The Role of Balloon Sinuplasty in the Treatment of Chronic Sinusitis

Joseph P. Cummings, PhD, Hoyee Leong, PhD, and Karl A. Matuszewski, MS, PharmD

Abstract

- *Objective:* To evaluate the status of balloon sinuplasty from a hospital-based perspective.
- *Methods:* A qualitative, systematic technology assessment.
- *Results:* The clinical evidence describing balloon sinuplasty comprises 6 published studies. The pivotal study was a phase 2–type prospective, nonrandomized case series with 6 months of patient follow-up. There were no randomized trials, long-term efficacy data, or cost-effectiveness studies. Analysis of the available evidence suggests balloon sinuplasty is a safe procedure, with a low rate of major complications. Data show balloon sinuplasty can effectively dilate the sinus ostia in 80% to 90% of cases. Ostial patency appears to be maintained at 6 months. Patient satisfaction with the procedure is favorable, with low postoperative pain and reduced follow-up care. The incremental costs associated with single-patient use balloon sinuplasty devices are approximately $1500 and may not be adequately reimbursed by some payers.
- *Conclusions:* Sinuplasty balloons are a viable surgical tool for use in selected patients during sinus surgery. There is no evidence comparing conventional tools with balloon sinuplasty for the same application, and the 2 techniques appear complementary.

Chronic sinusitis is a symptomatic inflammation of the paranasal sinuses and nasal cavity lasting for more than 12 weeks [1]. Symptoms may include facial pain or pressure, nasal obstruction, abnormal mucus production, loss of smell, headache, or fatigue. Chronic sinusitis affects an estimated 30.7 million U.S. adults (approximately 14% of the population) and accounts for 12.6 million office visits and 1.2 million hospital outpatient visits annually [2–4]. Approximately $6 billion in direct costs is spent annually on sinusitis treatments, and there are significant indirect costs associated with decreased quality of life (QOL) and lost productivity [5]. Because the disease state utilizes a significant amount of clinical and financial health care resources in the United States, chronic sinusitis treatments are important areas for technology assessment.

Medical therapy is the primary treatment for chronic sinusitis and resolves most cases [6]. Choice of medical therapy may depend on several factors, including extent and duration of sinusitis, tolerance and history of medication use, and the results of diagnostic tests [7,8]. Medications act generally to control predisposing factors, treat concomitant infections, reduce sinus edema, and facilitate sinus drainage. Medications may include antibiotics (broad-acting or culture-directed), intranasal corticosteroids, saline irrigations, oral steroids, decongestants, topical vasoconstrictors, mucolytics, antihistamines, leukotriene inhibitors, antifungals, and analgesics. Unfortunately, in up to 20% of patients, medication treatment may be ineffective.

Surgical therapy may be considered when an adequate trial of maximal medical therapy has failed and patients remain highly symptomatic with a decreased QOL or functional impairment, for documented anatomical variations causing local obstruction, complications secondary to sinusitis, and allergic fungal disease [9]. An estimated 500,000 surgical procedures are conducted annually for medically refractory sinusitis [10]. The mainstay of surgical therapy is functional endoscopic sinus surgery (FESS) using a nasal approach, endoscopic visualization, and specialized tools (eg, cutting forceps, power debriders) to surgically remove tissue causing sinus obstruction [11].

FESS studies generally show objective and subjective postprocedure improvements, durable relief of symptoms in approximately 80% to 90% of cases, and functional improvements [12,13]. Major complications (typically < 1%–2%) may include cerebrospinal fluid (CSF) leak, transcranial or intraorbital penetration, blindness, bleeding, or infection [14]. Although well established, there remains some controversy regarding the lack of randomized controlled trials (RCTs) comparing FESS with optimal medical management [15–17].

Initial use of balloons as a surgical tool for treating sinusitis began in the 1990s, with reports at professional meetings describing use of biliary balloon catheters applied

From the University HealthSystem Consortium, Oak Brook, IL.

to the sinuses [18]. The first dedicated balloon sinuplasty system (Relieva, Acclarent, Menlo Park, CA) received U.S. Food and Drug Administration 510(k) marketing clearance in April 2005 [19]. The manufacturer of this device estimates that approximately 3000 physicians have been trained in the procedure and more than 20,000 patients have been treated worldwide through 2007 [20].

A typical balloon sinuplasty procedure begins with a guide catheter placed into the nasal cavity under endoscopic guidance [21]. A guidewire is introduced through the guide catheter, across the ostia, and into the affected sinus. The guidewire facilitates placement of a balloon across the ostia, usually under fluoroscopic visualization. The balloon is inflated under high pressure (up to about 14–16 atm) with radiopaque fluid and dilates the opening by compressing and remodeling/molding both soft and hard tissues, with some tissue tearing, albeit minimal disruption of overall tissue integrity, bleeding, or scarring [22,23]. The size of the opening after dilation initially corresponds to the balloon diameter size (5–7 mm). Acute edema may decrease the opening size in the short term, with typical size stabilization at approximately 75% of the initial size [24]. The long-term (eg, 1-year and 5-year) ostial dimension and patency is unknown. After balloon deflation and removal, the sinus may be irrigated as needed.

The premise of dilating a sinus ostium is fundamentally different from conventional FESS techniques involving tissue removal. The size and shape of the opening will be significantly different after each type of procedure. FESS typically provides wider sinonasal outflow tracts that may facilitate drainage, postoperative monitoring, and medication delivery [18]. But this may be countered by increased patient morbidity and potential for complications. Further in contrast, FESS removes potentially inflammatory, microbial-laden tissue that may be contributing to the sinusitis process. Finally, the current pathophysiologic model of chronic sinusitis is predicated on surgical resection in the ethmoid sinus. This important area is not amenable to sinuplasty treatment.

The primary potential advantages cited for balloon sinuplasty are associated with the absence of tissue/bone cutting or removal [24]. This may lead to reduced bleeding, decreased need for nasal packing, decreased postoperative pain, faster recovery time, and increased patient satisfaction. The main disadvantages of balloon sinuplasty include the high cost of disposable tools, lack of reimbursement from some private payers, lack of long-term outcome studies, and the use of fluoroscopy. The latter is not routinely used by otolaryngologists, poses a cumulative radiation risk to clinicians, and exposes the patient, particularly the radiation-sensitive lens of the eye, to potential radiation-induced complications [25,26].

Due in part to premature marketing of this procedure before the clinical evidence base was well developed, there has been considerable controversy regarding the clinical role of balloon sinuplasty [18,20,24,27]. The purpose of our study was to assess the safety, efficacy, and clinical use of balloon sinuplasty using a rapid, objective, clinical evidence review methodology and apply this information to aid hospitals making technology resource decisions [28–30].

Medical Evidence Summary

Balloon sinuplasty clinical studies were identified via a search of the MEDLINE database conducted in June 2008. The goal was to identify all available published clinical studies related to balloon sinuplasty. The literature search used combinations of the keywords *Relieva, balloon, dilation, sinus,* and/or *sinuplasty.* Retrieved articles were limited to "clinical trials," "humans," "English" language, and those with abstracts. Abstracts of studies presented at professional meetings but not fully published were not included. There were no restrictions placed on the publication date. The bibliographies of key references and recent review articles were searched for relevant studies not uncovered in the computerized search. A general internet keyword search and a bibliography compiled by the manufacturer were also utilized to facilitate the literature search [31].

We identified 6 relevant clinical studies of varying types that met selection criteria [22,23,26,32–34] (**Table**). These included a preclinical (cadaver) study and an initial human feasibility study ($n = 10$) that were published in 2006 [22,23]. The pivotal evidence to date comes from a company-sponsored, prospective, multicenter, nonrandomized, phase 2–type trial called CLEAR (CLinical Evaluation to confirm sAfety and efficacy of sinuplasty in the paRanasal sinuses) that was published in 2007 [34]. A large ($n = 1036$) retrospective registry study of "real world" use, a radiation dosage study, and a small comparative outcome (patient satisfaction, cost) study were also identified in the biomedical literature [26,32,33]. Typical of evidence development for an emerging technology, all available studies (except the comparative outcome study) had some degree of manufacturer funding or included paid consultants to the company.

The CLEAR study originally enrolled 115 adult patients at 9 U.S. centers with a diagnosis of chronic sinusitis unresponsive to medical management who were scheduled for FESS [34]. Patients were evaluated regularly through 6 months of follow-up. An average of 3.1 sinuses per patient were treated with balloon dilation. Sinus symptoms and QOL outcomes, measured using the sinonasal outcome test (SNOT-20, 20 questions, scale from 0 = no problem to 5 = problem as bad as it can be [35]), improved from an average of 2.25 preoperatively to 1.09 at 6 months ($\Delta = -1.17$; $P < 0.001$). Patient questionnaire data showed 84% self-reported their symptoms were improved at 6 months. Ostial patency was endoscopically confirmed in

Table. Summary of Balloon Sinuplasty Clinical Studies

Study	Methodology	Results/Outcomes
Church et al 2008 [26]	Prospective radiation exposure study *n* = 93	Radiation exposure: Mean patient dose (over the eye), 0.32 mSv/sinus and 1.02 mSv/patient Mean patient dose (over the temple), 1.33 mSv/sinus and 4.22 mSv/patient Mean surgeon dose (chest), 0.025 mSv/sinus and 0.072 mSv/patient Mean surgeon dose (hand), 0.009 mSv/sinus and 0.023 mSv/patient Mean total fluoroscopy time, 3.6 min/patient
Friedman et al 2008 [32]	Retrospective comparative study using chart and billing records *n* = 70 (35 sinuplasty, 35 FESS controls)	SNOT-20 scores: Sinuplasty: preop, 2.8; 3-mo postop, 0.78; Δ = 1.99 FESS: preop, 2.7; 3-mo postop, 1.29; Δ = 1.41 Patient satisfaction: survey (would have procedure again?): Sinuplasty: 91% yes, 5.7% not sure FESS: 49% yes, 46% not sure Outcome survey (-5 to +5 scale): sinuplasty, +3.71; FESS, +2.94; *P* = 0.016 Postoperative narcotics: sinuplasty, 0.8 days; FESS, 1.34 days; *P* = 0.011 Costs: Sinuplasty: primary procedure, $14,021; revision, $10,346 FESS: primary procedure, $13,574; revision, $16,190 *P* = 0.555 for primary procedure; *P* < 0.001 for revision (sinuplasty revision surgery performed under local anesthesia)
Levine et al 2008 [33]	Retrospective (chart review) multicenter (27 U.S. centers) registry study *n* = 1036 consecutive patients (49.5% men vs. 50.5% women; mean age, 47.2 yr; 3276 sinuses)	Procedure: Balloons used in 3.2 sinuses/patient, 82.8% at hospital outpatient surgery centers, 17.2% at ambulatory surgery centers, all patients but 2 had general anesthesia (mean surgery time, 73 min [range, 6–230 min]); 44% received sinusotomy in 1 sinus type (26% maxillary, 16% frontal, 2% sphenoid), 41% in 2 sinus types, 15% in all 3 sinus types, ethmoidectomy by FESS used concomitantly in 63% of cases, (mean debridéments/patient, 1.2) Complications: No major adverse events. Revision rate, 1.3% of sinuses (2.4% of patients); mean follow-up, 40.2 wk (range, 8–88 wk) Patient satisfaction: Sinus symptoms improved, 95.2%; unchanged, 3.8%; worse, 1.0%
Bolger et al 2007 [34]	CLEAR: prospective, multicenter (*n* = 9) phase 2 study *n* = 115 patients (109 with some follow-up [358 sinuses]; 95 with 6-mo follow-up [304 sinuses])	Patency: At 24 wks, 80.5% patent ostia (247/307 sinuses); 1.6% nonpatent (5/307) Could not determine ostial patency status in 17.9% (55/307) due to inability to directly visualize. Of ostia visualized, 98% patent (247/252), 2% nonpatent (5/252) SNOT-20 scores: Preop, 2.25; 1 wk, 1.39; 12 wk, 1.07; 24 wk, 1.09; Δ, −1.17 at 6 mo, *P* < 0.001 Patient satisfaction: 84% reported improved symptoms Complications: Revision treatment, 3 sinuses (3/307, 0.98%) in 3 patients (3/109, 2.75%). No serious adverse events. Procedure: Median fluoroscopy/sinus, 0.81 min (730 mrem/patient). Device malfunction, 12/358 (3%) Mean sinuses treated/patient, 3.1
Brown et al 2006 [23]	Prospective feasibility study *n* = 10 patients, 18 sinuses, 80% had concurrent FESS	Outcomes: All 18 sinus ostia successfully catheterized and dilated Complications: No adverse events reported. Mucosal trauma and bleeding qualitatively appeared to be less than typically observed with FESS

Table. Summary of Balloon Sinuplasty Clinical Studies (*continued*)

Study	Methodology	Results/Outcomes
Bolger et al 2006 [22]	Preclinical cadaver study *n* = 6 cadavers (31 ostia)	Outcomes: Catheters successfully accessed and dilated 31 of 31 ostia Complications: CT scan showed no trauma to surrounding vital structures Gross dissection showed flattened, stretched, and torn mucosa that was still attached to underlying support Ostia dilated to approximately the size of the dilated balloon

CT = computed tomography; FESS = functional endoscopic sinus surgery; mSv = milli-Sieverts; SNOT-20 = Sinonasal outcome test–20 questions.

80.5% of sinuses (247/307) at 6 months. In a high number of sinuses (17.9%, 55/307), the ostia could not be visualized and patency was indeterminant, while 1.6% of sinuses (5/307) were deemed nonpatent at 6 months. There were no serious adverse events reported. Revision treatment was required in 3 sinuses (0.98%) in 3 patients (2.75%). The median fluoroscopy time per sinus was 0.81 minutes (730 mrem/patient).

Safety outcomes over a slightly longer follow-up period (mean, 40.2 weeks; range, 8–88 weeks) as well as typical clinical use characteristics were reported in the registry study [33]. Similar to the CLEAR study, the registry showed balloon dilation use in 3.2 sinuses per patient. However, 63% of cases also had concomitant use of conventional FESS, primarily for ethmoidectomy. Confirming safety, there were no reported major adverse events attributed to the use of balloon catheters. The revision rate was 1.3% of sinuses (2.4% of patients). The physician reported improvement in sinus symptoms in 95% of patients. Patient demographics showed balloon sinuplasty was used equally in men and women (mean age, 47.2 years). Procedure data showed balloon sinuplasty cases were used most often (82.5%) in patients for a primary sinus surgical episode (ie, no previous sinus surgeries), procedures lasted an average of 73 minutes (range, 6–230 min), and follow-up care requirements were low (mean, 1.2 debridéments and 1 endoscopy per patient).

In the only published comparative data, 35 balloon sinuplasty only cases were retrospectively compared with 35 FESS cases with respect to patient satisfaction, postoperative pain, and cost outcomes [32]. The cohorts were somewhat matched for severity but were not randomized, and the FESS patients included ethmoidectomy; thus, clinical treatments were not matched either. Because of differences in clinical treatment, efficacy outcomes were not compared. Both balloon sinuplasty and FESS showed clinically meaningful reductions in SNOT-20 scores at 3 months (sinuplasty: 2.8 preop to 0.78 at 3 months [$P < 0.05$]; FESS: 2.7 preop to 1.29 at 3 mos [$P < 0.05$]). On survey, 91% of patients reported they would have balloon sinuplasty again compared with 49% reporting yes for FESS, with 46% not sure. Use of postoperative narcotics was somewhat less for balloon sinuplasty (sinuplasty, 0.8 days vs. FESS, 1.34 days; $P = 0.011$), suggesting less postoperative pain.

Discussion

From a technology assessment–based perspective, the published clinical literature is significantly limited and strong evidence-based conclusions cannot be made at this time. The clinical evidence encompasses approximately 1300 treated patients, but most of these patients were included from a retrospective registry–type study. The pivotal cited study (CLEAR) was a phase 2 study with 6 months of follow-up. There were no RCTs, long-term efficacy data, rigorous comparative trials, or cost-effectiveness studies. Additional studies will be needed to more clearly define the efficacy, appropriate patient selection criteria, and clinical role of balloon sinuplasty.

Analysis of the available evidence suggests balloon sinuplasty is a safe procedure with a low rate of major complications and bleeding. In the best available evidence to date, the CLEAR study reported no incidences of CSF leak or orbital injury [34]. Rare cases of major complications, however, are possible, particularly in combined FESS/sinuplasty procedures, and have been reported [33]. There were reportedly no cases of postoperative epistaxis that required packing in the CLEAR study. Device malfunctions without sequelae were reported in 3.3% (12/358) applications. While complications are low, there are no rigorous data yet to compare the complication rates between sinuplasty and FESS. Also, long-term studies are needed to detect potentially late complications (eg, mucocele formation) secondary to sinuplasty use.

With regard to efficacy, studies show balloon sinuplasty can access and dilate the affected frontal, sphenoid, or maxillary sinus ostia in at least 80% of cases. The efficacy rate may be higher, but early trials have reported a high "indeterminant" finding due to failure to visualize the ostia. Better methods, including the use of pediatric endoscopes, may be used in future studies to better define this parameter. Ostial patency appears to be maintained through 6 months to 1 year. The revision rate ranges from approximately 2.5% to 3% of patients over the first year but may be highly dependent on duration of follow-up.

In 2007, both the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) and the American Rhinologic Society (ARS) issued position statements on balloon sinuplasty [36,37]. The ARS statement was revised from an earlier 2006 position statement that generally considered balloon sinuplasty to be investigational. Both statements are now in concordance, and these professional societies indicate that based on preliminary clinical evidence and expert opinion, balloon sinuplasty is a safe and effective procedure for the treatment of chronic sinusitis.

The professional society statements further suggest that sinuplasty balloons should be considered to be just another surgical tool, analogous to choosing a microdebrider, laser, or cutting forceps. The clinical role of balloon sinuplasty is therefore dictated by the judgment of the treating physician as to the best tool for the task. The statements do not rule out concomitant use of conventional FESS tools in a "hybrid" procedure for treatment of sinuses not amenable to sinuplasty. They also suggest that there will be a small subset of patients who may be able to undergo a balloon only procedure.

Additional costs for the tools and inadequate reimbursement are issues that may mitigate the dissemination of balloon sinuplasty. The single-patient use components of the balloon sinuplasty system cost around $1200 to $1500 per procedure [32]. These costs are incremental in hybrid procedures and may not be fully reimbursed in lump-sum payment scenarios. Further, many private payers may consider the use of balloon sinuplasty to be investigational and thus not subject to coverage [38].

Procedure costs are similar comparing balloon only cases to the costs associated with conventional FESS for primary procedures [32]. Thus, assuming equivalent coding, reimbursement between these procedures will be similar. AAO-HNS, in a separate position statement on balloon sinuplasty coding issued in March 2007, indicated that sinuplasty could be delineated using FESS current procedural terminology (CPT) codes (31256, 31276, 31287) when 2 conditions were met: (1) a sinus endoscope is used to position the balloon, and (2) the procedure significantly enlarges the ostia by moving bone and mucosa [39]. A unique health care common procedure coding system (HCPCS) code (S2344-nasal/sinus endoscopy, surgical: with enlargement of sinus ostium opening using inflatable device, ie, balloon sinuplasty) may also be used for coding balloon sinuplasty.

Appropriate patient selection criteria is an issue that has not yet been adequately addressed by clinical studies. Typical candidates enrolled to date have involved chronic or recurrent sinusitis despite antibiotic use, topical steroids, and/or allergic management, as well as evidence from persistently abnormal computed tomography scans [7,8]. Basically, the selected patients are candidates who would be considered for FESS and have 1 or more sinuses accessible to balloons. Potential unique applications of balloon sinuplasty include febrile intubated patients with suspected sinus causes, patients on anticoagulants, maxillary sinus hypoplasia, atelactic infundibulum, or silent sinus syndrome [40]. Balloon sinuplasty is contraindicated in patients with polyps, esoinophilic mucosal membrane disease, sinonasal tumors, certain anatomical variants, and sinus disease with significant osteoneogenesis [23].

One major drawback of balloon sinuplasty involves the use of fluoroscopy. Because this technology is not typically used in otolaryngology, the introduction of balloon sinuplasty may affect institutional practice patterns. Operators may need specialized training in the use of fluoroscopy to ensure safety of patients and staff. Radiation dose to the lens of the eye, especially in children, is of particularly concern. Fluoroscopy equipment should be operated in modes that self-limit radiation exposure. Operators should endeavor to limit fluoroscopy to a level as low as reasonably achievable to perform the procedure. Current analysis in the literature suggests the typical balloon sinuplasty procedure maintains radiation exposure at acceptable levels [26].

Eliminating or reducing the need for fluoroscopy may make sinuplasty more clinically acceptable to surgeons and patients [20]. There are some new technologies in development that will potentially reduce fluoroscopy times. A recently developed fiberoptic light wire is advanced across the target ostia, with confirmation of placement in the intended sinus made by visual inspection of light transmitted through the facial tissue [41]. Clinical evidence development for the light wire system may be expected by late 2008 [42]. Tools to integrate sinuplasty devices with surgical navigation systems are also available [43]. These may facilitate accurate device placement and reduce fluoroscopy times, although further study is needed to show these advantages.

The future significance of this technology may lie in its role as a more tolerable choice of therapy than FESS, especially in patients with less severe cases of sinusitis. Preliminary studies reported at meetings have noted a high rate of patient satisfaction with the procedure and the postoperative follow-up [24]. Further, the first series of patients ($n = 11$) undergoing balloon sinuplasty under local anesthesia, with or without conscious sedation, has also been recently reported [32]. The latter concept, although part of the original marketing intent, is not common at this time as evidenced by the registry study, which reported use of conscious sedation rather than general anesthesia in 0.2% (2/1036) of patients.

These findings suggest the possibility of moving the procedure, for highly selected cases in patients without significant comorbidities, from the hospital setting to other settings. For example, there is currently a growing trend moving all types of FESS procedures from the hospital outpatient surgery setting to the ambulatory surgical center setting. The registry study reported approximately 83% of procedures using

sinuplasty were performed in hospital outpatient surgery centers, with approximately 17% currently performed in ambulatory surgical centers. In the next progression, these procedures may be carried out in the clinic setting as well.

Conclusions

Based on the available evidence, balloon sinuplasty appears to be a safe procedure and has shown short-term efficacy in relieving symptoms associated with chronic sinusitis. As a surgical tool, its mechanism of action provides distinct differences as compared with conventional tools. There are, however, a number of unanswered questions to consider before further widespread adoption occurs. For example, significant questions remain regarding the use of sinuplasty to replace FESS in select sinuses, how to use FESS in conjunction with sinuplasty, better quantification of the clinical risks and efficacy, formulation of appropriate patient selection criteria, and determining the incremental cost-effectiveness of sinuplasty.

Ideally, future clinical studies will be conducted that compare sinuplasty treatment with controls undergoing best medical care and/or placebo treatments. Studies are also needed comparing outcomes (both short-term surgical and long-term functional and QOL outcomes) between conventional FESS and balloon sinuplasty to aid in the decision to select 1 tool over another. Ideally, RCTs comparing the 2 alternatives are needed, however, because both techniques are often used in the same patient and because FESS treats the ethmoids, this type of trial will be difficult to conduct [24]. All institutions opting to use sinuplasty are encouraged to collect and publish prospective data that can be used to refine usage decisions.

Corresponding author: Joseph P. Cummings, PhD, University HealthSystem Consortium, 2001 Spring Rd., Ste. 700, Oak Brook, IL 60521, cummings@uhc.edu.

Financial disclosures: None.

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