Healthy Blue

Clinical UM Guideline

Subject:	Balloon Sinus Ostial Dilation		
Guideline #:	CG-SURG-73	**Publish Date:**	07/06/2022
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Description

This document addresses the use of balloon sinus ostial dilation for surgery of the sinuses, including for the treatment of sinusitis. These procedures involve insertion of a balloon catheter device into a nasal sinus cavity to open blocked sinus ostia.

Note: Please see the following related documents for additional information:

- CG-SURG-18 Septoplasty
- CG-SURG-24 Functional Endoscopic Sinus Surgery (FESS)
- CG-SURG-57 Diagnostic Nasal Endoscopy
- MED.00091 Rhinophototherapy
- SURG.00089 Self-Expanding Absorptive Sinus Ostial Dilation
- SURG.00132 Drug-Eluting Devices for Maintaining Sinus Ostial Patency
- SURG.00151 Balloon Dilation of the Eustachian Tubes

Clinical Indications

Note: When Functional Endoscopic Sinus Surgery (FESS) is performed in conjunction with a procedure addressed in this policy, the criteria contained in CG-SURG-24 must be met for the FESS procedure.

Medically Necessary:

The use of balloon sinus ostial dilation is considered **medically necessary** for the treatment of uncomplicated sinusitis (for example, sinusitis confined to the paranasal sinuses without adjacent involvement of neurologic, soft tissue, or bony structures) when **all** (A, B, and C) of the following have been met:

A. Either of the following:
   1. Four or more documented episodes of acute rhinosinusitis (for example, less than 4 weeks duration) in 1 year; **or**
   2. Chronic sinusitis (for example, greater than 12 weeks duration); **and**

B. Maximal medical therapy has been attempted, as indicated by **all** of the following:
   1. Antibiotic therapy; **and**
   2. Trial of inhaled steroids; **and**
   3. Nasal lavage; **and**

4. Allergy testing (if symptoms are consistent with allergic rhinitis and have not responded to appropriate environmental controls and pharmacotherapy [for example, antihistamines or intranasal corticosteroids or leukotriene antagonists, etc.]); **and**

C. Abnormal findings from diagnostic work-up, as indicated by **any one** of the following:
   1. Computed tomography (CT) findings suggestive of obstruction or infection for example, but not limited to, air fluid levels, air bubbles, significant mucosal thickening, pansinusitis, or diffuse opacification; **or**
   2. Nasal endoscopy findings suggestive of significant disease; **or**
   3. Physical exam findings suggestive of chronic/recurrent disease (for example, mucopurulence, erythema, edema, inflammation).

Not Medically Necessary:

The use of balloon sinus ostial dilation is considered **not medically necessary** in all other circumstances not stated above, including when the following conditions are present:

A. The criteria above have not been met; **or**
B. The individual has been diagnosed with presence of sinonasal polyposis; **or**
C. The procedure is being used to treat the following conditions in the absence of CT-confirmed chronic sinusitis or recurrent acute sinusitis:
   1. Headache; **or**
   2. Sleep apnea.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

31295	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); maxillary sinus ostium, transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal sinus ostium
31297	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); sphenoid sinus ostium
31298	Nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia

HCPCS

Note: this document applies to following HCPCS code only when the device is associated with a balloon ostial dilation procedure listed above

C1726	Catheter, balloon dilatation, non-vascular [when specified as a balloon sinus ostial dilation device]

ICD-10 Diagnosis

J01.01	Acute recurrent maxillary sinusitis
J01.11	Acute recurrent frontal sinusitis
J01.21	Acute recurrent ethmoidal sinusitis
J01.31	Acute recurrent sphenoidal sinusitis
J01.41	Acute recurrent pansinusitis
J01.81	Other acute recurrent sinusitis
J01.91	Acute recurrent sinusitis, unspecified
J32.0-J32.9	Chronic sinusitis

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses including, but not limited to the following:

ICD-10 Diagnosis

G43.001-G43.919	Migraine
G44.001-G44.89	Other headache syndromes
G47.00-G47.9	Sleep disorders
J33.1-J33.9	Nasal polyp
J34.1-J34.9	Other and unspecified disorders of nose and nasal sinuses
R51.0-R51.9	Headache

Discussion/General Information

Chronic sinusitis is defined as a prolonged or recurrent infection and inflammation of the nasal sinuses. Nasal sinuses are open spaces in the head connected by small passageways to the nasal passageways leading from the nose. Under normal conditions, air passes in and out of the sinuses and mucus and fluid drain from the sinuses into the nose.

Sinusitis occurs when there is infection or inflammation in one or more of the sinuses. Temporary or acute sinusitis is often associated with upper respiratory infections or irritation due to allergic reactions which cause temporary blockage of the passages leading from the sinuses. Blocked sinuses can accumulate nasal secretions and bacteria, leading to infection.

Chronic, long-term sinusitis may develop in people with chronic allergies, deviated nasal septum or other obstruction of the nose. Additionally, dental infections such as tooth abscesses may also spread into the sinus and infect it directly.

When sinusitis recurs frequently, or lasts for a prolonged period of time, it is classified as chronic. While acute sinusitis is usually caused by infection with a single type of bacteria or virus, chronic sinusitis is usually caused either by allergies or by infection with a mixture of different types of bacteria.

Chronic sinusitis may have less severe symptoms than acute sinusitis but can cause damage and destruction to the tissues of the sinuses. It may flare up spontaneously or may follow respiratory infections such as colds.

Treatment of chronic sinusitis usually involves the use of antibiotics if the infection is bacterial. Oral sinus decongestants are sometimes used as well. In more serious cases related to allergies, topical steroids in the form of nasal sprays may be helpful in controlling inflammation. Surgery to clean and drain the sinuses may be necessary to clear serious chronic infections. Finally, surgical repair of a deviated nasal septum or other nasal obstruction may prevent recurrence of chronic sinusitis.

Sinus surgery is commonly done with the use of thin fiberoptic tools that are passed through the nostrils. This method, referred to as endoscopic sinus surgery, allows visualization and manipulation of the surgical site without the need for surgical incisions in the mouth or face. Once the endoscopic tools are in place in the surgical site, small tools are used to obliterate the sinus tissue and bone to open the sinus passages.

A technique referred to as balloon sinus ostial dilation has been proposed as an alternative or addition to standard endoscopic surgery. This procedure proposes the use of a small balloon-like device instead of the other devices usually used. There are two different types of devices available on the market that dilate the sinuses. With one type of device, the balloon is placed in the blocked sinus passage under endoscopic guidance through the nostril. The other type is placed in the sinus through an incision made in the gums and maxillary bone under the front lip of the individual. In both cases, once the balloon is in place in the ostia of the targeted sinus, the balloon is inflated to push the sinus tissue and bone out of the way, creating a larger airway passage and allowing drainage of nasal secretions.

The U.S. Food and Drug Administration (FDA) has cleared several devices for the catheterization and balloon dilatation of the paranasal sinus ostia, a procedure known as balloon sinus ostial dilation, for the treatment of chronic sinusitis. These devices include the Acclarent Relieva™ Sinus Balloon Catheter (FDA clearance August, 2005 for transnasal use), the Entellus FinESS™ device (FDA clearance June, 2008 for transantral use), the Entellus XprESS® Multi-Sinus Dilation Tool (FDA clearance September, 2010 for transnasal use), the NuVEnt™ EM Sinus Dilation System (FDA clearance July, 2013 for transnasal use), and the Ventera® Sinus Dilation System (FDA clearance 2012 for transnasal use). In 2020, the Next Generation Balloon Dilation System (Acclarent, Inc., Irving, CA), an integrated balloon sinuplasty and eustachian tube dilation device, received 510(k) clearance. Balloon Sinuplasty™ is a trademarked term describing transnasal use of the Acclarent Relieva Sinus Balloon Catheter.

In 2017, the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) endorsed a position statement addressing the use of balloon dilatation. The statement says:

> Sinus ostial dilation is a therapeutic option for selected patients with chronic rhinosinusitis (CRS) and recurrent acute rhinosinusitis (RARS) who have failed appropriate medical therapy. Clinical diagnosis of CRS and RARS should be based on symptoms of sinusitis and supported by nasal endoscopy documenting sinonasal abnormality and evidence of mucosal thickening on computed tomography of the paranasal sinuses. This approach may be used alone to dilate an obstructed sinus ostium (frontal, maxillary, or sphenoid) or in conjunction with other instruments ([for example], microdebrider, forceps). The final decision regarding use of techniques or instrumentation for sinus surgery is the responsibility of the attending surgeon.

The AAO-HNS published a clinical consensus statement for balloon dilation of the sinuses (Piccirillo, 2018). This document published the following statement that reached consensus:

- Balloon dilation is not appropriate for patients who are without both sinonasal symptoms and positive findings on CT.
- Balloon dilation is not appropriate for the management of headache in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
- Balloon dilation is not appropriate for the management of sleep apnea in patients who do not otherwise meet the criteria for chronic sinusitis or recurrent acute sinusitis.
- CT scanning of the sinuses is a requirement before balloon dilation can be performed.
- Balloon dilation is not appropriate for patients with sinonasal symptoms and a CT that does not show evidence of sinonasal disease.
- Balloon dilation can be appropriate as an adjunct procedure to FESS in patients with chronic sinusitis without nasal polyps.
- There can be a role for balloon dilation in patients with persistent sinus disease who have had previous sinus surgery.
- There is a role for balloon sinus dilation in managing patients with recurrent acute sinusitis as defined in the AAO-HNSF guideline based on symptoms and the CT evidence of ostial occlusion and mucosal thickening.

Brown (2006) reported on 10 subjects who underwent 18 procedures with the Relieva device. This initial study is representative of the literature which is generally limited to small numbers with short-term follow-up (often less than 6 months). Chronic sinusitis is a complex and chronic illness which persists, often despite treatment, for years, and, accordingly, short-term follow-up data does not allow conclusions as to whether a procedure benefits the individual treated. Where longer-term follow-up has been reported, there is often a lack of concurrent comparison or other methodological concerns including a high rate of loss to follow-up or inability to distinguish the impact of the balloon from concomitant functional endoscopic sinus surgical (FESS) procedures performed on the same individual.

Bolger (2007) published the CLinical Evaluation to Confirm SAfety and Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR) Study. This prospective multicenter case series study included 109 subjects with sinusitis treated with the Relieva device and followed for 6 months postoperatively. In over half of these subjects (52.3%), Balloon Sinuplasty was conducted in at least one sinus while FESS was used to treat other sinuses. The authors reported a low revision rate and no serious complications. Self-reported data measured by the sino-nasal outcome test (SNOT-20) evaluation tool indicated significantly improved sinusitis symptoms, although only 77% (84/109) of subjects provided a complete set of data. Data presented evaluating the balloon-only group (n=49) vs. the combined approach group (n=57) found no significant differences between groups for symptom relief measures. While the authors concluded that Balloon Sinuplasty produced favorable results, significant methodological concerns, including small sample size, lack of a prospectively selected control group, no blinding, use of self-reported data, short follow-up period (24 weeks), and significant loss to follow-up (23%), all negatively impact the usefulness of this data. Additionally, the post-hoc nature of group selection and inability to separate out the impact of Balloon Sinuplasty from traditional FESS undermine the ability to draw firm conclusions.

Kuhn (2008) and Weiss (2008) published longer-term data of the same population reported on by Bolger (2007) in the CLEAR study. Kuhn describes 1-year follow-up data from 66 of the original 109 subjects (40% drop out rate). At 1 year, endoscopy demonstrated that 85% of sinuses treated with Balloon Sinuplasty were still patent, 1% were not patent and 14% were indeterminate. Fourteen of the 26 subjects (53%) with indeterminate patency were found to have patent ostia on CT scans, for a clinical patency rate of 91.6%. SNOT-20 scores were statistically improved over pre-operative scores, and demonstrated continuation of the improvement reported by Bolger. Weiss reported on CLEAR participants at 2 years post-operation with 65 of the original 109 subjects (40% drop out rate). The SNOT-20 scores reported by Weiss were stable into year 2, which showed some durability of the benefits of the balloon procedure. These are important findings, but since both the Kuhn and Weiss studies are continuations of the CLEAR study population, the methodological flaws discussed with the Bolger study carry through to these reports as well. The small sample size, lack of a prospectively selected control group, no blinding, use of self-reported data, and significant loss to follow-up all impact the usefulness of this data.

Friedman (2008) described the results of a nonrandomized controlled clinical trial of Balloon Sinuplasty with the Relieva device (n=35) and standard FESS (n=35). Individuals with medically refractory chronic sinusitis self-selected which procedure they received, and those with severe disease were excluded. The results found that SNOT-20 scores were significantly better for the FESS group than the balloon group at the 3-month postoperative follow-up visit. There also may have been a statistically significant difference in postoperative pain (measured by total narcotic use), with the balloon group experiencing less pain than the FESS group. The authors cautioned, however, that "lack of records regarding amount of narcotics used each day may have prevented accurate measurement." The only significantly higher complication reported was turbinate lateralization in the Balloon Sinuplasty group. However, the authors also cautioned that 1 subject undergoing Balloon Sinuplasty required a second surgical procedure within 3 months due to persistent infection, and that longer-term studies would be required to determine if this was indeed an incrementally more significant problem following this type of surgery as compared with standard FESS. Finally, the authors state that this study was not designed to demonstrate the efficacy of Balloon Sinuplasty. In their Discussion section they state, "Because efficacy cannot be assessed with 3-month follow-up, this study specifically avoided drawing conclusions about efficacy. Nevertheless, ongoing studies are essential to determine if balloon dilatation technology is worthy of continued clinical use." They conclude by stating "valid comparisons could not be made between the two [balloon sinuplasty and FESS] groups… this study provides data to justify ongoing study of this new tool…"

Levine (2008) published a retrospective case series study of 1036 subjects who received either Balloon Sinuplasty alone or some form of hybrid procedure combining balloon and FESS. The mean follow-up was 40 weeks with a range of 8-88 weeks, with a median time for follow-up was 39 weeks. The authors report no complications related to the balloon procedure with the Relieva device. Sinus symptoms, both pre- and postoperatively, were self-reported. The authors state that there were differences between groups with regard to blood loss, operation time, debridements, and endoscopies, with outcomes favoring the balloon-only group. However, no statistical data or analysis is provided to demonstrate or support this finding. It should also be noted that no data are presented for sinus patency. Finally, the revision rate for individuals receiving Balloon Sinuplasty only (n=328) vs. "hybrid" surgery of Balloon Sinuplasty plus FESS (n=708) was approximately 50% higher (3.1% vs. 2.1% by subject, and 2.2% vs. 1.2% by sinus). This is significantly higher for those receiving Balloon Sinuplasty alone, but the authors did not provide an explanation. The authors caution that this retrospective registry review was not a prospective, controlled study and did not provide a comparative outcome analysis.

Stankiewicz (2009) reported results of the Balloon Remodeling Antrostomy Therapy [BREATHE I] study, a nonrandomized, uncontrolled case series of 30 consecutive subjects with chronic maxillary sinusitis who were followed for 6 months after treatment with the Entellus FinESS device. The authors reported no serious adverse events or unexpected device effects. SNOT-20 scores were significantly improved and 95.8% of sinuses dilated continued to be patent at 3 months. Patency data were not reported at the 6-month follow-up visit. Stankiewicz (2010) reported the findings of the first 29 BREATHE I subjects to complete the 12-month trial period, all of whom had been successfully treated with the FinESS device alone. Significant improvements in SNOT-20 measures of rhinologic symptoms, ear and facial symptoms, sleep function and psychological issues were reported. Cutler (2011) reported on 67 BREATHE I subjects (52 treated in the OR and 19 treated in the clinic) at 12 months follow-up. Ostial patency at 3 months via CT scans was 90% (106/117). However, patency data were not provided for other time points. SNOT-20 data were significantly improved at 12 months ($p<0.0001$), with symptoms improving 67% in subjects with isolated maxillary involvement compared to 47% in those with both maxillary and anterior ethmoid disease. Similar results were reported in subjects treated in the OR vs. the clinic. Five subjects were reported to have had adverse events, including facial or tooth numbness possibly related to the procedure. These symptoms were ongoing at the completion of the study. Stankiewicz (2011) published a study on the BREATHE I subjects which evaluated the impact of balloon sinus ostial dilation using the FinESS device on work productivity. Using the Work Productivity and Activity Impairment (WPAI) and Work Limitations Questionnaire (WLQ) instruments, the report indicates significant improvements in all domains, including activity impairment, absenteeism, lost productivity, work output, and timeliness. Stankiewicz (2012) reported 2-year results from the BREATHE I study group. Of the 71 subjects available at the 1-year time point, 59 (83%) successfully completed the study to the 2-year time point. At 2 years, the average symptom scores, as measured by the SNOT-20 tool, improved from 2.65 ± 0.97 at baseline to 0.79 ± 0.71 ($p<0.0001$). Gains seen on the WPAI and WLQ tools at 1 year continued to be significantly improved for all domains at 2 years. A total of 4 subjects (5.6%) underwent revision surgery for continued sinus disease. No major complications were mentioned, including whether or not the facial and tooth numbness mentioned in the 1-year report had resolved satisfactorily. As noted earlier, the BREATHE I study is an unblinded case series study with no control group for comparison. Additionally, only short-term patency data have been published. No long-term patency data are available. The results shown by the SNOT survey tool data are promising. However, the findings of this ongoing study are limited by methodological flaws which hamper generalization of the results to a wider population.

The use of the FinESS device for the treatment of critically ill individuals has been described in a small case series study published by Wittkopf and others (2009). In this study, 5 immunocompromised or critically ill subjects with acute sinusitis were treated with subantral balloon sinus ostial dilation. The results provided in the published article are limited, stating that all subjects returned to baseline health and met discharge criteria after surgery. Only 2 subjects received follow-up CTs, at 2 and 3 months respectively, and both confirmed resolution of disease. No statistics or objective data are provided. The results of this study are interesting, but provide no significant data to allow conclusions to be made regarding the comparative safety or efficacy of balloon sinus ostial dilation in critically ill subjects compared to other techniques.

In 2011, the Cochrane Collaborative published a review entitled, "Functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis." The authors of this review conclude:

> At present there is no convincing evidence supporting the use of endoscopic balloon sinus ostial dilation compared to conventional surgical modalities in the management of CRS refractory to medical treatment. With the escalating use of balloon sinuplasty, there is an urgent need for more randomised controlled trials to determine its efficacy over conventional surgical treatment modalities.

Plaza (2011) published the results of a randomized controlled double-blind study involving subjects with frontal sinus disease who underwent either standard FESS with the Relieva device or combination FESS-balloon dilation. In addition to procedures to address sinus tract patency, participants also underwent septoplasty and/or partial middle turbinectomy, and polypectomy when indicated. The study began with a total of 40 subjects randomized, 20 to each group, but completed with only 16 in each group (20% loss to follow-up). The study does not clearly describe how individuals were chosen for randomization or how many individuals might have been eligible but not randomized. Outcomes were measured by subjective visual analog scale measures of common rhinosinusitis symptoms, a Spanish adaption of the rhinosinusitis disability index (RSDI), olfactory threshold testing, Lund-Mackay scores, and both endoscopic and CT measures of sinus patency at baseline and at the end of the 12-month follow-up period. The main outcome measure was resolution of frontal sinus disease as shown by CT scan at 12 months. The authors reported that 80.76% of the operative balloon procedures were successfully conducted compared to 91.7% of control group procedures. No statistical significance data is available for this comparison. Significant improvement was noted in both groups in terms of Lund-Mackay score and Frontal sinus Lund-Mackay scores. Again, no statistical significance data is available between the two groups. Resolution of frontal sinus disease, as shown on CT scans, was 80.76% for the balloon group and 75% for the control group. This difference was not significantly different. However, the published report indicated in the abstract section that frontal sinus permeability was significantly better in the balloon group, and in the body of the results section they contradict this by stating that no significant difference was found. After initial publication, a letter to the editor was submitted making this point and, in response, the authors agreed and attributed the error to final editing (Lefevre, 2012; Plaza, 2012). This correction is important, as the erroneous statement in the Plaza abstract has been frequently cited as demonstrating the superiority of the balloon procedure. Given this correction, such claims should no longer be made based on this study. Other limitations to Plaza (2011) include the small sample size, brief follow-up, results reported without analysis for statistical significance, the lack of information on postoperative debridement procedures, and the use of hybrid procedures, mixing standard FESS and balloon approaches, as well as concomitant septoplasty, turbinectomy, and polypectomy. These limitations complicate the ability to separate out the effect of the balloon procedure on global rhinosinusitis measures. The lack of an intent-to-treat analysis impairs the statistical validity of the results. Finally, the study design used by Plaza, as well as the study population size, were not pre-specified to allow for a "non-inferiority" determination. This study should not be interpreted as demonstrating that balloon sinuplasty is comparable to FESS. In summary, this study does not demonstrate that balloon sinus dilation is as good as standard FESS approaches, nor does it demonstrate that balloon sinus dilation is safer than existing techniques.

Heimgartner (2011) evaluated the causes of balloon sinus ostial dilation failure in 64 subjects with 136 sinuses treated with the Relieva device. The authors report that of the 104 frontal sinuses for which balloon treatment was attempted, 12 (12%) failed. This was in comparison to no failures of treatment in the maxillary or sphenoid sinuses. The reasons cited for failure were predominantly anatomic variations of the frontal recess, such as agger nasi cell, frontoethmoidal cell or frontal bulla cell and significant osteoneogenesis. The authors stated that further anatomic

studies are needed to answer the specific influences of these factors. Additionally, they state that surgical technique learning curve also may play a role, but that their study was not designed to evaluate that aspect of the procedure.

Albritton (2012) and the ORIOS investigators published a case series of in-office balloon sinus dilation with the Relieva device. This study involved 37 subjects in whom 59 sinuses were treated, including maxillary (n=28), frontal (n=21), and sphenoid (n=10). Seventeen subjects (46%) were revisions of prior FESS procedures and 22% (n=8) had polyp disease. The overall rate for technical success in ostial treatment was 91%, with 2 subject's sinuses inaccessible due to scarring from prior FESS and another 2 with only some of the target sinuses treated successfully. Of the initial 37 subjects, 29 (78%) completed the procedure tolerability questionnaire, and 36 (97%) completed the post-procedure pain assessment. There was significant loss to follow-up over the course of the study, with 86.5% (n=32) of subjects completing the first week, 83.8% (n=31) the fourth week, 70.2% (n=26) the 24th week, and only 56.8% (n=21) the 52nd week. For the remaining subjects, SNOT-20 scores were significantly improved at all time points up to 52 weeks ($p<0.001$ at 1, 4, 24, and 52 weeks). Nasal polyposis did not significantly impact SNOT-20 scores for this population ($p=0.66$). A total of 29 subjects were available for CT evaluation at 24 weeks. In this group, Lund-Mackay scores significantly improved from 6.62 to 2.79 ($p<0.0001$). Longer-term Lund-Mackay data were not provided for 52 weeks. This study has several methodological flaws, including a lack of control group and randomization. Large loss to follow-up and lack of 52-week Lund-Mackay scores further limit the usefulness of this data.

The ORIOS 2 study investigators also published results of a larger prospective case series study of 203 subjects (Karanfilov, 2012) who were separated into 3 cohorts treated with the Relieva device. The first "lead-in" cohort included a minimum of 3 subjects enrolled by each investigator with all targeted sinuses successfully treated (n=26). The second "standard enrollment" cohort consisted of approximately 15 subjects enrolled after the lead-in subjects (n=84). Subjects in these two cohorts were followed for 24 weeks, including CT evaluations. The third "extended enrollment" cohort (n=83) involved any subjects enrolled after a site's standard enrollment phase was complete. Participation in the 24-week follow-up study was optional for this last cohort. A reported 38.1% (n=77) of subjects had previous sinus surgery, and 8.4% (n=17) had polyposis. Ninety-three (77.5%) subjects in the first two cohorts completed the 24-week follow-up, but only 24 (28.9%) in the third cohort were evaluated at 24 weeks. Successful dilation was completed in 552 of 592 sinuses (93.2%), with 251 of 268 (93.7%) being frontal sinuses, 263 of 282 (93.3%) maxillary, and 38 of 42 (90.5%) sphenoid. Reasons for unsuccessful dilation included anatomical variation (n=22), intolerance of the procedure (n=6), disease (n=4), scarring (n=2) and polyps (n=1). No data was available for 5 subjects with failed procedures. No device or procedure-related serious adverse events were reported during the study period for all followed subjects. One subject had a non-serious adverse complication of periorbital swelling that resolved spontaneously. As with the previously mentioned ORIOS study, SNOT-20 results indicated significant improvement at all time points (2 weeks, 8 weeks, 24 weeks; $p<0.001$). Lund-Mackay results were available for 110 subjects at 24 weeks, with significant improvements reported (6.9 ± 3.6 at baseline to 2.5 ± 3.0 at 24 weeks, $p<0.0001$). There were 6 revisions out of the total 203 subjects within the 24-week follow-up period (3.0%). The results of this study are promising, like those previously discussed. However, as with those studies, this study suffers from the same methodological flaws, lack of control group and randomization. Additionally, the follow-up period is very short and long-term benefits are not demonstrated. Another major flaw with this study is the subject selection method used, which introduced significant selection bias. It is not clear how many subjects were needed to reach the first 3 successful subjects included in the lead-in cohort at each site, nor are the reasons some subjects in the extended enrollment cohort were included and others were not.

Achar (2012) and colleagues published the results of a small prospective, non-blinded, randomized controlled trial (RCT) involving 24 subjects treated with an unspecified balloon sinus ostial dilation device and followed for 6 months. The sino-nasal outcome test (SNOT)-20 questionnaires and saccharine clearance time (SCT) were used to measure outcomes. Individuals with extensive sinonasal polyps, previous sinonasal surgery or trauma involving sinonasal complex, Samter's Triad (aspirin sensitivity, asthma, sinonasal polyposis), sinonasal tumors or obstructive lesions, known ciliary dysfunction or cystic fibrosis, and pregnancy were excluded. In this study, the investigators compared FESS to what they refer to as "Endoscopic dilatation sinus surgery (FEDS)," but do not explicitly say which balloon device is used. The balloon group (n=12) had dilation on the frontal and maxillary sinuses only. The FESS group (n=12) underwent middle meatal antrostomy (n=18 sinuses) and ethmoidectomy (n=16 sinuses). Fourteen frontal sinuses were treated as well. Thus, some subjects in the FESS received much more extensive procedures than the FEDS group. The authors reported that the SNOT-20 scores were significantly better in the balloon group (p=0.026), as were SCT (p=0.03). No significant postoperative complications were recorded in either group. No subject in the FEDS group had any bleeding, and all were ready for discharge within hours of the procedure. The authors conclude that functional endoscopic dilatation sinus surgery (FEDS) was as effective as functional endoscopic sinus surgery (FESS) in treatment of chronic rhinosinusitis. The conclusion must be considered in light of the primary outcome measure, SNOT-20, being subjective and self-reported. In addition, the study was very small and short in duration.

Tomazic (2013) published the results of a non-randomized comparative study of the Relieva device with 45 subjects (112 sinuses) undergoing endoscopic sinus surgery for chronic sinusitis (2013). Of the 112 sinuses, 68 (60%) were assigned to undergo treatment with Balloon Sinuplasty (BSP) only and 44 (40%) were assigned to a hybrid procedure combining FESS and balloon techniques. In the balloon-only group, the procedure failed in 44 of 68 sinuses, equating to a failure rate of 65%. In the hybrid group 29 of 44 procedures failed, giving a failure rate of 66%. The authors concluded:

> According to literature, BSP can be a useful adjunct technique to standard FESS. In our experience, however, a failure rate of 65% for balloon-only and of 66% for hybrid procedures occurred, which was regarded as unacceptable by the study group. Therefore, the study initially scheduled for 200 consecutive patients, was abandoned.

The methods section of the article indicates that two of the four investigators received training directly from the manufacturer, with the remaining two being trained by the first pair. All investigators were described as "very experienced sinus surgeons," and they undertook a 37 subject break-in period prior to beginning enrollment in the study. This was intended to allow the investigators to acclimate to the procedure. As noted by the authors themselves, these results are in contrast to the previously described trials of the Relieva device.

Brodner (2013) published a case series of 175 subjects using the Entellus XprESS Multi-Sinus Dilation Tool who were followed for 1 month postoperatively. The ostia treated varied considerably; the first 50 subjects had balloon treatment of the frontal and sphenoid ostia and some of the remainder had the maxillary and ethmoid ostia also treated. Only 8 subjects (4.6%) had balloon-only procedures. The remainder of the population had standard FESS or other surgical procedures done concurrently with the balloon procedure. It is unclear how many of the initial pool of 50 subjects followed for 1 year had balloon-only treatment and how many received hybrid treatment. The authors report that 18 dilations in 12 subjects were unsuccessful (3.6%). Ostial patency data was available for 41 of the 50 subjects followed for 1 year (82%), with a 91.6% overall patency being reported. Frontal ostia were patent in 93.5%

of subjects and sphenoid ostia were patent in 85.7%. SNOT-20 data were available for 44 of the 50 subjects followed for 1 year. The authors report significant improvement in the SNOT-20 scores (1.9 ± 1.1 at baseline vs. 0.8 ± 0.7 at 1 year; p<0.0001); however, the clinical significance of this change is uncertain and further study is needed to demonstrate the efficacy of the XprESS device.

Cutler (2013) reported the results of the REMODEL study, a non-blinded [though there was some reviewer blinding for measured endpoints], non-inferiority RCT with 6 months follow-up. A total of 53 subjects were randomized to undergo FESS with maxillary antrostomy and uncinectomy with or without anterior ethmoidectomy, and 52 subjects underwent balloon dilation of the maxillary sinus ostia and ethmoid infundibula only with either the XprESS or FinESS devices. Between randomization and the assigned procedures, 11 FESS subjects and 2 balloon subjects withdrew. One additional balloon subject was lost to follow-up after the procedure leaving 49 subjects in the balloon group and 42 in the FESS group. Uncinectomy was conducted on all FESS group subjects, with or without ethmoidectomy (n=42 with 80 maxillary uncinectomies; n=72 total and n=8 partial). Ethmoidectomy was conducted in 22 of the 42 FESS subjects. The authors reported that both groups had statistically and clinically significant improvements in the SNOT-20 scores at 6 months with no significant differences between groups, demonstrating non-inferiority (p<0.0001). Clinically significant was defined as SNOT-20 change of ≥ 0.8 units based on Piccirillo (2002). There was a significant difference between groups with regard to postoperative debridements, with 4 balloon subjects and 31 FESS subjects requiring debridements. The mean number of debridements in the FESS group was 1.2 ± 1.0 vs. 0.1 ± 0.6 in the balloon group (p<0.0001). Use of postoperative pain medications was less in the balloon group vs. the FESS group as well (0.9 vs. 2.8 days, p<0.001). No significant complications were reported for either group. While this study does provide new information about postoperative debridement and pain management, the relatively short 6-months follow-up is not sufficient to address whether there are long-term benefits of the procedures performed. In addition, this was a small, non-blinded non-inferiority design. The null hypothesis that the treatments are non-inferior may not have been demonstrated. Also, while the apparent improvement in pain management and fewer debridements may be clinically meaningful, the clinical significance of change in SNOT-20 is uncertain. Finally, the authors state that:

> In patients with more advanced inflammatory or sinonasal disease pathology including severe polyposis, Samter's triad, fungal sinusitis, hyperplastic sinusitis, ciliary dysfunction, obstructive septal deviation, obstructive lesions, facial trauma, or cystic fibrosis, tissue resection continues to be the standard of care because tissue remodeling via balloon dilation has yet to be proven in these populations and further studies are warranted. Thus, the ability to generalize the results remains unclear.

Levine (2013) reported the results of a prospectively enrolled case series study of 74 individuals with chronic rhinosinusitis (CRS – 12 weeks of sinus symptoms and documented inflammation) or recurrent acute rhinosinusitis (RARS – 4 or more episodes of acute bacterial infection per year) of the maxillary sinus or ethmoid infundibula who were treated with the FinESS device in the office setting after failure of medical management (antibiotics for at least 3 weeks and oral or intranasal steroids). Individuals with evidence of disease in other sinuses were excluded. There was no comparison made to conservative management or FESS. Results were reported for 69 subjects (4% lost to follow-up) at 1 year. Reported outcomes included the overall technical success (able to cannulate the ostia) rate of the procedure which was 91.9% (85.5% success rate for the first 30 subjects and a 96.3% success rate for remaining subjects); and symptom scores measured by SNOT-20 (baseline 2.3, improved to 1.1 at 6 months and 1.0 at 1 year [p<0.0001]). The authors indicate that a change in SNOT-20 of 0.8 units is considered clinically

significant; however, there was no citation in support of that statement. A (non-pre-specified) sub-analysis comparing subjects with chronic rhinosinusitis (n=49) vs. recurrent acute rhinosinusitis (n=16) found no differences in terms of SNOT-20 results at any time period. Nasal steroid and antibiotic use decreased in both groups. Days of work missed, homebound days, the number of physician visits and acute infections were also significantly improved compared to baseline; however, the method of measuring the baseline values for these metrics was not disclosed. Persistent mild numbness in the tissue around the canine fossa was reported in 5 (6.8%) subjects. The surgical revision rate was 5.8%, with 4 subjects continuing to have standard FESS due to persistent radiographic signs of maxillary and/or ethmoid sinus disease. The authors note that the findings of this study suggest either equivalency or superiority of the balloon dilation procedure vs. traditional FESS and further comment that, "randomized studies to compare balloon dilation to standard-of-care treatments for rhinosinusitis, including medical management and traditional ESS, continue to be necessary."

Results of the RELIEF (HealthcaRE UtiLization and Outcomes of FInESS Treatment in the OFfice) study were reported by Levine in 2013. This case series study involved 47 subjects at 12 different centers with maxillary or anterior ethmoid sinus disease who underwent treatment with the FinESS device in the office setting. Individuals with frontal posterior ethmoid, or sphenoid disease were excluded from the study, and no concomitant surgical procedures were allowed. The overall technical success rate was 99.9%, with 124 of 135 ostia successfully treated and 5 subjects with treatment failure. Of the 69 evaluable subjects, 66 (95.7%) completed the 1-year follow-up. The mean improvement in the SNOT-20 was 1.2 points at 6 months, which was sustained through 1 year ($p<0.0001$). A total of 49 subjects with CRS and 16 with RARS completed the study. Significant improvements in all major and minor symptom measures of the Rhinosinusitis Symptom Inventory (RSI) tool were reported for both subpopulations of subjects ($p<0.0001$). The use of nasal steroids decreased significantly in the CRS group only ($p=0.036$), while both RARS and CRS subjects experienced significant decrease in antibiotic use ($p\leq0.001$). Persistent numbness in the region of the canine fossa was reported by 5 subjects (6.8%), and 4 subjects (5.8%) underwent subsequent revision surgery with FESS. While these results are promising, the lack of a comparison group does not allow an understanding of the incremental outcomes benefit of balloon over the standard of care, FESS.

In a small RCT, Marzetti and others (2014) evaluated the impact of an unspecified balloon sinus ostial dilation device on the improvement of headache symptoms. The study enrolled 83 subjects, 75 (91.4%) of whom completed the study to the 6-month follow-up time point. Of those subjects who completed the study, 40 underwent FESS of the frontal sinuses, and 35 underwent treatment with the balloon device. Of the balloon subjects, 12 (34.3%) underwent Hybrid FESS/Balloon procedures. Additionally, some subjects in both groups also underwent endoscopic septoplasty (n=15, 42.8% of the FESS group; n=20, 57% of the balloon group). FESS treatment of additional sinuses was also conducted on subjects in both groups, but no data describing this distribution are presented. Finally, inferior turbinate reduction was conducted in all subjects. Neither the subjects nor the evaluators were blinded to group assignment. The investigators report significant improvements in both postoperative SNOT-22 ($p<0.0001$) and headache scores on a visual analog scale ($p<0.0001$). No results regarding changes in headache days or use of analgesic or other medications were provided. This study has many confounding factors, such as the various concurrent surgical procedures and the small population of subjects who actually received balloon-only frontal sinus treatment, to properly isolate the impact of the balloon device on outcomes.

In 2014, Gould reported the results of a prospective case series study of 81 subjects who underwent treatment with the XprESS device. Turbinate reduction was conducted in 46 subjects. At 1-year follow-up, 76 subjects (94%) were

available for final evaluation. The technical success rate was 98.1%, with 307 attempted dilations successful in 313 attempts. SNOT-20 results indicated a significant improvement with a mean improvement of -1.57 points ($p<0.0001$). The authors also stated that 78.7% of subjects experienced a clinically meaningful improvement in sinus symptoms at 1-year post-treatment. On the RSI at 1 year compared to baseline, the treatment effect for all major rhinosinusitis symptom measures was "large" and statistically significant ($p<0.0001$). Significant decreases were reported for all of the following: antibiotic use ($p<0.0001$), nasal steroid and antihistamine use ($p<0.0001$), sinus-related doctor visits ($p<0.001$ and $p<0.0001$, respectively), and acute sinus infections ($p<0.0001$). No serious adverse device or procedure-related events were reported. Subgroup analysis based on which sinus was treated resulted in no significant differences noted. While this study does demonstrate beneficial, short-term results, the authors noted that a limitation of this study was a lack of a control group, which did not allow for assessment of possible placebo effects. Other limitations include small size, the short follow-up time and lack of patency data.

In the first report on the use of the Ventera Sinus Dilation System, Hathorn (2014) described a single-blind RCT involving frontal sinusotomy in 30 subjects. This paper does not describe how subjects were referred into the study, raising the possibility of referral bias. The authors do not describe the pretreatment condition or prior treatment of the subjects which limits generalizability. Randomization involved assignment of either the left or right sinus ostia to undergo treatment with standard FESS or a hybrid FESS-balloon procedure. The contralateral sinus underwent the other treatment option. The primary outcome measure was sinus ostial patency at 3 months by direct visualization. Although the methods section states that the clinician making the postoperative evaluations was not aware of group assignments, the discussion section states that the evaluation of patency was made by a single clinician who was also the surgeon. No significant differences were reported between groups with regard to ostial patency at the 5-week and 3-month time periods. The report claims that both operative times and blood loss were statistically better in the hybrid group; however, the mean values for each parameter were within the 95% confidence limits in each treatment arm. Primary data are not presented for validation of statistical significance. The clinical significance of these differences is questionable. The average operating time for the hybrid procedure is reported to be 243 seconds less than the FESS procedure. Average blood loss for the hybrid procedure was 58 cc vs. 91 cc for FESS. The blood loss difference calculation is confounded by the fact that the decision of which procedure to do first was not completely random. Blood loss for the second procedure may have included some continued oozing from the first treated side. The study randomized which side would receive the hybrid or FESS procedure. The intent was to always start with the left side, but in fact the surgeons would start on the least obstructed side. The authors do not include data to show how often FESS was the second procedure done. At 1-year postoperative follow-up, 22 of the original 30 subjects were available (73%), and patency was noted to be 100% for both groups (no difference between groups). No revision surgeries were reported. Of the 30 subjects, 12 (40%) were reported to have nasal polyps. A subgroup analysis found that there were no significant differences in ostial patency between subjects with and without polyps.

One-year follow-up data from the REMODEL study was published by Bikhazi in 2014. Complete data were available for 82 of the original 92 subjects (96.7%; n=48 balloon group, n=41 FESS group). The study's primary endpoint was improvement in sinonasal symptoms as measured by SNOT-20 scores. The mean improvement in SNOT-20 scores at 1 year was -1.64 ± 1.06 in the balloon group and -1.65 ± 0.94 in the FESS arm ($p<0.001$ for both groups). The authors reported that no significant between-group differences were found on any of the four subscales on the SNOT-20 tool, demonstrating the non-inferiority of the stand-alone balloon procedure (p=NS [not significant] for all scales). Similarly, both groups demonstrated statistically significant improvements in rhinosinusitis symptoms ($p<0.001$) and no differences were found between groups (p=NS). A total of 47 balloon

subjects (97.9%) and 41 FESS subjects (100%) had data available on maxillary ostial patency. Overall patency assessed by CT scanning was reported to be 96.7% in the balloon group and 98.7% in the FESS group (p=NS). Patency data from the ethmoid infundibula was not provided. The study also measured work productivity using the WPAI score. Subjects in each of the treatment arms saw statistically significant decreases in daily activity impairment, percent of impairment while working, and overall work impairment. There were no statistical differences between groups in WPAI measures. The authors further reported the 18-month follow-up results for the first 45 subjects treated in the REMODEL study. Of the initial 45 subjects, data was available for 43 (95.5%; n=22 balloon group, n=21 FESS group). It was reported that the previously reported improvements in the SNOT-20 tools were sustained (p<0.0001), and there continued to be no difference between groups (p=NS).

Chandra (2015) reported the final 2-year follow-up data for the 71 balloon group and 61 FESS group subjects (total n=135) included in the REMODEL study described above. Complete 24-month data was available for 20.3% (15/74) of balloon group subjects and 16.4% (10/61) of FESS subjects, for an overall loss to follow-up of 88.8%. In the subjects available at 24 months, the balloon group had significantly shorter recovery time (1.7 vs. 5.0 days, p<0.001), less nasal bleeding after discharge (32% vs. 56%, p=0.009), and shorter duration of post-operative pain medications use (1.0 vs. 2.8 days, p<0.001). The primary outcome of the number of post-operative debridements was significantly lower in the balloon group (0.2 vs. 1.0, p<0.001). Additional 1-year data was provided beyond that published by Bikhazi, indicating that there were no significant differences between groups in acute exacerbations of rhinosinusitis (p=0.258). The authors reported that the balloon procedure was non-inferior to FESS with regard to 2-year SNOT-20 scores (p<0.001). No significant differences between groups were reported with regard to overall revision rates or complication rates. As with the previously described studies, the results are promising. However, this trial had a very large loss to follow-up of almost 90% at 24 months. These results do not provide substantial or robust data sufficient to demonstrate the mid-term durability of balloon sinus ostial dilation.

The Chandra paper also included a meta-analysis of stand-alone balloon procedures. Data was presented from pooled case series studies as well as controlled studies. The analysis included data from six trials, all of which are addressed in this document, accounting for a total of 358 subjects. With the exception of the REMODEL study, all included trials were single arm studies with no comparator groups. The majority of the trials had a maximum follow-up of 12 months. Only the REMODEL trial had a longer follow-up. They reported good 12-month follow-up data, with 93% of subjects having data available. Technical success for the pooled data was 97.5%, and overall SNOT-20 mean change was significantly improved from baseline. The authors reported finding statistically significant improvements with regard to results from the Work Limitation Questionnaire (data from two studies, no p-value data provided) and as well as from the Rhinosinusitis Symptom Inventory (data from 160 subjects) (p<0.001). Subgroup analysis for subjects with chronic rhinosinusitis (n=291) vs. recurrent acute rhinosinusitis (n=52) was conducted. No significant differences were reported, but both groups did demonstrate significant improvements on SNOT-20 scores (p<0.001). Similar findings were reported for subjects with and without ethmoid disease (p<0.001). As stated earlier, the lack of comparison groups, short follow-up, lack of blinding, and other methodological flaws impair the value of this data.

Sikand and others reported the 1-year results of the ORIOS 2 study (2015), including data from 122 subjects who volunteered for extended follow-up (mean 1.4 years). The authors reported a mean SNOT-20 reduction of -1.1, which they state is both statistically (p<0.001) and clinically significant. Of the total subject population, 61 subjects had ethmoid disease. SNOT-20 scores did not differ significantly between the ethmoid and non-ethmoid groups at 1-year follow-up. A total of 7.3% (9/122) subjects underwent revision surgery due to recurrence, 8 of whom had

ethmoid disease. Radiographic evaluation was conducted in 7 of the ethmoid subgroup subjects at 24 weeks, with 5 having residual ethmoid disease and 2 with none.

Levy and colleagues reported the results of a meta-analysis of 11 RCTs meeting their inclusions criteria (2016). They observed that potential conflicts of interest were identified in 10 of the 11 studies included in their analysis. The authors identified five studies containing extractable data regarding change in SNOT-20-scores 1 year following the balloon procedure, with significant improvement in self-reported quality of life ($p=0.04$). Additionally, another five studies were reported to have a significant change in paranasal sinus opacification following balloon ostial dilation ($p<0.001$). Only two studies were reported to have directly compared change in SNOT-20 between the balloon procedures and endoscopic sinus surgery. Neither demonstrated a significant difference in outcomes ($p=0.07$). Finally, a subgroup analysis was conducted that identified that the change in SNOT-20 score was greater after balloon procedures in the operating room than in the office ($p=0.004$). Overall, the authors concluded that the current evidence supporting the role of balloon sinus ostial dilation for chronic rhinosinusitis remains incomplete. Long-term within-group improvements in quality-of-life and sinus opacification scores are demonstrated among a restricted adult population with CRS, but additional study is needed to further evaluate the role for this technology in specific settings and participant subgroups.

In 2016, Payne and others published the results of a nonrandomized controlled trial involving 198 subjects with chronic rhinosinusitis. Subjects self-selected to receive continuing medical management (n=52) or treatment with balloon ostial dilation (n=146) and followed for 24 weeks post-procedure. The medical management arm did not have a proscribed regimen, which was left to the discretion of the treating physician. The balloon procedures were done either in the operating room (n=41) or in the office (n=105), again at the discretion of the treating physician. The authors reported that the study was stopped early following an interim analysis indicating the superiority of the balloon procedure. Technical success of the dilation procedure was reported to be 97.6%. At 24 weeks, improvements in SNOT-20, RSDI, and Chronic Sinusitis Survey (CSS) measures were all significantly better in the balloon group ($p=0.002$, $p<0.001$, and $p=0.001$, respectively). As with the other studies described above, the findings reported by Payne indicate significant benefit to the balloon procedure. However, it should be noted that these findings are impaired by the weak methodology utilized, including non-random assignment, no blinding, short follow-up times, and more.

Koskinen and others (2016) published the results of a retrospective-prospective, nonrandomized or blind controlled trial involving 208 subjects older than 13 years of age with bilateral maxillary sinus disease who underwent either FESS involving bilateral partial uncinectomy and middle meatal antrostomy (n=105) or balloon sinus dilation of the maxillary sinuses with the Relieva device (n=103). Subjects were identified through record review and contacted by phone at a mean of 6 years for FESS subjects and 6.4 years in the balloon group. The phone interview involved a questionnaire addressing the subject's medical history, smoking habits, occupational exposure, family history, number of sinusitis episodes in the past year, use of nasal steroids, and recent nasal lavage treatments. The FESS group was reported to begin the study with significantly lower Lund-Mackay scores on the right side. The authors reported that the number of episodes of acute sinusitis, thick nasal discharge and right sided nasal blockage were significantly improved in the FESS group vs. the balloon group. However, no differences were found in nasal symptom score ($p>0.05$). No significant differences between groups were reported with regard to maxillary lavage or antibiotic courses for acute sinusitis. The overall number of subject-reported episodes of acute sinusitis were significantly decreased in the FESS group ($p<0.01$). Revision procedures were conducted in 4 balloon group subjects and no FESS group subjects ($p=0.048$).

Chaaban and colleagues (2018) reported the results of a retrospective cohort study involving data from the Clinformatics Data Mart (CMD) database involving data from 16,040 subjects aged 7 to 65 year diagnosed with CRS and treated with FESS alone (n=11,955), balloon sinus dilation alone, (n=2,851) or hybrid FESS-balloon sinus dilation (n=1,234) procedures. Data from 2012-2014 were analyzed. They reported that during the first postoperative 6 months the balloon-only group had a complication rate of 5.26% vs. 7.35 for FESS-only group (no p-values provided). Revision rates for the same timeframe were 7.89% for the balloon-only group, 16.5% for the FESS–only group and 15.5% for the hybrid group (no p-values provided). The authors reported that FESS was associated with an almost 4-fold increase in risk of revision procedures (OR, 3.8). Complications included orbital complications (2.95% in the balloon-only group vs. 3.47% in the FESS-only group), bleeding (2.03% vs. 3.46%, respectively), and skull base/CNS complications (0.35% vs. 0.39%, respectively. Skull base injuries included pneumocephalus and CSF leaks. The rate of secondary procedure was 0.91% for balloon-only vs. 1.40% for FESS-only subjects. The authors concluded, despite the low overall risk, major complications do occur with balloon-only procedures, including cerebrospinal fluid leak, pneumocephalus, orbital complications, and severe bleeding.

Long term results from the Payne (2016) mentioned above were reported by Stolovitzky in 2018. At 52 weeks data were available for 122 (83.6%) of balloon group subjects and 27 (51.9%) of the control medical management group. Improvements in SNOT-20 symptom score, RSDI, and Chronic Sinusitis Survey (CSS) measures were all significantly better in the balloon group (p=0.023, p=0.003, and p=0.001, respectively). As with the other studies described above, the findings reported by Payne indicate significant benefit to the balloon procedure. However, as noted above these findings are impaired by the weak methodology utilized, as well as significant loss to follow-up in both the experimental and control groups.

Another study reported by Kutluhan and others (2020) described a split-face randomized controlled study involving 61 subjects with mild to severe CRS. Subjects with bilaterally consistent mild/mild (Lund-Mackay score ≤ 6) or severe/severe (Lund-Mackay score ≥7) RCS had each side randomly treated with Balloon-only of FESS-only procedures. Follow-up occurred between 13 and 17 months. The results indicated that overall, there were no significant differences in Lund-Mackay scores between the balloon and FESS groups (p=0.24). Similarly, no significant differences in Lund-Mackay scores were reported between treatment groups in subjects with mild CRS (p=0.63). For subjects with severe disease, Lund-Mackay scores were significant better in the FESS group (p=0.01). The authors concluded that for mild CRS, balloon and FESS procedures provide similar outcomes. However, as RCS severity increases the efficacy of balloon procedures decreases.

Balloon Sinus Ostial Dilation in Children

In 2014, Brietzke and others published a clinical consensus statement regarding the management and diagnosis of pediatric chronic rhinosinusitis (PCRS). The document included three statements, statements 28 through 30, specifically discussing balloon sinuplasty.

> Consensus was reached that there was insufficient current evidence to compare balloon sinuplasty to ESS for PCRS (statement 28). Not unexpectedly, the panel subsequently could not reach consensus regarding the effectiveness of balloon sinuplasty in treating PCRS although there was near consensus (mean Likert score = 6.56) regarding the safety of balloon sinuplasty…

Soler (2017) reported the results of a prospective cohort study of 50 (157 sinuses) children (< 21 years of age) with medically refractory, CT-confirmed CRS treated with balloon sinus dilation with the XprESSS Multi-Sinus Dilation system. Subjects' parents were asked to complete the Sinus and Nasal Quality of Life Survey (SN-5) and SNOT-22 survey tools at 1, 3, and 6 months postoperatively. Overall follow-up was 99%. The SNOT-22 tool was only given to subjects greater than or equal to 12 years old. A total of 157 sinus dilations were attempted (98 maxillary, 30 frontal, and 29 sphenoid sinuses). The authors reported that all attempts (100%) were successful with no complications noted. Bilateral treatment was conducted in 92% of subjects. Concurrent procedures were conducted in 30 subjects, including adenoidectomy (n=21), inferior turbinate reduction (n=13), and ethmoidectomy (n=6). No serious adverse events or revision procedures were reported. Significant improvements were reported on the SN-5 tool for all subjects at 6 months vs. baseline ($p<0.0001$). A minimal clinically important difference (MCID) of 1.0 or more was reported in 92% of subjects. Subjects aged 2 to 12 years with balloon-only treatment demonstrated similar improvements between baseline and 6 months ($p<0.0001$). For subjects aged 12 to 21, SNOT-22 mean scores were also significantly improved at 6 months ($p<0.0001$). The authors concluded that, "Balloon sinus dilation is safe and appears effective for children with CRS aged 2 years and older."

Jia and colleagues (2020) reported the 3-year follow-up results of a prospective study of 30 (65 sinuses) children (6 to 15 years of age) with 3 to 6 months of failed medical management for CRS treated with balloon sinuplasty. Outcomes were measured using a VAS for subjective symptoms, assessment of quality of life using the SN-5 (< 12 years of age) or SNOT-22 (≥ 12 years of age), and CT findings graded using Lund-Mackay scoring system. If the SN-5 was used at baseline, it was used again at follow-up for consistency of measurement. Other data collected included reports on the use of nasal medications and irrigation, revision surgeries, assessment of adverse events, and a short survey assessing degree of satisfaction with the procedure. The VAS and SN-5 or SNOT-22 scores were all reported to be significantly lower ($p<0.001$) at 3-year follow-up. The authors reported that post-procedure Lund-Mackay scores were significantly lower ($p=0.028$) compared to baseline. Participants with a significant improvement in symptoms at the time of 3-year follow-up were not reexamined by CT. However, criteria for that determination was not provided. The most common post-procedural complication was nasal cavity adhesion. Three cases were identified at 15 to 30 days after surgery and two cases were identified at 3-years post-procedure. One participant had several complications that led to a revision surgery by FESS in the second year after the balloon procedure and was excluded from further follow-up. The authors also reported that most participants did not require post-procedure nasal medication for symptom management and that 29 of 30 participants were satisfied with the procedure. Some limitations of this study include a small sample size, non-randomized design, and lack of comparison group.

Conclusion

Overall, the number of studies addressing the use of sinus ostial dilation continues to grow. While the quality of the data remains low, there is growing consensus in the otolaryngological practice community that the use of balloon sinus ostial dilation provides significant benefits over FESS in terms of postoperative pain, blood loss and loss of work, while delivering similar health outcome benefits. While questions of long-term outcomes remain, the use of this procedure is reasonably safe and effective when used in appropriately selected populations. The use of this procedure for the treatment of individuals with polyposis, headaches, sleep apnea is as of yet unclear.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	05/12/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, References, and Websites sections.
Reviewed	05/13/2021	MPTAC review. Updated Description, Discussion, References, and Index sections. Reformatted Coding section.
	10/01/2020	Updated Coding section with ICD-10-CM diagnosis codes considered NMN; including 10/01/2020 coding updates R51.0-R51.9.
Reviewed	05/14/2020	MPTAC review. Updated Rationale and References sections.
	12/31/2019	Updated Coding section with 01/01/2020 CPT changes; revised descriptors.
Reviewed	06/06/2019	MPTAC review. Updated Rationale and References sections.
Revised	07/26/2018	MPTAC review. Removed MN criteria text related to time limit for antibiotic therapy for uncomplicated sinusitis. Updated References sections.
New	03/22/2018	MPTAC review. Initial document development. Moved balloon ostial dilation related content from SURG.00089 Balloon and Self-Expanding Absorptive Sinus Ostial Dilation to new clinical utilization management guideline document.