

Balloon Sinuplasty

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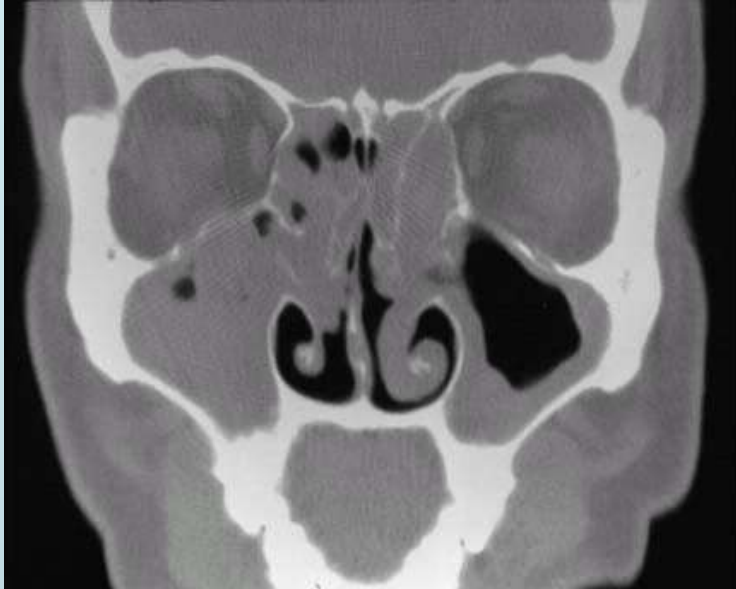
Department of Otolaryngology

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Grand Rounds Presentation

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Introduction



- ▶ 31 million Americans suffer from chronic sinusitis
- ▶ Surgical treatment for chronic sinusitis has evolved tremendously since its inception



Historical perspectives

- ▶ End of 19th century:
 - ▶ George Caldwell and Henri Luc described the canine fossa approach to maxillary sinus
- ▶ 1901:
 - ▶ Hirschman was the first to perform nasal endoscopy using a modified cystoscope
- ▶ 1960:
 - ▶ Hopkins rod telescope was patented
- ▶ 1978:
 - ▶ Messerklinger published a landmark collections of endoscopic images
- ▶ 1980s:
 - ▶ Stammberger published a series of papers on FESS



Balloon technology



- ▶ Available in other specialties cardiology, gastroenterology, endovascular surgery, and urology
- ▶ Angioplasty has effectively provided an alternative to open heart surgery



ARS position statement on balloon sinuplasty (2006)

- ▶ -- Balloon dilation technology may have potential application where surgical management of sinus disease is required.
- The technology has limited surgical indications at this time.
- Patients treated with balloon dilation may still require conventional sinus surgery.
- In a small group of very selected patients, the use of balloon dilation technology alone may eliminate the need for other surgical procedures.



Manufacturers

- ▶ Three companies that manufacture balloon catheters have reported their use in endoscopic sinus surgery:
- ▶ **Acclarent, Inc (Menlo Park, CA, USA)**
- ▶ **Quest Medical, Inc (Allen, TX, USA)**
- ▶ **Entellus Medical, Inc (Maple Grove, MN, USA)**



Acclarent, Inc

- ▶ Based in Menlo Park, CA
- ▶ Started investigation in sinuplasty in 2002
- ▶ Fluoroscopic confirmation
- ▶ Lighted guidewire called LUMA recently released



Fig. 3. Acclarent Relieva Luma Sinus Illumination System. (Courtesy of Acclarent, Inc, Menlo Park, CA.)



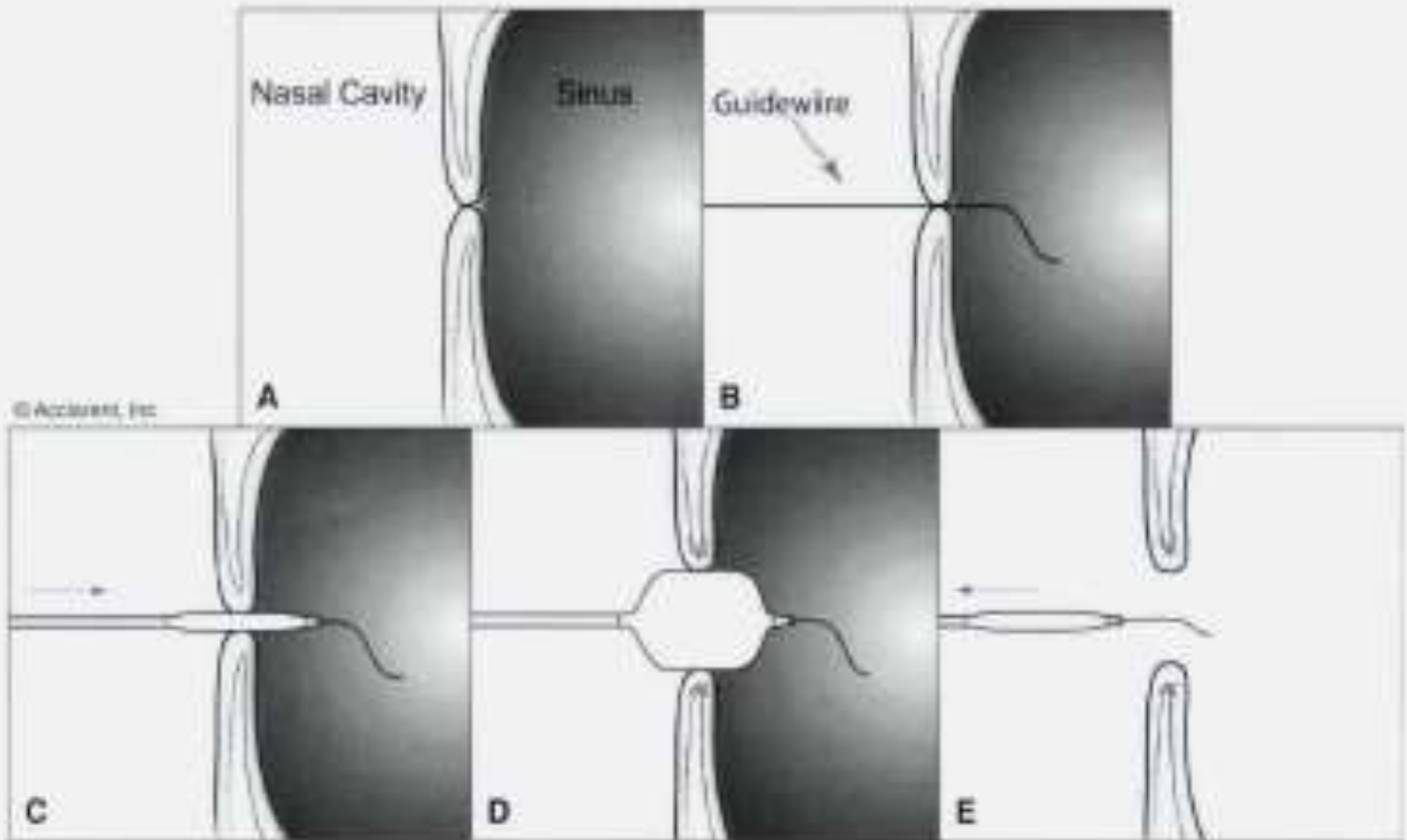
Acclarent Relieva sinus catheter



Fig. 1. Acclarent Relieva Solo Pro Sinus Balloon Catheter. (Courtesy of Acclarent, Inc, Menlo Park, CA.)



Schematics of Balloon Sinuplasty



Luma Sinus Illumination System (Luma light)



Fig. 1. A discrete focus of transillumination over the targeted sinus indicates guidewire presence within the sinus. Small manipulations of the guidewire should result in movement of the transillumination focus over the region of the anterior sinus wall.



Fig. 2. Diffuse transillumination over the targeted sinus is a false positive result. This pattern of transillumination does not confirm guidewire presence within the sinus.

Comparison of Luma and fluoroscopy

TABLE II.
Success Rates of Sinus Cannulation for Each Technique By Sinus and in Total.

	Sinuses Successfully Cannulated			
	Maxillary	Frontal	Sphenoid	Total
Luma light	102/102 (100%)	46/57 (80.7%)	N/A*	148/159 (93.1%)
Fluoroscopy	108/108 (100%)	36/44 (81.8%)	19/19 (100%)	163/171 (95.3%)
P value	.922	.902	N/A*	.977

*Luma light is not used in the sphenoid sinus due to the inability to visualize translumination. Data is displayed in counts and percent. A significant difference between groups required a P value < .05.

Friedman M. Laryngoscope. 2009 Jul;119(7):1399-402.



Initial study 1: Bolger et al. (2006)

- ▶ 6 human cadaver heads,
- ▶ CT before and after balloon dilation
- ▶ Catheters successfully dilated 31 of 31 ostia:
 - ▶ 9 maxillary, 11 sphenoid, and 11 frontal recesses
- ▶ Mucosal trauma appeared to be less than that normally seen with standard endoscopic instruments.
- ▶ Minimal trauma to surrounding structures such as the orbit or skull base per CT and nasal endoscopy



Initial study 2: Brown et al. (2006)

- ▶ Prospective non-randomized cohort
- ▶ 10 patients, 18 sinuses
 - ▶ 10 maxillary, 3 frontal, 5 sphenoid
- ▶ Exclusion criteria:
 - ▶ Age < 18
 - ▶ CF
 - ▶ Significant nasal polyposis
 - ▶ Sinus osteoneogenesis
 - ▶ Previous FESS
- ▶ Fluoroscopic guidance with C arm
- ▶ Balloon inflated to mean pressure of 13 atm (range: 10-16)



Maxillary ostium after balloon dilation



Fig 6. Endoscopic view of middle meatus and maxillary sinus following balloon catheter ostial dilation. Frontal recess curette is gently mobilizing middle turbinate to position endoscope within middle meatus. Spoon of curette provides reference for final ostium size after balloon dilation.

Brown et al. (2006) results

- ▶ No adverse events
 - ▶ Minimal bleeding
 - ▶ High degree of mucosal preservation
 - ▶ Ease of dilation: Sphenoid > frontal > maxillary
 - ▶ Mild difficulty in dilating maxillary sinus in 5 of 10 patients
 - ▶ Disadvantage: Difficulty to examine ostia postop (uncinate, ethmoid cells not removed)
 - ▶ Weakness of the study:
 - ▶ Small # patients
 - ▶ No quality of life evaluation
-

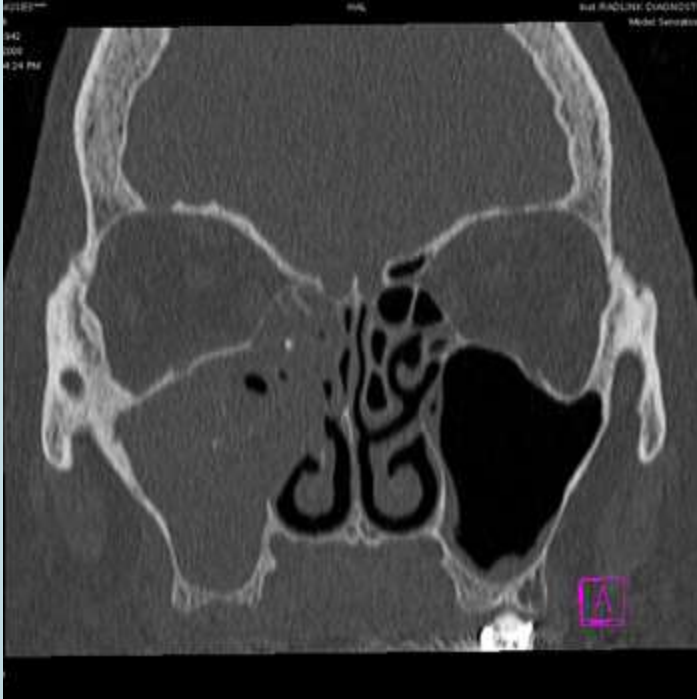


Levine et al (2008)

- ▶ PatiENT Registry retrospective review
- ▶ Multi-center, 27 ENT practices
- ▶ 1036 patients, 3276 sinuses treated
- ▶ 1438 Maxillary, 1284 frontal, 554 sphenoid
- ▶ No major adverse events
- ▶ 2 CSF leaks from ethmoidectomy done by standard FESS
- ▶ 41 of 3276 sinuses required revision (1.3%)
- ▶ 95% patients with symptom improvement
- ▶ Less debridement required for balloon only vs. hybrid



Measurement of success in balloon sinuplasty



- ▶ SNOT-20
- ▶ CT sinus
- ▶ Lund-Mackay CT score
- ▶ Nasal endoscopy to look for ostia patency



Sino Nasal Outcome Test (SNOT-20)

- ▶ 0 = Not present/no problem
- ▶ 1 = Very mild problem
- ▶ 2 = Mild or slight problem
- ▶ 3 = Moderate problem
- ▶ 4 = Severe problem
- ▶ 5 = Problem as “bad as it can be”



SNOT - 20

Table 4
Individual SNOT-20 scores, ranked by magnitude of change: All patients

Question	Symptom	N	Preoperative mean	Postoperative 2-year mean	Δ from baseline	P value
10	Facial pain/pressure	61	3.0	1.0	-2.0	S
14	Wake up tired	61	2.8	1.1	-1.8	S
13	Lack of a good night's sleep	61	2.6	1.0	-1.7	S
15	Fatigue	61	2.7	1.0	-1.6	S
18	Frustrated/restless/irritable	61	2.4	0.8	-1.6	S
16	Reduced productivity	61	2.4	0.8	-1.6	S
12	Wake up at night	61	2.4	0.9	-1.5	S
5	Postnasal discharge	59	3.0	1.5	-1.5	S
17	Reduced concentration	61	2.2	0.8	-1.4	S
11	Difficulty falling asleep	61	2.2	1.0	-1.2	S
6	Thick nasal discharge	61	2.2	1.0	-1.2	S
4	Cough	60	2.0	0.9	-1.2	S
7	Ear fullness	61	2.1	1.0	-1.1	S
8	Dizziness	61	1.5	0.5	-1.0	S
9	Ear pain	61	1.6	0.6	-1.0	S
3	Runny nose	61	1.9	0.9	-1.0	S
1	Need to blow nose	59	2.1	1.1	-1.0	S
20	Embarrassed	61	1.3	0.4	-1.0	S
2	Sneezing	60	1.9	0.9	-0.9	S
19	Sad	61	1.2	0.5	-0.7	S

S, significant change from baseline (alpha = 0.05/20).

Lund- Mackay scores

Chart 2. Lund-Mackay score of CT scan.

paranasal sinuses	Right	Left
Maxillary (0,1,2)		
Anterior Ethmoid (0,1,2)		
Posterior Ethmoid (0,1,2)		
Sphenoid (0,1,2)		
Frontal (0,1,2)		
Ostiomeatal Complex (0,2)*		
Total		
Note: 0- without abnormalities; 1- partial opacification; 2- total opacification		
*0- no obstruction; 2- obstructed		



Ostia patency



Figure 4 Endoscopic view of ostium immediately after balloon catheter dilation. A suction catheter is placed to allow placement of the endoscope and to reference ostial size. Erythematous and edematous mucosa and purulence are evident within the maxillary sinus.

CLEAR study

- ▶ **C**linical **E**valuation to confirm **sA**fety and efficacy of sinuplasty in the **pA**ranasal sinuses
- ▶ Multi-center prospective non-randomized study
 - ▶ Bolger et al. (2007): 10 centers (24-week , 109 patients)
 - ▶ Kuhn et al. (2008): 7 centers (1 year f/u, 66 patients)
 - ▶ Weiss et al. (2008): 6 centers (2 years f/u, 65 patients)



Goals of CLEAR study

- ▶ 1) To evaluate the effectiveness of balloon catheter devices in relieving sinus ostial obstruction and in maintaining sinus ostia patency
- ▶ 2) To confirm the safety of sinusotomy using balloon catheters in a larger patient group
- ▶ 3) To gain insight into the ability of sinusotomy with balloon catheters to relieve sinus symptoms, either alone or in combination with standard endoscopic sinus surgery techniques.



Inclusion & Exclusion criteria

▶ **Inclusion criteria :**

- ▶ Adult > age of 18 years
- ▶ Chronic sinusitis unresponsive to medical management

▶ **Exclusion criteria:**

- ▶ Extensive sinonasal polyps, cystic fibrosis
 - ▶ Extensive previous sinonasal surgery
 - ▶ Extensive sinonasal osteoneogenesis
 - ▶ Sinonasal tumors,
 - ▶ History of facial trauma
 - ▶ Ciliary dysfunction
 - ▶ Pregnancy
-



CLEAR study design

- ▶ 3 parts, starting with 24-week data, followed by 1-year data and then by 2-year data
- ▶ Start off with 109 patients
- ▶ 2 arms
 - ▶ Balloon sinuplasty combined with traditional FESS (hybrid)
 - ▶ Balloon sinuplasty alone
- ▶ Nasal endoscopy to access ostia patency
- ▶ CT sinus/ Lund Mackay scores
- ▶ SNOT-20 survey for sinus symptoms
 - ▶ Preop
 - ▶ 24 weeks, 1 year, 2 years postop



Weiss 2 year study (2008)

- ▶ Continuation of CLEAR and Kuhn study
- ▶ Prospective multi-center study
- ▶ 65 patients and 195 sinuses
- ▶ 34 patients “balloon only”, 31 hybrid (FESS + balloon)
- ▶ Septoplasty and turbinectomy also performed in a subset of patients (more in the hybrid group)
- ▶ 32 patients with CT scan at 2 years



CLEAR study – SNOT 20 results

▶ Preop:

- ▶ Balloon: 2.09
- ▶ Hybrid: 2.27

▶ 24 week:

- ▶ Balloon: 1.07 (p< 0.0001)
- ▶ Hybrid: 0.92 (p< 0.0001)

▶ 1 year:

- ▶ Balloon: 0.99
- ▶ Hybrid: 0.68

▶ 2 years:

- ▶ Balloon: 1.09
 - ▶ Hybrid: 0.64
-



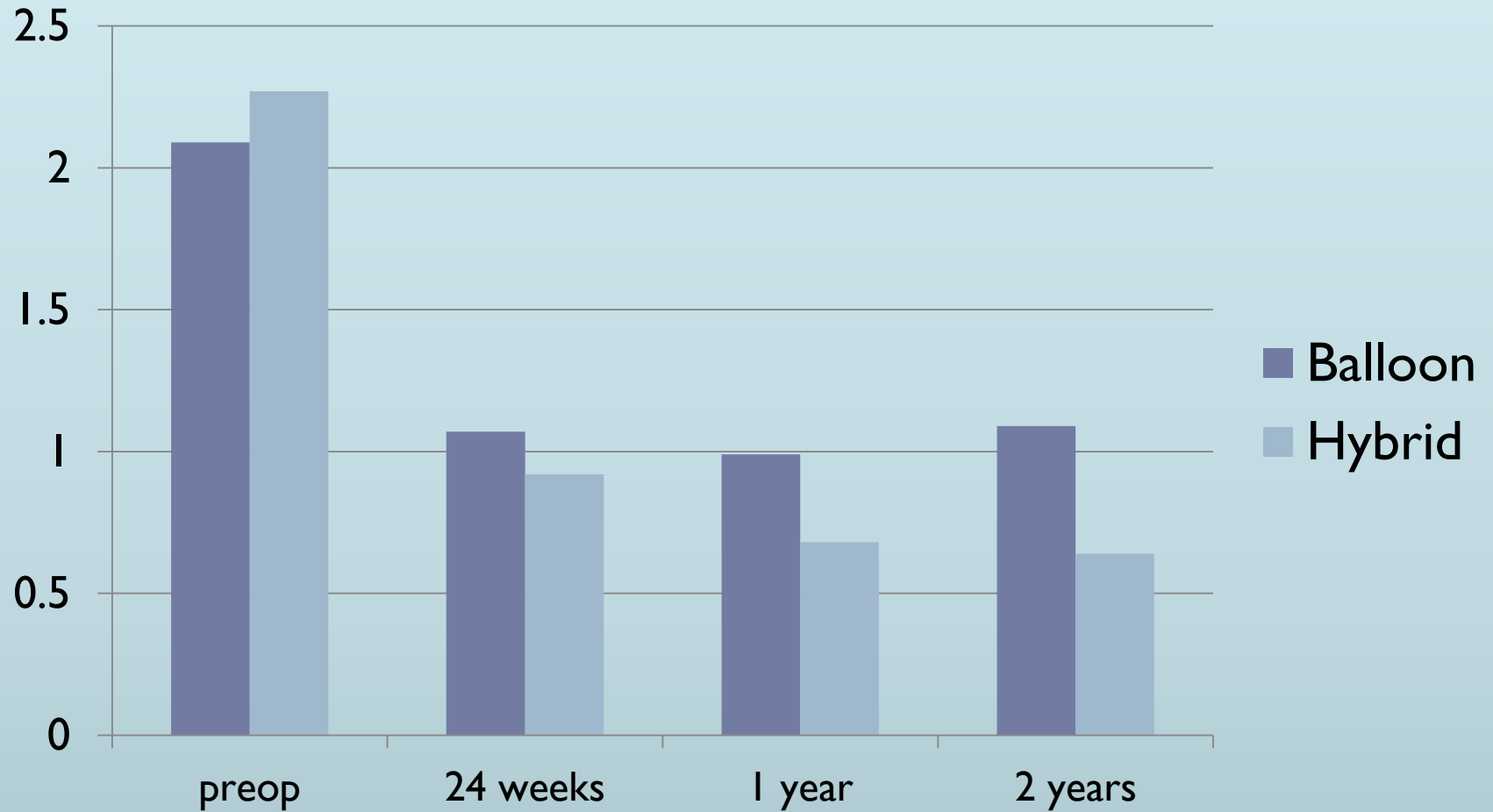
SNOT - 20

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SNOT-20 scores summary



CT sinus: Maxillary



Preop

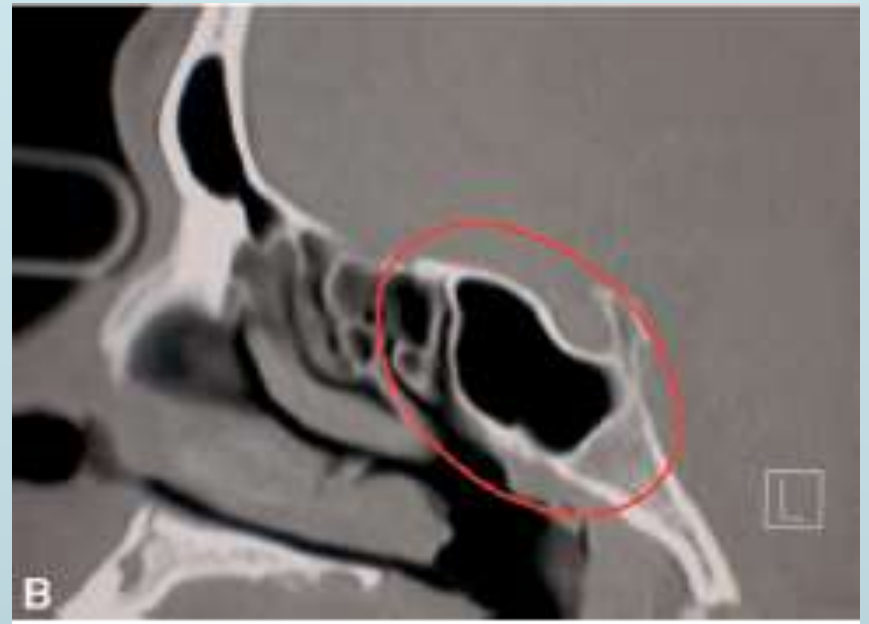


2 years postop

CT sinus: Sphenoid



Preop



1 year postop

CT sinus: Frontal



Preop



1 year postop

CLEAR STUDY- CT Lund-Mackay scores

▶ Preop:

- ▶ Balloon: 5.67
- ▶ Hybrid: 12.05

▶ 24 week:

- ▶ Balloon: No data
- ▶ Hybrid: No data

▶ 1 year:

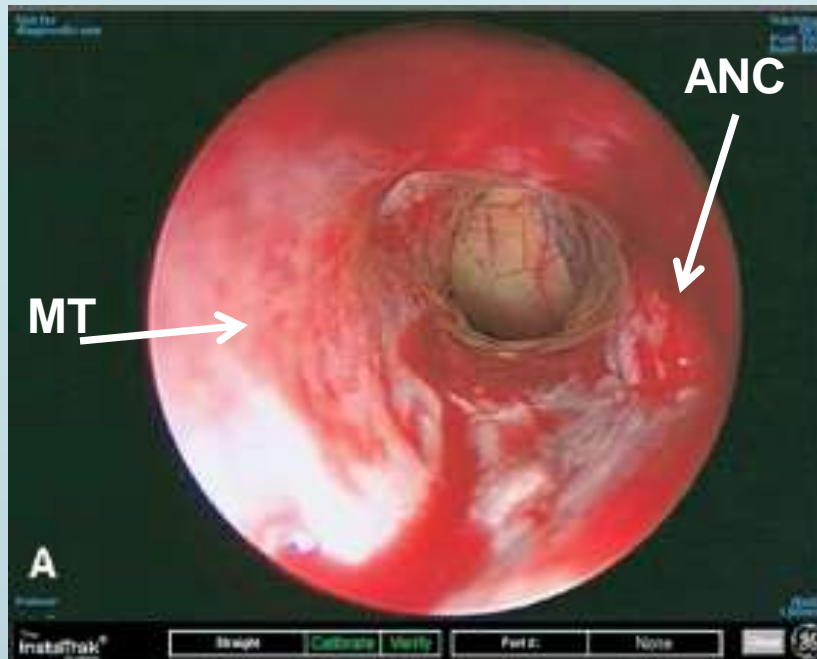
- ▶ Balloon: 1.13 (p=0.07)
- ▶ Hybrid: 1.13 (p<0.001)

▶ 2 years:

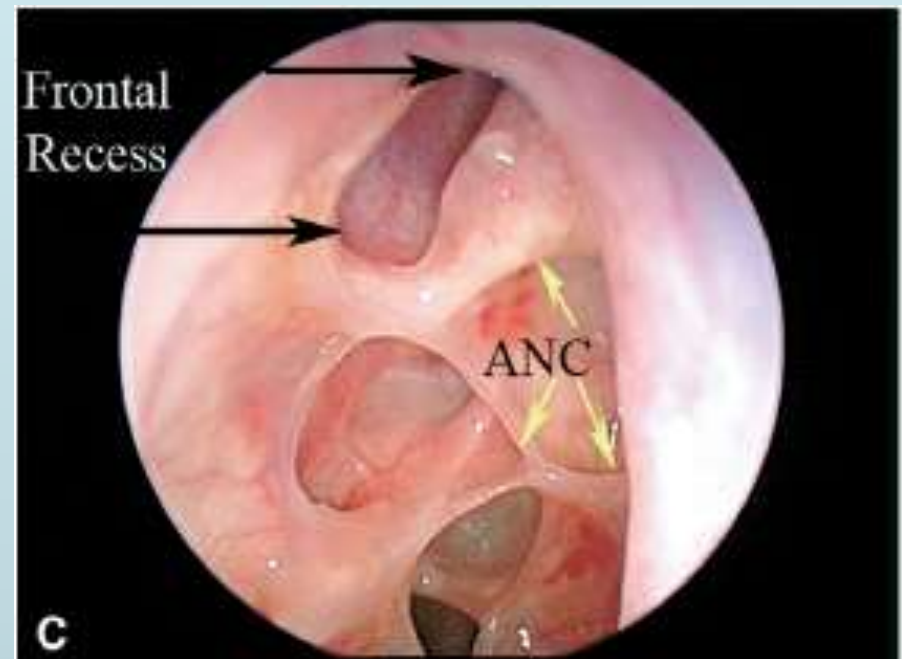
- ▶ Balloon: 1.75 (p=0.02)
 - ▶ Hybrid : 3.25 (p<0.001)
-



Ostia patency: frontal



Intraop



9 months postop

Ostia patency by nasal endoscopy

Table 1
1-year postoperative patency by sinus

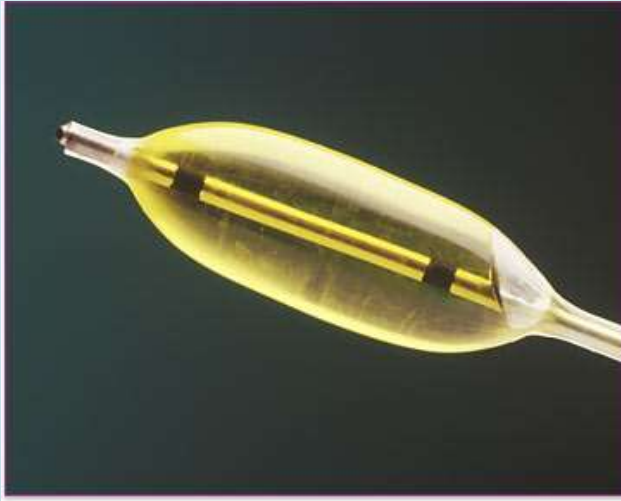
	Maxillary	Frontal	Sphenoid	Total
Postoperative endoscopic patency	90% patent (83/92)	85% patent (63/74)	72% patent (26/36)	85% patent (172/202)
All 1-year patients	0% nonpatent (0/92)	3% nonpatent (2/74)	0 nonpatent (0/36)	1% nonpatent (2/202)
Hybrid and balloon only	10% (9/92) indeterminate	12% (9/74) indeterminate	28% (10/36) indeterminate	14% (28/202)
Functional patency CT L/M = 0 all 1-year patients	3/9 stage 0	5/9 stage 0	5/10 stage 0	13/28 stage 0 (46%)
Overall patency	93.5% (86/92) (83 + 3/92)	91.9% (68/74) (63 + 5/74)	86.1% (31/36) (26 + 5/36)	91.6% (185/202)

Pediatric population

- ▶ Ramadan et al (2008)
 - ▶ Prospective study of 30 children
 - ▶ Failed medical therapy and confirmed CRS on CT
 - ▶ Exclude CF, immunodeficient, ciliary dysmotility patients
 - ▶ Use of C-arm / fluoroscopy
 - ▶ 56 sinuses (48 maxillary, 6 sphenoid, 2 frontal)
 - ▶ 5 mm balloon
 - ▶ Successful dilation in 51 / 56 sinuses (91%)
 - ▶ Adenoidectomy performed in 13/30 cases (younger children)
 - ▶ Reason for failure: 4 hypoplastic maxillary sinuses, 1 frontal
 - ▶ No complications
 - ▶ No quality of life or follow up information



LacriCATH by Quest medical (Allen, Tx)



- ▶ Ophthalmologist has used this to treat nasolacrimal duct obstruction
- ▶ Off label for use in sinus ostia obstruction
- ▶ Catheters with balloon at the end of a malleable (no guide wire needed)



LacriCATH study



- ▶ **Citardi (2007)**
 - ▶ Cadaver study
 - ▶ 9-mm balloon
 - ▶ No fluoroscopy used
 - ▶ Maxillary sinus dilation successfully performed in only 3 of 6 sinuses

- ▶ **Atkins (2009)**
 - ▶ Report successful dilatation of 6 frontal sinus ostia in the office setting without the use of fluoroscopy.



Entellus Medical, Inc

- ▶ Direct access to maxillary sinus through canine fossa puncture with a small trocar
- ▶ Direct visualization of natural ostium via 0.5 mm flexible endoscope



Fig. 4. Karl Storz 0.5-mm flexible endoscope. (Courtesy of Entellus Medical, Inc, Maple Grove, MN: with permission.)



Radiation exposure in fluoroscopy

- ▶ Radiation to the eyes can cause damage to the proliferating cells in the epithelium, ultimately leading to cataract formation.
- ▶ Cataract threshold: acute doses of 2 Gy or 4 Gy in 3 months
- ▶ Balloon sinuplasty fluoroscopy: ~ 4 mGy per eye
- ▶ Luma illumination provides an alternative to limit radiation to both patients and surgeons



Cost

- ▶ Friedman et al. (2008)

- ▶ Primary surgery:

- ▶ Traditional FESS: \$ 13,574
- ▶ Balloon sinuplasty: \$ 14,021 (p=.55)

- ▶ Revision surgery:

- ▶ Traditional FESS: \$ 16,190
- ▶ Balloon sinuplasty: \$ 10,346 (p< .0001)



Coding

- ▶ Use of “pure” sinuplasty requires the use of CPT Unlisted Code 31299.

- ▶ For hybrid procedures, use FESS codes:
 - ▶ Maxillary: 31256 / 31267 (tissue removal)
 - ▶ Sphenoid: 31287/ 31288
 - ▶ Frontal: 31276



Pain

- ▶ Well tolerated by most patients.
- ▶ Friedman et al. (2008) on narcotic pain meds duration
 - ▶ Traditional FESS: 1.34 days
 - ▶ Balloon sinuplasty: 0.8 days (p=0.011)
- ▶ BREATHE-I trial (2007)
 - ▶ Narcotic pain meds rarely needed
- ▶ Less postoperative debridement



Sinuplasty: A new tool

- ▶ “Sinuplasty is a new technique in performing endoscopic sinus surgery—not a new procedure but rather a new tool that further reduces mucosal damage and advances us toward our ultimate goal of improving function with maximal mucosal preservation.”

Raymond Weiss, MD



Conclusions:

- ▶ Balloon sinuplasty is a novel technology for otolaryngologists
- ▶ It is a safe technique with low morbidity
- ▶ It is shown to improve patient symptoms in data of 2 year follow up in a selected group of patients
- ▶ It holds promises for office type sinus procedures
- ▶ More study is needed to define its role in sinus surgery in particular patient selection and disease type best suited for this technology



Thank You

