

Long-Term Successes of Various Sinus Surgeries: A Comprehensive Analysis

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Abstract Outcome studies often examine the efficacy of sinus surgery with 1 year of follow-up data, while longer-term postoperative data is less easily available. This article reviews long-term outcomes of various endoscopic techniques to further delineate risk factors for surgical failure. A systematic review of the literature was performed and studies were stratified based on surgical technique and recognized risk factors of postoperative failure. A total of 126 abstracts were identified, 82 articles were retrieved for full review, and 56 were included in this report. A total of 30 studies had longer than 1 year of follow-up data and the longest follow-up period was 10 years. Based on the available evidence, endoscopic sinus surgery has a high success rate, but with well-recognized risk factors for failure. Aggressive postoperative local care and medical therapy should be tailored to each patient's particular disease process, and form an integral part of surgical management.

Keywords Chronic rhinosinusitis · Functional endoscopic sinus surgery · Balloon sinus dilatation · Hybrid procedure · Mucociliary clearance · Quality of life · Rhinosinusitis disability index · Chronic sinusitis survey · Visual analog score · Sinonasal outcome test · Samter's triad · Polyposis · Debridement · Success · Long-term success · Sinus surgery

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Introduction

It is estimated that chronic rhinosinusitis (CRS) affects nearly 13 % of Americans causing 12.5 million outpatient visits annually with a tremendous financial burden on the economy [1, 2]. Indeed, CRS has been estimated to generate annual health-related costs of more than US\$5 billion [3]. Since the advent of functional endoscopic sinus surgery (FESS) in the 1980s, many published series have looked at treatment outcomes with varying success. With 300,000–500,000 ambulatory sinus procedures being performed each year in the United States and the increasing focus on containing health care costs, long-term outcomes studies will take on increasing importance in the future [4].

For the majority of patients, first-line optimal medical therapy appears to be as effective as endoscopic sinus surgery [5, 6]. This medical treatment includes topical nasal steroids with a combination of antibiotics, systemic steroids, antihistamines, or leukotriene receptor antagonists, depending on the dynamic interplay between allergic and infectious etiologies. Medically refractory CRS, however, requires surgical techniques that aim to improve sinus ostial patency and mucociliary clearance and, with traditional FESS, remove inflamed tissue and bone. FESS and balloon dilatation are the two differing modalities that have been described, with various combinations of each technique that are published as hybrid procedures.

Since it was first described, FESS emphasizes “functional” surgery that preserves healthy mucosa and natural anatomic pathways [7, 8]. In the setting of chronic infection and inflammation, this technique removes polyps and osteitic bone as well as bacterial, fungal, and biofilm debris, thereby decreasing the load of inflammatory mediators and improving the efficacy of medical therapy. The creation of open and accessible sinus cavities also optimizes the sinonasal penetration of topical medical therapy and reduces underlying mucosal inflammation.

More recently, minimally invasive techniques have been described with the application of high-pressure balloons to

sinus ostia. Using the Seldinger technique, whereby a catheter is advanced over a guidewire, the inflated balloon compresses the mucosa and causes microfractures of the underlying circumferential bone. The aim of this technology, which has gained wider use in community practices due to its ease of use and safety profile, is to restore natural sinus drainage pathways while preventing mucosal stripping and scarring.

Methods

A systematic review of the literature was preformed using PubMed and Cochrane Review Databases up to October 31, 2012. All abstracts were reviewed covering outcome studies of CRS related to endoscopic sinus surgery, balloon sinuplasty, hybrid procedures and risk factors for surgical failure. Study inclusion criteria included adult population >18 years old with CRS based on published diagnostic criteria [9, 10]. A total of 126 abstracts were identified, 82 articles were retrieved for full review, and 56 were included in this report. The manuscript was developed with an overall focus on long-term outcome studies and 30 studies were recognized as having longer than 1 year of follow-up data. The longest follow-up period in a single study was 10 years (see Table 1 for a list of studies with the longest follow-up data). Lower level studies with less than 1-year outcomes data were included when the topic contained insufficient evidence.

Surgical Techniques

Functional Endoscopic Sinus Surgery

Studies have consistently proven the heavy burden of CRS on patients and also report that the success rate of FESS in patients that fail medical management ranges from 76 to

97.5 % [11]. This includes a prospective study of 108 patients by Glicklich and Metson that showed significant improvement in 82 % of patients after 1 year [12]. A study by Senior and Kennedy also demonstrated an improvement in 98.4 % of patients at a median follow-up of 7.8 years following surgery combined with medical therapy and careful postoperative care [13]. Similar studies have also revealed significant improvement [14–25] with the longest median follow-up period being 10 years after surgery [26•]. Long-term improvement in asthma, reduced requirement for medical therapy, and a decrease in asthma attacks have also been demonstrated [27]. More recently, a review of 75 articles that specifically addressed quality of life (QOL) outcomes found an overall improvement across multiple studies, but demonstrated mostly level IV evidence with few randomized or prospective studies [28].

While there is no single outcome measure that has become the gold standard to study the effect of FESS, there is an increasing interest in using validated and standardized QOL tools to facilitate study comparisons. Most recent studies have shown similar QOL improvements during the first 1–2 years of the postoperative period. A prospective cohort of 552 patients with a mean follow-up of 17–18 months showed a significant QOL improvement in primary FESS patients compared to revision cases using the Rhinosinusitis Disability Index (RSDI) and Chronic Sinusitis Survey (CSS) [29]. Also, a study of 207 patients followed for 18 months demonstrated statistically and clinically significant improvements in six out of seven symptoms measured with the Visual Analog Score (VAS) [30].

The quality of outcome studies has also improved as measurement tools have become more sophisticated, reliable, and standardized between different institutions. A recent prospective multi-institutional study of 115 patients with 1-year follow-up demonstrated the most improvement in the first 6 months using the same RSDI and CSS tools [31•]. This study included three cohorts who elected endoscopic sinus surgery, medical management, and patients who crossed over from medical treatment to the surgical arm. The surgical cohort demonstrated significantly greater improvement, nearly twice as much improvement in most QOL domains, while the crossover cohort initially worsened and had eventual improvement after 3 months.

Balloon Dilatation

Balloon dilatation is a potential technique for limited chronic sinusitis, but is not recommended in polyposis. Also, it is not available for the ethmoid sinuses, the region most commonly involved in chronic rhinosinusitis. Due to its more recent application in the paranasal sinuses, the published efficacy of balloon sinus dilatation has predominantly focused on feasibility and safety. Following the United States Food and Drug Administration (FDA) clearance of this novel procedure in 2005, most studies have focused on short-term data to establish ideal applications of the technique [32–35].

Table 1 Characteristics of included studies with long-term follow-up data

Source	Mean follow-up (years)	Follow-up period (years)	Sample size (patients)
Chambers et al. 1997 [47]	3.5	1–7	182
Chan et al. 2009 [55]	3.8	0.18–8.5	161
Dufour et al. 2004 [21]	6.5	5–8	60
Friedman et al. 2006 [48]	6	4.5–8.4	152
Giger et al. 2004 [64]	4.8	3–9	77
Khalid et al. 2004 [22]	3	2.5–3.4	150
Mendelsohn et al. 2011 [26•]	10	5–10	549
Schaitkin et al. 1993 [18]	4	3–4.3	100
Senior et al. 1998 [13]	7.8	6.3–11	72
Young et al. 2007 [44]	3	1–3	31

These studies predominantly reported uncontrolled, non-randomized case series. One of the largest early retrospective reviews in 2008 included 1,036 patients from multiple centers with no reported major complications. This study showed an improvement in 95.5 % of patients that was maintained in 73.8 % of patients at a mean follow-up period of 40.2 weeks [36]. The only comparative study between FESS and balloon dilatation during this time period was a retrospective chart review that showed balloon dilatation produced a significantly lower sinonasal outcome test (SNOT-20) score compared to conventional FESS after 3 months, but without randomizing patients [37].

The most cited literature relates to the “Clinical evaluation to confirm safety and efficacy of sinuplasty in the paranasal sinuses” (CLEAR) study [38, 39]. This multi-centered prospective cohort included 115 patients with CRS that were treated either by balloon dilatation alone or a hybrid procedure. Over the course of three papers, this study has provided the longest outcomes data of this technique. After 97 % of patients were successfully cannulated, endoscopic patency was established in 80.5 % at 6 months, 85.1 % after 1 year and 91.6 % after 2 years using radiological measurements [40]. These stable improvements in ostial patency were paralleled with sustained improvements in SNOT-20, but with 43 % of patients lost to follow-up (50 of 115 patients) the results have met heavy criticism. Also, cadaveric studies have demonstrated that trans-nasal maxillary sinus ostial dilatation typically does not, in fact, dilate the natural ostium, but instead creates a separate accessory ostium that does not assist in mucociliary transport [41].

In fact, in a Cochrane review of all the literature covering balloon sinus ostial dilation, only one prospective, randomized controlled trial was considered reliable enough to be included in their review [42]. The study by Plaza et al. [43] was considered the first prospective, double-blind, randomized controlled trial, with a focus solely on chronic frontal sinusitis refractory to medical therapy. A total of 34 patients were randomized evenly into a hybrid procedure of the frontal sinus versus a purely FESS only procedure with 1 year outcomes data. This study showed a statistically significant improvement in both groups in VAS, RSDI scores, measured olfactory thresholds, and the severity of nasal polyposis. But, the results also demonstrated no significant difference in outcomes between the two groups.

Risk Factors for Failure

Patient risk factors that predict postoperative failure have long been the focus of outcomes studies, particularly for traditional endoscopic sinus surgery. The high success rate of FESS in studies using 6- to 12-month follow-up periods has been well established, but these risk factors clearly affect long-term outcomes that follow patients for 5 years or more [44]. These

studies have consistently demonstrated that patients with CRS with polyps, asthma, combined airway disease, and atopic disease are at higher risk of postoperative failure. Indeed, patients with Samter’s triad (defined as asthma, aspirin intolerance, and nasal polyposis) have an approximately 37 % rate of revision within 5 years of their primary surgery [26]. These patients have a severe underlying chronic inflammatory disease that requires aggressive surgical management, comprehensive postoperative care, and medical management.

Patient stratification based on these criteria is an important element of long-term outcome studies because patients with underlying inflammatory and autoimmune conditions represent distinct clinical groups. CRS in patients with ciliary dysfunction, cystic fibrosis, and autoimmune disease are often excluded from multi-center prospective studies, and therefore are a largely neglected group in the literature. But some studies have even suggested that up to 50 % of patients with CRS may have an undiagnosed immune system disorder that can be recognized in serum analysis [45].

There is also controversy regarding the importance of certain risk factors in dictating worse outcomes. Asthma, allergy, tobacco use, and gastroesophageal reflux are the most contested risk factors with comprehensive studies providing countervailing opinions [27, 44, 46–49]. Multi-institutional prospective studies will continue to analyze these possible risk factors in the future.

The need for revision surgery, however, may be the most accurate marker of disease severity and symptom outcomes. In fact, a multi-institutional prospective study showed that patients who undergo primary FESS are 1.8–2.1 times more likely to have an improvement in QOL outcomes than revision FESS [50]. The extent of improvement between different cohorts of revision FESS patients, however, was similar regardless of other risk factors. Better mean endoscopy scores after primary surgery compared to revision cases has also been well demonstrated [29]. Thus, although it is controversial, and some studies have shown otherwise [13], primary surgery may take on increasing importance in determining overall prognosis and patient benefit may decrease with each subsequent revision procedure.

Long-term outcome studies have also reliably shown that the postoperative period is a crucial time period in the treatment of CRS and in determining outcomes. Persistent asymptomatic disease is the rule following endoscopic sinus surgery, but if persistent inflammation is adequately treated with medical therapy and debridement following surgery, the chance of revision surgical intervention is essentially eliminated over a nearly 8-year follow-up period [13]. As recommended in current treatment guidelines, frequent endoscopic follow-up and extensive debridements allow the clinician to detect and resolve early pathologic changes that cannot always be detected in symptom scores or QOL instruments [20, 47, 51]. Postoperative endoscopy scores are one of the most important prognostic factors and these debridements take on special importance in

patients who have failed previous surgery or who have other risk factors that indicate significant inflammatory disease [52].

Anatomical causes of treatment failure are often the major focus in studies from the last two decades. In a review of 153 patients, Chu isolated causes of surgical failure including surgical manipulation of the middle turbinate in 48.3 %, scarring of the middle meatus in 14.7 % and a missed obstructing agger nasi in 4.9 % [53]. These findings have been supported by others including Ramadan [11] in a review of 682 cases and Rice [54] who reported scarring of the middle meatus as a cause of failure in 7 % of patients.

Recurrent frontal sinusitis, in particular, has been strongly associated with the need for revision surgery. Due to the lack of a true ostium and the variable anatomic pathway of the narrow frontal recess, the rate of iatrogenic injury and scar formation is exceedingly high [26•, 55–57]. Chiu and Vaughan showed that failed frontal sinus surgery was attributed to residual anterior ethmoid partitions in 79 % of cases, retained uncinate process in 38.8 % and a lateralized middle turbinate in 35.8 % [58]. Compared to primary procedures, revision cases demonstrate a higher rate of frontal sinus surgery with increasingly more extensive dissection during each subsequent procedure.

Anatomic causes of surgical failure, however, must always be interpreted with great caution because there is a well-documented dissociation between symptomatic improvement and objective findings [59–63]. Studies have shown that while 97 % of patients may experience symptomatic improvement after surgery, on nasal endoscopy 76.5 % of these patients exhibit persistent or recurrent mucosal disease [51]. In general, it appears that environmental factors and general host factors, such as immunodeficiency or other underlying medical problems, are much more common causes of failure than purely anatomic issues, especially if a comprehensive initial surgery is performed within the area of disease. Other causes of failure that should be considered include poor postoperative care and limited patient compliance. The latter is particularly important because most persistent disease following surgical intervention is asymptomatic. Accordingly, patient compliance becomes a significant issue in overall medical management.

The Lund-MacKay computed tomography and Kennedy-Lund endoscopic staging systems helped to standardize measurements of disease severity, but clearly demonstrated that abnormal objective findings may be found in patients that are completely asymptomatic [64]. With respect to frontal sinus surgery, Friedman demonstrated that 92 % of patients improved after undergoing frontal sinusotomy with only 67 % of these patients showing frontal recess patency on postoperative endoscopy [48]. Therefore, objective measures that address anatomic findings such as osteomeatal complex patency, scar banding, recirculation, radiologic findings and endoscopic scores do not always correlate with validated QOL measures.

Discussion

As part of the Healthcare Affordability Act, newly instituted Accountable Care Organizations will demand peer-reviewed publications that address long-term outcomes of chronic sinusitis, focusing on the unique costs of medical and surgical management. Long-term outcomes data that compare traditional FESS procedures with balloon dilatation and hybrid procedures will be particularly important, given the significant added cost of balloon technology.

The Cochrane Group's review of endoscopic sinus surgery in 2006 [5] and of balloon sinus dilatation in 2011 [42•], however, critiqued the existing literature on the efficacy of sinus surgery compared to continued medical therapy. They called attention to the weaknesses of these studies that lack a control group, analyze small patient cohorts, and provide short-term outcomes data, with significant patient attrition once the postoperative period is extended past 2 years. The Cochrane reviews called for more rigorous analysis to prove long-term efficacy and to identify high-risk groups.

This task, however, is challenging because blinded, randomized studies are almost impossible to perform with surgical procedures, and even randomized studies of medical versus surgical therapy are difficult in patients who are ideal candidates for surgical intervention—namely, those who have failed prolonged medical therapy and frequently develop strong treatment preferences.

Also, more accurate disease stratification and standardized treatments will require a better knowledge of the pathogenesis of CRS. Many discrete factors remain unstudied in a comprehensive manner. This includes the patient's environmental conditions and local immune response as well as the postoperative regimen of culture-directed antibiotics, steroid use, methods of irrigation, and extent of postoperative debridement. These latter variables have yet to be standardized and often vary markedly between studies.

The discord between objective findings and the severity of patient complaints has long been demonstrated and will also require an increasing focus on validated QOL measures. Surgical interventions must be examined not only by their ability to restore ventilation, drainage and mucociliary clearance but also whether they improve QOL outcomes with either traditional FESS procedures, balloon dilatation, or hybrid procedures. Finally, a chronic inflammatory disease like CRS requires prolonged follow-up. After surgery or other trauma, mucocoeles may take up to 30 years to develop and become symptomatic.

Multi-institutional efforts that address the inherent weaknesses of past studies and accurately measure long-term efficacy will take on increasing importance in the future. These studies must standardize surgical approaches and techniques, surgical instruments, and technology (including angled endoscopes, specialized power instruments, and stereotactic image-guidance), as well as validated outcome measures to

compare management strategies. They must also try to control for surgeon experience which, it has been shown, strongly affects rates of revision surgery and long-term outcomes [65].

A significant challenge always remains in determining when recalcitrant disease is due to a failure of surgical technique, postoperative management, or the complex pathologic nature of CRS. Endoscopic sinus surgery is recommended after concerted efforts at medical therapy have failed, but the planned surgery should always be appropriate to the patient's anatomy, extent of disease, and expectations as well as the surgeon's skills and ability to manage the patient in the postoperative setting.

Conclusions

While the existing literature clearly does demonstrate the long-term efficacy of endoscopic sinus surgery combined with medical therapy in those patients who have failed medical therapy alone, additional studies are required. As an integral part of this effort, an improved understanding of pathogenesis, risk factors, and disease stratification is required, as well as greater standardization of medical management.

Furthermore, it is important to recognize that persistent, but frequently asymptomatic, disease is common following surgical intervention. Management of this persistent inflammation is critical for long-term disease resolution. For the vast majority of patients, risk factors that predict treatment failure should always guide treatment strategies both surgically and during the postoperative period. Additional studies will be required to determine whether minimally invasive procedures such as balloon dilatation, particularly when combined with drug eluting stents, can provide the same long-term improvement that has been demonstrated with traditional FESS in combination with postoperative medical therapy. In order to resolve some of the remaining questions, long-term multi-institutional studies will be required to better understand the underlying pathogenesis of the spectrum of disorders included within CRS.

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