

Office-Based Balloon Sinus Dilation

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No surgery that otolaryngologists perform conjures up more intense imagery than sinus surgery. Even today, when discussing treatment options with patients for chronic sinusitis, I am confronted with the ghosts of sinus surgery past. Stories come up of relatives or friends who had intense pain and pressure in the postoperative period, with complete nasal congestion and black eyes, topped off by excruciating removal of packing. Thankfully, these situations rarely occur with current sinus surgery.

Historically, sinus surgery was performed through an external approach. In 1912, Harris Mosher observed, "Theoretically, an ethmoidal operation is easy; in practice, however, it has proved to be one of the easiest operations with which to kill a patient."¹ In the century since Mosher's humble statement, sinus surgery has undergone several transformations that have allowed easier access and better surgical visualization with more precise imaging and a more thorough understanding of sinus physiology.

Until the 1970s, the maxillary sinuses were accessed by an incision on the mucosa above the gum line in the gingivobuccal sulcus, known as the



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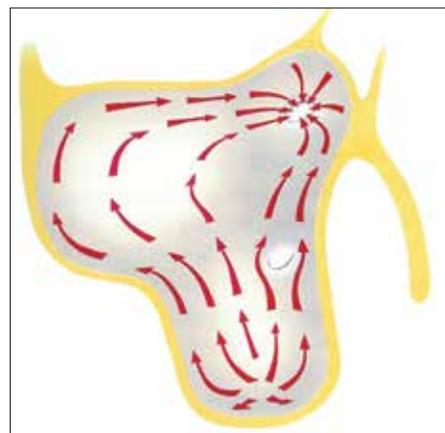
Caldwell-Luc procedure. The anterior face of the bone would be chiseled away, and the mucosa of the sinus would be stripped. This was a straightforward operation anatomically, but it was also a blunt, invasive approach that did not allow for normal functioning of the sinus afterward. A direct open approach to the frontal sinus involved a full cranial incision, drilling out the anterior table of the frontal sinus, stripping the mucosa off the bone, and replacing the initial bony window. A less invasive approach used a trephine (small burr hole) to drain the sinus externally through an incision next to the nasal bridge, but this would only resolve acute infections without addressing any chronic problems.

For life-threatening infections, these were the only options available. The purpose of these early types of sinus surgery was to drain pus and prevent or treat serious complications, which were mostly orbital and intracranial.

Although the first endoscopic manipulation of the maxillary sinuses came in 1902, it wasn't until 1959, when Harold Hopkins invented rod lenses, and 1963, when Karl Storz combined rod lenses with fiber bundles for illumination, that the technology for the endoscopic approach to the sinuses became available.

In Europe during the 1970s, Hilding Messerklinger, Wolfgang Draf and Malte Wigand advanced the concept

Figure 1. Natural mucociliary drainage pattern in a maxillary sinus

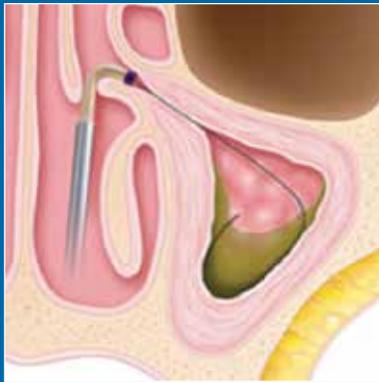


SOURCE: See reference 11.

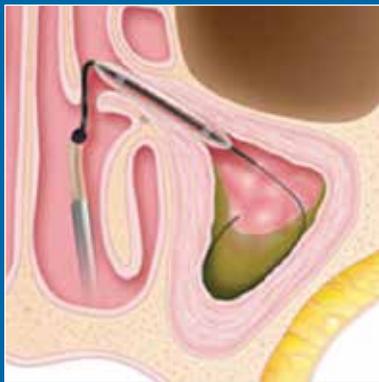
of natural mucociliary drainage patterns in the sinuses. Every sinus has an ostium that needs to be patent for the sinus to function properly. Establishing the patency of the ostium would allow for normalization of the sinus mucosa, with a resolution of inflammation and a return of the mucociliary drainage. Prior to this, sinus surgery was directed at removing diseased mucosa and relied on gravitational drainage. This approach was often unsuccessful in treating the diseased sinus.

In 1985, in the United States, David Kennedy built upon the concepts developed in Europe and coined the term "functional endoscopic sinus surgery" (FESS) to focus on returning function to the sinuses in a more natural way, without stripping away mucosa. FESS

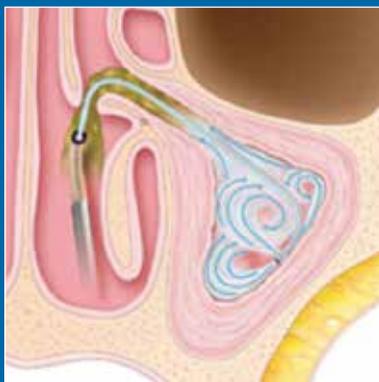
Figure 2. BSD procedure



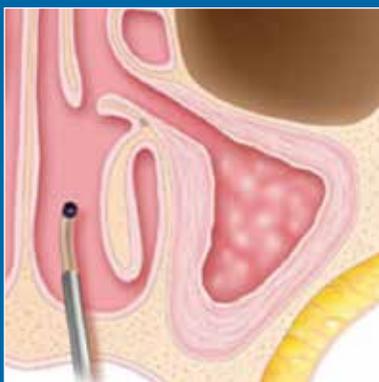
1. Introduction



2. Dilatation



3. Irrigation



4. Removal

SOURCE: See reference 12.

was done completely endoscopically and was a significant step in the evolution of sinus surgery.²

The frontal sinuses have one mucosal duct leading to the nasal cavity; the maxillary and sphenoid sinuses have one ostium. These exits are the natural focal points for mucociliary clearance of the sinuses. The ethmoid sinuses are more like a honeycomb of cells lined with mucosa, and the cells must be removed, all the way up to the mucosal lining of the bony skull base. In an FESS operation, the goal is to open up the natural sinus exits, and to preserve mucosa wherever possible, removing only the mucosa and bone that would otherwise prevent the return of normal sinus function.

Over the next 20 years, FESS became more refined, with even greater attention paid to preserving normal structures such as the inferior and middle turbinates. As normal mucosa was left, both intraoperative and postoperative bleeding were decreased, and the need for obstructive packing was largely obviated.

FESS has been successful in increasing quality of life and in decreasing the frequency and severity of chronic sinusitis symptoms in those patients who fail medical therapy.^{3,4} Unlike a tonsillectomy, which generally cures all tonsil-related problems, the success of sinus surgery depends on the ability of the underlying mucosa to return to normal. Sometimes, there is dysfunctional mucosa that will never return to normal. At other times, postsurgical scarring closes areas that were once open. Continued mucosal inflammation can occur secondary to allergic or non-allergic rhinitis, or there can be regrowth and return of polypoid tissue. Inability to remove all obstructing tissue may also play a role, either due to distorted anatomy, or proximity to the orbit or dura.

A good rule of thumb is that patients with mild disease tend to do better in the long term postoperatively than patients with more severe disease. The patients who do the best are those with purely anatomic blockage, with no in-

herent underlying mucosal dysfunction. One example of this is a patient who has recurrent acute sinus infections because of narrowing of the sinus exits, which are transiently blocked during an acute upper respiratory infection. Widening the exits surgically can prevent the inflammatory cycle that leads to these sinus infections.

In 2005, the FDA approved a new device to open the sinuses.⁵ The device was based on the concept of widening the sinus exits without dissecting or removing surrounding tissue. The technique calls for a thin flexible wire to be threaded through a handpiece that allows its manipulation and placement into either the maxillary, frontal or sphenoid sinus. The ethmoid sinus is not anatomically compatible with this technique, as it does not have a single ostium or duct, being a collection of mucosa-lined cells.

After the guidewire is placed into the proper sinus, its anatomic position is confirmed visually. The first iteration of the device used X-ray fluoroscopy; later versions use a bright light at the tip of the guidewire for trans-illumination of the sinuses. A small balloon (the active portion is typically 6 mm x 16 mm) is then slid over the guidewire, Seldinger-style, until it is at the ostium or duct of the sinus. The balloon is inflated to dilate the ostium or duct, and then deflated and removed. A special catheter is then used to irrigate the sinus.

This technique is called balloon sinuplasty or balloon sinus dilation (BSD). There is now more than one company producing equipment for BSD. Several studies have focused on its efficacy with the frontal and maxillary sinuses, finding the results non-inferior to traditional FESS.^{6,7} Most surgeons initially used BSD in conjunction with FESS tools to access the sinuses and clear disease. The frontal sinus was an especially attractive place to use BSD, as the duct could be quite narrow and is very near the thin bone that covers the skull base.

The two main advantages of using BSD in the operating room are confir-

mation of sinus location and reduction in tissue removal, which theoretically leads to decreased postoperative pain, crusting and scarring. The disadvantage, however, is that if no diseased tissue is removed, there can potentially be recurrent disease. In addition, there is no direct endoscopic visualization in the office postoperatively of the maxillary sinus, and possibly of the frontal sinus, which makes diagnosis of any sinus-related symptoms more difficult in the future. Severe polypoid and thickened mucosa around the ostia are also not ideal environments for BSD. In the operating room, I have used BSD sparingly, mostly reserving it for frontal sinuses that would be difficult to access in a more traditional endoscopic fashion because of anatomic characteristics.

One additional use of BSD is in the pediatric population. In 2009, a pediatric indication was made, and children with chronic sinusitis who had BSD of the maxillary sinuses in addition to an adenoidectomy had an 87% success rate of clearing the sinusitis, compared to 50% with adenoidectomy alone.⁸ BSD allows more effective treatment for children with chronic rhinosinusitis unresponsive to medical therapy, especially as FESS in children is becoming more controversial.

In 2012, researchers published a prospective multicenter study (albeit sponsored by a BSD device manufacturer) on the efficacy of using BSD techniques in offices.⁹ The study showed clinically significant improvements in quality of life in patients with chronic sinusitis two years postoperatively. Using topical anesthesia, supplemented with injected anesthesia, the same tools that one uses in the operating room can be used on a patient who is fully awake in an exam-room chair. The office procedure is not a hybrid surgery combining BSD with other techniques, but rather a pure BSD surgery. This significantly alters the risk/benefit ratio in assessing intervention for patients with sinusitis.

In a pure BSD surgery, there are no incisions and no removal of tissue, al-

lowing quick return to normal activity. The rare risks associated with FESS are essentially eliminated, and there is no general anesthesia. For patients who have recurrent acute sinusitis multiple times per year, but do not want to undergo a full FESS in the operating room, office-based BSD allows an option that is compatible with their level of disease. The surgeon explains that traditional FESS may be necessary if the office procedure fails, and a decision is made about the best treatment plan for each patient. For patients who cannot tolerate general anesthesia, BSD is the only surgical option available.

As with any procedure, careful selection of patients is key. In my two years of experience with in-office BSD, patients with some of the following characteristics have done well:

- Recurrent acute sinusitis that is bothersome to patients, but clears in between
- Isolated maxillary, frontal or sphenoid disease
- Mild to no nasal inflammation
- Mild to early moderate thickening of mucosa on CT scan
- No polypoid disease
- No significant ethmoid disease
- No known ciliary dysfunction

Patients who are not good candidates for BSD include those with severe sinus disease, sinonasal polyposis, or significant septal deviation. As BSD does involve manipulation of sinus tissue, patients with low pain thresholds or squeamishness also do not do well.

Some studies have suggested that patients with more severe disease or ethmoidal disease can benefit from BSD.¹⁰ These patients may opt for a trial of office-based BSD, knowing that it may be unsuccessful. If it is successful, however, the indications may be expanded.

At this point, FESS is still the gold standard for many chronic sinusitis patients, but the new option of avoiding general anesthesia, experiencing easier recovery and essentially eliminating rare but potential complications make office-based BSD an attractive new tool in the fight against chronic sinusitis. ◇

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