# Trans-Antral Balloon Dilation Under Local Anesthesia

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## ABSTRACT

**Objectives**:
1. Assess the durability of balloon dilatation of the ostiomeatal complex (OMC) through 12-month follow-up.
2. Demonstrate a long-term safety profile of a new medical device designed to treat chronic rhinosinusitis (CRS) using trans-antral, endoscopic visualization and balloon dilatation.

**Methods**: Subjects with chronic rhinosinusitis and CT evidence of mucosal thickening or an air-liquid level in the maxillary atrum along with a narrow maxillary sinus outflow tract underwent balloon antrostomy of the OMC. Subjects completed symptomatic assessment using the Sino-Nasal Outcome Test (SNOT 20) at 12 months post-procedure and adverse events were monitored through 1-year follow-up.

**Results**: Twenty subjects (36 ostia) underwent dilation of the maxillary sinus ostia and ethmoid infundibulum without the use of general anesthesia and have completed the end of study follow-up requirement at 12 months. During this one-year period, no serious device-related or procedure-related adverse events or unanticipated adverse device effects were reported. One subject underwent a revision surgery 5.4 months post-procedure to treat left sphenoid sinusitis. The average overall SNOT 20 score at baseline was 3.2 +/- 0.7 and decreased to 0.9 +/- 1.0 (p-value < 0.0001).

**Conclusion**: Trans-antral balloon dilatation without general anesthesia is safe and symptomatic improvement subsequent to anatomical remodeling of the boney structures within the OMU due to balloon dilatation as a stand-alone intervention is sustainable through 12 months.

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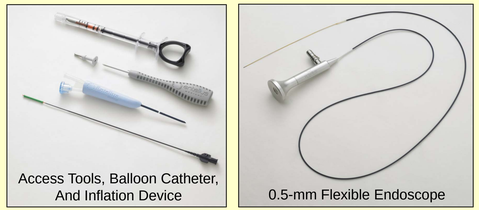
## INTRODUCTION

In 2007, Entellus Medical initiated a single-arm, prospective clinical study (Breathe I) to evaluate the safety and effectiveness of FinESS™ Sinus Treatment. FinESS was developed to provide physicians with a toolkit to treat maxillary and anterior ethmoid sinus disease in an office setting under local anesthesia. This system, as shown in Figure 1, uses proprietary technology to allow direct, endoscopic visualization of the maxillary sinus ostium and balloon advancement into the ethmoid infundibulum by accessing the maxillary antrum at the canine fossa through a small hole approximately 3 millimeters in diameter (Figure 2).

Recently, 6-month interim results from the first 30 subjects treated with FinESS Sinus Treatment under the Breathe I protocol (NCT00645762 ) were reported[1]. The primary objectives of this study were to assess device and procedural safety during the treatment of maxillary sinus outflow tract narrowing and inflammation of the maxillary and anterior ethmoid sinuses and also evaluate the feasibility of remodeling the ethmoid infundibulum without the use of imaging equipment or general anesthesia. In addition to these safety outcomes, subjects also consented to long-term follow-up for post-procedure assessment of symptoms through 12 months. Updated results to the patient population included in the abstract are presented here.

**Figure 1.** FinESS Sinus Treatment.


Access Tools, Balloon Catheter, And Inflation Device


0.5-mm Flexible Endoscope

**Figure 2.** Access to the Treatment Site through the Canine Fossa.


## METHODS

Adults age 18 and older with chronic rhinosinusitis, isolated maxillary disease with or without coexistent anterior ethmoid disease, and documented computed tomography (CT) evidence of either OMU narrowing and maxillary mucosal thickening ≥ 2 millimeters or an air/fluid level in the maxillary antrum after maximum medical therapy were eligible to enroll in the study.

Subjects were ineligible to participate if there was radiographic evidence of frontal, posterior ethmoid, or sphenoid disease or fungal sinusitis. FinESS Sinus Treatment was the only sinus surgery permitted in the study. Subjects requiring concomitant septoplasty, turbinate reduction, or any other endoscopic sinus surgeries were also excluded.

Subjects returned to the investigational site at one week and 3 months post-procedure for physician evaluation and completion of the Sino-Nasal Outcome Test (SNOT-20) survey[2]. After three months, the subjects were not required to return to the study center. The preferred method of survey completion at 6 and 12 months was via mail to reduce the likelihood of bias.

Standard summary statistics were calculated for all study variables by an independent statistician. For continuous variables, statistics included mean, standard deviation, and 95% confidence intervals for the means, while categorical variables were summarized using frequency distributions. All statistical tests were two-sided, with p-values less than 0.05 deemed significant. Statistical analyses were conducted in SAS version 9.1 or above (SAS Institute, Cary, N.C.).

## RESULTS

Thirty patients (56 ostia) were successfully treated with FinESS alone. Twenty-nine (97%) procedures were performed under local anesthesia with or without IV sedation. Follow-up compliance through one-year was 97%. One subject withdrew after completing 6-month follow-up and subsequently undergoing endoscopic sinus surgery to remove a large fungal ball in maxillary sinus that was cultured and confirmed to be aspergillus. A second subject underwent a second sinus surgery just prior to the 6-month follow-up for treatment of sphenoid sinusitis. Twenty-nine subjects successfully completed one-year follow-up and end of study requirements. Baseline characteristics are shown in Table 1.

The SNOT-20 survey is a validated quality of life assessment where subjects rank 20 unique symptoms related to their sinusitis on a scale from 0 (no problem) to 5 (problem as bad as it can be). Figure 3 shows the mean overall SNOT-20 scores through 12 months for the first 30 subjects treated in the clinical study.

At baseline, 60% of this study cohort showed CT evidence of maxillary sinus disease only and 40% also presented with partial or complete opacification of the anterior ethmoid sinuses. Comparison of the mean overall SNOT-20 scores between these two subgroups at each follow-up (Figure 4) show a similar trend in clinically and statistically significant improvement in sinusitis symptom scores.

**Table 1: Baseline Characteristics**

| Characteristic | N | Mean +/- SD | Range |
|---|---|---|---|
| Age (years) | 30 | 47.6 +/- 12.7 | 24.2 – 77.8 |
| Gender | | | |
| Male | 10 | 33.3% (10/30) | - |
| Female | 20 | 66.7% (20/30) | - |
| CRS Disease Characteristics | | | |
| Maxillary Only | 18 | 60.0% (18/30) | - |
| Maxillary & Anterior Ethmoid | 12 | 40.0% (12/30) | - |
| Duration of CRS (months) | 30 | 177.1 +/- 140.9 | 9.0 – 480.0 |
| Medical Management | | | |
| No. Treated with Antibiotics | 28 | 93.3% (28/30) | - |
| No. of Days of Antibiotics for Current Episode | 28 | 27.7 +/- 12.8 | 5.0 – 53.0 |
| No. Treated with Steroid | 22 | 73.3% (22/30) | - |

**Figure 3: Mean Overall SNOT-20 Scores at 12-Month Follow-Up**

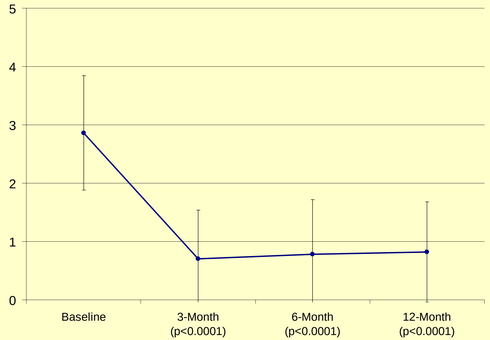
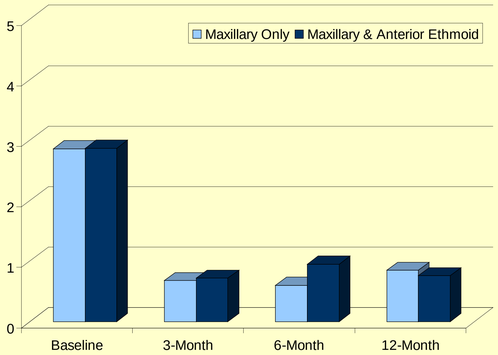



**Figure 4: Mean 12-Month SNOT-20 Scores by Sinuses Affected**




## CONCLUSIONS

The role of catheter-based balloon technologies to treat chronic sinusitis continues to evolve as long-term outcomes data are reported, but it is widely acknowledged that balloon antrostomy is not intended to replace functional endoscopic sinus surgery (FESS). However, the results presented from this research study demonstrate improvement in long-term symptomatic status similar in magnitude to the results previously reported by other balloon dilation device manufacturers[3] and further demonstrate that sinus disease of the anterior sinuses due to narrowing of the ethmoid infundibulum can be effectively treated with FinESS Sinus Treatment and without tissue removal and without general anesthesia.

## REFERENCES

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