Is there support for structural and functional preservation in sinus surgery? An evidence-based review

Raymond Weiss, MD¹, Judith Farrar, PhD², Michael Benninger MD³

Background: Technical innovation has enabled the goal of combined structural/functional preservation during maxillary sinus intervention; and the balloon catheter has provided insight into how intact bony structures affect postoperative airflow and mucosal processes. However, the clinical relevance remains unclear.

Objective: Perform a systematic evaluation of the long-term clinical outcomes of endoscopic sinus surgery (ESS) and balloon sinuplasty (BSP).

Methods: The MEDLINE database and other sources were searched (2000-2011) for surgical and subjective outcomes associated with ESS and BSP studies of ≥12mo in patients (≥12yr) with chronic rhinosinusitis.

Results: Of 320 identified articles, 21 met the inclusion criteria: 17 ESS, 4 BSP. All studies were single-center; 75% were prospective. Regardless of procedure, the majority of patients showed long-term improvements as determined by surgical parameters, endoscopy scores, CT scores, symptom scores, and/or QoL indices. When evaluated, mean post-surgery decreases in SNOT-20 scores approximated 50-75% for both. Other objective comparisons were not possible due to methodological differences.

Conclusion: The existing evidence makes it difficult to compare clinical outcomes for ESS and BSP. While it can be inferred that ESS is a successful procedure based on prevalence of use and generally positive QoL outcomes, objective evidence in terms of radiographic, endoscopic, or revision-rate outcomes are lacking. For BSP, the available data based on validated measures of patient symptoms and QoL are intriguing, but appropriate comparison to ESS is limited. Current data provide some support for either intervention used appropriately, but more studies – preferably randomized, controlled – are needed to validate any comparison.

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The evolution of sinus surgery since George Caldwell and Henri Luc first described an anterior approach to the maxillary sinus in the late 1800s through the introduction of balloon catheters in 2005 has paralleled the current (at the time) understanding of sinus structure and function. Endoscopic sinus surgery (ESS) virtually replaced the Caldwell-Luc procedure after 1960. Since then, ongoing refinement of the ESS approach as well as the introduction of newer methodologies has brought attention to the dual (and sometimes seemingly opposing) goals of maximizing function (i.e., drainage, ventilation) while at the same time minimizing structural alteration. The need for structural preservation versus functional preservation is an ongoing dialogue, sometimes controversial. However, review of the available data suggests some points of agreement.

1. ESS set the stage for the concept of a minimally invasive approach; and most sinus surgery today reflects advances in technologies and/or tools developed to enhance ESS through an increased ability to target specific structures, reduce operating time, minimize trauma, and improve patient outcomes.

2. ESS for treating chronic sinus disease has been associated with high success rates (≥ 80% depending on the study, patient population, and how success is defined). Nonetheless, a substantial number of patients continue to have symptoms. The reasons for recurrent disease are not well understood.

3. The idea of using a balloon-style catheter to open sinus and nasal passageways in a minimally invasive manner was adopted from other specialties, notably cardiology. The first FDA-approved device for Balloon Sinuplasty™ (Acclarent, Inc., Menlo Park, CA) was introduced in 2005 as a catheter-based system for dilating the paranasal sinuses’ ostia, particularly for the maxillary, frontal and sphenoid sinuses. The balloon catheter permits expansion of the sinus ostia and surrounding outflow tracts with little or no tissue removal. It has become a relevant tool, and, depending on the surgeon’s preference and patient’s diagnosis, it may be used alone or with other procedures to optimize access to the sinuses.

Experience with the balloon catheter has provided further insight into sinonasal function. Since bony structures remain intact, there are differences in postoperative airflow and morphology when compared to traditional ESS. The body of current evidence regarding structure preservation related to nasal/sinus function centers around the maxillary sinus (uncinate physiology, meatal airflow patterns, maxillary intrasinus nitric oxide levels). How these impact clinical outcomes is not clear. While traditional maxillary ESS is widely practiced and believed to be an effective procedure, there is no review of the literature focused specifically on subjective and objective outcomes related to uncinectomy/antrostomy. To that end, we undertook a systematic evaluation of published studies of traditional ESS and balloon sinuplasty (BSP) in terms of clinical outcomes.

Methods

The MEDLINE database from 2000 to 2010 was searched on the topic of surgical and subjective (symptoms; quality of life, QoL) outcomes associated with ESS and balloon sinuplasty using the search terms endoscopic sinus surgery, functional endoscopic sinus surgery, Sinus*[TI] and Surg*[TI], balloon dilatation, balloon sinuplasty, balloon catheter. The search terms were limited to: English language and studies of human patients with chronic (rhino)sinusitis (CRS) or recurrent acute sinusitis. Identified abstracts were reviewed and articles identified as being potentially relevant were obtained. Relevant studies were also identified by cross-referencing major review articles and meta-analyses. Non-peer-reviewed articles, conference abstracts, safety studies that did not report the results of surgical outcomes, and papers describing studies that otherwise did not meet the inclusion criteria were specifically excluded. Studies that met the inclusion criteria (Table 1) were evaluated and are used in the data table.
Table 1. Inclusion and exclusion criteria

<table>
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<th>Inclusion</th>
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<tr>
<td>Primary study report</td>
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<td>Adult and adolescent patients (≥ 12 yr)</td>
<td>Studies of children (&lt; 12 yr)</td>
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<td>N ≥ 25</td>
<td>N &lt; 25</td>
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<td>Mean follow-up ≥ 12 months</td>
<td>Mean follow-up &lt; 12 months</td>
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<td>Surgical intervention of ≥ 1 sinus</td>
<td>ESS solely for treatment of polyp disease or nasal carcinoma</td>
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<td>CRS not related to other disease or condition (e.g., ciliary dyskinesia, cystic fibrosis)</td>
<td>CRS due to radiation therapy</td>
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<td>Relevant outcome measure: QoL scores, symptom scores, endoscopic scores, CT scores, endoscopy scores, revision rates</td>
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Results
The initial search yielded 320 possible articles of interest; of which 133 were determined to be potentially relevant and subjected to full text review (Figure 1).

Figure 1. Development of the data table from the initial search of the literature
Twenty-one studies are included in the final evidence table (Table 2 - following Discussion section), 17 ESS studies\(^{11-27}\) and 4 BSP studies.\(^{28-31}\) All the studies were single-center investigations: 5, all ESS, were retrospective reviews of patient charts;\(^{13,14,15,21,23}\) the remaining studies (75%) were prospective. Three studies (15%, all ESS) included appropriate control groups.\(^{11,14,25}\)

In all studies, regardless of procedure, the majority of patients showed long-term (i.e., ≥ 12 month) improvement in outcomes as determined by surgical parameters, endoscopy scores, CT scores, symptom scores, and/or QoL indices.

The studies varied widely in how they were conducted, including the evaluation of patient populations, duration of follow-up, and outcomes measured. As such, the available data cannot be used to directly compare the different procedures (BSP vs. ESS).

Within the ESS group, outcomes were generally positive. However, the studies used different methods and employed different measures (sometimes, not validated) for scoring symptoms and QoL and, thus, cannot be directly compared.

Three of the BSP studies used validated standard outcomes in terms of mean Sino-Nasal Outcome Test (SNOT-20) scores and Lund MacKay (LMK) scores.\(^{28,29,31}\) In these studies the mean SNOT-20 scores decreased by 48-75%, and the mean LMK scores decreased by 45-73%. The largest changes were observed in “hybrid” patients – those who underwent both ESS and BSP for their sinonasal disease. Substantial decreases in LMK scores were also observed when BSP was added to ESS in a randomized controlled trial of patients with refractory frontal sinusitis, though the added improvement beyond ESS did not reach statistical significance.\(^{30}\) The ranges for improvement for the SNOT-20 scores were similar to those reported in 3 of the ESS studies (56%-75%).\(^{15,17,21}\) Again, further comparison is not possible due to differences in study designs, outcome measures, and patient populations.

Revision rates were not reported by most studies, and no study reported the specific sinuses that required revision so that a sinus-specific failure rate could not be assessed. Likewise, pre- and post-operative endoscopy and/or CT scoring was not reported for many of the papers, and when reported was not suitable for sinus-specific analysis.

Other measures (e.g., sinus patency, subjective symptom scores, QoL scales) used to determine success are described in Table 2.

**Discussion**

Overall, the existing body of evidence makes it difficult to compare clinical outcomes for ESS and BSP. The lack of standard and objective measures and differences in study designs, while not unexpected, is disappointing. This is particularly true for the ESS literature. The available data are largely qualitative. It can be inferred that uncinectomy/antrostomy is a successful procedure based on the high prevalence of use and generally positive quality of life outcomes, but direct evidence in terms of radiographic, endoscopic, or revision-rate outcomes are lacking. In all of the ESS studies, intervention was performed concomitant with other sinus procedures, as dictated by patient symptoms, anatomy, and pre-op CT scans. It is, therefore, challenging to make definitive statements about symptom and QoL improvements related to maxillary interventions alone.

Although still developing, the balloon dilation literature shows promising results, with objective measurements demonstrating good long-term endoscopic patency, significant LMK reduction, and a low revision rate. In the context of overall patient symptoms and QoL improvements as measured by validated instruments, the strong results of balloon technology in the sinus are provocative.
Our findings are in agreement with two Cochrane publications - one that reported no evidence supporting the use of BSP “over and above conventional surgical modalities,” and the other indicating that ESS could not be shown to confer added benefit to that obtained by medical treatment alone (e.g., sinus irrigation) in CRS. Although the single comparative study available appears to demonstrate that BSP does confer benefit above and beyond conventional surgery, we agree that the evidence requires further development. Additionally, when contrasted against the lack of similar direct evidence for traditional methods, we believe it is appropriate to re-evaluate the relationship between nasal/sinus structure and function and potential implications for tissue preservation vs. excision.

While maxillary antrostomy can be performed without removing the uncinate process (UP), removal of this structure on the lateral wall of the nasal cavity is generally performed during ESS to expose the ethmoid air cells and maxillary sinus ostium. As evidenced by the data (Table 2), the overall clinical outcomes are good for most patients, so that until recently, there was little interest in the function of the UP or how its removal might affect airflow and NO equilibrium.

Balloon dilation of the maxillary sinus enlarges the ostium and widens the infundibular space without removing the UP. These patients also have positive outcomes (Table 2), raising questions about whether there might be beneficial effects of leaving the intranasal anatomy intact.

Based on its location in the anterior part of the middle meatus, two protective functions have been suggested for the UP: first, as a physical barrier to environmental contaminants, including allergens, particulates, and micro-organisms; and second, by diverting airflow away from the middle meatus/osteomatal complex, thus preventing air current trauma of sensitive structures and potentially excessive ventilation of the maxillary sinus.

Airflow modeling by computational fluid dynamics has shown that under normal conditions more than 90% of incoming air is directed towards the front of the middle turbinate and the prominent medial side of the UP, resulting in preferential deposition of airborne antigens and pathogens on the mucosa at the entrance to the middle meatus and lateral nasal wall. In contrast, the hidden mucosa of the lateral UP is less accessible to air currents and more accessible to mucous draining from the sinuses. This side may have a modulatory role in secretions and clearance.

Some investigators have suggested that removing the UP might promote air current trauma-related changes in mucosal morphology, concomitant with increased access of airborne contaminants to the sinuses, ultimately resulting in recurring cycles of infection, inflammation, and cellular damage. We had hoped to examine that possibility in our systematic review. Unfortunately, the data are very limited and difficult to decipher due to differences in methodologies and reporting. The answer remains unclear. However, data from patients who underwent uncinectomy without maxillary antrostomy noted no change in the environment within the maxillary sinus when the natural ostium remained <25 mm2. Thus, the UP may not be all that protective of the intra-sinus membrane when the natural ostium is not violated.

Based on infundibular anatomy, uncinectomy may be required for some patients – specifically, those who have edematous mucosa with polyps, purulent discharge, allergic mucin, or possibly, biofilms. Independent observations have reported that the microbial flora differs in patients with CRS who have undergone ESS with uncinectomy with antrostomy compared to those without antrostomy. Changing the anatomy of the transition space might explain the changes in bioflora as suggested by earlier studies, but carefully designed prospective studies are needed.

NO is suggested to have both bacteriostatic and mucociliary-regulating properties. A recent literature review regarding intranasal NO levels has failed to show clear clinical relevance. Despite this, the importance of intrasinus NO levels and the impact of altering structure on the exchange of NO between the maxillary sinus and nasal cavity are less clear and may be more complex. A role for the maxillary sinus as a functional reservoir for NO is suggested by extremely high NO concentrations measured in the sinuses of healthy individuals – up to 49 times that of the nasal cavities, which greatly exceeds bacteriostatic
Changes in sinus ventilation also have been shown to decrease NO concentrations and impair mucociliary transport.  To date scientific evidence directly linking low intrasinus NO and recurrent maxillary sinusitis is lacking, although administration of the potent NO inhibitor, N-monomethyl-L-arginine (L-NMMA), to one nostril in a healthy subject with no history of sinus disease was shown to produce acute purulent sinusitis.  Controlled studies are warranted.

If poor sinus ventilation related to decreased ostial size is a factor in low nasal NO, then opening the ostium through medical intervention or surgery should restore normal nasal NO levels.  Unfortunately, the data are sparse, and the importance of changes in intrasinus NO levels in relation to structural alteration are unclear.  In rabbits undergoing traditional antrostomy, lower levels of NO metabolites were also observed, but there was no change in mucociliary transport as had been predicted.

However, the size of the surgical opening and volume of air exchanged may be critical in the response.  The literature demonstrates that the normal maxillary sinus has very low air exchange with less than 0.1% of the volume of each breath making its way into the maxillary sinus.  After ESS, NO levels in the maxillary sinus and nasal cavity were significantly lower in patients with ostial openings greater than the natural size of 20mm², and the sinus NO levels were correlated with the size of the ostial opening.  Rapid sinonasal gas exchange could result in increased washout of NO, possibly preventing NO reaccumulation in the sinus cavities.  Recently published cadaveric and computational flow dynamics study noted preservation of the UP significantly reduced the alteration of nasal and sinus cavity airflow dynamics that occurs during a traditional ESS.

Another recently published study is the first to examine the relationship between NO levels and Staphalococcus aureus biofilms, which are known to be present in patients with CRS and associated with poor prognosis.  The methods are complex but demonstrated that low levels of NO were associated with S. aureus biofilm enhancement while high levels noted antibiofilm effects.  These findings, combined with NO washout demonstrated in large antrostomies, may shed light on the subset of difficult to treat patients who experience recurrent S. aureus infections after ESS.  The clinical significance is unclear, and more data are needed.

In addition to a surgically enlarged ostium, excessive ventilation due to an accessory ostium could also result in low maxillary sinus NO levels.  Computational simulations with 81mKr and gamma-scintigraphy have shown different ventilation patterns in sinuses with a single ostium versus those with an accessory ostium.  Ventilation via the natural single ostium sinus was diffusive and slow whereas convection was more prominent with larger openings (e.g., due to surgically increased diameter or an accessory ostium), resulting in faster gas exchange that exceeded the maxillary sinus NO production rate.

The clinical implications of the data – whether patients with low levels of intrasinus NO are more prone to inflammation, pooling of secretions, and/or recurrent infections with more virulent organisms - are not known.  The effect of balloon dilation on intrasinus NO levels also remains to be studied.  Similar findings to ESS would be expected in terms of the relationship between ostial size, sinus ventilation, and NO; however, at this time it remains difficult to evaluate the relationship between intrasinus NO and ostial patency in situ without an antrostomy.

Another unresolved issue, which can be inferred from the above, is that it is difficult to compare disease severity between studies, and clinical decisions regarding resection of the uncinate or antrostomy size often reflect the severity of disease.  In such cases, there may be indications to be more or less aggressive that are disease dependent.
Conclusion

Technological innovation has enabled the goal of combined structural and functional preservation during maxillary sinus intervention. Evidence from basic science and animal models supports this concept, yet review of the published literature in humans fails to show conclusive supportive outcomes data. However, this gap in clinical evidence does not invalidate the concept, as much as it leaves the question open and intriguing. Understandably, the acceptance of BSP has been cautious, due in part to surgeons having greater experience and, thus, more comfort with traditional maxillary sinus procedures. Nevertheless, conventional medical teaching dictates that we first do no harm, and when an intervention is required, that we consider the least intrusive and lowest risk procedure. Therefore, it is incumbent upon us to thoroughly assess both emerging and traditional surgical approaches to insure that assumptions, both new and “established,” are truly valid. Interestingly, despite the wide use of ESS in ENT practice for several decades, our review and others indicate that the development of ‘Cochrane-level’ supportive evidence based on randomized clinical trials has not yet occurred. Ultimately, answers will be derived from better data, both well-designed randomized clinical studies and directed basic research.
Table 2. Studies of ESS and BSP in adult patients with at least moderate to severe refractory CRS. Only studies published after 2000 were included in the review. See the text for methods including inclusion and exclusion criteria.

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<tr>
<th>Study</th>
<th>Design &amp; Procedure</th>
<th>Criteria</th>
<th>N, Mean Age, Other Patient</th>
<th>Outcomes</th>
<th>Comments</th>
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<tr>
<td>Baudoin et al., 2006</td>
<td>P, NR, C</td>
<td>Followed 24 mo Ant &amp; post bilat ethmoidectomy w uncinecomy</td>
<td>N=100 43 yr</td>
<td>Sx rated by severity (0-3) and frequency (0-3); Sx scores improvements @ 12 mo: ≤ 25%, 6; 26-50%, 2; 51-75%, 63; &gt; 75%, 29. @ 24 mo: 0%, 3; ≤ 25%, 5; 26-50%, 7; 51-75%, 67; &gt; 75%, 18. Majority of patients improved &gt; 50%; 92% at 12 mo and 85% at 24 mo</td>
<td>While goblet cells best correlated with Sx, overall there were no good histopath predictors for positive or negative outcomes</td>
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<td>Bhattacharyya, 2006</td>
<td>P, NC</td>
<td>Followed &gt; 12 mo Standard ESS w sinusotomies</td>
<td>N=161 40.2 yr</td>
<td>RSI net changes: nasal, -30.1; facial, –26.1; oropharyngeal, –13.4; systemic, –17.0; total, –20.8: (P &lt; 0.001 for all)</td>
<td>No correlation between Sx change and CT staging pre-op by the Lund-Mckay, Kennedy, or Harvard staging systems</td>
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<td>Chiu and Vaughn, 2004</td>
<td>Re, NC</td>
<td>Followed ≥ 24 mo Revision ESS of frontal sinus w/ surgical navigation; dissect remnant agger nasi</td>
<td>N=67 Age not reported* Polyps, 30%</td>
<td>RSOM-31: 57% change* Patent frontal recess by nasal endoscopy at last clinic visit: 86.6%</td>
<td>9 patients developed endoscopic frontal recess obstruction; 7 were revised (average time post-surgery, 18 mo); 6 of these had obstructive polypoid edema and/or nasal polyps, 3 had scarring, 2 w further neo-osteogenesis of the frontal recess</td>
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<td><strong>ESS Study</strong></td>
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<td>Cho et al, 2008</td>
<td>Re, C</td>
<td>ASx but w CRS refractory to maximal medical Tx (incl. oral Ab, INS, OCS, other allergy Tx)</td>
<td>Group1: primary ESS, n=25, 42.4 yr Group2: revision ESS, n=15, 47.5 yr Control (septal deviation, septoplasty), n=25, 36.0 yr</td>
<td>LMK scores significantly increased in revision group (group 2, P = 0.009) and NBF+ patients (P=0.014) NBF increased in Group 2 compared with Group 1 (OR = 0.127; P = 0.006) Significant between group differences in bone density for Groups 1 and 2 v. controls (P&lt;0.001)</td>
<td>Suggest increased soft tissue and bone remodeling in revision ESS v. primary ESS. In revision ESS: increased incidence of NBF and higher bone density could affect completeness of revision surgery and recurrence. CRS groups had smaller maxillary sinus size v. controls</td>
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<tr>
<td>Coclasure et al, 2004</td>
<td>Re, NC</td>
<td>CRS refractory to medical Tx for 3-4 mo (nasal saline, INS, guaifenesin, ≥ 14d broad spectrum Ab)</td>
<td>N=56 67 yr</td>
<td>Mean SNOT-20 score: Pre-op, 29.7; Post-op 10.6 @ 3 mo, 8.0 @ 6 mo, 7.4 @ 12 mo (post-op decreases of 64.3, 73.1, 75.1 respectively) Mean rigid nasal endoscopic score: pre-op, 4.9; post-op, 1.2 @ 3 mo, 1.7 @ 6 mo, 1.2 @ 12 mo</td>
<td>Concluded that ESS in geriatric population is a safe and effective treatment modality for CRS refractory to medical therapy</td>
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<tr>
<td>Damm et al, 2002</td>
<td>P, NC</td>
<td>CRS refractory to medical Tx</td>
<td>N=279 50.7 yr Polyps, 38%</td>
<td>Pt Questionnaires for CRS Sx and QoL using scale 0-4: Leading CRS-Sx (nasal obstruction, PND, DURTS, hyposmia) improved (p&lt;0.001) QoL: improved, 85%; No change, 12%; Deteriorated, 3%</td>
<td>Improvement in QoL correlated with improvement in leading CRS-associated Sx</td>
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<td>Das et al, 2009</td>
<td>P, NC Followed, short-term 3.1 mo Followed, long-term 40.3 mo (in 111 non-smk, 26 smk)</td>
<td>Persistent CRS refractory to ≥ 4 wk medical Tx (INS, nasal saline irrigations, Ab if evidence of purulence on endoscopy)</td>
<td>N=235 47.8 yr Revision, 20% Smk, 50</td>
<td>Mean SNOT-20 score: Pre-op: Smk, 27.8; Non-smk, 26.2 ST F/U: Smk, 5.7; Non-Smk, 10.1 (decreases, 79.5%, 61.5%; p&lt;0.0005 both) LT F/U : Smk: 8.3, Non-Smk 11.4 (decreases, 70.1%, 56.5%: P&lt;0.0001 both)</td>
<td>Concluded that smoking status should not be an absolute contraindication for ESS</td>
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<td>Dejima et al, 2005</td>
<td>P, NC Followed ≥ 5 yr ESS</td>
<td>CRS Sx &gt; 3 mo and preop severity @ stage III or IV (Kennedy’s classification)</td>
<td>N=79 Asthma, n=22 55 yr No asthma, n=57 57 yr Polyps, 100%</td>
<td>Sx scores and endonasal findings rated on scale, 0-2 Overall endonasal findings and Sx scores were worse in the asthma group Asthma patients also had improvement in bronchial Sx</td>
<td>Findings suggest that CRS and asthma are 2 components of a one airway disease; treating CRS may improve asthma</td>
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<td>Fernandes, 2006</td>
<td>P, NC Followed 28-40 mo Bilat totl uncinctomy, + bilat ethmoidal bullectomy, + unilat or bilat inf turbinectomy, + MMA</td>
<td>Chronic and recurrent RS refractory to adequate medical Tx (including Ab, INS ≥ 4 wk)</td>
<td>N=102 14-81 yr (mean age not reported)</td>
<td>Subj Sx ratings: no nasal obstruction, 98%; no facial pain, 100%; improved PND, 84% No pt reported worsening of Sx overall</td>
<td>Suggested that a minimal approach to surgery can be beneficial as well as only 3 mo follow-up</td>
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<td>Study</td>
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<tr>
<td>Jacobsen and Svendstrup, 2000</td>
<td>P, NC</td>
<td>LT CIS (mean duration, 9.3 yr) refractory to optimal medical Tx (Ab, INS, OCS) and/or NPP</td>
<td>N=237 45.7 yr Revision, 24 CIS, n = 88 NPP, n = 143</td>
<td>@ 1-yr For CIS: Sx-free, 32 (36%); felt better, 41 (47%); unchanged, 14 (16%); somewhat worse, 1 (1%) For NPP: Sx-free, 71 (50%); felt better, 61 (43%); unchanged, 11 (8%)</td>
<td>Objective findings @1 yr for NPP did not correspond w subjective results. No sinus pain, but synechia in 20% and recurrent diminutive polyps in 24% who were Sx-free, suggesting potential for Sx of nasal stenosis in future</td>
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<tr>
<td>Kaplan and Kountakis, 2004</td>
<td>Re, NC</td>
<td>Symptomatic and objective evidence of CRS w RSTF criteria&lt;sup&gt;6&lt;/sup&gt;</td>
<td>N=254 48 yr Asthma, n=47 No asthma, n=207</td>
<td>Mean SNOT-20 score: No asthma: pre-op, 41.6; 1 yr, 13.0 Asthma: pre-op, 44.6; 1 yr, 15.8 Mean endoscopy grade: No Asthma: pre-op, 8.0; 1-yr, 2.0 Asthma: pre-op, 5.1; 1-yr, 2.0</td>
<td>No correlation between nasal endoscopy findings and Sx scores. Nasal endoscopy findings correlated with pre-op CT scores in non-asthmatics only; no correlation in asthmatics</td>
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<td>Khalid et al, 2004&lt;sup&gt;22&lt;/sup&gt;</td>
<td>P, NC</td>
<td>CRS</td>
<td>N=150 46.9 yr 22% revision 40% polyps 40% asthma</td>
<td>SF 36 (BL/3 yr): PF: 80.8 / 81.5 RP: 56.9 / 71.8 BP: 60.0 / 68.4 GH: 56.2 / 67.7 SF: 62.4 / 76.1 VT: 49.6 / 58.1 RE: 75.1 / 75.6 MH: 70.0 / 74.3</td>
<td>Suggest that ESS w appropriate medical Tx can improve patient QOL for at least 3 yr in pt w medically refractory CRS, returning overall QOL to within normal ranges</td>
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<tr>
<td>Ling and Kountakis, 2007&lt;sup&gt;23&lt;/sup&gt;</td>
<td>Re, NC Followed 1 yr ESS</td>
<td>CRS by RSTF criteria&lt;sup&gt;b&lt;/sup&gt;</td>
<td>N=158 49.4 yr</td>
<td>RSTF scores significantly improved in all domains (P&lt;0.0001), most &gt;80%.</td>
<td>No correlation between RSTF and SNOT 20</td>
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<td>Ragab et al, 2004&lt;sup&gt;24&lt;/sup&gt;</td>
<td>P, C Followed 1 yr ESS</td>
<td>≥8 wk Sx and signs CRS w ≥2 major Sx, OR 1 major + 2 minor Sx, OR 4 episodes/yr recurrent acute sinusitis each ≥10 d and w/persistent changes on CT for weeks after medical Tx w/o intervening acute infection</td>
<td>N=90 43 yr Surgery, n=45 Polyps, 42% Medical Tx, n=45 Polyps, 35%</td>
<td>Significant improvement in total SNOT-20 at 6 and 12 mo in both groups (p&lt;0.01). Significant improvement in SF-36 domains except PF at 6 and 12 mo both groups</td>
<td>No difference between outcomes for medical and surgical groups, incl. nasal NO and saccharine transport. Some differences in acoustic rhinometry depending on polyp status</td>
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<td>Soler et al, 2008&lt;sup&gt;25&lt;/sup&gt;</td>
<td>P, NC Followed 18 mo ESS</td>
<td>CRS refractory to medical Tx according to 2003 RSTF criteria,&lt;sup&gt;a&lt;/sup&gt; then 2007 AAOHNS Sinusitis Guideline&lt;sup&gt;c&lt;/sup&gt;</td>
<td>N=275 44.4 yr Revision, 57% Polyps, 33% Asthma, 37%</td>
<td>Individual Sx (nasal discharge, congestion, facial pain-pressure, decreased olfaction, HA, fatigue, toothache, sinus congestion) evaluated by VAS: All improved except HA – clinical significance varied over time</td>
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<td>Young et al, 2007&lt;sup&gt;26&lt;/sup&gt;</td>
<td>P, NC Followed 3 yr ESS</td>
<td>CRS by SHAP criteria refractory to conservative medical Tx (incl Ab, steroid)</td>
<td>N=82 47.5 yr Asthma, 47.5%</td>
<td>Initial Tx success with respect to 5 Sx studied. Anosmia /Hyposmia was initially severe and dropped to moderate; Nasal obstruction was severe and dropped to mild; Anterior nasal discharge and facial pain / HA were both moderate and improved to mild</td>
<td>ESS appears to be a successful treatment for CRS for short term symptom management. However, long-term treatment outcomes may depend on host factors such as atopy, asthma, and Samter’s Trait</td>
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<tr>
<td>Study</td>
<td>Design &amp; Procedure</td>
<td>Criteria</td>
<td>N, Mean Age, Other Patient</td>
<td>Outcomes</td>
<td>Comments</td>
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<td><strong>Kuhn et al, 2008</strong></td>
<td>P, NC</td>
<td>Followed 1 yr after 24 wk study (see Bolger et al, 200729)</td>
<td>N=66</td>
<td>Pre-op/Post-opMean SNOT-20 scores: BCS, 2.01/0.95 (P&lt;0.0001); Hybrid, 2.26/0.87 (P&lt;0.0001); ALL individual Sx decreased significantly (P&lt;0.0001)</td>
<td>BCS compared favorably with std ESS results for management of moderate CRS</td>
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<td><strong>BSP Study</strong></td>
<td></td>
<td>BCS or BCS + ESS (hybrid)</td>
<td></td>
<td>LMK Scores: BCS, 6.0/1.1 (P&lt;0.001); Hybrid, 11.3/2.7 (P&lt;0.001)</td>
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<td>CRS refractory to medical Tx, + clinical decision to perform ESS</td>
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<td>Sinus Patency post-op: Endoscopic: Maxillary, 90%; Frontal, 85%; Sphenoid, 72%</td>
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<td>CT L/M: Maxillary, 93.5%; Frontal, 91.9%; Sphenoid, 86.1%</td>
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<tr>
<td><strong>Kutlahan et al, 2009</strong></td>
<td>Re, NC</td>
<td>Followed 12 mo</td>
<td>N=30</td>
<td>Pre-op/Post-opMean SNOT-20 scores: 25.7/6.5 (P&lt;0.01)</td>
<td>Did not separate results for Hybrid vs BCS alone</td>
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<tr>
<td><strong>BSP Study</strong></td>
<td></td>
<td>BCS or BCS + ESS (hybrid)</td>
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<td>LMK scores: 0.95/ 0.52 (P&lt;0.01)</td>
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<td>CRS refractory to medical Tx, + clinical decision to perform ESS</td>
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<td><strong>Plaza et al, 2011</strong></td>
<td>DB, R, C</td>
<td>Followed 12 mo</td>
<td>N = 40 (32 completed)</td>
<td>At 12 mo post surgery, ESS/BSP+ESS: % directly observed patent frontal recesses: 62.5%/73.1% (p&lt;0.05)</td>
<td>Additional surgery needed after 1 patient in BSP+ESS group and 3 patients in ESS group</td>
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<td><strong>BSP Study</strong></td>
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<td>BSP of frontal recess + ESS of other involved sinuses (n = 16) v. ESS</td>
<td>41.3 yr</td>
<td>Similar improvements in olfactory thresholds, Sx scores, radiological resolution of frontal sinuses</td>
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<td>(Draf I/2a procedures of frontal sinuses, N= 16)</td>
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<td>LMK scores pre-op/post-op: ESS, 18.6/4.2; BSP+ESS, 19.2/3.6 (p&lt;0.05, both v. pre-op)</td>
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<td>Weiss et al, 2008&lt;sup&gt;11&lt;/sup&gt;</td>
<td>P, NC Followed 2 yr BCS or BCS + ESS (hybrid)</td>
<td>CRS refractory to medical Tx, + clinical decision to perform ESS</td>
<td>N=85</td>
<td>Pre-op/Post-op SNOT-20 scores: ALL, 2.17/0.87 (P&lt;0.001); BCS, 2.09/1.09 (P&lt;0.001); Hybrid, 2.26/0.64 (P&lt;0.001); All individual Sx significantly decreased post-op (P&lt;0.05)</td>
<td>This study indicated LT durability of clinical outcomes of BCS, w improvements in pt Sx sustained through 2 yr post-surgery and radiographic evidence of resolution of disease at 24 mo post-surgery</td>
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<td><strong>BSP Study</strong></td>
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<td>LMK scores:</td>
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<td>ALL, 9.66/2.69 (P&lt;0.001); BCS, 5.67/1.75 (P=0.015); Hybrid, 12.05/3.25 (P&lt;0.001)</td>
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<td>Patients reporting improvement: ALL, 85%; BCS, 77%; Hybrid, 93%</td>
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</table>

*Age > 18 yr confirmed by personal communication with author

**ABBREVIATIONS**

Ab, antibiotic; Ant, anterior; ASx, asymptomatic; BCS, Balloon Catheter Sinostomy; Bilat, bilateral; C, controlled; CIS, chronic infectious sinusitis; Inf, inferior; INS, intranasal steroids; LMK, Lund MacKay; MMA, middle meatal antrostomy; NC, non-controlled; NPP, nasal polyposis; NR, non-randomized; OCS, oral corticosteroids; P, prospective; PE, physical examination; R, randomized; Re, retrospective; RS, rhinosinusitis; RSI, Rhinosinusitis Symptom Inventory; RSOM – Rhinosinusitis Outcome Measure; RSTF, Rhinosinusitis Task Force; smk, smoker; SHAP, Sinus Health and Allergy Partnership; SNOT, Sino-Nasal Outcome Test; ST, short-term; Sx, symptom; Tx, treatment; Unilat, unilateral;

<sup>a</sup>R Somali – a 30% change is considered significant

<sup>b</sup>RSTF criteria: ≥ 3 wk medical Tx w INS, nasal saline; guaifenesin (1200 mg bid), ≥ 14 d Ab (if evidence of purulence on endoscopic exam)

<sup>c</sup>AAOHNNS criteria: ≥ 12 wk w ≥ 2 of the following: mucopurulent drainage (ant and/or post); nasal obstruction (congestion), facial pain-pressure fullness; decreased sense of smell; AND inflammation documented by ≥ 1 of the following: purulent mucus or edema in middle meatus or ethmoid region; polyps in nasal cavity or middle meatus; radiographic imaging showing inflammation of paranasal sinuses
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Conflict of Interest: Dr. Weiss - consultant for Acclarent, Inc. Dr. Benninger - no disclosure.
Key Words: endoscopic sinus surgery, functional endoscopic sinus surgery, balloon sinuplasty, balloon catheter, structural preservation, functional preservation, chronic rhinosinusitis, nitric oxide, antrostomy, uncinate process, uncinecetomy
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References:
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