

TITLE: Balloon Sinuplasty

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Introduction

Millions of Americans suffer from sinusitis each year. Functional endoscopic sinus surgery (FESS) has transformed the field of Rhinology and how we treat sinus disease in the past few decades. This is attributed to several pioneers who laid the foundation for the popularity of FESS. Towards the end of the nineteenth century, George Caldwell and Henri Luc published the canine fossa approach to the maxillary sinus. Hirshman was the first to describe the use of nasal endoscopy in 1901 through modifying a cystoscope. The Hopkins rod telescope was developed and patented in 1960, greatly enhancing the visualization of nasal cavity. In 1978, Messerklinger documented his endoscopic experience with a collection of images. In the mid-1980s, Stammberger published a series of papers describing endoscopic sinus surgery techniques. Later, Kennedy and colleagues brought these techniques to the United States and coined the term "functional endoscopic sinus surgery."

The concept of balloon sinuplasty stemmed from the success of similar balloon devices employed in other specialties such as cardiology, urology, GI, and vascular surgery. The idea of mucosal preservation in balloon sinuplasty is appealing for its potential to minimize scarring and re-stenosis of dilated sinus ostium. Whether balloon sinuplasty will be as popular as angioplasty remains to be seen, but there is no question this technology has gained significant momentum within our specialty in the past few years.

American Rhinology Society statement on balloon sinuplasty (2006):

- Balloon dilation technology may have potential application where surgical management of sinus disease is required.
- The technology has limited surgical indications at this time.
- Patients treated with balloon dilation may still require conventional sinus surgery.

- In a small group of very selected patients, the use of balloon dilation technology alone may eliminate the need for other surgical procedures.

How it works:

A catheter is first introduced near the natural ostium of a sinus, for instance, behind the uncinata for the maxillary sinus. A guidewire is then passed through this catheter to enter into the sinus. The wire should never be pushed against any resistance. Once the guidewire passes easily into the sinus, its location is confirmed by either fluoroscopy with a c-arm or transillumination with the new LUMA illumination guidewire. Friedman compared fluoroscopy and LUMA and reported that the successes of cannulation were similar. Once the guidewire is confirmed to be within the sinus, the tip of the guide catheter is held outside of the sinus (confirmed by endoscopic visualization). The white band on the proximal end of the balloon is fully inserted into the guide catheter. This advances the balloon into the sinus so that the distal end of the balloon is just out of the guide catheter. This is confirmed endoscopically by visualizing the yellow marking on the balloon that indicates it has exited the distal tip of the guide catheter. The technique then is standard, in that the balloon is inflated, deflated, and then removed.

Initial feasibility studies:

Bolger performed an initial feasibility study on 6 cadaver heads in 2006. Balloon dilation was successful in all 31 sinuses (9 maxillary, 11 sphenoid, 11 frontal). Postoperative CT scan showed microfracture of ostia sites without injury to orbit or skull base. Brown performed a prospective non-randomized cohort on 10 patients and showed that dilation was easiest with sphenoid sinus, followed by frontal and maxillary sinuses. There was mild difficulty in dilating 5 of 10 maxillary sinuses. There was again no complication or adverse events associated with balloon dilation.

The CLEAR study:

Arguably the most comprehensive study for balloon sinuplasty to-date, the CLEAR study is a multi-center, prospective non-randomized study published in 3 parts, starting with a 24-week data, followed by 1-year and 2-year data. The 2 study groups consisted of patients who underwent hybrid procedures (FESS plus balloon) and those who just had balloon sinuplasty. The study did not compare the two groups directly, but rather the preoperative and post-operative SNOT-20 scores, Lund-Mackay scores, and ostia patency based on nasal endoscopy for each group.

The following patient selection criteria were used:

Inclusion criteria:

- ▶ Adult > age of 18 years
- ▶ Chronic sinusitis unresponsive to medical management

Exclusion criteria:

- ▶ Extensive sinonasal polyps, cystic fibrosis

- ▶ Extensive previous sinonasal surgery
- ▶ Extensive sinonasal osteoneogenesis
- ▶ Sinonasal tumors,
- ▶ History of facial trauma
- ▶ Ciliary dysfunction
- ▶ Pregnancy

For SNOT-20 results, there was significant improvement of patient symptoms between preop and postop for each group. The differences between 24-week, 1-year, and 2-year data were not significant. Weiss et al reported that the most improved symptom was facial pain/pressure relief. Similarly, Lund-Mackay scores showed significant improvement of CT findings between preop and both 1-year and 2-year data, and no difference between 1-year and 2-year data.

The overall ostia patency rate was 85% (172/202 sinuses) at 1 year postop. For the indeterminant ostia (obscured by uncinata and ethmoid that were left intact for balloon sinuplasty), their corresponding CT scans were reviewed to evaluate ostia patency. Taken the CT findings into account, the overall patency rate was 91.6% (185/202 sinuses), with maxillary sinus having the highest patency rate (93.5%) and sphenoid the lowest (86.1%). There were no adverse events such as CSF leak or orbital injury reported.

Pediatric population:

Ramadan reported in a prospective study of 30 children that balloon dilation was successful in 51/56 sinuses from pediatric patients suffering from chronic sinusitis (excluding cystic fibrosis, immunodeficient, ciliary dysmotility patients). Of the 5 sinuses that failed balloon dilation, 4 were hypoplastic maxillary sinuses and 1 was frontal sinus. There was no complication reported. No information on quality of life was reported in this study.

Radiation exposure:

Radiation exposure during fluoroscopy carries the risk of cataract formation. The International Commission on Radiological Protection has stated that acute doses of 2 Gy may cause cataract formation. It has also been reported that an average of 4.2 mGy per eye in balloon sinuplasty, which is much less than the cataract threshold. The new Luma illumination system provides an alternative to identify sinus location and avoids the potential complications with radiation exposure.

Future directions:

Balloon sinuplasty provides a new armamentarium for otolaryngologists to treat sinus disease. According to Dr. Raymond Weiss, “sinuplasty is a new technique in performing endoscopic sinus surgery—not a new procedure but rather a new tool that further reduces mucosal damage and advance us toward our ultimate goal of improving function with maximal mucosal preservation”. It has been recently reported that balloon sinuplasty can be safely and successfully performed under local anesthesia in the BREATHE-1 trial. While it holds great promise for office-based sinus procedures, further study is needed to better define its role in the

surgical management of chronic sinusitis especially with regard to patient selection and disease types best suited for this technology.

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