

Sinusitis and the Primary Care Practice

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Dr. Leonard Brown - Disclosure

I have a financial relationship with or interest in a commercial interest connected with this presentation.

Speaker and Training site for IOBS
Acclarent /J&J

Dr. Jan Zieren - Disclosure

Dr. Zieren has no financial relationships to disclose.

Learning Objectives

- Be able to diagnose sinusitis and allergies
- Recognize the incidence and economic impact of sinus and allergy
- Discover current recommended treatment
- Recognize the need for long term therapy
- Recognize SAHP disease classifications
- Discover current surgical technique
- Understand usage of tools such as the SNOT-22

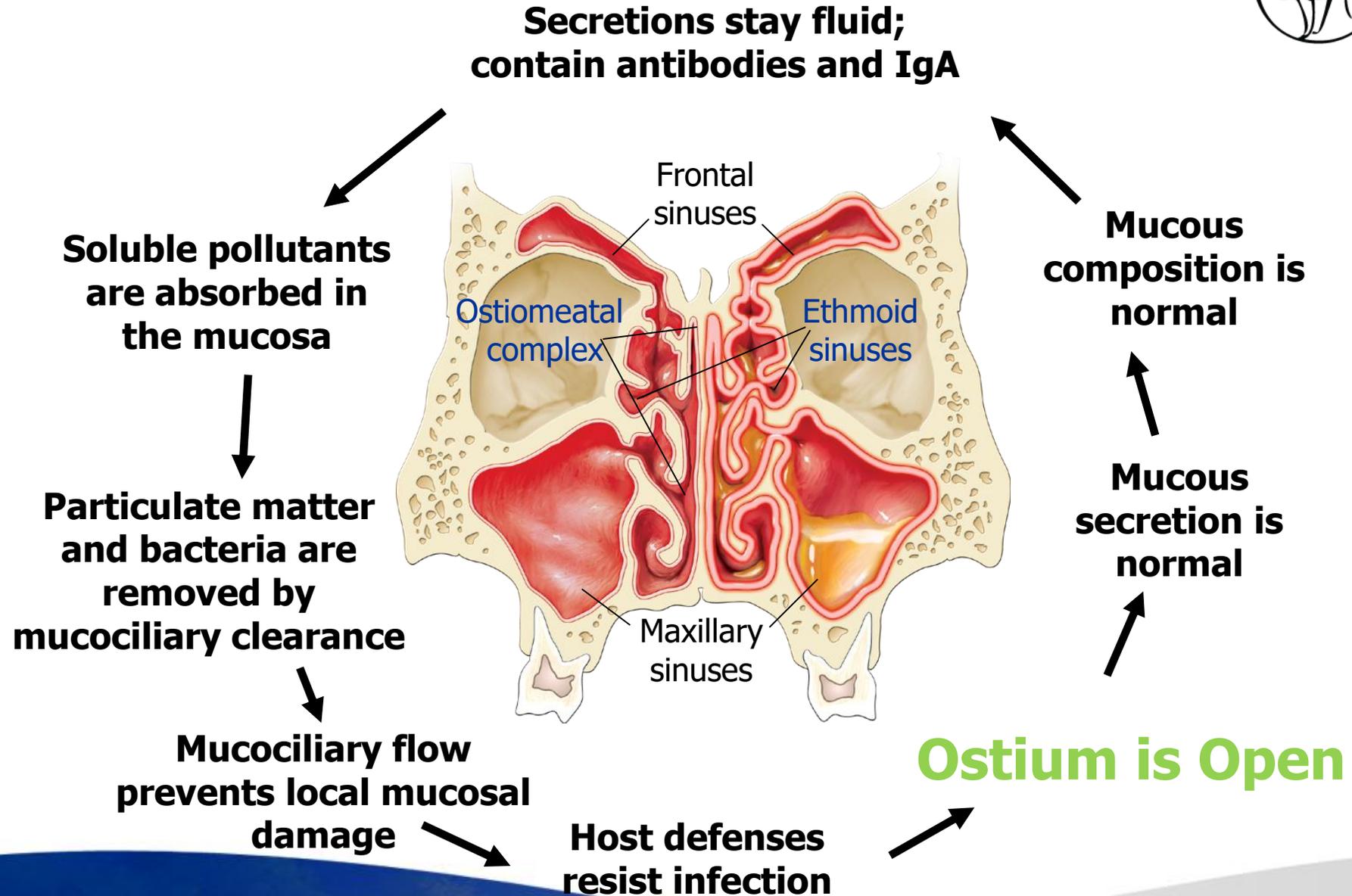
Disease Burden of Sinusitis - U.S. Data

- Estimated 37 million cases of sinusitis each year
 - 26.7 million hospital outpatient, physician office and emergency department encounters attributed to sinusitis* (1996)
 - Over 15 million office visits per year result in primary diagnosis of sinusitis* (1996)
- Approximately 20 million cases of acute bacterial sinusitis (ABS) in the U.S. annually
- Sinusitis is the fifth most common diagnosis for which antibiotics are prescribed
- The economic impact of work loss in the United States for sinus and allergy disease is greater than back and heart conditions combined.

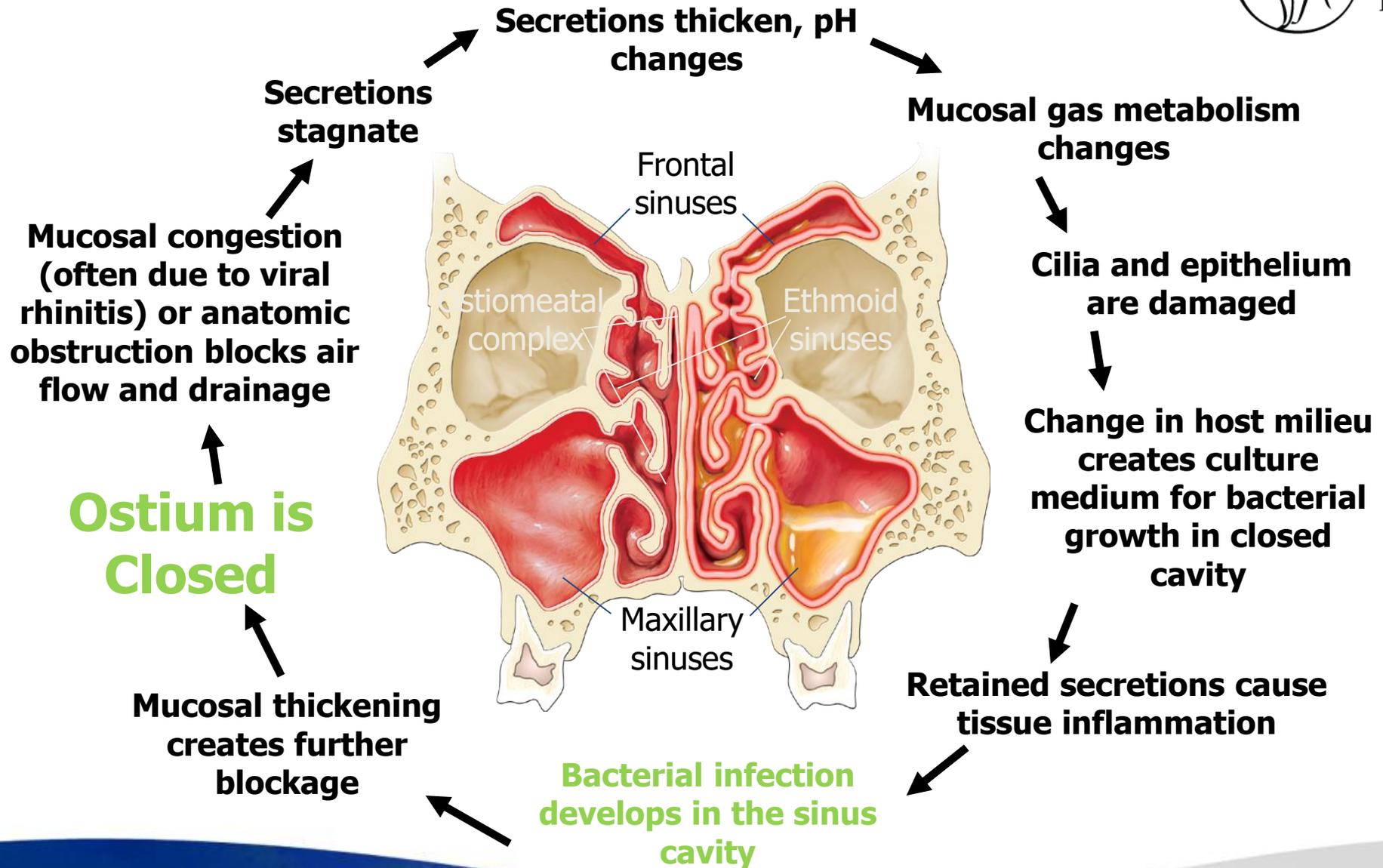
Nasal/Sinus Organ

- MUCOUS PRODUCTION
- HEATING
- COOLING
- FILTERING
- LACTOFERRIN
- LYSOZYMES
- NITRIC OXIDE
- IMPROVED VENTILATION
- IMPROVED PULMONARY FUNCTIONS
- IMMUNOGLOBULINS
- GLYCOPROTEINS

Normal Sinus Health Cycle



Sinus Cycle Leading to Sinusitis



Rhinosinusitis

Epidemiology and Impact

- 31 million cases annually
- 25 million office visits for acute bacterial sinusitis from 1993-1994
- Most often preceded by viral upper respiratory tract infection

DIAGNOSIS AND TREATMENT OF RHINOSINUSITIS



Types of Sinusitis

- **Acute**
 - Less than 4 weeks
- **Recurrent Acute**
 - 4 or more episodes of acute sinusitis per year
 - Potential Balloon Sinuplasty candidate
- **Chronic**
 - More than 12 weeks
 - Potential Balloon Sinus Dilation candidate

Facts About Sinusitis

- Sinusitis affects 37 million Americans each year, making it one of the most common health problems in the U.S.
- Sinusitis affects approximately 14% of the adult U.S. population
- Sinusitis affects 17% of women and 10% of men each year
- Chronic sinusitis (not including acute sinusitis) results annually in an estimated 7 million physician office visits
- Direct healthcare expenditures due to sinusitis costs are well over \$8 billion each year
- Total restricted activity days due to sinusitis are over 58 million per year
- At least 20% of chronic sinusitis patients are not successfully treated with medical therapy

Sinusitis Care Continuum

Medication

Nasal Steroids
Antibiotics
Decongestants
Oral Steroids
Mucus-thinning Drugs

FESS

Functional
Endoscopic
Sinus
Surgery

**Balloon Sinus
Dilation**

2004 SAHP Sinusitis Guidelines

Definition & Diagnosis

MAJOR

- Nasal congestion/fullness
- Nasal obstruction/ blockage
- Nasal purulence/drainage
- Facial pressure/pain
- Hyposmia/anosmia
- Fever

MINOR

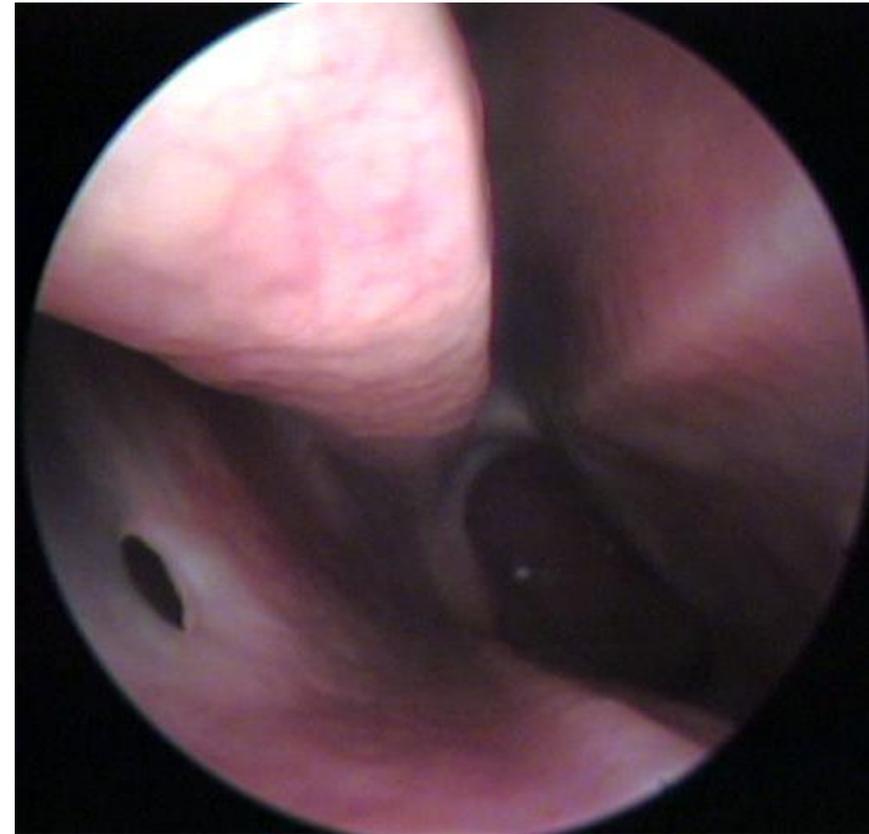
- Cough
- Ear pressure/fullness
- Fatigue
- Halitosis
- Headache
- Maxillary dental pain

Diagnosis is made when two or more major factors are present, or one major and two minor factors are present and there is purulence on examination.

Diagnosis

Nasal Endoscopy

- Normal Anatomy
- Patent Ostia
- Culture must come from the ostia or the sinus



SNOT-22

Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by CIRCLING the number that corresponds with how you feel using this scale:

	No problem	Very mild problem	Mild or slight problem	Moderate problem	Severe problem	Problem is as bad as it can be
1. Need to blow nose	0	1	2	3	4	5
2. Nasal obstruction (blockage)	0	1	2	3	4	5
3. Sneezing	0	1	2	3	4	5
4. Runny nose	0	1	2	3	4	5
5. Cough	0	1	2	3	4	5
6. Post-nasal discharge	0	1	2	3	4	5
7. Thick nasal discharge	0	1	2	3	4	5
8. Ear fullness	0	1	2	3	4	5
9. Dizziness	0	1	2	3	4	5
10. Ear pain	0	1	2	3	4	5
11. Facial pain/pressure	0	1	2	3	4	5

Considering how severe the problem is when you experience it and how frequently it happens, please rate each item below on how "bad" it is by CIRCLING the number that corresponds with how you feel using this scale:

	No problem	Very mild problem	Mild or slight problem	Moderate problem	Severe problem	Problem is as bad as it can be
12. Decreased sense of smell or taste	0	1	2	3	4	5
13. Difficulty falling asleep	0	1	2	3	4	5
14. Wake up at night	0	1	2	3	4	5
15. Lack of a good night's sleep	0	1	2	3	4	5
16. Wake up tired	0	1	2	3	4	5
17. Fatigue	0	1	2	3	4	5
18. Reduced productivity	0	1	2	3	4	5
19. Reduced concentration	0	1	2	3	4	5
20. Frustrated/restless/irritable	0	1	2	3	4	5
21. Sad	0	1	2	3	4	5
22. Embarrassed	0	1	2	3	4	5

Computerized Tomography

- Plain Sinus X-rays are no longer recommended
- CT of the Sinus is superior
- CT is required before surgical intervention
- Volumetric CT for GPS location
- MACRA GUIDELINES

Etiology of Sinusitis

- Viral
- Allergic
- Bacterial
- Pollutant
- Anatomic
- Mass/Tumors
- Foreign Bodies
- GERD
- Tobacco

Medical Treatment of Sinusitis

- Antibiotic Therapy
- Nasal Lavage
- Oxymetazoline 3/5
- Nasal Steroids
- Culture of Osteomeatal Complex
- Mucolytics/ Guaifenesin 1200mg bid

Medication Options

Healthcare professionals often find it difficult to treat chronic sinusitis sufferers with medication.

At least 20% of chronic sinusitis patients are not successfully treated with medical therapy. If multiple uses of antibiotics, medications or other sinusitis treatments have failed to relieve your symptoms, your ENT doctor may recommend sinus surgery.

WHAT IS THE GOAL?



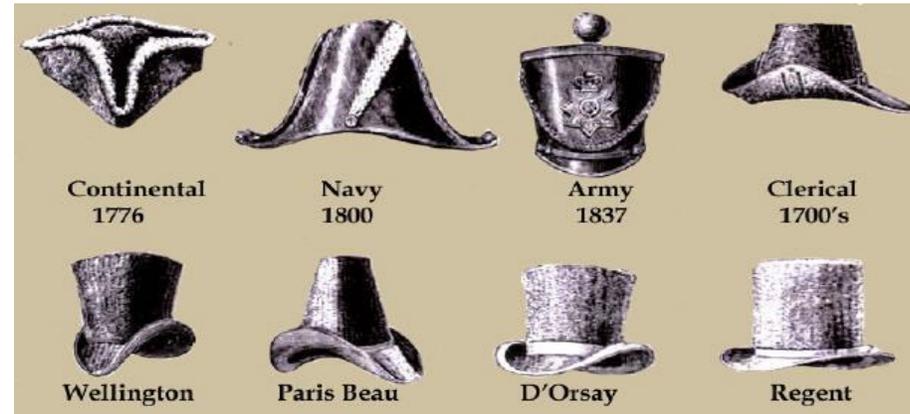
Restore Normal Flow



Beaver Dam Scenario

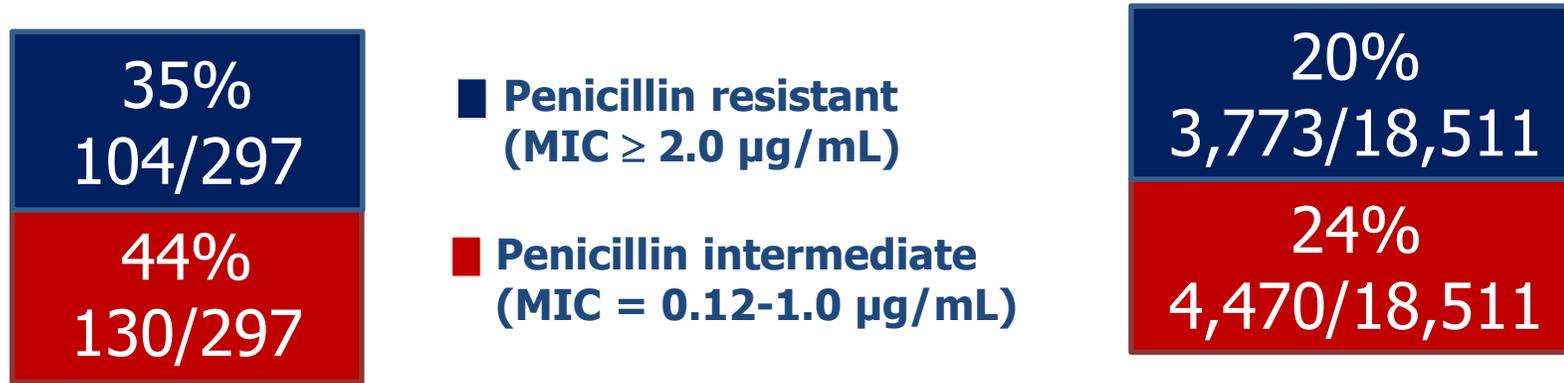


Etiology Directed Therapy



Normal sinuses drain over a liter a day. If there is chronic obstruction or sinusitis then you have established the BEAVER DAM SCENARIO. In order to alleviate the problem you must not only BLOW UP THE DAM, but you must also REMOVE THE BEAVERS

Local Surveillance Data U.S., 2001-2002 Penicillin- Nonsusceptible *S. pneumoniae* TENNESSEE

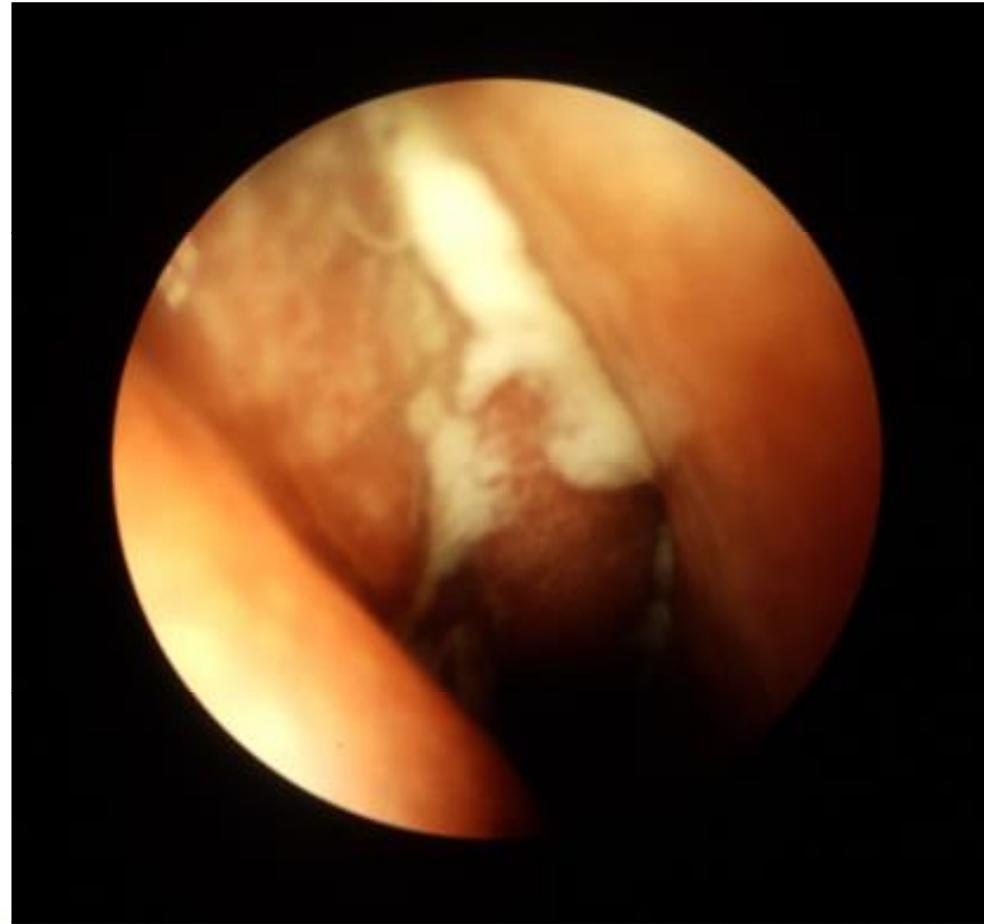


What are the Beavers?



Bacterial

CULTURE O-M COMPLEX



Pollutants

- Tobacco smoke
- Toxic fumes
- Perfumes
- Poor ventilation
- Smog
- Ozone

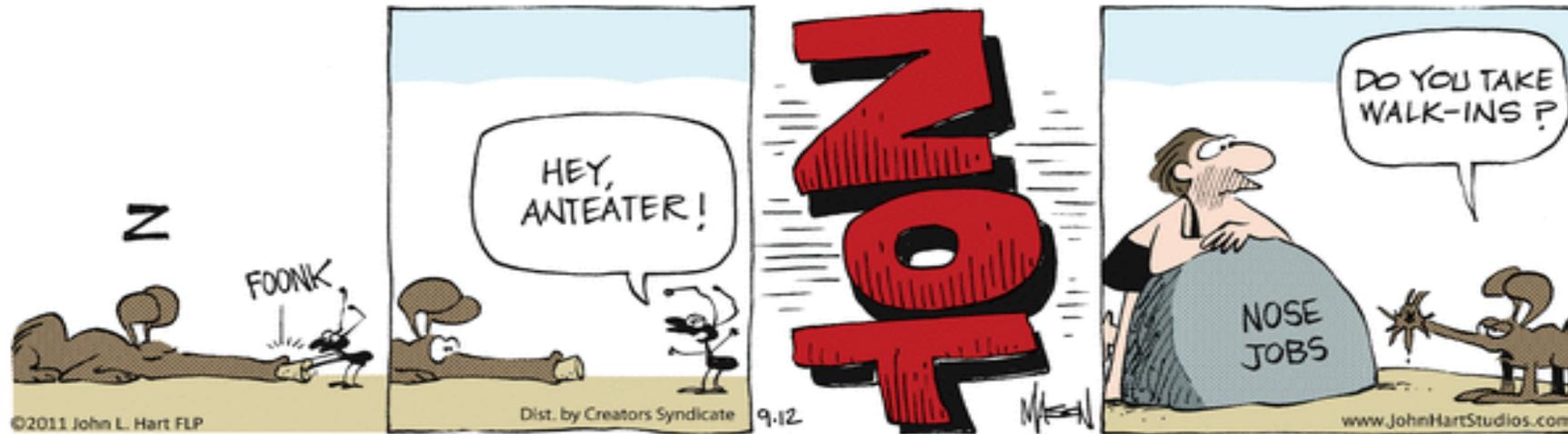
Anatomic



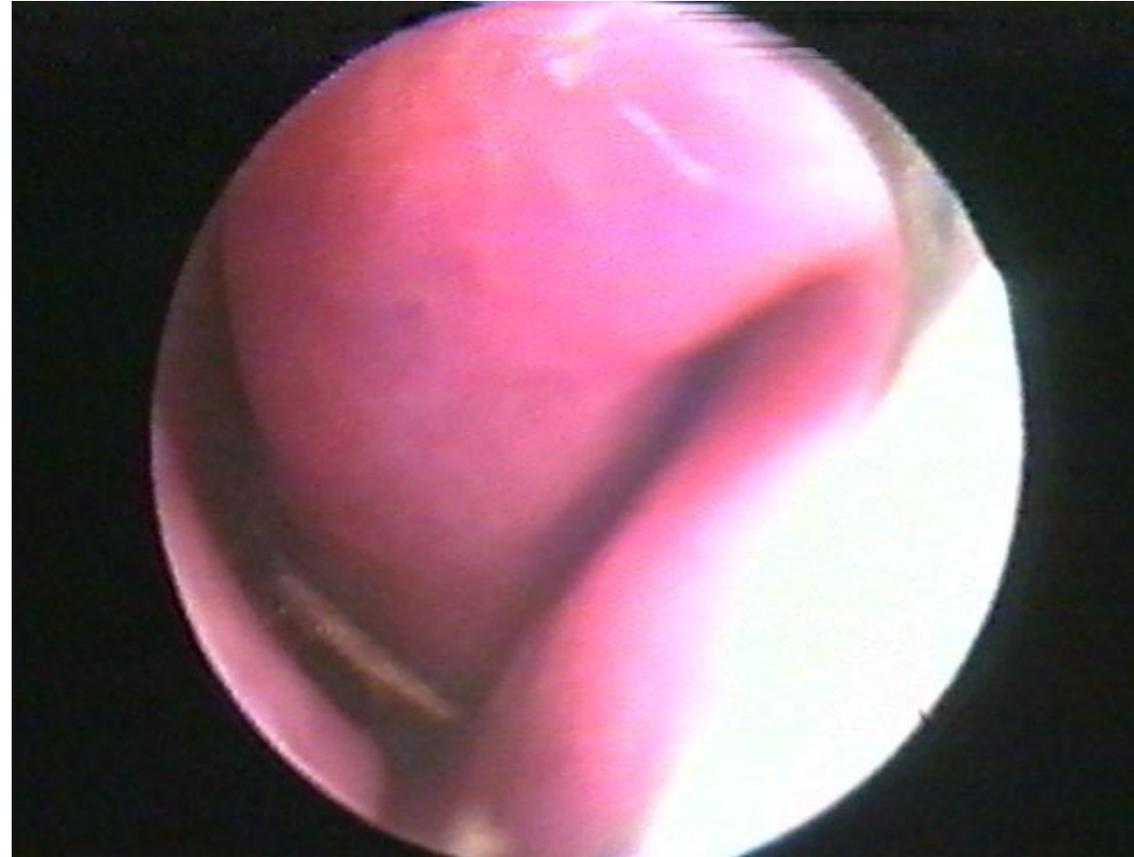
- Septal deviation
- Turbinate hypertrophy
- Concha bullosa
- Septal perforation
- Choanal atresia



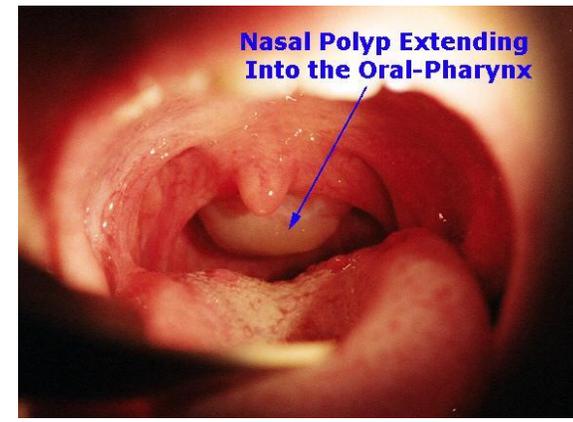
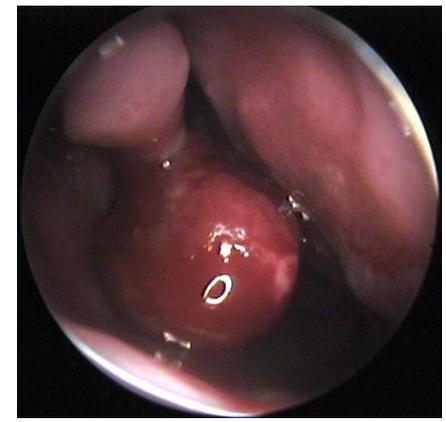
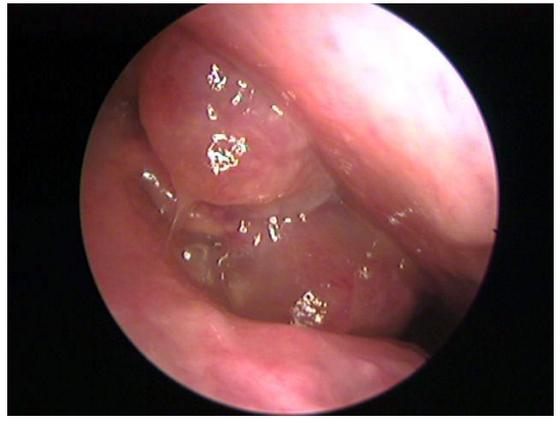
Foreign Bodies



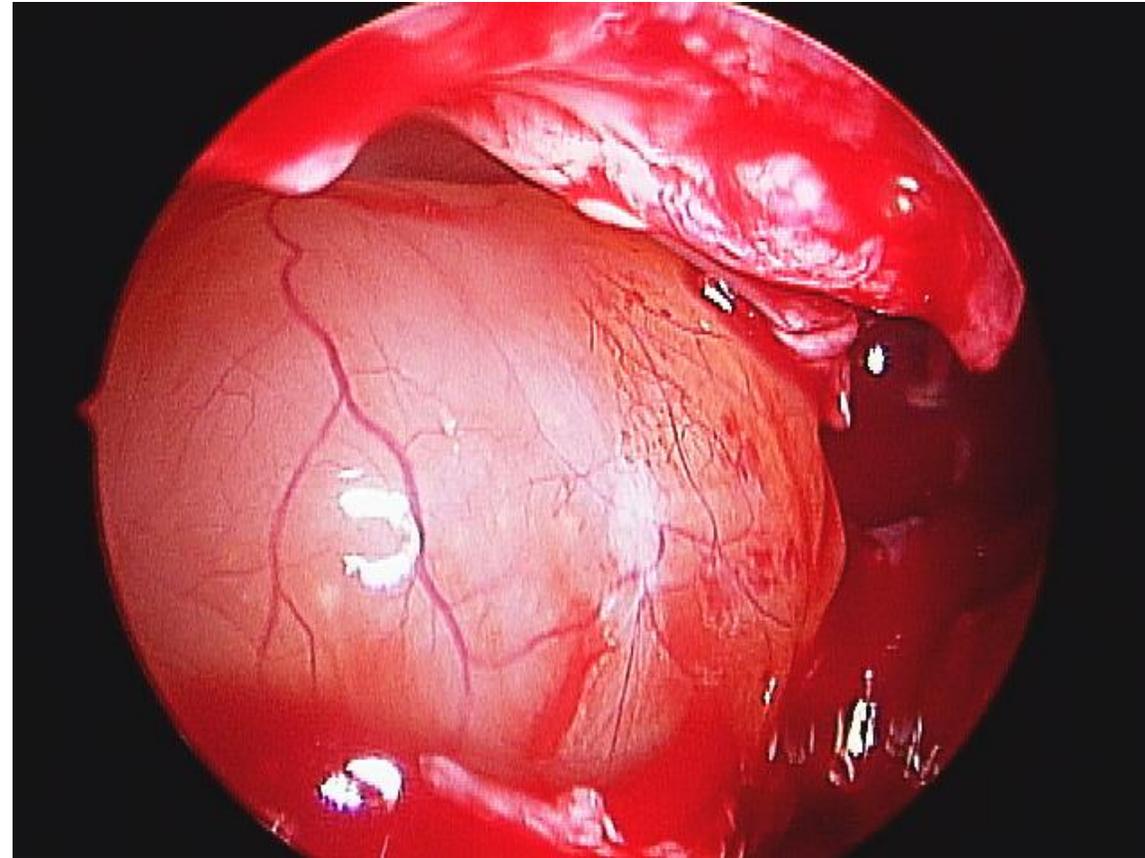
Foreign Body



Masses/Tumors



Antral Mucocele



Smoking



You need to develop a smokers cessation program and offer it to all of your smoking patients in a non-confrontational manner. Include in your program support, follow-up and rewards.

Blow Up the Dam, Relocate the Beavers



GUIDELINE RECOMMENDATIONS FOR ANTIMICROBIAL THERAPY IN ABS



Goals of Antimicrobial Therapy for ABS*

- Eradication of bacterial pathogen from site of infection
- Return sinuses back to health
- Decrease duration of symptoms
- Prevent severe complications
- Decrease likelihood of chronic disease

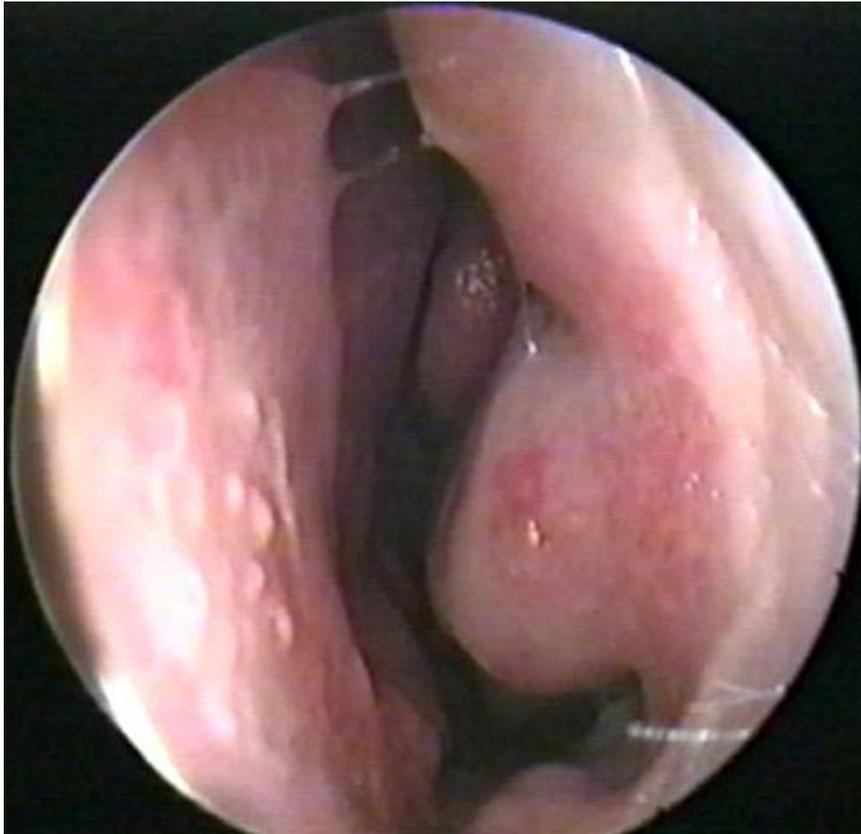
Antibiotic Therapy

- Initial first line therapy
- No response to therapy within 4-6 weeks
- Amoxicillin/Clavulanic Acid 4000mg/day
- Levofloxacin
- Moxifloxacin HCL
- Clindamycin
- No response – refer for possible procedure

PREVALENCE AND SOCIOECONOMIC IMPACT OF ALLERGIC RHINITIS



Pathophysiology Allergy



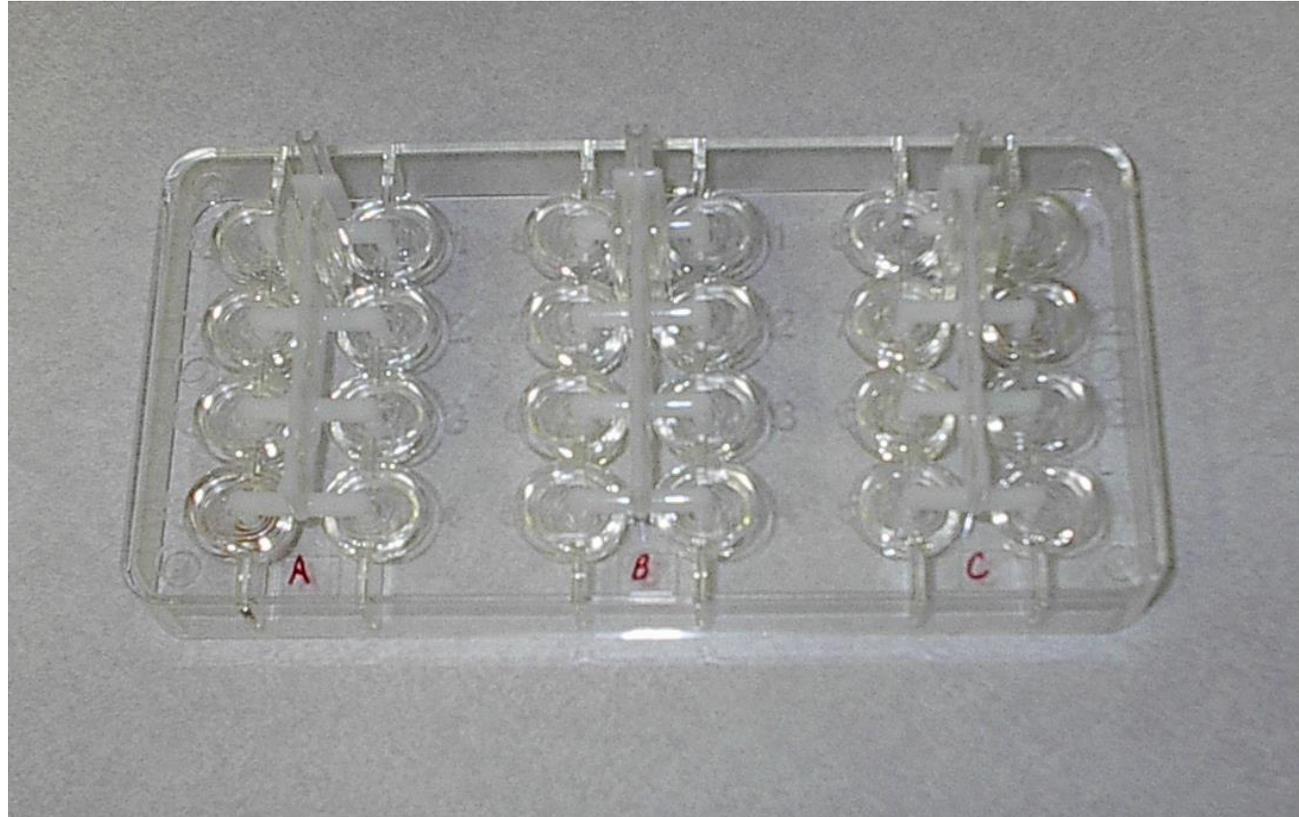
- Blue Mucosa
- Cobblestoning
- Clear Drainage
- Food
- Environmental

Prevalence of Allergic Rhinitis

- Affects 20–40 million Americans
 - 10% – 30% of adults
 - Up to 40% of children affected
- Remains constant in young adults but gradually declines in later years
- More common in young boys than girls but little gender difference after adolescence
- No impact of race or socioeconomic status



Prick Testing Allergen Tray



RAST



Intradermal Testing











BALLOON SINUS DILATION TECHNOLOGY



What is Balloon Sinus Dilation?

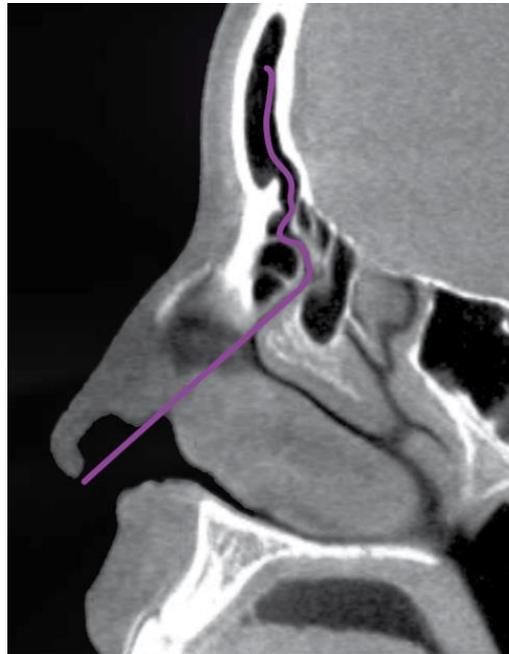
- Balloon Sinuplasty is an innovative procedure used by ENT doctors to treat patients with **recurrent acute or chronic sinusitis**. Balloon Sinuplasty relieves the pain and pressure associated with sinusitis.
- Balloon Sinuplasty uses a soft, flexible guidewire to access the inflamed sinuses. A small balloon catheter is advanced over the flexible guidewire, gradually inflated to restructure the previously blocked nasal passage, and then removed.
- Balloon Sinuplasty preserves the normal anatomy of the sinuses and mucosal tissue, and unlike traditional sinus surgery, Balloon Sinuplasty requires **no cutting** and **no removal** of bone and tissue.

Benefits of Balloon Sinus Dilation In-Office

- **Local Anesthesia**
Balloon Sinuplasty In-Office is an option for patients who decline or are ineligible for general anesthesia.
- **Fast Recovery**
While recovery time varies with each patient, patients who have Balloon Sinuplasty In-Office procedure may return to work and normal activities as soon as 24 hours.¹⁰
- **Comfortable Surroundings**
Experience the procedure in the comfort of your physician's office rather than a hospital operating room.
- **High Patient Satisfaction**
The majority of patients who had Balloon Sinuplasty In-Office would recommend the procedure to family and friends.¹⁰
- **Potential for Significant Cost Savings**
Some eligible patients may have lower out-of-pocket costs if the procedure is performed in a lower cost of care setting, such as a physician's office.

Instrumentation is the Key

- Flexible Instrumentation
 - Excellent for when the surgical goal is to restore sinus drainage and function with maximum bone and tissue preservation



Balloon Sinus Dilation In-Office Patient Experience

In-Office Procedure

- No fasting period
- Local anesthesia
- Wear own clothes
- Potential out of pocket savings
- Patient return to normal activity in as soon as 24 hours

Hospital Surgery

- Designed for customized access
- Fasting prior to surgery
- General anesthesia
- Hospital gown
- Intubation and IV
- May be conducted in conjunction with other procedures requiring general anesthesia



Pre-endoscopic Surgery Assessment

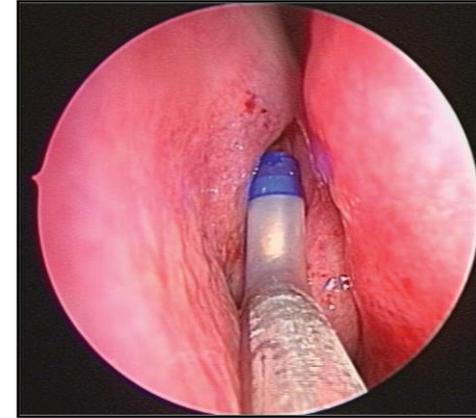
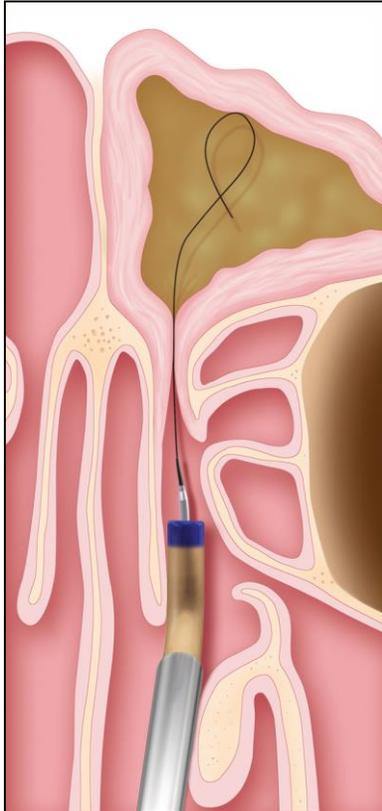
- Assess the patient's condition
- Determine the appropriate care pathway



Frontal sinus
Pre-procedure CT scan

Step One

Gain initial access and deliver the Balloon Sinus Dilation Catheter

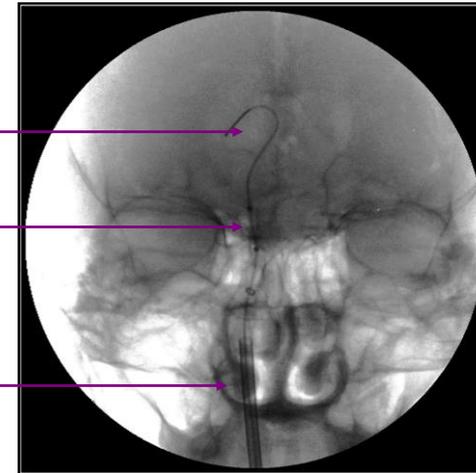


Sinus Guide Catheter
Access under endoscopic guidance

Sinus Guidewire

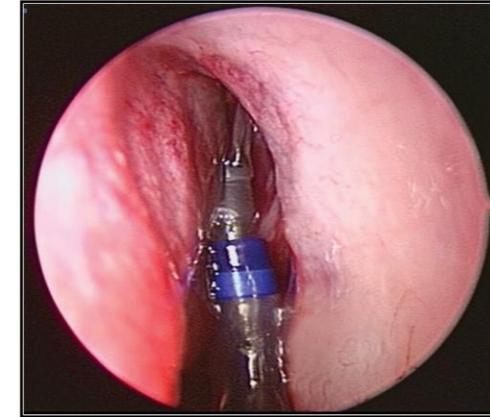
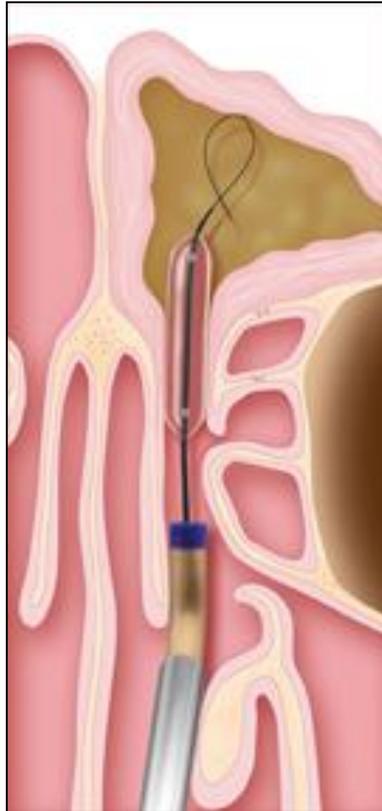
Sinus Balloon Catheter

Sinus Guide Catheter

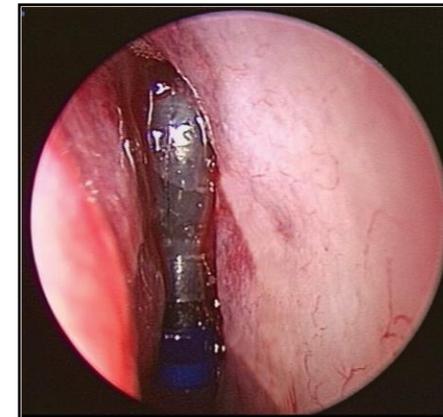


Step Two - Endoscopic view

Place the Balloon Sinus Dilation Catheter across the ostium



Sinus Balloon Catheter
Placed under endoscopic guidance



Inflated to gently remodel the ostium

Step Two – Fluoroscopic view

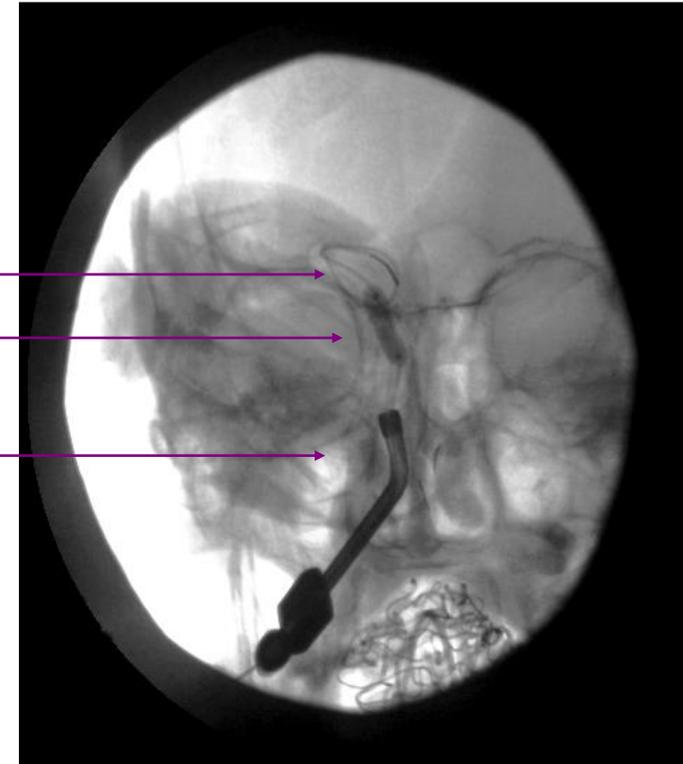
Relieva™ Sinus Balloon Catheter inflated to gently remodel the ostium



Sinus Guidewire

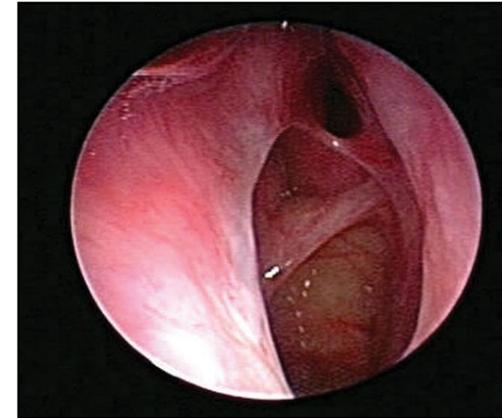
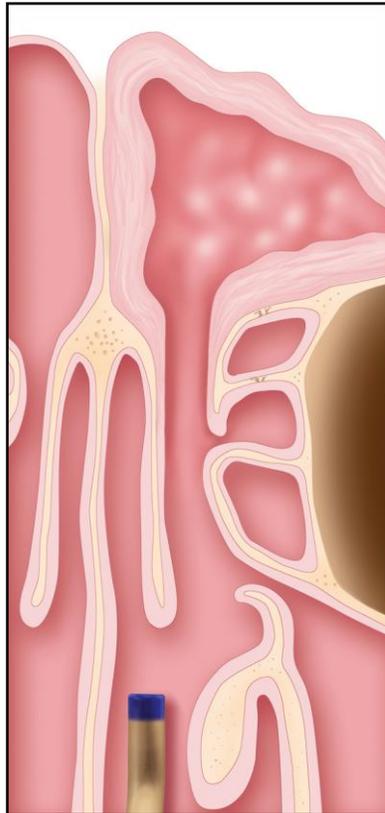
**Sinus Balloon Catheter
(inflated)**

Sinus Guide Catheter

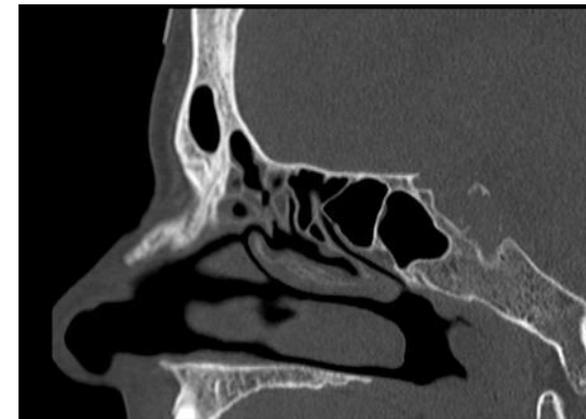


Step Three

Deflate and remove the Relieva Balloon Sinuplasty™ devices

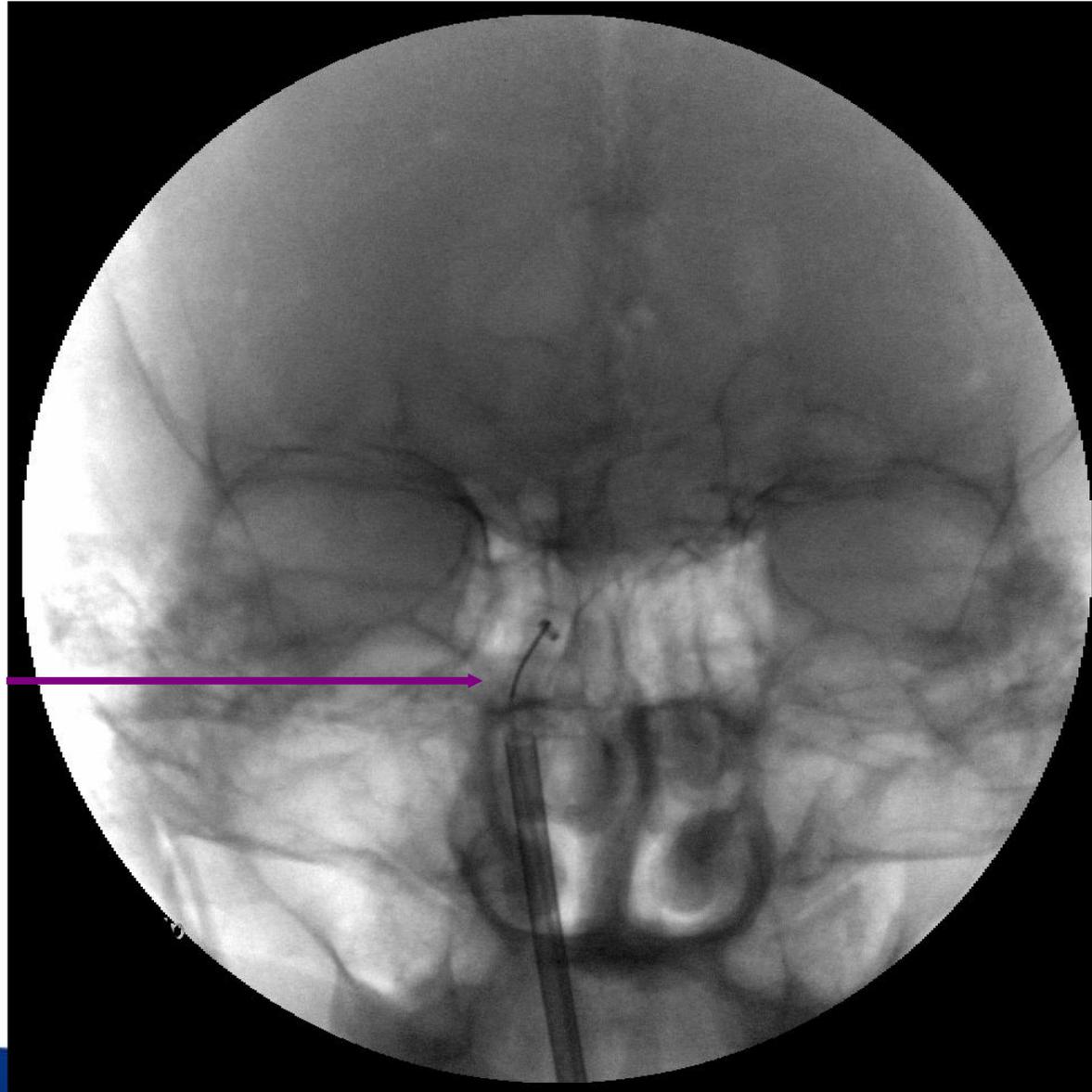


Frontal Sinus Dilation
Final endoscopic image

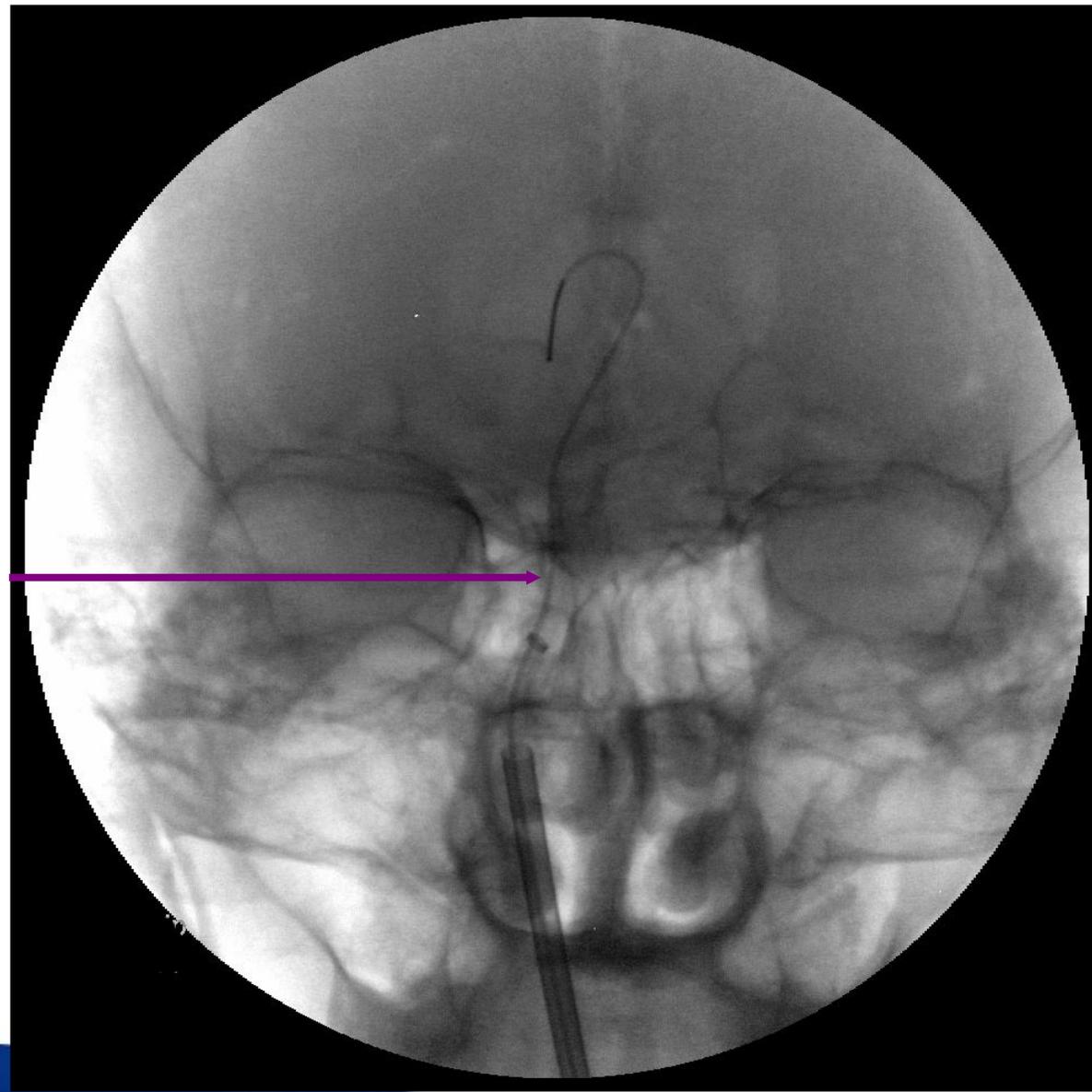


Frontal sinus
Post-procedure CT scan

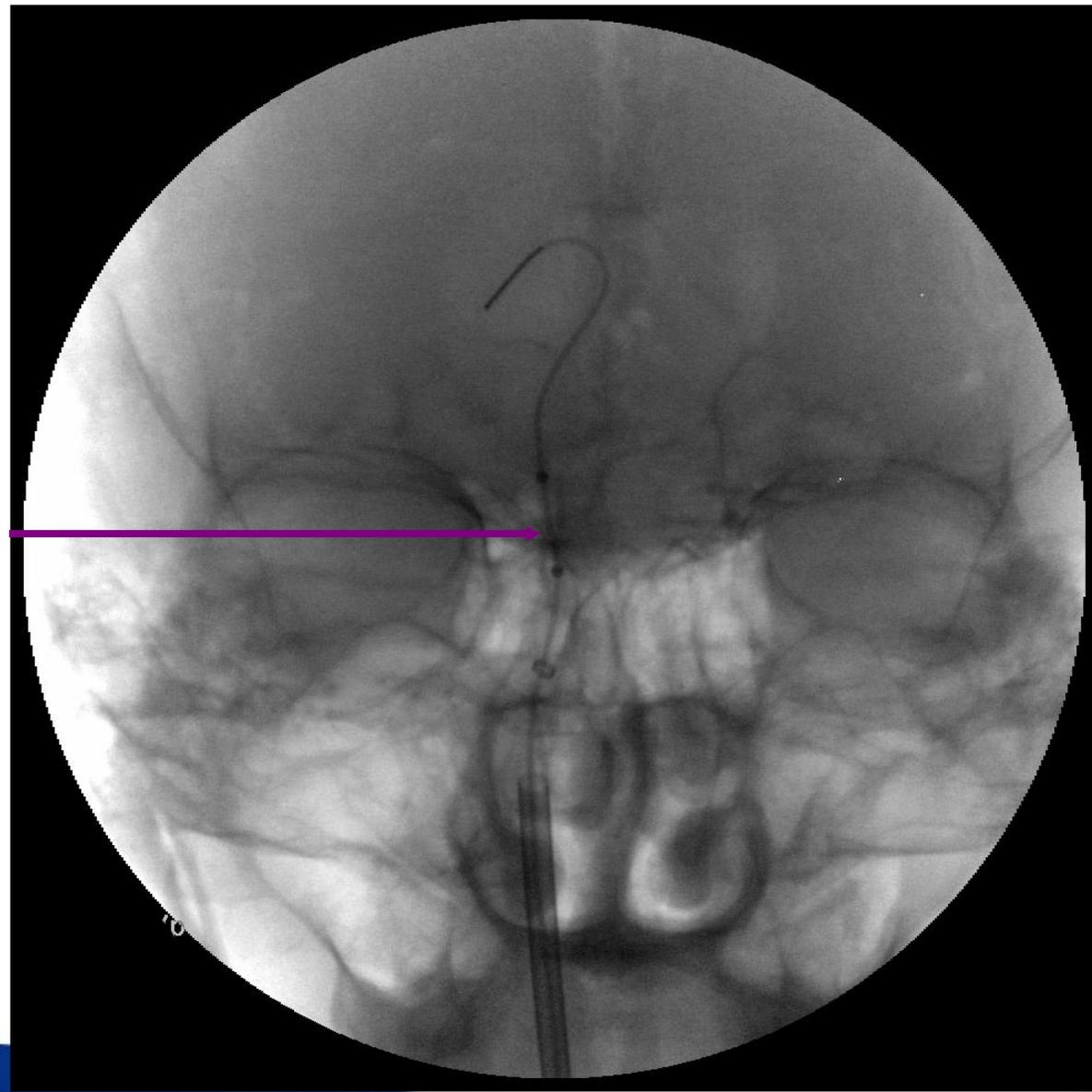
**Sinus Guide
Catheter**



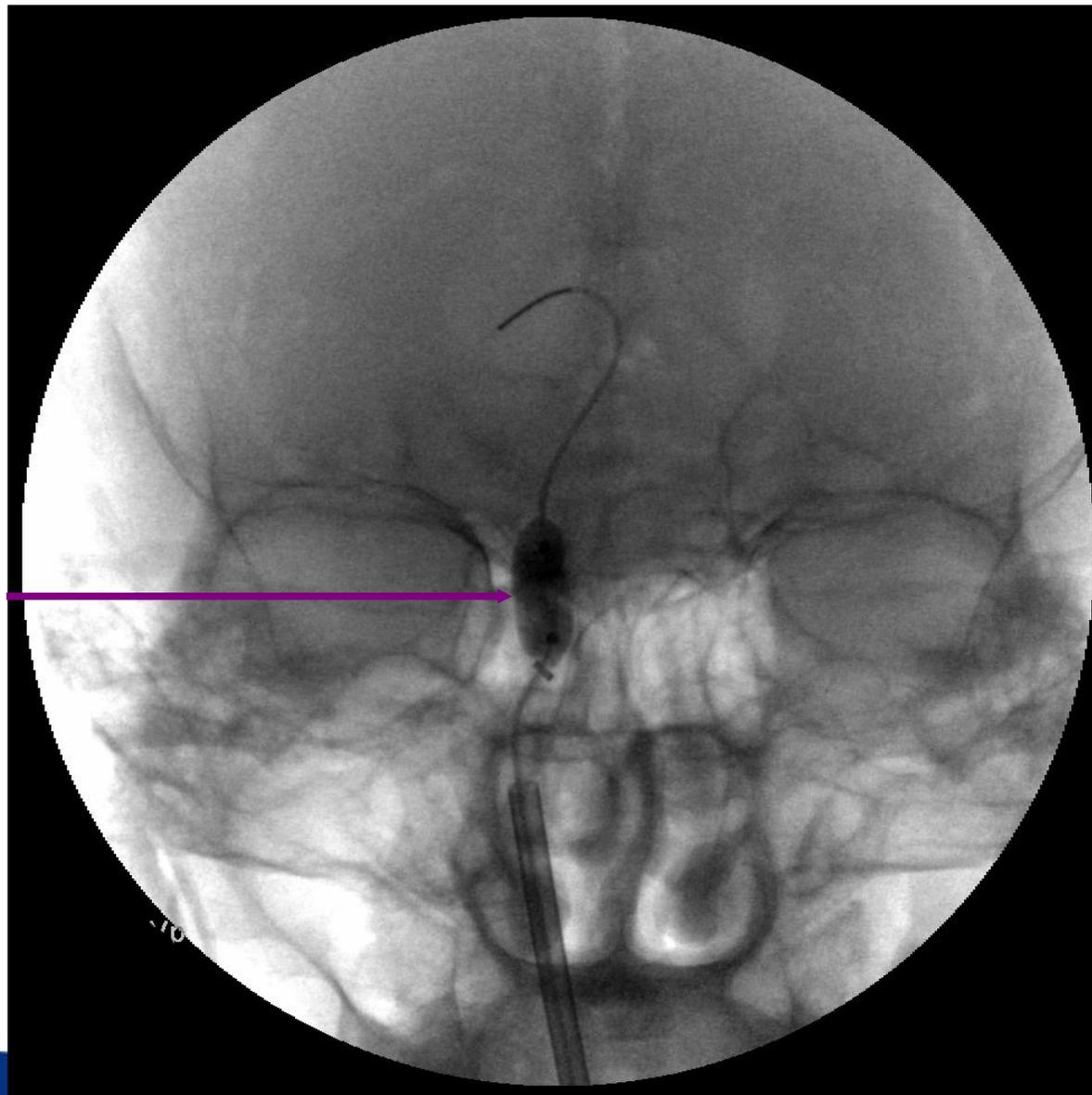
**Sinus
Guidewire**



**Sinus Balloon
Catheter**
(prior to inflation)

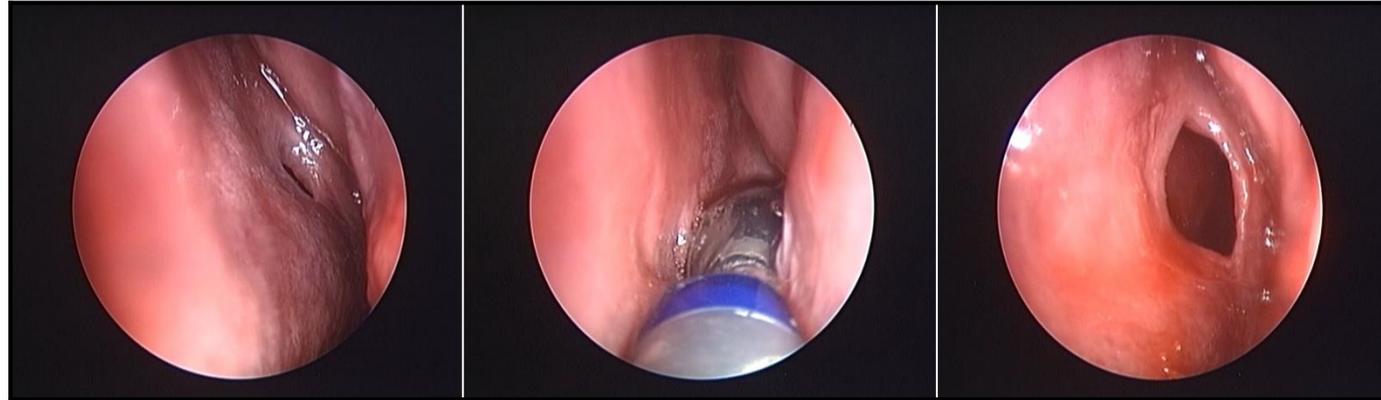


**Sinus Balloon
Catheter**
(during inflation)

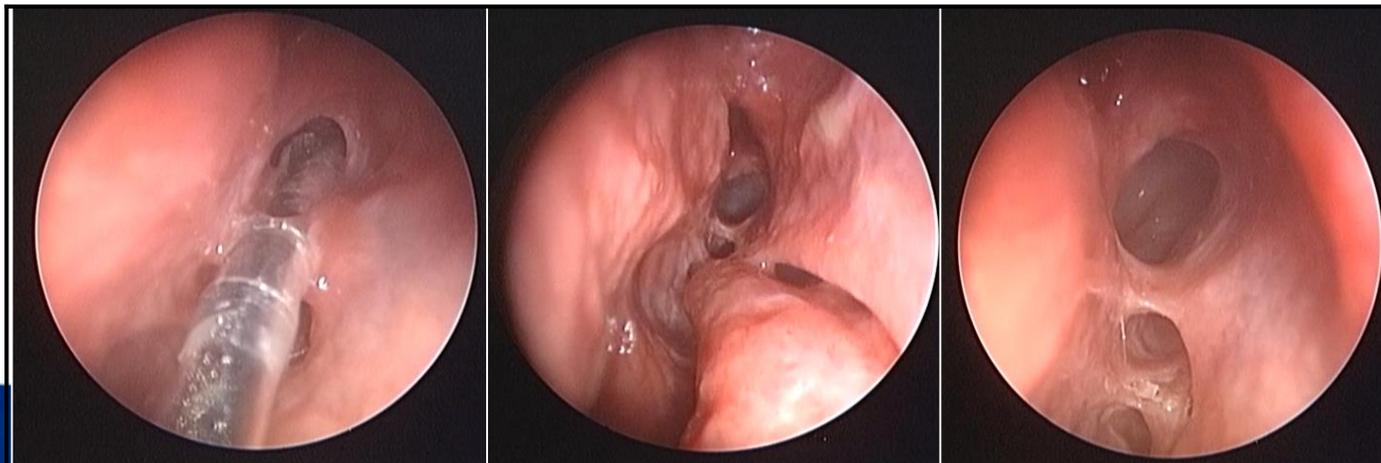


Catheter-based Dilation of the Sinus Ostia

Initial Safety and Feasibility Analysis in a Cadaver Model



- Endoscopic examples
 - Dilated ostia carefully examined for unwanted catheter-induced trauma

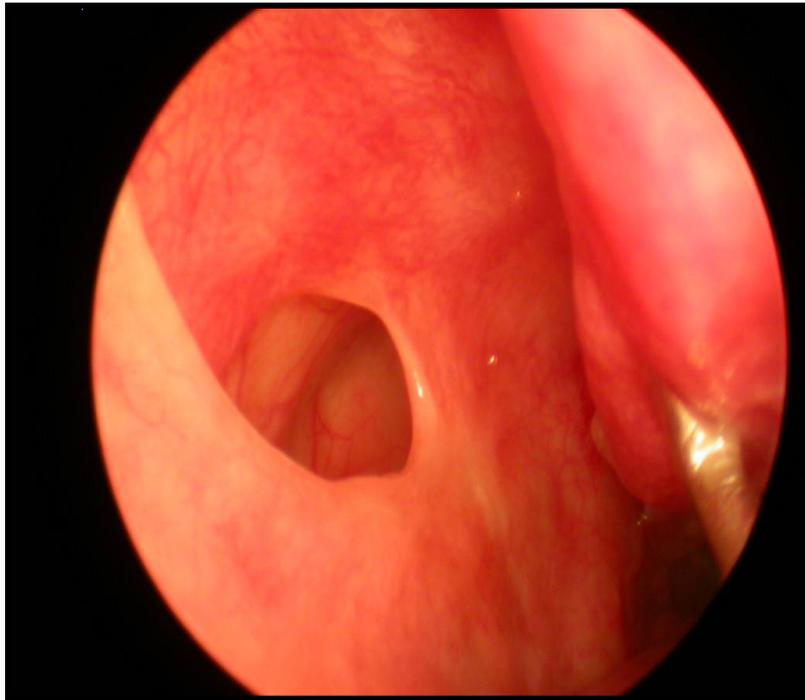


Safety and Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia

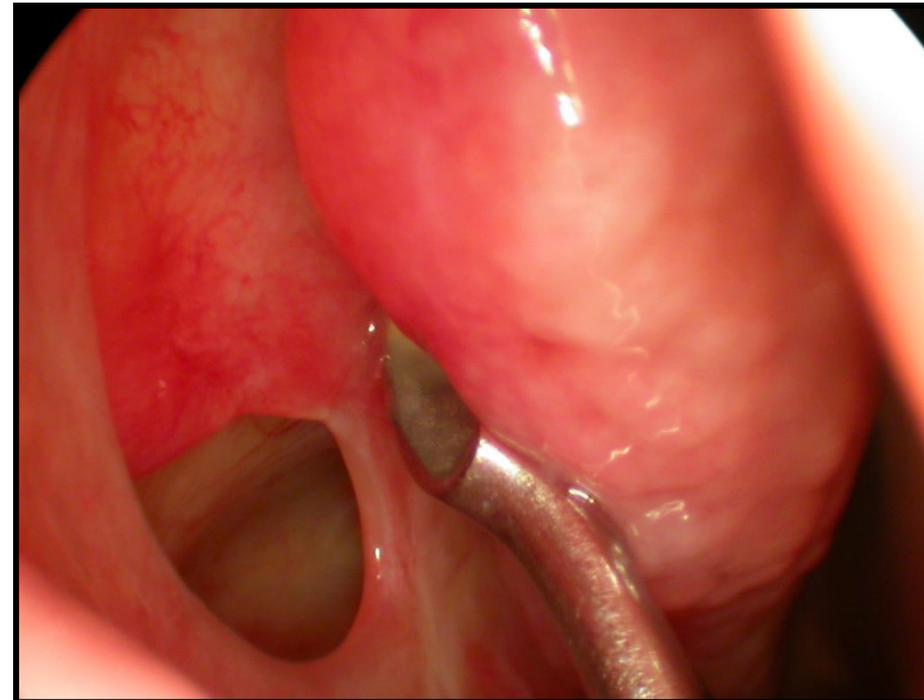
- Study objective
 - Assess safety and feasibility of dilation of sinus ostia and recesses in patients with rhinosinusitis
- Primary end points
 - Procedural success
 - Ability to access targeted sinus and complete balloon dilation
 - Procedural safety
- Absence of significant adverse events

Safety and Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia *Right Maxillary Sinus - Patient A*

6-weeks Post-op



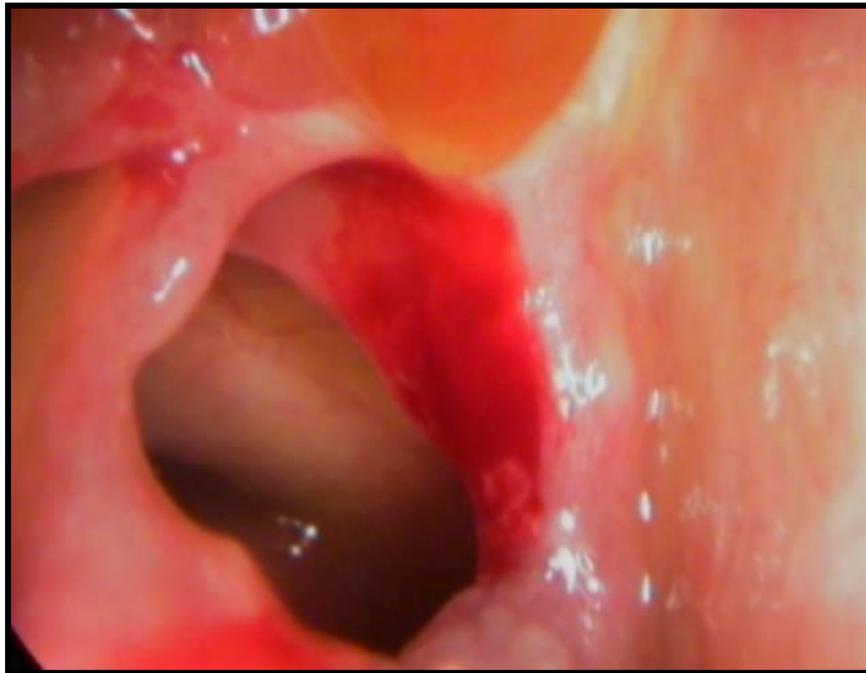
9-months Post-op



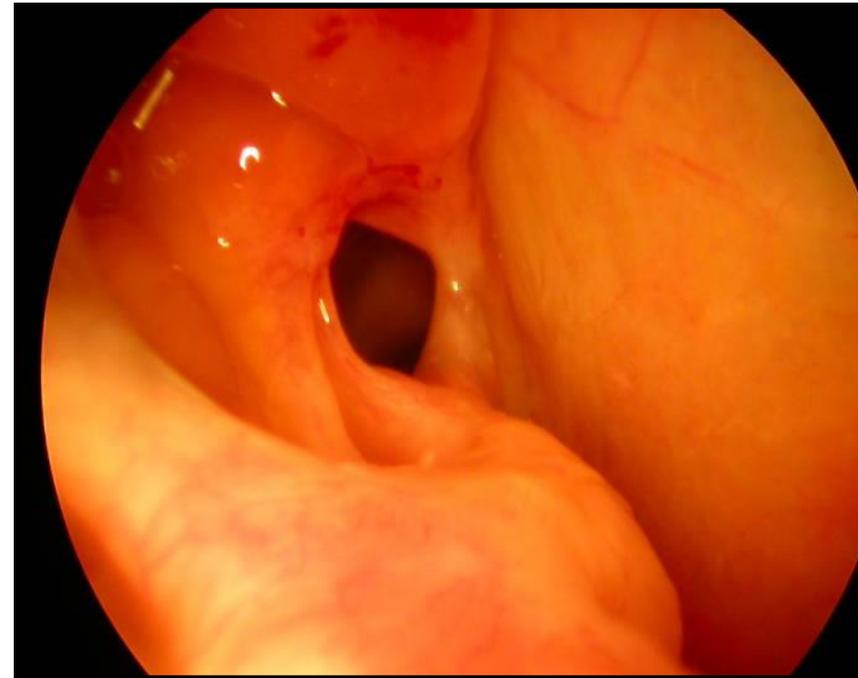
Note: Uncinate process taken down

Safety and Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia *Right Sphenoid Sinus - Patient B*

2-weeks Post-op



6-weeks Post-op



Clinical Evaluation to Confirm Safety & Efficacy of Balloon Sinus Dilation in the Paranasal Sinuses (CLEAR)



Type of Event	Frequency	Description
Mild	0	nasal bleeding requiring packing or intervention
Moderate	0	periorbital swelling or bruising, moderate pain
Severe	0	cerebrospinal fluid leak, orbital hematoma, visual loss, loss of sense of smell, nasolacrimal duct injury, orbital entry/injury, severe pain.

- There were no serious adverse events
 - 9 events of bacterial sinusitis post dilation : resolved with antibiotic treatment

Clinical Evaluation to Confirm Safety & Efficacy of Balloon Sinus Dilation in the Paranasal Sinuses (CLEAR)

Case Study - Frontal Sinusitis

Baseline



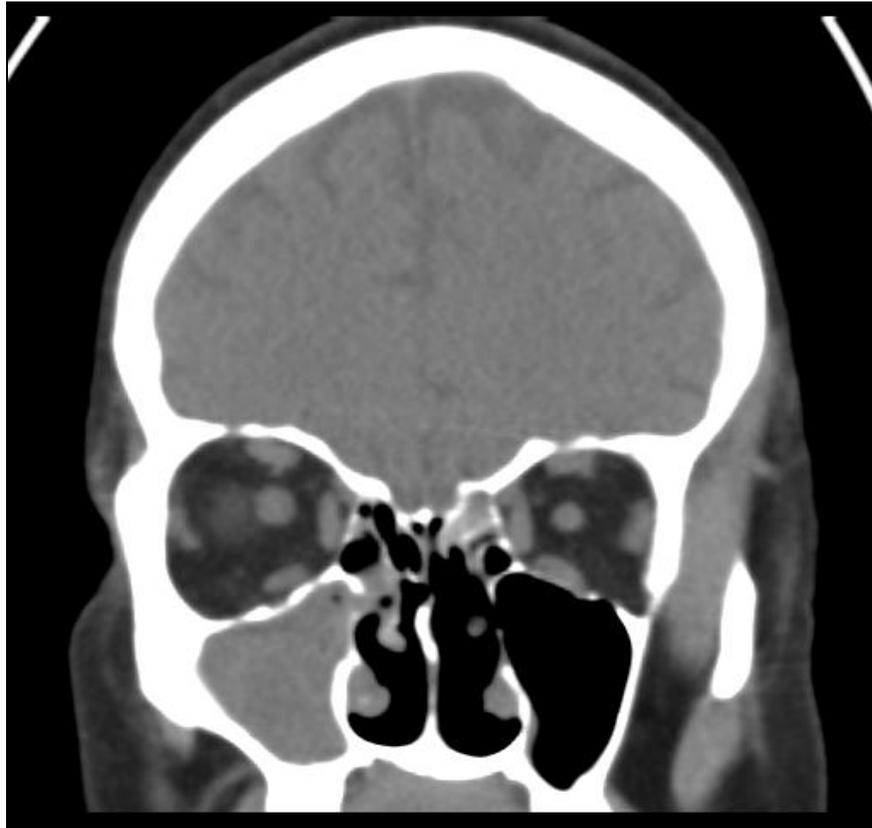
24-weeks Post-op



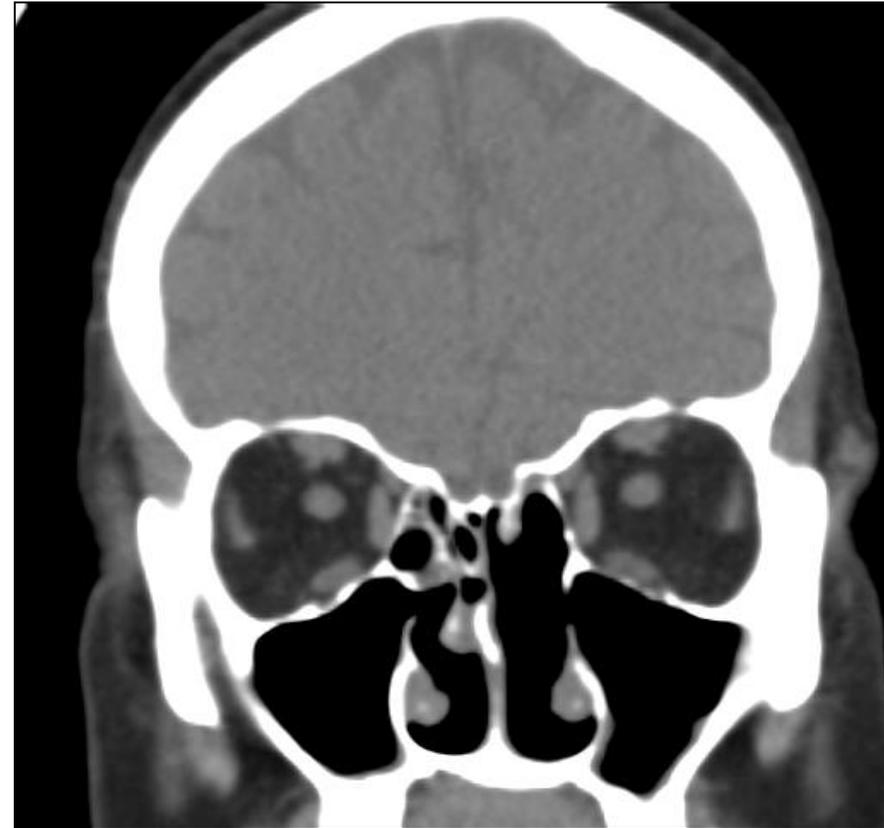
Clinical Evaluation to Confirm Safety & Efficacy of Balloon Sinus Dilation in the Paranasal Sinuses (CLEAR)

Case Study - Right Maxillary Sinusitis

Baseline



24-weeks Post-op



Clinical Evaluation to Confirm Safety & Efficacy of Balloon Sinus Dilation in the Paranasal Sinuses (CLEAR)

- Sinus Balloon Catheter devices demonstrate a remarkable safety profile
- Observed patency of 98% at 24 weeks was achieved, indicating an efficacious and durable result
- Via a validated patient outcomes measure, patients show significant symptom improvement at all time points

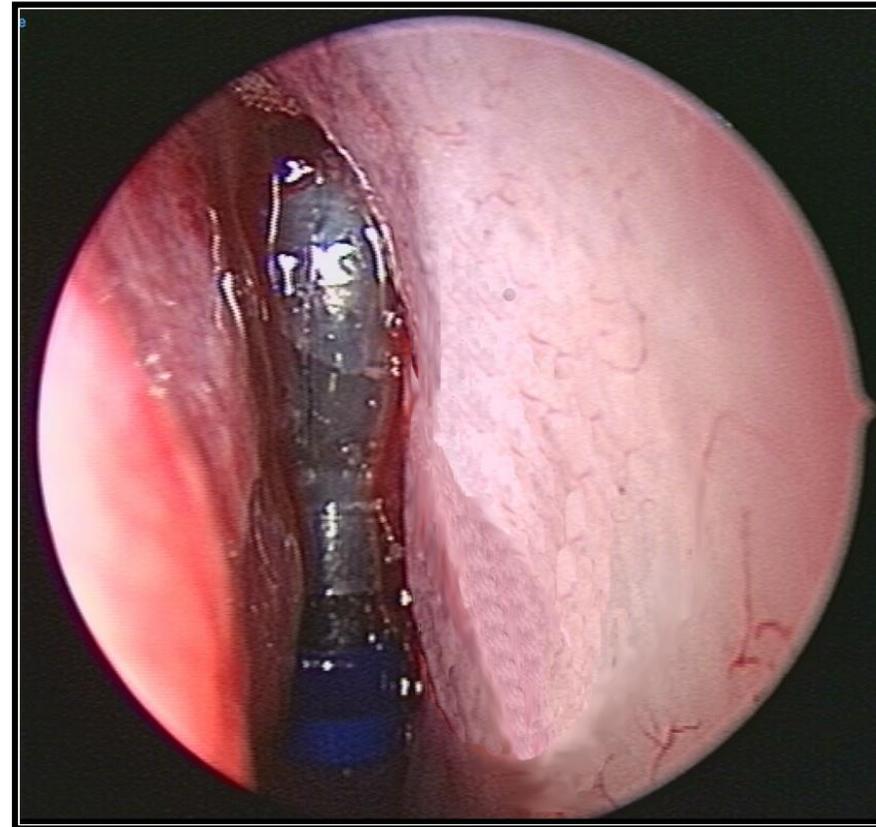
Case Study: Chronic sinusitis unresolved following maximum medical therapy

- 23 yo female, unilateral left sided AFS, operated on in 1998, no current Rx
- Right sided chronic ethmoid, frontal, maxillary, and sphenoid sinusitis, diagnosed March 2005
- Maximal medical Rx
 - Clindamycin, 150 mg tid x 6 weeks
- Sinuses do not completely clear
- Patient still symptomatic

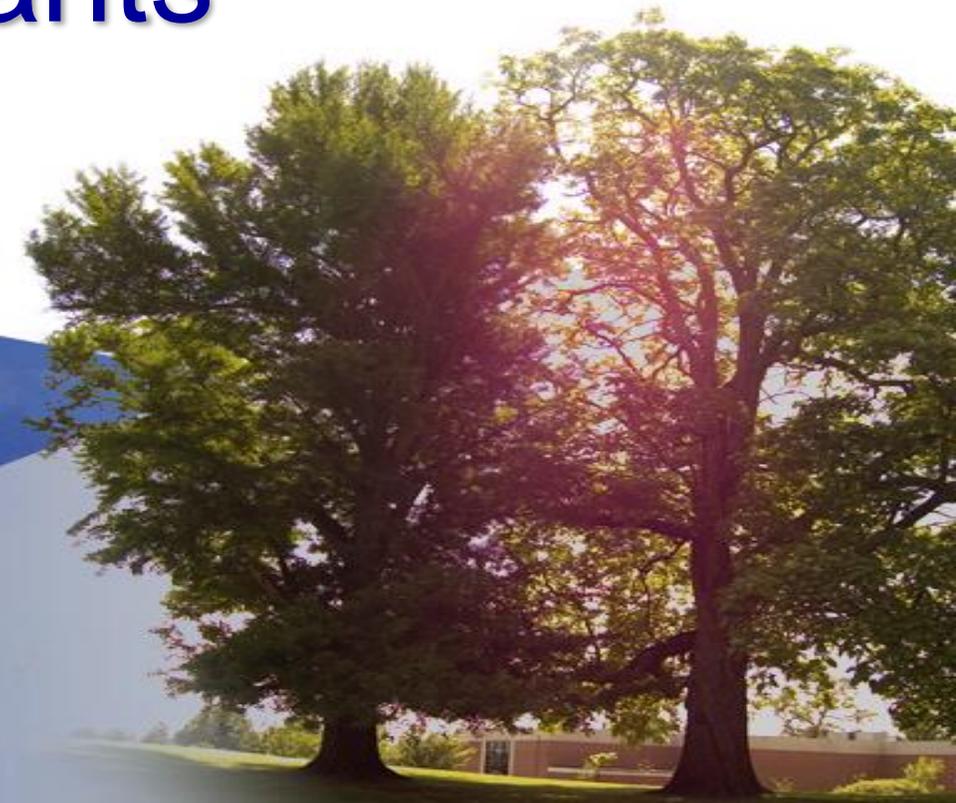
Case Study: Right frontal sinus

Sinus Balloon Catheter

– During inflation

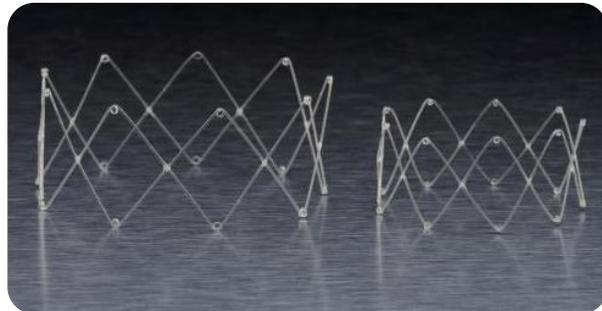


Steroid Eluting Implants



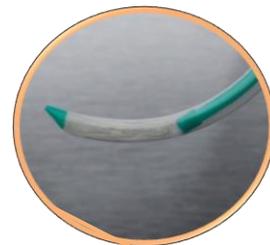
Steroid-Releasing Implants

- First localized, controlled drug delivery technology for chronic sinusitis patients
- Targeted, sustained delivery of 370 ug of Mometasone Furoate for 30 days
- Spring-like implant provides middle turbinate support
- Implant bioreabsorbs after 4-6 weeks
- **Maintains surgical result by preventing inflammation & scarring**
- **Only sinus surgery product with Level 1-A clinical evidence**

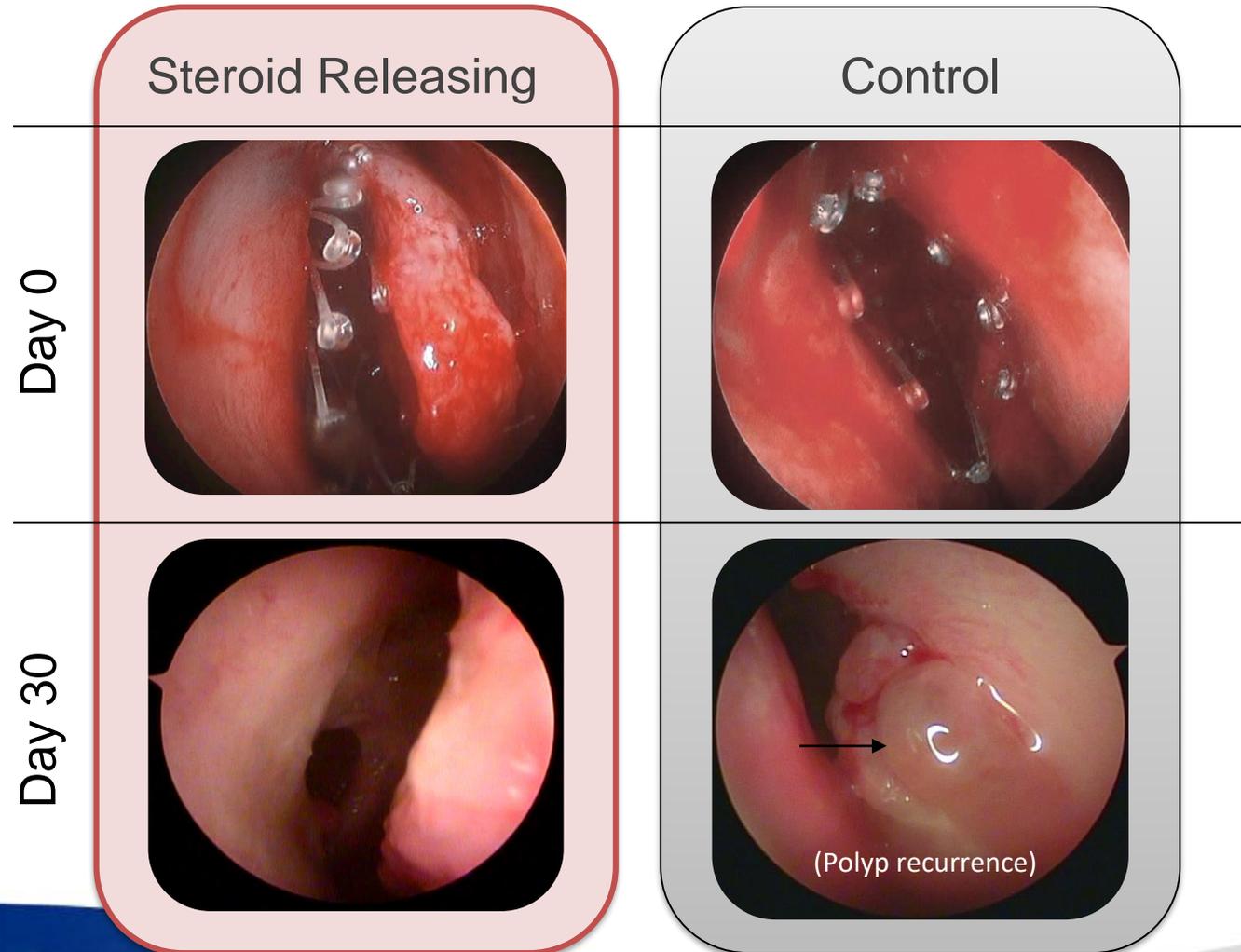


standard
mometasone furoate implants

mini
mometasone furoate implants



Significant improvement observed in post-op outcomes



Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis

Joseph K. Han, MD¹, Bradley F. Marple, MD², Timothy L. Smith, MD, MPH³, Andrew H. Murr, MD⁴, Brent J. Lanier, MD, CPI⁵, James W. Stambaugh, BS⁶, Andrew S. Mugglin, PhD⁷

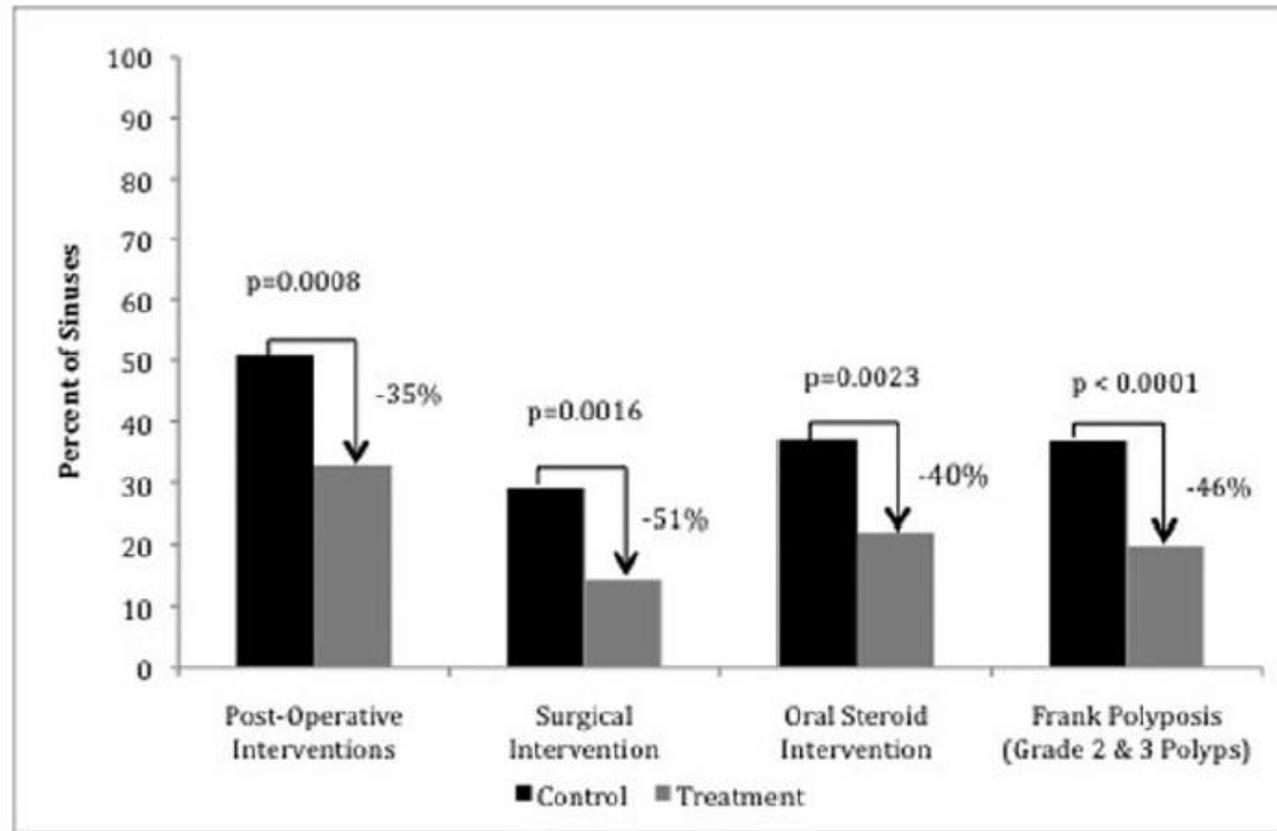
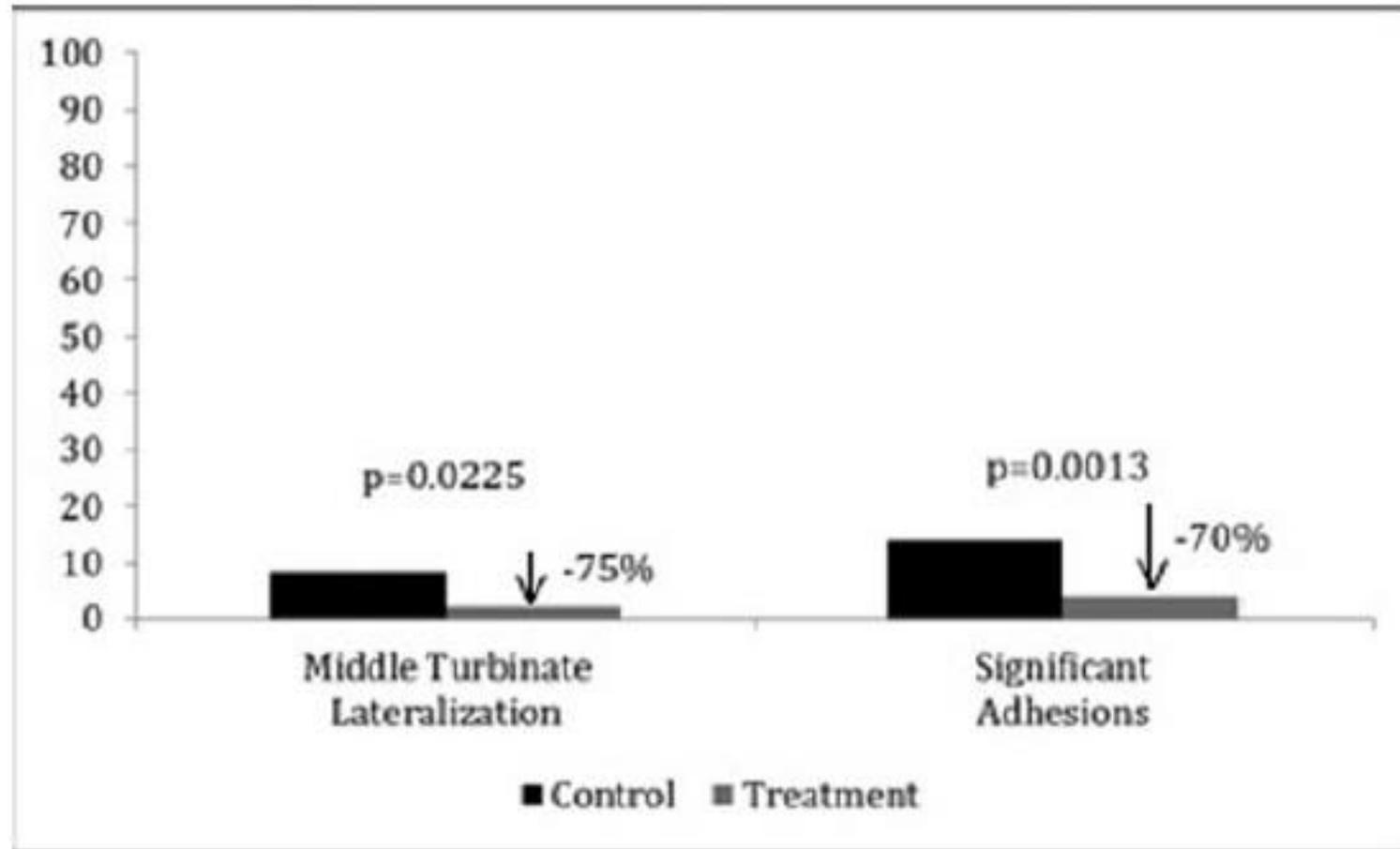


FIGURE 4. Frequency of postoperative interventions and frank polyposis by treatment group at day 30 for combined analyses as judged by independent panel. Postoperative intervention is a composite of surgical intervention and/or oral steroid intervention. Arrows with percentages indicate relative reductions.

Effect of steroid-releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis

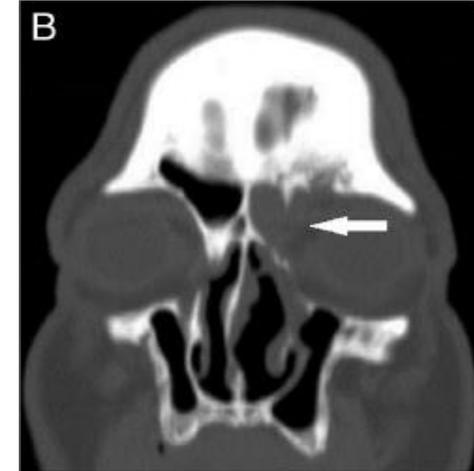
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In-office use of a steroid-eluting implant for maintenance of frontal ostial patency after revision sinus surgery

Agnieszka Janisiewicz, M.D.,¹ and Jivianne T. Lee, M.D.^{1,2} Allergy Rhinol. 2015; 6(1): e68-e75.

- 63-year-old male w/ hx of multiple ESS
- Recurrent unilateral, left-sided frontal pressure and headache refractory to medical therapy.
- Stenosed frontal recess with complete opacification of the left frontal sinus
- Multiple surgical procedures unsuccessful; Declined Draf 3
- Endoscopic frontal sinus ostial balloon dilation in the clinic
- Steroid eluting sinus stent was placed in the frontal sinus at the end of the procedure.

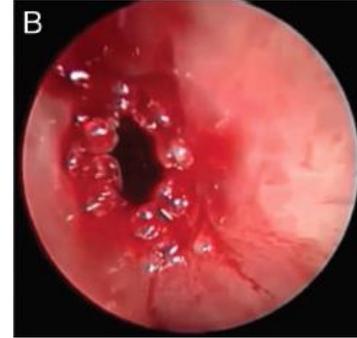


In-office use of a steroid-eluting implant for maintenance of frontal ostial patency after revision sinus surgery

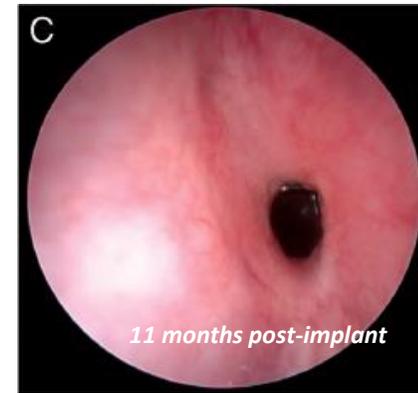
Agnieszka Janisiewicz, M.D.,¹ and Jivianne T. Lee, M.D.^{1,2}



Frontal Obstruction

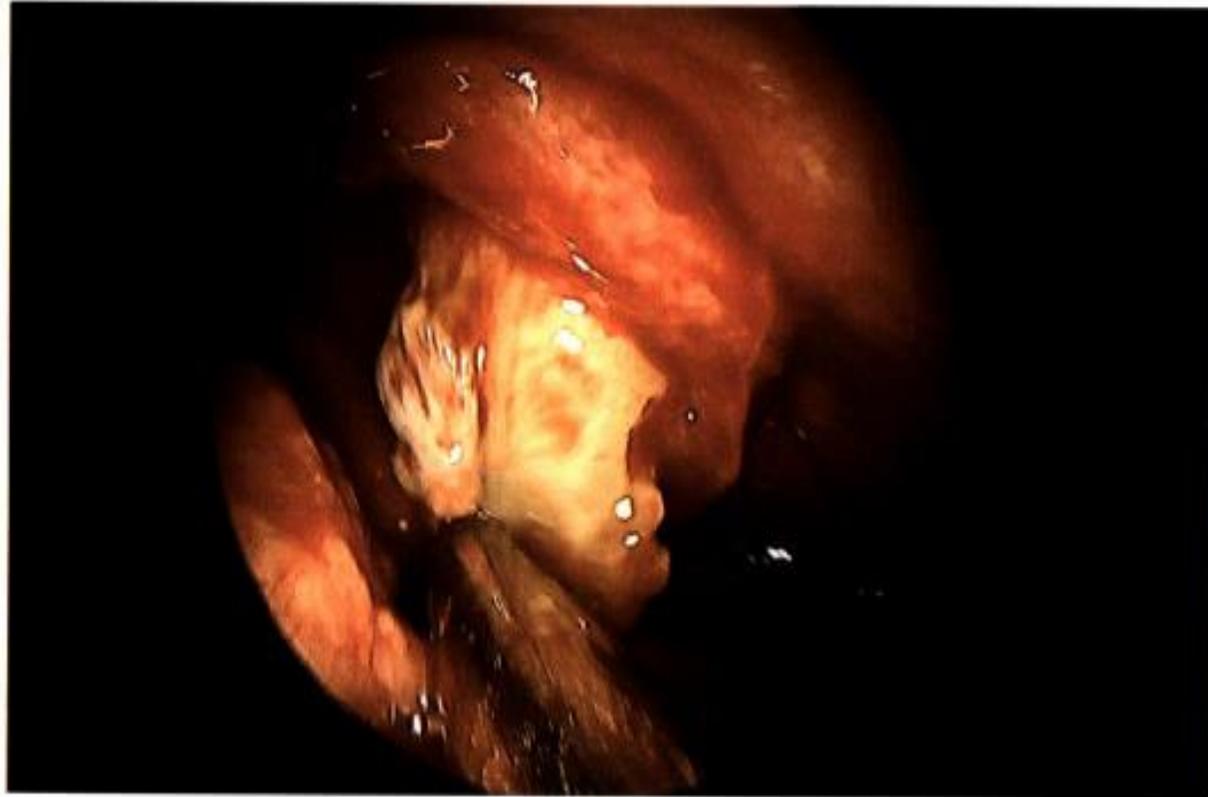


Steroid eluting device placement after in-office balloon dilation



Frontal ostial patency maintained at 11 months follow-up

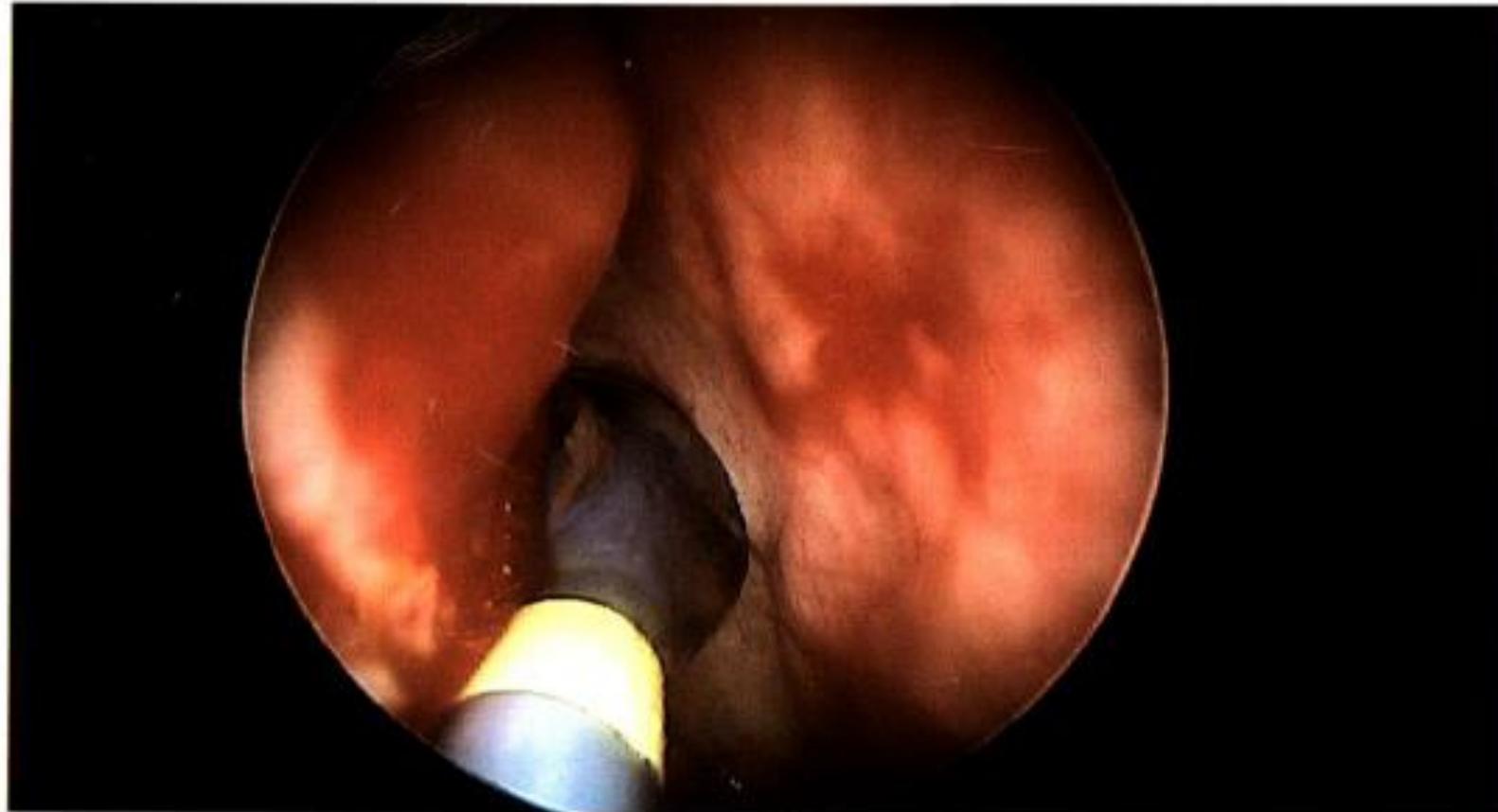
PURULENT DISCHARGE FROM OSTIA



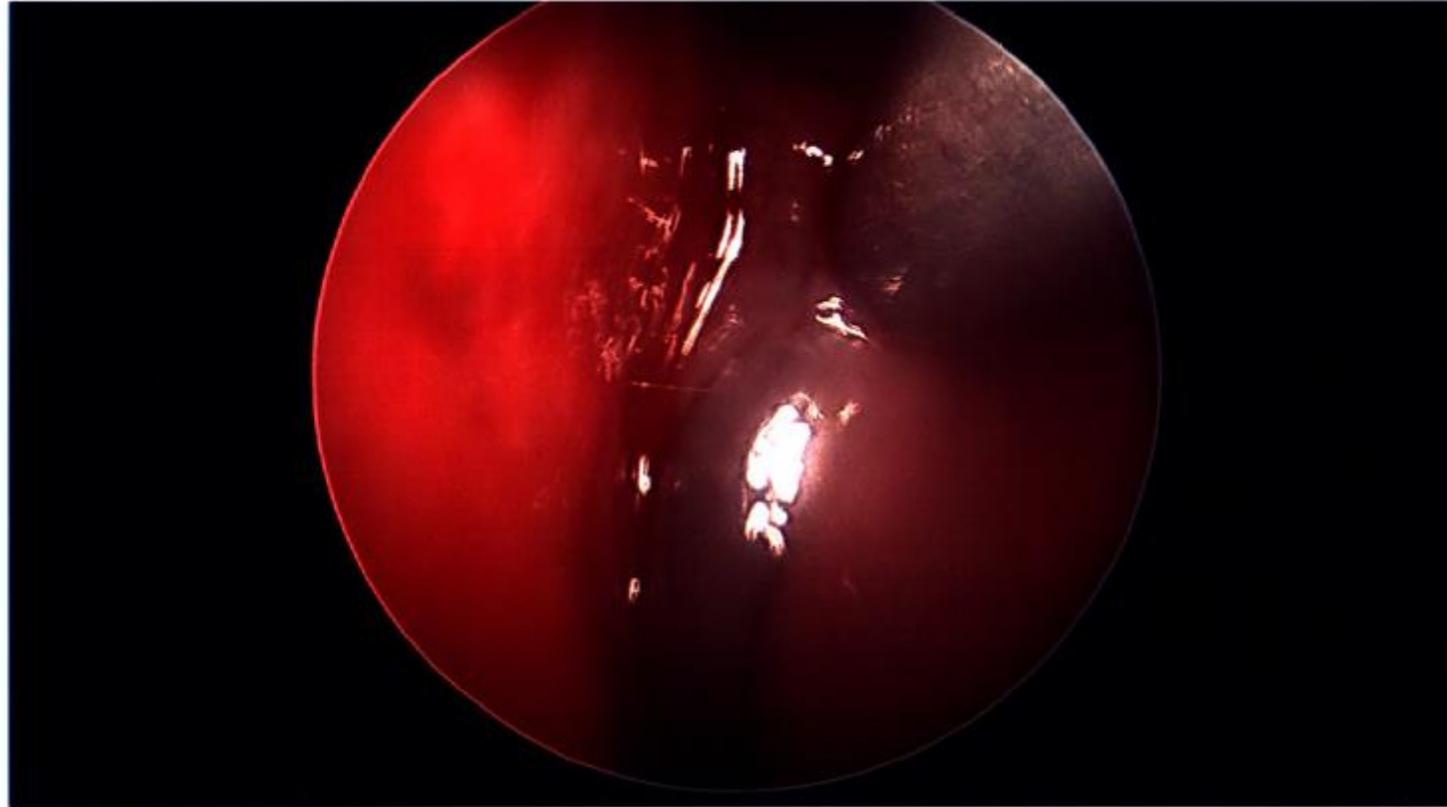
SPHENOID OSTIA PRE DILATION



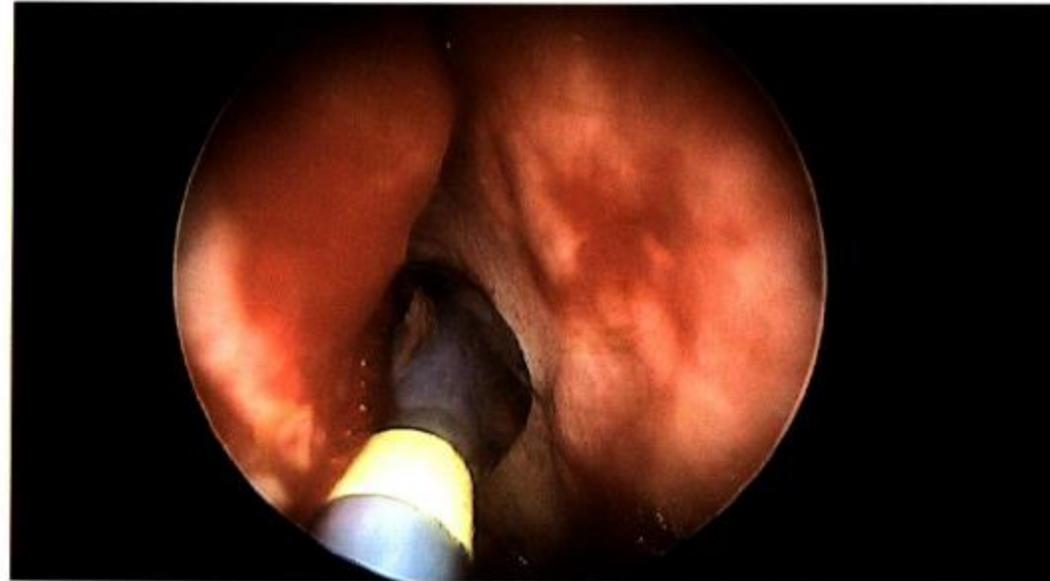
SPHENOID DILATION



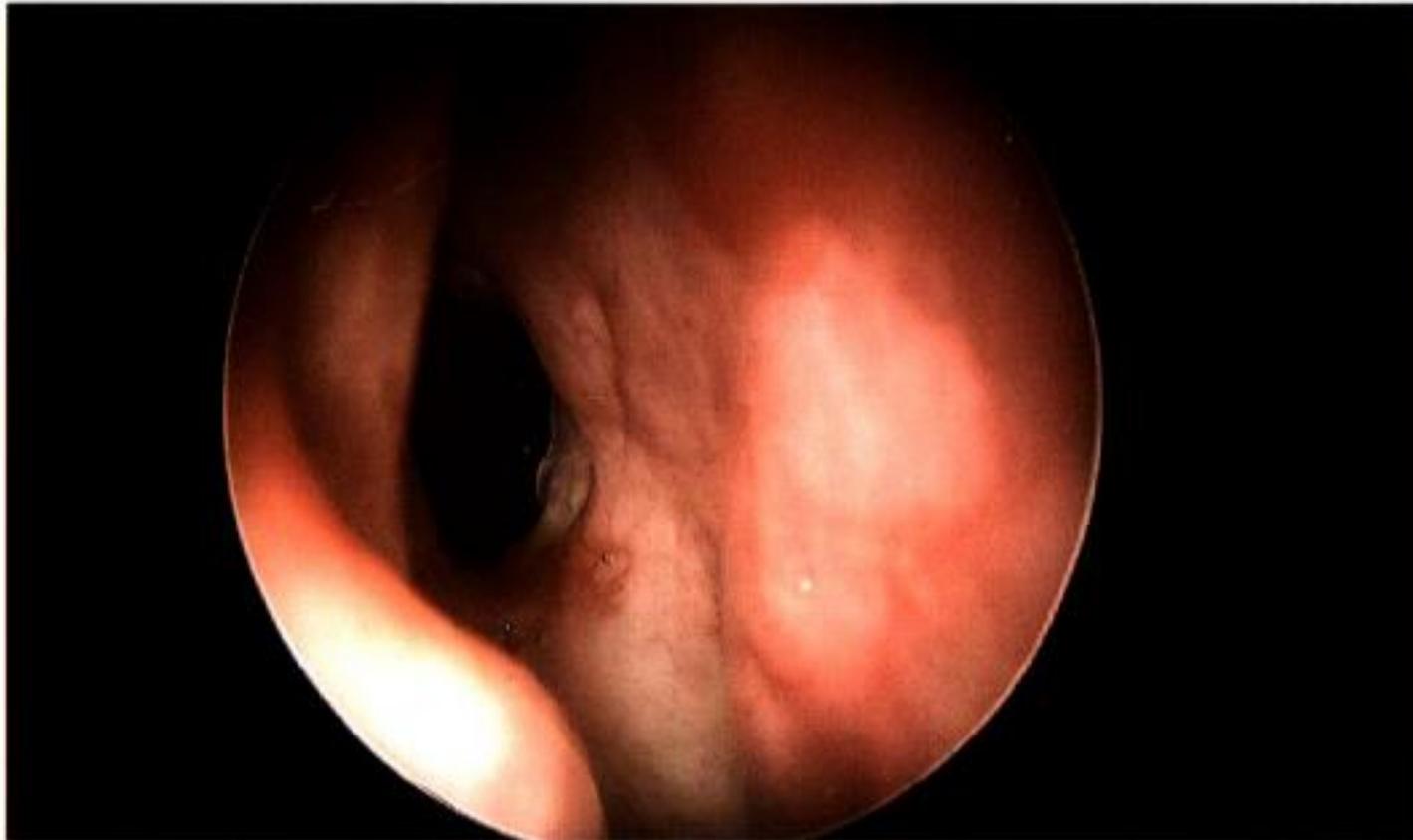
POLYP



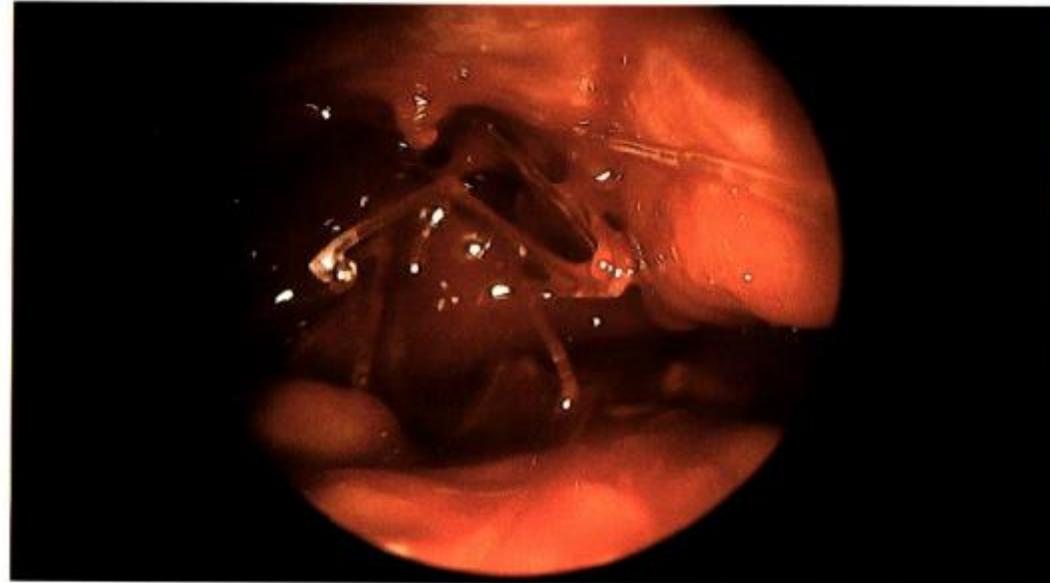
SPHENOID BALLOON DILATION



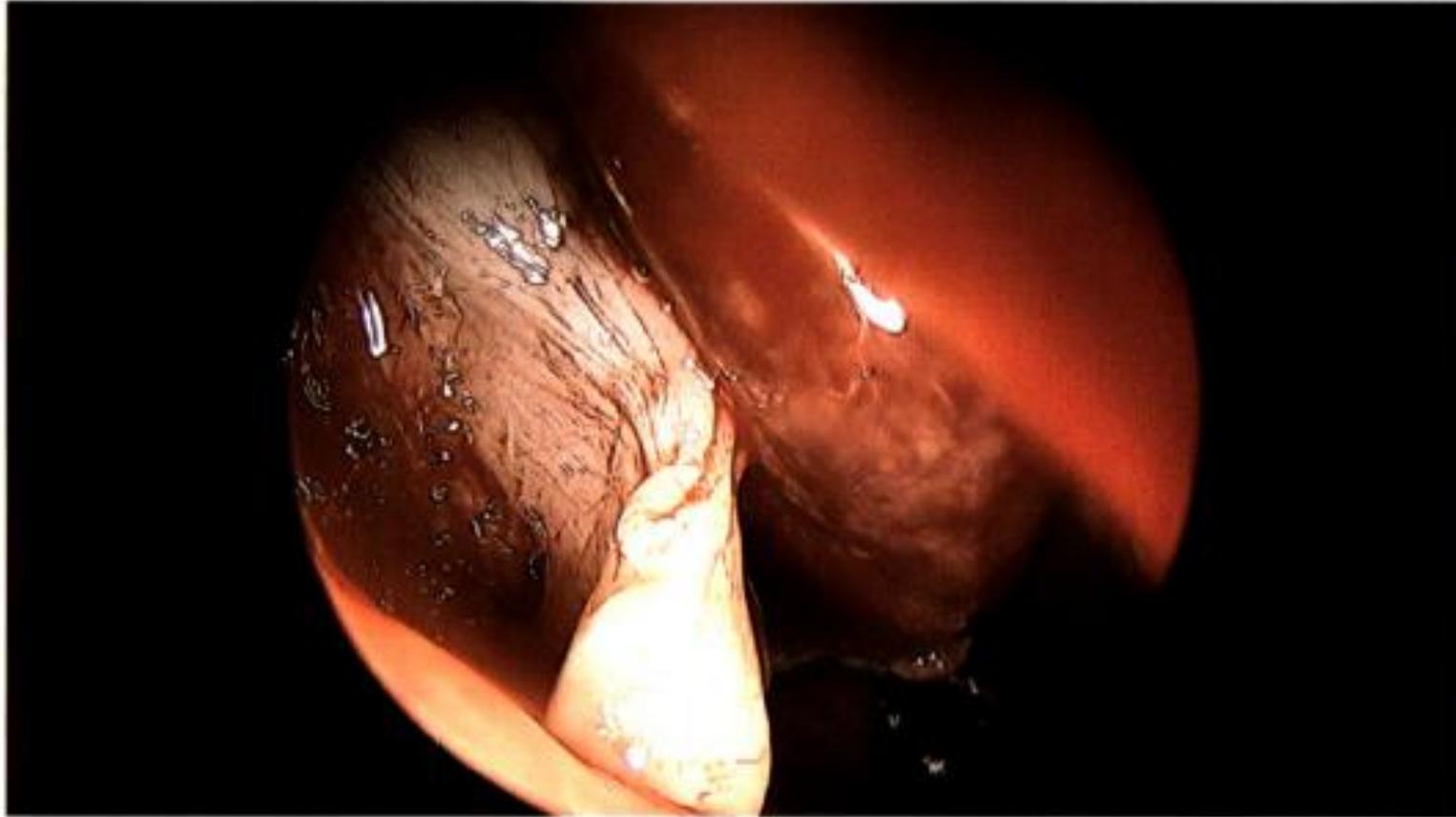
SPHENOID POST DILATION



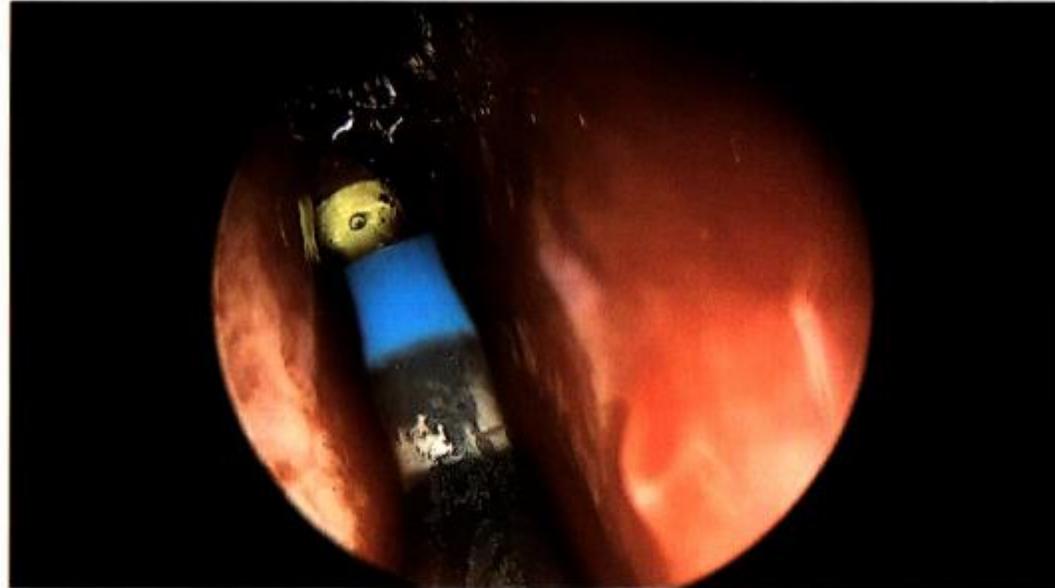
STEROID ELUTING IMPLANT



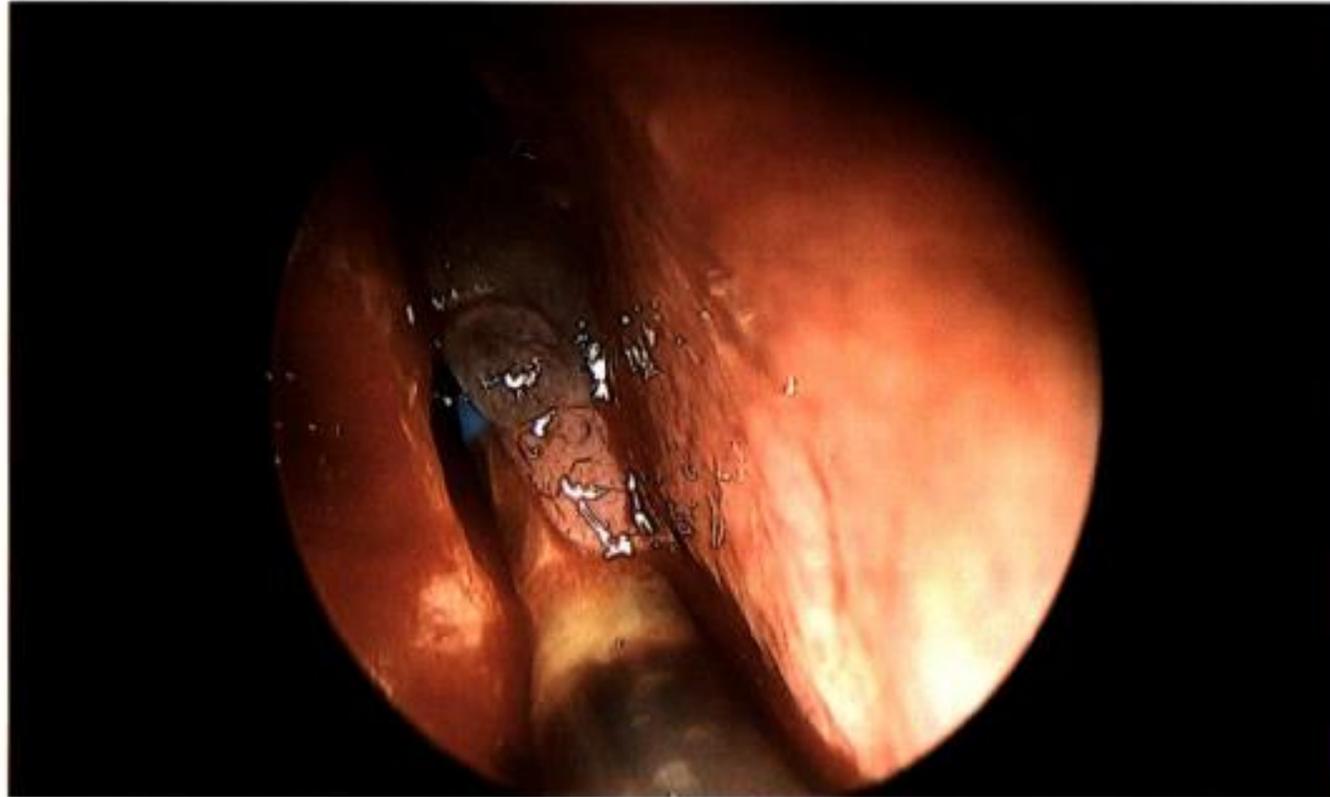
ENCEPHALOCELE



FRONTAL SINUS BALLOON



POLYP EXTRUDING FROM FRONTAL SINUS AFTER DILATION



PYOMUCOCELE IN MAXILLARY ANTRUM



Summary

- Sinusitis is diagnosed with the use of nasal endoscopy, SNOT-22, and CT scans.
- The economic impact of work loss in the United States for sinus and allergy disease is greater than back and heart conditions combined.
- Current recommended treatment for sinusitis includes antibiotic therapy, nasal lavage, nasal steroid, and sinus surgery or balloon sinus dilation.
- Long term therapy for allergies or other underlying conditions is needed in order to prevent recurrent episodes.
- Sinusitis may be classified as acute, recurrent acute, or chronic.
- Current surgical techniques include traditional endoscopic sinus surgery or balloon sinus dilation

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