

Clinical Study – Interim Data Summary

STUDY NAME

Balloon **RE**modeling **A**ntrostomy **THE**rapy Study (BREATHE I)

CO-PRINCIPAL INVESTIGATORS

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TITLE PAGE

Trans-Antral, Endoscopically-Guided Balloon Dilatation of the Osteomeatal Complex for Chronic Rhinosinusitis (CRS) under Local Anesthesia

ABSTRACT

Background: A multi-center study (BREATHE I – Entellus Medical, Inc.) was performed to assess the safety and outcomes of a new trans-antral, endoscopically-guided balloon system to dilate the maxillary sinus ostia and ethmoid infundibulum. General anesthesia was avoided in most subjects to determine if this procedure might be successfully performed in an office setting.

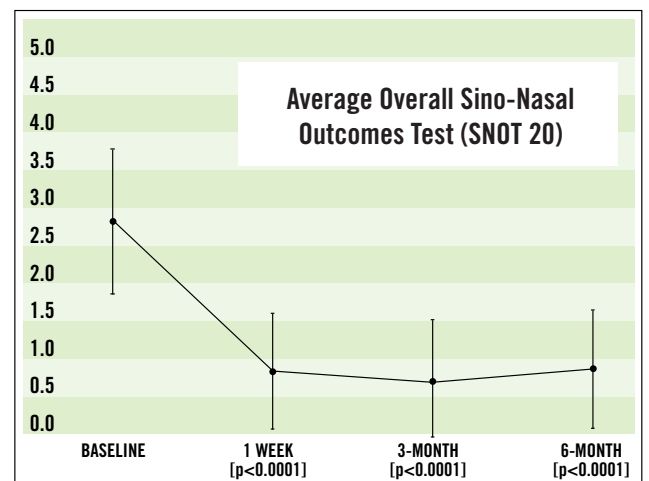
Methods: Subjects with CRS of the maxillary sinuses alone or maxillary and anterior ethmoid sinuses underwent baseline evaluation including CT imaging after maximal medical therapy and symptom assessment using the Sino-Nasal Outcome Test (SNOT 20). Subjects underwent trans-antral balloon dilation and follow-up evaluation was performed at 1 week, 3 months and 6 months post-procedure.

Inclusion Criteria: At least 18 years of age. Chronic rhinosinusitis of the maxillary or maxillary and anterior ethmoid sinuses. Evidence of air/fluid level within the maxillary antrum or narrowing of the outflow tract of the maxillary sinus ostium or infundibulum with ≥ 2 mm of mucosal thickening in the maxillary sinus antrum.

Exclusion Criteria: Evidence of chronic posterior ethmoid, sphenoid or frontal sinusitis. Features consistent with fungal sinusitis. Previous sinus surgery.

Results: 30 subjects were treated at 3 centers. Fifty-five of 58 maxillary ostia were successfully treated for an overall procedural success rate of 94.8%. Ninety-seven percent of the procedures were completed under local anesthesia with or without minimal IV sedation. There were no device-related serious adverse events or unanticipated adverse device effects. The mean overall SNOT 20 score at baseline was 2.9 +/- 1.0. Mean overall SNOT 20 scores at 1-week (n=30), 3-month (n=30), and 6-month (n=20) follow-up were 0.8 +/- 0.8, 0.7 +/- 0.8, and 0.9 +/- 0.8 respectively. Patency at 3-months as confirmed by CT imaging was 95.8%. Protocol compliance with all follow-up visits is 100%. Only 20 of the 30 subjects presented here have completed 6-Month follow-up at the time of data lock.

Conclusion: These results indicate that trans-antral balloon dilation of the osteomeatal complex under local anesthesia appears to be a safe and effective technique for managing isolated maxillary or maxillary and anterior ethmoid sinusitis and can potentially be performed safely in an office setting.



Primary Endpoint: reduction in symptoms (SNOT 20 scores) and patency (CT Scans)