated. Six to 8 mL are necessary to reach the required pressures, and the system needs to be purged of air for appropriate functioning.

The standard sinus balloon size is 5 mm, although there are 7 mm and 3 mm balloons, depending on the size of the target sinus ostium and the surgeon's judgment (Figure 3). The maximum pressure recommended by the manufacturer is 16 atm, although usually pressures of 8-12 atm are used with satisfactory results. The same sinus balloon can be used when multiple attempts are required to dilate the sinus ostium, as well as if multiple sinus ostia are going to be dilated in the same session. The manufacturer provides a detailed explanation on how to re-prepare the sinus balloon for adequate functioning. In addition, sinus lavage catheters are also available (Figure 2D), which permits the irrigation and suction of the target sinus.

Although otolaryngologists rarely use the C-arm, it is readily available in the operating room and is relatively easy to use. The C-arm is positioned at the head of the table, to provide fluoroscopic guidance when cannulating the involved sinuses and performing sinus balloon catheter insertion and inflation at the sinus ostia (Figure 4). Depending on the involved sinus(es), anteroposterior (AP) or lateral views are used during catheter insertion and balloon positioning/inflation (Table 1). Unlike FESS, which is usually performed on all involved sinuses on one side, followed by the involved sinuses on the contralateral side, FEDS devices are best used on each set of involved sinuses bilaterally (when indicated), to minimize the need to reposition the C-arm.

In patients with involvement of all 3 groups of sinuses (sphenoid, maxillary, and frontal sinuses), it is suggested to start with the AP view for both maxillary sinuses, and then to proceed with both frontal sinuses under AP fluoroscopic control. If the cannulation of either frontal sinus is not achieved with AP views, the contralateral sinus is treated first; then the C-arm is switched to the lateral position to obtain a lateral view, to aid in directing the guidewire into the sinus, across the frontal recess. The sphenoid sinuses are cannulated last, with the guidance of a lateral fluoroscopic view. This again minimizes the time required for repositioning the C-arm and obtaining the appropriate image with the help of the technician. A proper positioning of the C-arm enables the surgeon to have the most adequate view, to facilitate sinus cannulation, and keep the patient's radiation exposure to a minimum. During the procedure, live fluoroscopy is usually only used for guidewire cannulation of the involved sinuses, for positioning of the balloon after it is advanced over the wire, and during inflation/deflation. An effort should be made to use still images whenever possible, in order to not exceed a total radiation exposure time of 5-10 minutes.

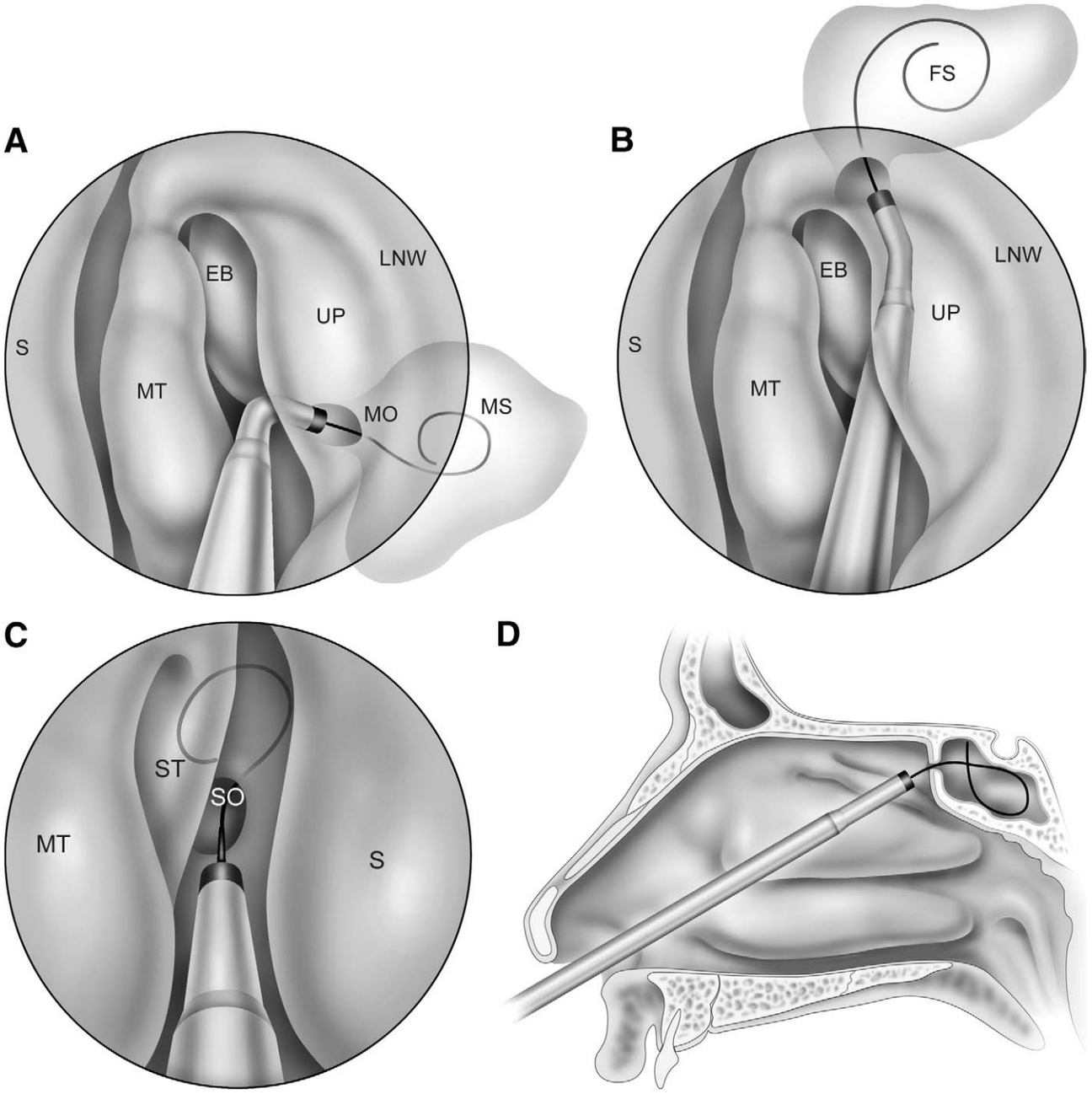

Figure 5 The guiding catheter is positioned close to the sinus ostia to guide the insertion of the guidewire into the sinus. Maxillary sinus ostium (A). Frontal recess (B). Sphenoid sinus ostium (C). Sphenoid sinus, lateral view (D). EB, ethmoid bulla; FS, frontal sinus; LNW, lateral nasal wall; MO, maxillary sinus ostium; MT, middle turbinate; S, septum; SO, sphenoid sinus ostium; ST, superior turbinate; UP, uncinate process.

Anesthesia

Sinuplasty devices are used while FESS is performed with the patient under general anesthesia, or with local anesthesia with or without sedation. Since the devices shorten the time of the procedure, local anesthesia is more commonly used than it is with conventional FESS alone.

Technique

Topical anesthesia with 4% cocaine is applied in cotton pledgets, followed by a 1% Xylocaine (AstraZeneca PLC, London, UK) with epinephrine (1:100,000) transpalatal sphenopalatine block. Under direct fiberoptic endoscopic visualization of the nasal cavity and sinus ostia, further local anesthetic is injected as necessary. The sinus guiding catheter is then inserted close to the sinus ostia (Figure 5). Table 1 shows the angle and sinus guiding catheter usually required to enter each type of sinus. Sinus guidewires are advanced through the catheters under fluoroscopic guidance, until their presence inside the sinus is confirmed. The wires are passed only through open spaces, and pressure should never be used when attempting insertion into the sinus.

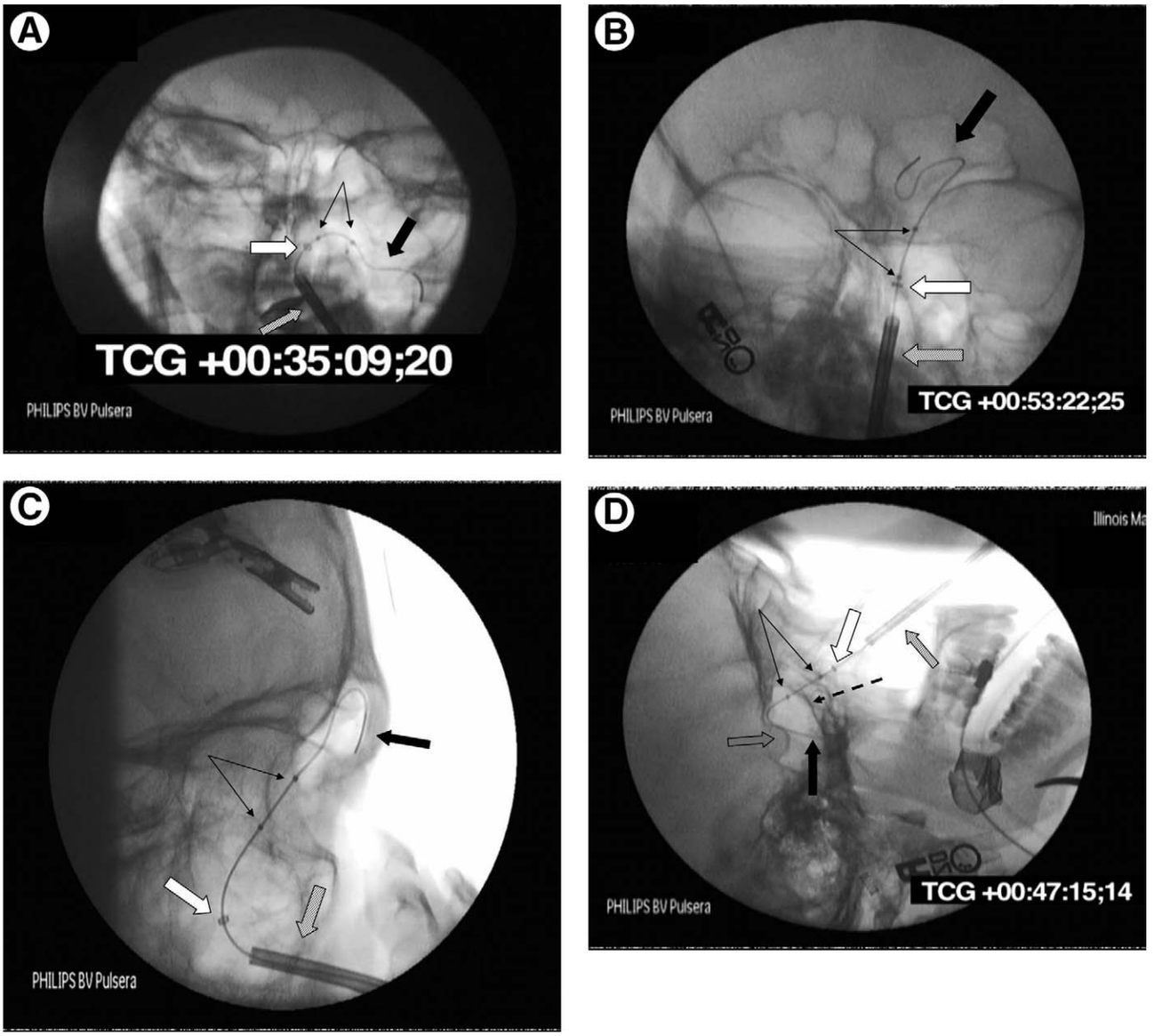

Figure 6 Fluoroscopic imaging guidance for sinus cannulation and balloon positioning. Guiding catheters in position, wire advanced into sinus, balloon catheter advanced over the wire, and deflated balloon in position. AP view of the left maxillary sinus (A). Notice the curvature of the deflated balloon when positioned across the natural ostium. AP view of the left frontal sinus (B). Lateral view of the frontal sinus (C). Lateral view of the sphenoid sinus (D). The anterior wall of the sphenoid sinus helps position the balloon across the sinus ostium. Tip of guiding catheter (white arrow). Guidewire in sinus (bold black arrow). Tip and tail markings of balloon (black arrows). Sella turcica (gray arrow). Sinus guiding catheter (striped arrow). Anterior wall of the sphenoid sinus (dashed arrow).

The sinus balloon catheter is advanced over the wire, into the sinus guiding catheter, and into the sinus, until it is positioned across the sinus ostium (Figure 6). Radiopaque markings at the tip and tail of the actual balloon enable the surgeon to establish the exact position of the balloon, which permits an exact positioning across the sinus ostium, right in the middle of both markings. The sinus balloon catheter must be completely out of the guiding catheter, past the tip, to achieve dilatation of the ostium (Figure 7). Fluoroscopic landmarks also help determine the location of the ostium when cannulating the sphenoid sinus in the lateral view (Figure 6C) and the frontal sinus in the AP view (Figure 6B). Good positioning across the maxillary sinus ostium results in a curved position of the sinus balloon because of the regional anatomy (Figure 6A). The position of the balloon can alternatively be confirmed with an endoscope.

Pressure is gradually increased in the sinus balloon by the surgical technician, who turns the inflation device and carefully reads off the pressure in the manometer, usually in increments of 2 atmospheres, until the surgeon determines an adequate ostium dilatation (Figure 8). The surgeon will determine the size of the sinus balloon and actual pressure, after assessment of the sinus ostium and regional anatomy. In general, a pressure greater than 8-12 atm will rarely be necessary to perform an adequate dilatation of the ostium. When dilating the frontal recess, pressures over this limit may crush the agger nasi cells and terminal recess. Sinus balloon inflation is visualized live in fluoroscopy, at which point the slipping of the balloon into the sinus cavity or out of the ostium may be detected. This occurs due to inadequate positioning of the balloon across the ostium (Figure 9). Adjustments in the positioning of the balloon should be made at this point, which may require the balloon to

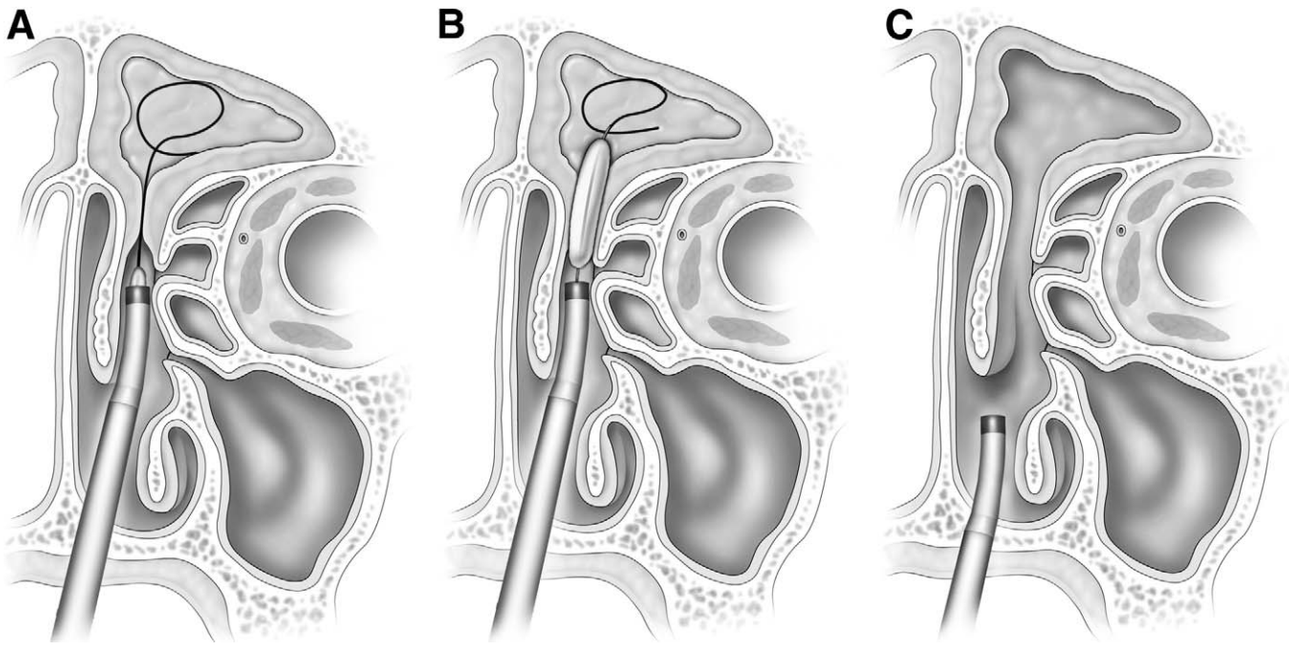

Figure 7 Frontal sinus ostium balloon dilatation sequence. Guiding catheter in position, wire advanced into frontal sinus, and balloon catheter at the tip of guiding catheter (A). Balloon catheter out of guiding catheter and inflated balloon positioned across ostium (B). Dilated ostium, drained sinus, and balloon catheter and wire removed (C).

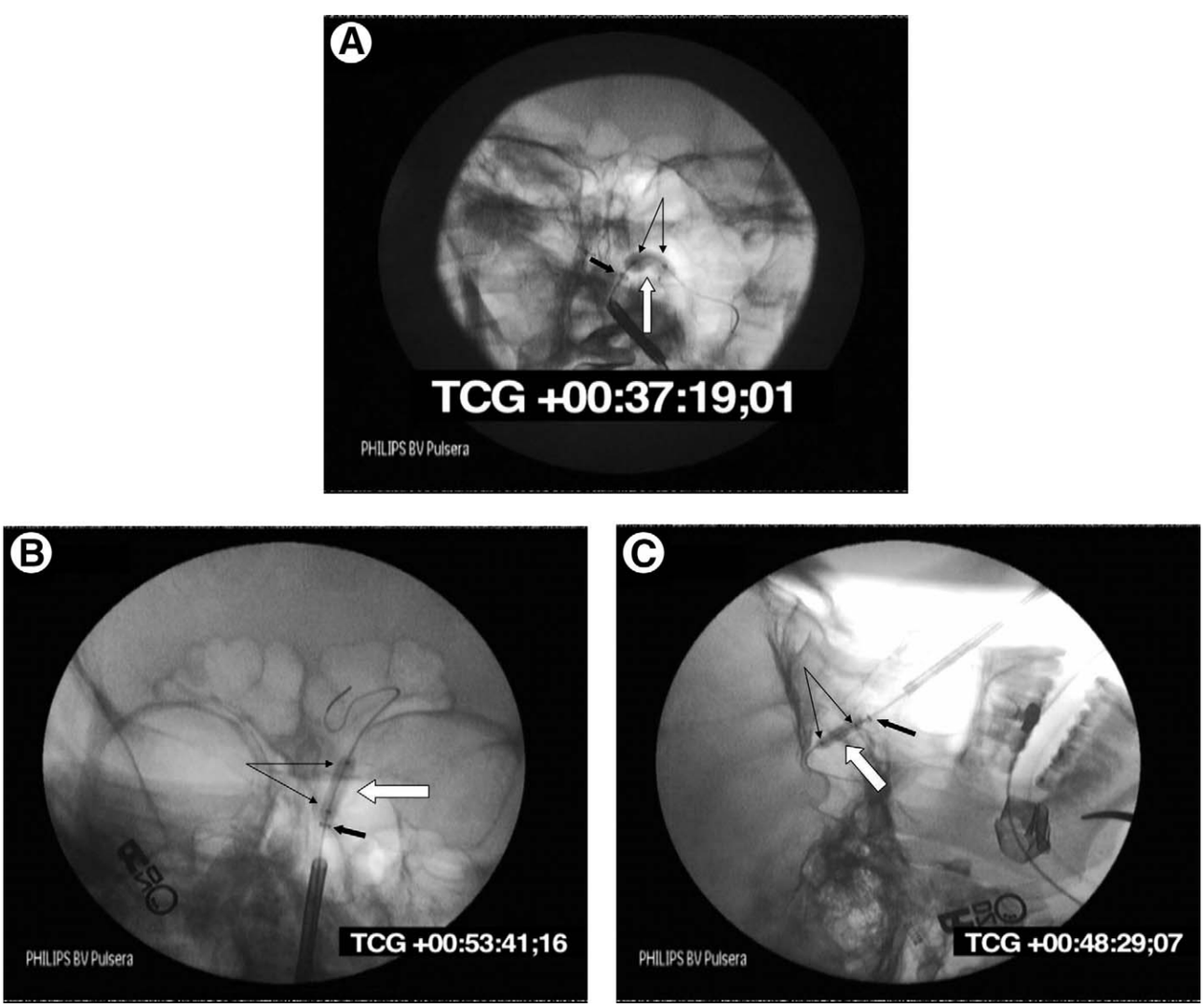

Figure 8 Inflated balloons in position. Maxillary sinus (A). Frontal sinus (B). Sphenoid sinus (C). Tip and tail markings in balloon (black arrows). Inflated balloon (white arrow). Tip of guiding catheter (bold black arrow).

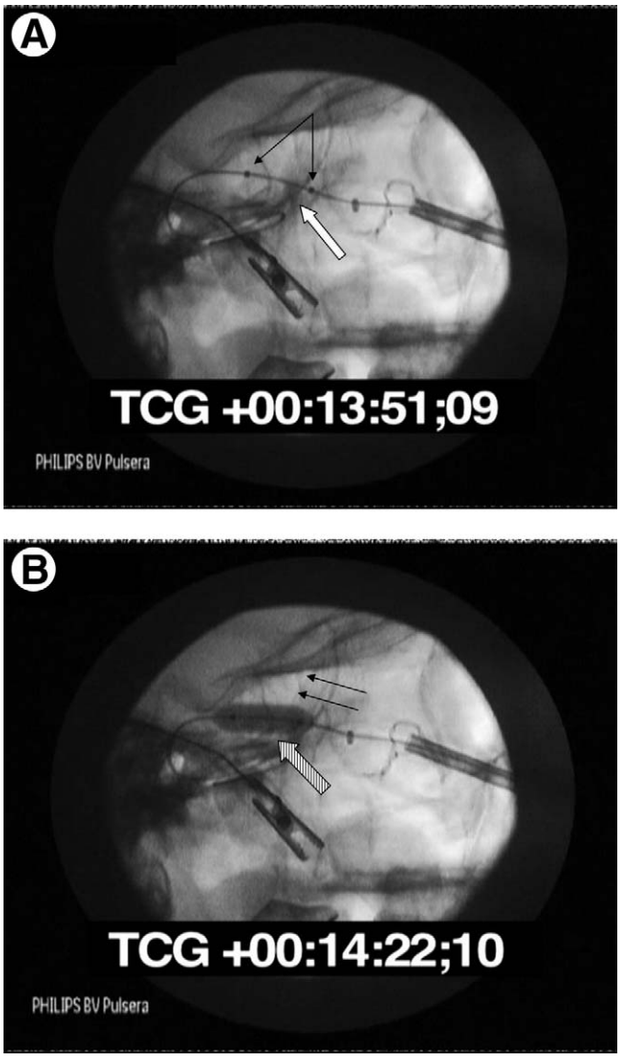

Figure 9 An inadequate positioning of the balloon across the ostium (A) causes slipping of the balloon into the sinus (B) on inflation. Anterior wall of the sphenoid bone (white arrow). Direction of balloon movement (black arrows). Inflated balloon (striped arrow).

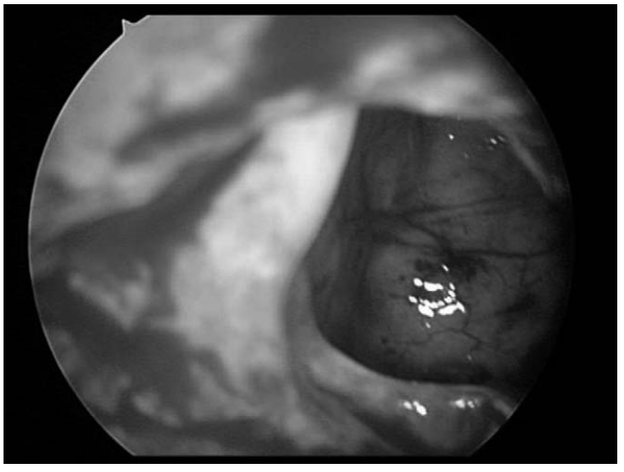

Figure 10 Sphenoid sinus ostium visualized endoscopically after dilatation, with minimal mucosal injury.

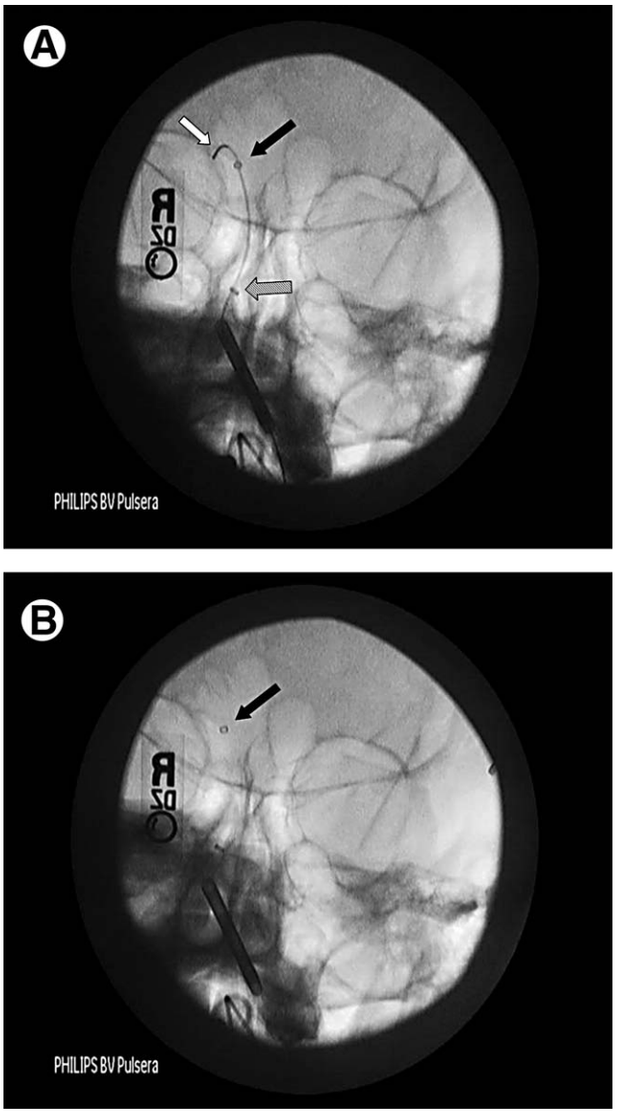

Figure 11 Sinus lavage catheter insertion, frontal sinus. Over-the-wire lavage catheter positioning (A). Lavage catheter in position, guidewire removed (B). Tip of lavage catheter (bold black arrow). Guidewire in frontal sinus (white arrow). Tip of guiding catheter (striped arrow).

be positioned slightly more or less across the ostium, in order for it to remain in position once maximum pressure is reached.

Balloon inflation is performed once, and pressure is then released by aspirating the contrast back into the pressure device. Due to the fact that the frontal outflow tract is not a true "ostium," two overlapping dilatations should be performed to ensure that the entire outflow tract is dilated. A confirmatory fluoroscopic image of the deflated balloon is obtained before pulling the balloon catheter out through the guiding catheter. The dilated ostium is also visualized with an endoscope, to confirm adequate dilatation of the ostium and assess the sinus interior (Figure 10). The frontal sinus should transilluminate well after dilatation, which is a reliable indicator in differentiating it from neighboring cells when access is difficult for visualization.[7] The sinus balloon catheter can be exchanged for a sinus lavage catheter at this point, for the purpose of performing culture sampling, sinus drainage, and/or irrigation. Sinus irrigation and lavage follow the same principles as bal-

loon dilatation. The sinus lavage catheter is advanced over the wire, after its appropriate positioning inside the sinus under fluoroscopic guidance (Figure 11). Drainage and lavage are then performed with saline solution or antibiotic irrigation. A variety of instruments can also be inserted under fluoroscopic guidance to perform biopsies, if indicated.

Morbidity and complications

In theory, sinuplasty morbidity and complications are the same as with FESS.[8] However, due to the less invasive nature of ostium balloon dilatation, they are likely to be less common. Vascular or nerve injuries, the inability to identify the natural ostium, and inadvertent injury to the orbit or brain are all possible. Obviously, the surgeon must be familiar with performing surgery under fluoroscopic control, and must have intimate knowledge of the sinus, orbit, and brain anatomy as visualized with the C-arm. Most importantly, the surgeon must be prepared to handle potential complications associated with any sinus surgery. Despite these potential risks, the use of sinuplasty tools has thus far proven extremely safe.

Due to the fact that the uncinate process is left intact and the middle turbinate may be abraded while using FEDS devices together with FESS, the incidence of turbinate-uncinate adhesions was higher in the initial group of patients who underwent sinuplasty than in patients who underwent classic FESS alone. To prevent middle turbinate lateralization, we perform a microdebridement medialization technique, previously described by the senior author.[9] In addition, absorbable packing (MeroGel; Medtronic Xomed, Inc, Jacksonville, FL) is now also routinely used in our patients, to serve as a spacer between the middle turbinate and uncinate process.

Postoperative care is the same as for conventional FESS. All the routine instructions, which include no blowing of the nose, no straining, keeping the head of the bed elevated, and gradual resumption of normal activities, are given to the patient. Narcotic pain medication is rarely needed. Antibiotics are prescribed as indicated. Endoscopic evaluation of the middle meatus and sphenoethmoid recess should be performed in follow-up visits, and should be documented periodically. Visualization of the dilated sphenoid ostium is usually possible, but visualization of the frontal and maxillary ostia is usually obstructed by the intact uncinate. The most significant risk of the procedure is failure to achieve the desired results. Short-term success of the use of FEDS devices is based on elimination of symptoms, and in some cases, radiologic evidence of improvement in the follow-up CT. Long-term studies, however, will be necessary.

The procedure is relatively new. As the number of patients treated with sinuplasty increases, the number of complications may increase as well, until a learning curve is established. Increasing experience and proper patient selection will likely keep complications at a minimum so that outcomes are not compromised by technical difficulties. The CLEAR trial is currently in the late stages of 6-month patient follow-up and will be submitted shortly for peer review. It will hopefully establish the effectiveness of balloon catheter dilatation of the sinus ostia in achieving and maintaining patency, as well as establish its effectiveness in relieving symptoms of CRS and decreasing medication requirements, either alone or in combination with FESS. Ongoing studies will also continue to monitor long-term results.

Cost

The overall cost of the use of FEDS devices is considerably less than conventional FESS. Although the cost of the balloon system (approximately $1500) and use of the C-arm (approximately $500) must be included, there are considerable cost savings due to the nature of the technique. Shorter operating time and the use of local anesthesia with or without sedation avoids the costs of operating room and recovery room time. The use of a microdebrider and disposable microdebrider blades are not necessary. Postoperative debridement is rarely needed or is significantly minimized. Ongoing randomized trials are comparing the costs of noninvasive medical treatment versus FESS and FEDS.

Conclusion

Sinuplasty devices are available for a select group of patients who are in need of surgical intervention but who have disease considered appropriate for this minimally invasive technique. Although limited to the frontal, maxillary, and sphenoid sinuses, the technique for the use of the tools described in this article is achievable with appropriate training, minimal morbidity, and complications. However, its long-term value as a stand-alone procedure has not yet been proven.

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