The ORIOS 2 Study: Office-Based Balloon Sinus Dilation

A prospective multi-center study of 203 patients

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Investigators

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Background

- Balloon Sinus Dilation (BSD) instruments afford the opportunity for office-based sinus procedures in properly selected Chronic Rhinosinusitis (CRS) patients, offering potential advantages over OR-based surgery:
  - Avoidance of general anesthesia
  - Potential for significant cost savings
  - Patient convenience

- There are several preliminary reports of feasibility of BSD in an office setting, but conclusions are limited by the sample size and disease under study[1,2,3,4]

The objective of this study is to evaluate the safety and efficacy of office-based trans-nasal BSD for a broad spectrum of sinus disease in a large number of patients using validated outcome measures.

1 Cutler J, Truitt T, Atkins J, et al. First clinic experience: patient selection and outcomes for ostial dilation for chronic rhinosinusitis. Int Forum Allergy Rhinol 2011; 1(6):460-465, 2 Eloy JA, Friedel ME, Eloy JD, et al. In-office balloon dilation of the failed frontal sinusotomy. Otolaryngol Head Neck Surg 2012; 146(2):320-322., 3 Luong A, Batra PS, Fakhri S, et al. Balloon catheter dilatation for frontal ostium stenosis in the office setting. Am J Rhinol 2008; 22:621-624.,4 Albritton FD, Sillers MJ, Casiano RR. Feasibility of in-office endoscopic sinus surgery with balloon sinus dilation. Am J Rhinol Allergy 26, 1-6. doi: 10.2500/ajra.2012.26.3763, 2012.

Study Design

Design	Prospective, multi-center, single arm, IRB-approved
# Patients	203
# Investigators / Centers	14 Investigators / 14 Centers
Patient Population	Medically-refractory adult CRS per AAO-HNS Guidelines (2007)[1], planned endoscopic sinus surgery.
Intervention/Location	Trans-nasal balloon sinus dilation (BSD) in an office setting for all peripheral sinuses
Anesthesia	Local (without IV sedation)
Follow-up	2,8,24 weeks post-procedure
Primary Endpoints	QOL (SNOT-20)[2], Radiographic (Lund-MacKay)[3]
Secondary Endpoints	Safety, Technical Success, Patient Tolerability, Return to Normal Activity, Need for Post-op Debridement, Need for Revision Procedure
Subgroup Analysis	Patients with ethmoid disease entering the study + no office ethmoidectomy

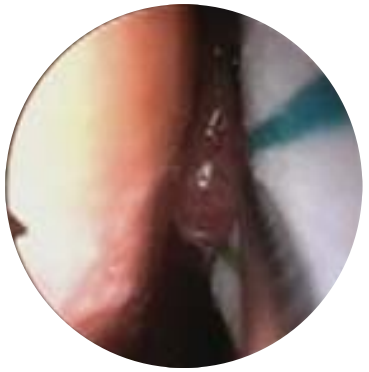
1 Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: Adult sinusitis. Otolaryngol Head Neck Surg 2007; 137: S1-S31.
2 Picirrillo JF, Merritt MG, Richards ML. Psychometric and clinimetric validity of the 20-item Sino-Nasal Outcome Test (SNOT-20). Otolaryngol Head Neck Surg 2002; 126:41-47.
3 Lund VJ, Mackay IS. Staging in rhinosinusitis. Rhinology 1993; 31:183-184.

Demographics and Anesthesia

Demographics

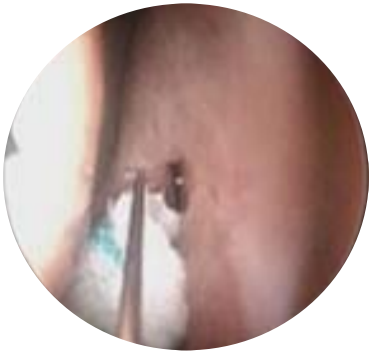
Patients	203
Mean Age (range)	48.6 (20-88)
Male	46.8%
Prior sinus surgery	38.1%
Polyps	8.4%

Local Anesthesia



Typical protocol:

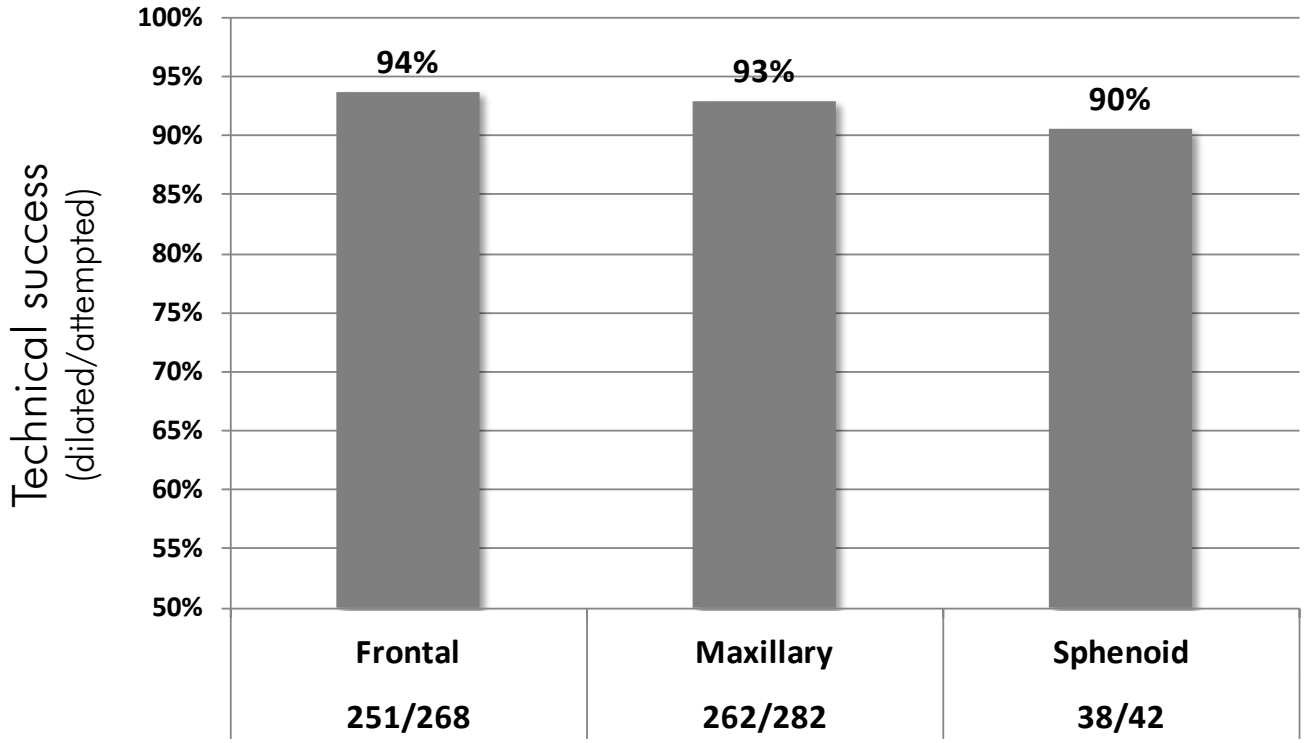
- Step 1: Aerosolized local anesthetic and decongestant
- Step 2: Topical soaked on cottonoid or pledget
- Step 3: Infiltration



Oral Medication:

- 56.7% of patients received no oral medication
- 43.3% of patients received oral medication
  - 1% narcotic
  - 33% anxiolytic
  - 9.4% both

93% Overall Technical Success



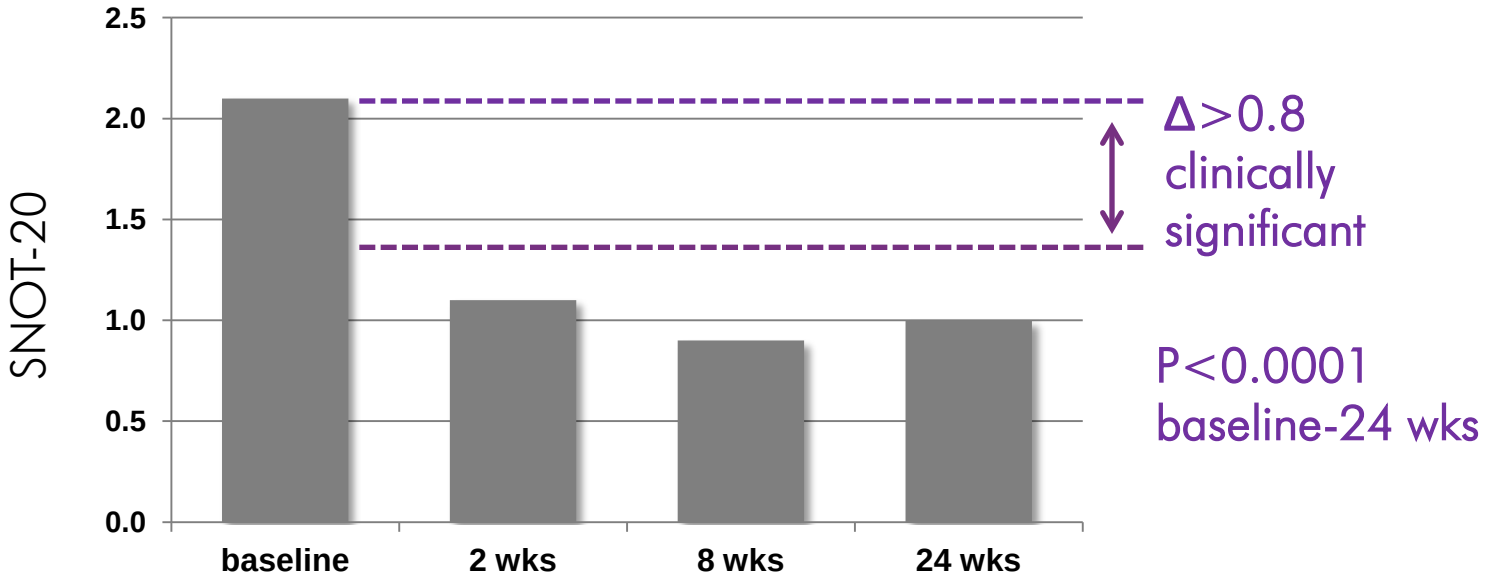
- 551 out of 592 (93.1%) sinuses successfully dilated
- Average of 2.7 sinuses dilated/patient
- 71.9%, 74.9%, 11.3% of patients had at least one frontal, maxillary, or sphenoid dilated, respectively

No Device-related Adverse Events

- 1 serious *non-device related* event
  - Pneumonia requiring hospitalization approximately two months post-procedure
- 1 *procedure-related* adverse event
  - Self-limiting periorbital swelling that resolved shortly after the procedure without further sequelae.*

*The lamina papyracea may have been damaged with a seeker device that was used to separate the uncinate, which was closely adherent to the bulla. Periorbital swelling occurred when the patient blew her nose that night. Problem resolved without further sequelae.

Significant Improvement in QOL & LMK; Low Revision Rate



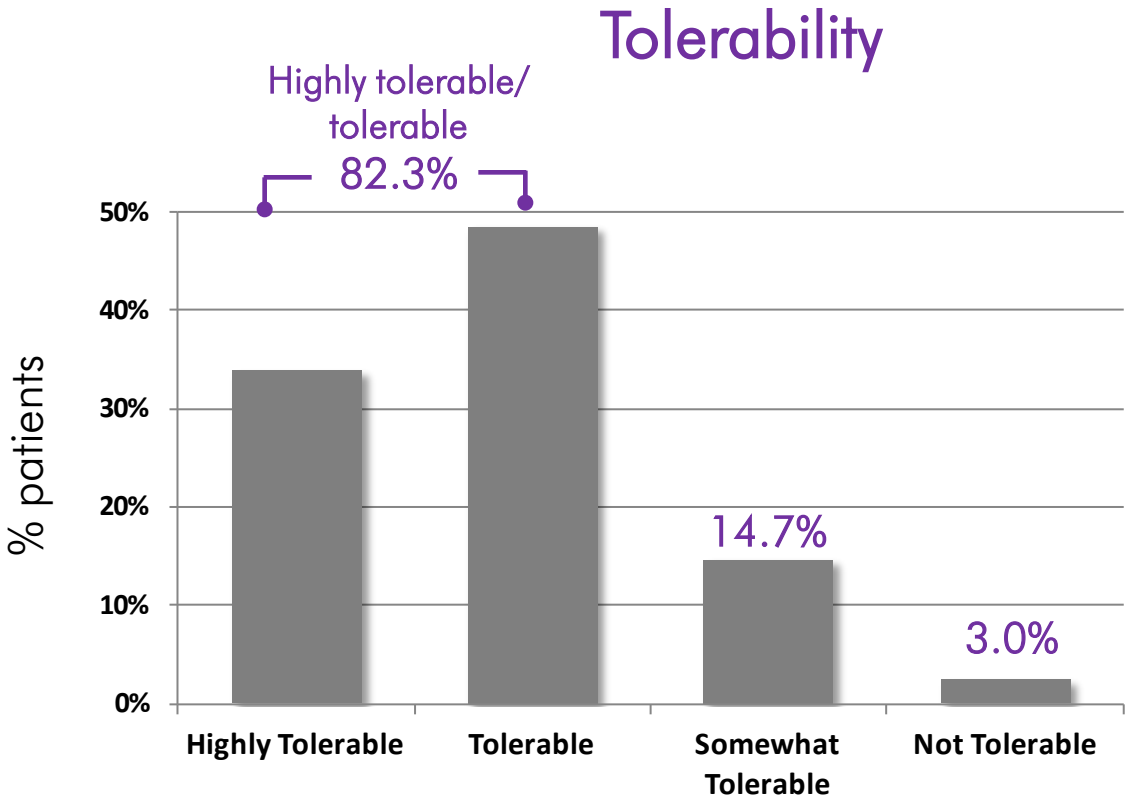
- **SNOT-20** dropped from 2.1 @ baseline to 1.0 @ 24 weeks. This is similar to previously reported OR-based balloon dilation[1] and 'traditional' ESS procedures[2,3].
- **Lund-MacKay** (LMK) dropped from 6.9 pre-op to 2.5 @ 24 weeks ($p<0.0001$).
- 6 **revisions** out of 203 patients (3%) with median follow-up of 22 weeks.

Matched pair reduction in SNOT-20 @ 24 weeks. 1 Kuhn FA, Church C, Goldberg A, Levine H, Sillers M, Vaughn W, Weiss R. Balloon Catheter Sinusotomy: One-Year Follow-Up Outcomes and Role in Functional Endoscopic Sinus Surgery. Otolaryngology Head and Neck Surgery, September 2008, Vol. 139, Number 3S3, S27-S37 2 Moghadasi, H, *et al*. Correlation of Lund-Mackay and SNOT-20 before and after functional endoscopic sinus surgery (FESS): Does the baseline data predict the response rate? Iran J Radiol 2009; 6(4):. 3 Jones ML, *et al*. Functional endoscopic sinus surgery: Do ratings of appropriateness predict patient outcomes? *Am J Rhinol*, 1998; 12:249-255.

Well Tolerated & Rapid Return to Normal Activity

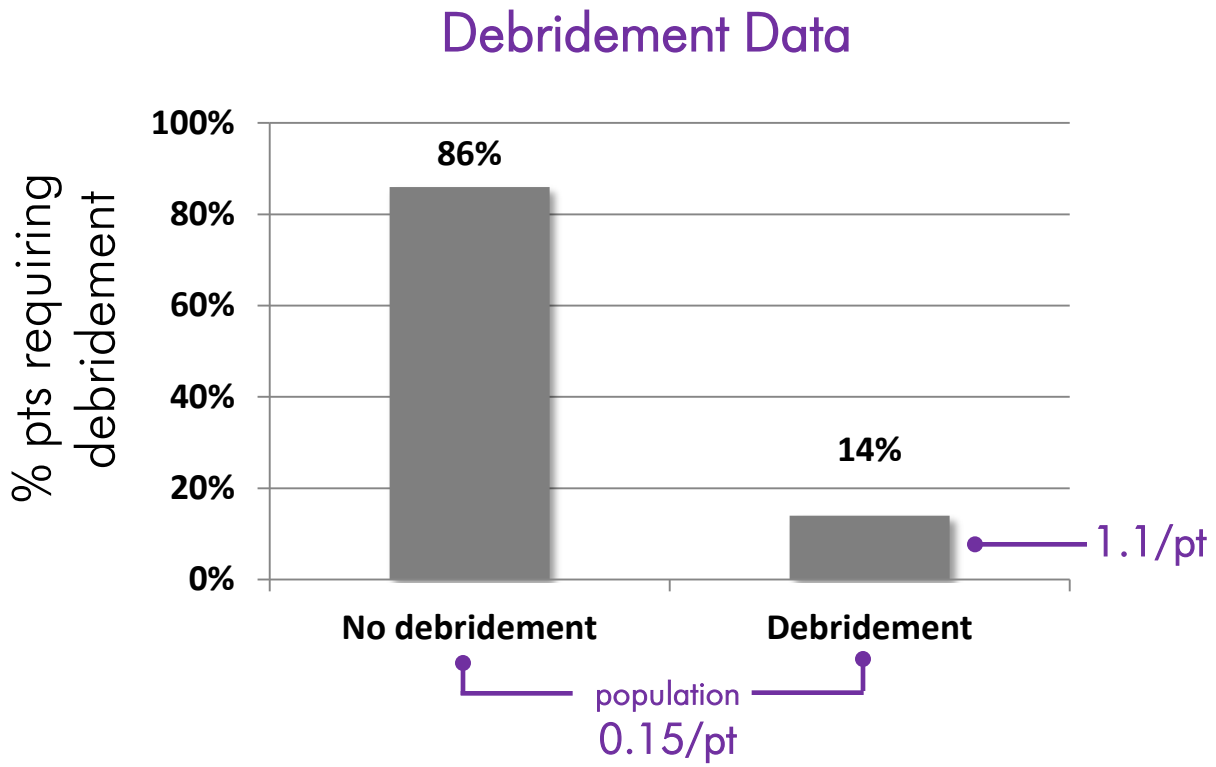
- Average time to Return to Normal Activity = 2.4 days post-procedure (2.0 median)
  - 68% returned to normal activity within 2 days after the procedure

- 82.3% rated the procedure as tolerable or highly tolerable. 14.7% somewhat tolerable, and 3.0% not tolerable.



Low Debridement Rate

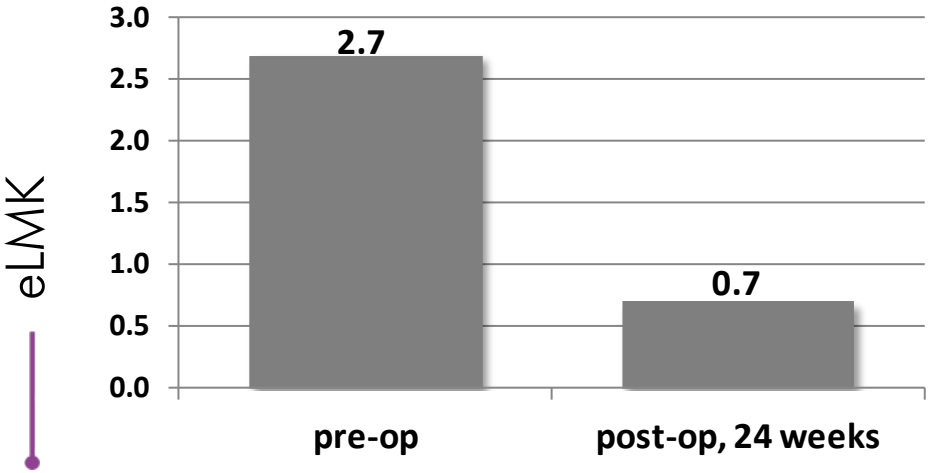
- 86% of subjects had no debridement
- 14% required debridement (29 debridements/26 subjects)



65% of Ethmoid Subgroup showed Ethmoid Disease Resolution with *BSP* Alone

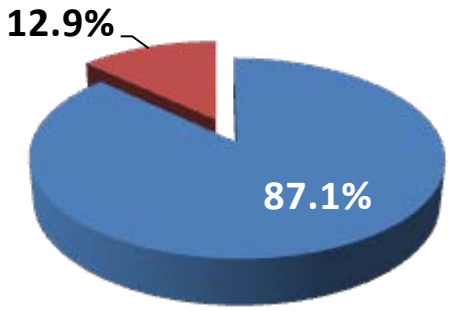
- 31 patients in Ethmoid Subgroup Analysis
  - Definition: Ethmoid disease entering study, no ethmoidectomy during study, 24 wk CT available

Radiographic Ethmoid Measurement



Ethmoid-specific Lund MacKay score, bilateral total possible range 0-8

eLMK Change



- 87.1% (27/31) improved
- 12.9% same
- 0% worse

64.5% (20/31) showed complete radiographic resolution of ethmoid disease without ethmoidectomy

Conclusions

- Trans-nasal BSD in the office setting can be safely performed in all peripheral sinuses
- In-office BSD is effective in relieving symptoms of CRS, as evidenced by significant SNOT-20 improvement and low revision rate
- Patient tolerability is acceptable
- Patients with mild/moderate ethmoid disease may be suitable candidates for in-office BSD, with potential option to avoid ethmoidectomy