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New Treatment Options for Chronic Sinusitis

Jesse Ryan, M.D.
Assistant Professor
Head and Neck Surgery & Reconstruction
Department of Otolaryngology

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Knowing changes everything.™

Disclosures

- I have no financial relationship with any of the companies or products discussed in this presentation.

Sinusitis: Definition

- Chronic Sinusitis
  - Symptoms for more than 12 weeks
    - Nasal congestion
    - Post nasal drip
    - Facial pressure/fullness/headache
    - Decreased sense of smell
  - Evidence of inflammation on exam or imaging

- Recurrent Acute Sinusitis
  - More than four acute sinus infections per year – feel fine in between episodes

Sinusitis: Overview

Statistics

- 37 million afflicted in the US alone
- $8.6 billion in healthcare costs
- Over 58 million days of restricted activity/year
- Accounts for 1 in 5 antibiotic Rx
- 525,000 sinus surgeries per year in the US

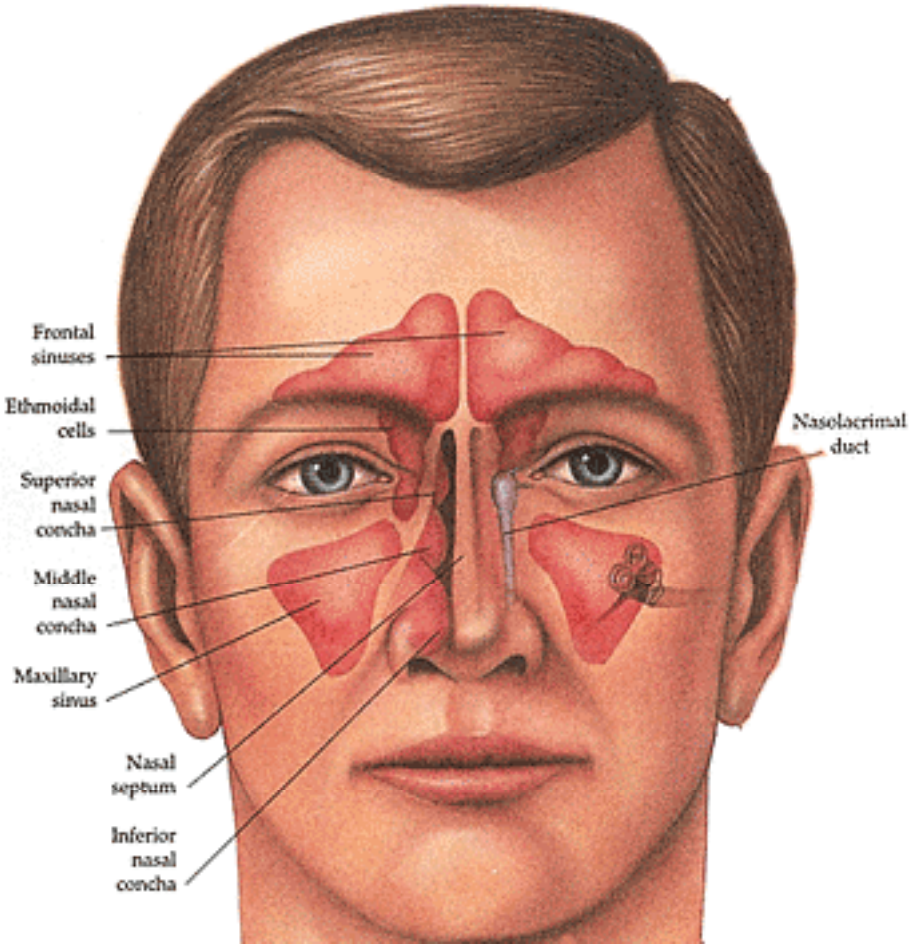
Common Symptoms

- Purulent drainage
- Facial pressure and fullness
- Nasal congestion
- Fatigue
- Facial or dental pain
- Headache

- Anatomy
- Historical Context
- Progression of Surgical Techniques

Anatomy

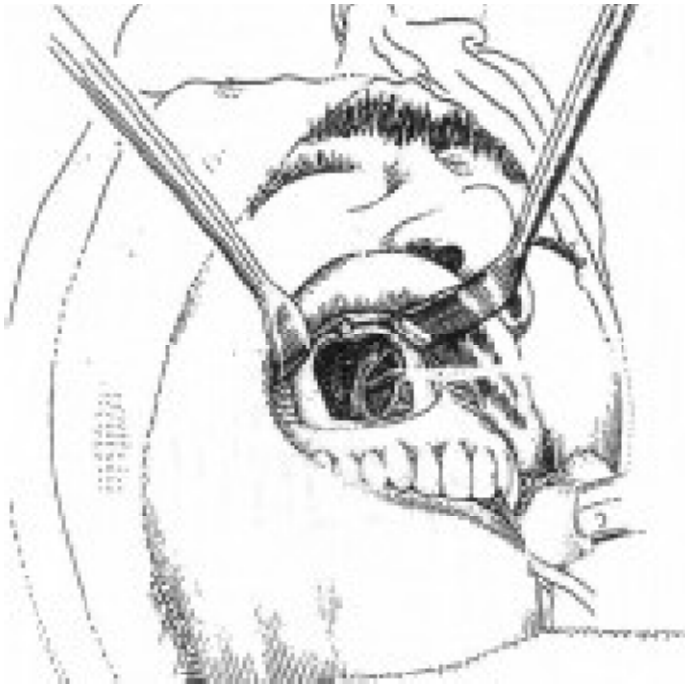
- 8 paired sinuses
- Development continues into adulthood
- Significant variability
- Drainage pathways
  - Anterior
  - Posterior



http://care.american-rhinologic.org/sinus_anatomy

History

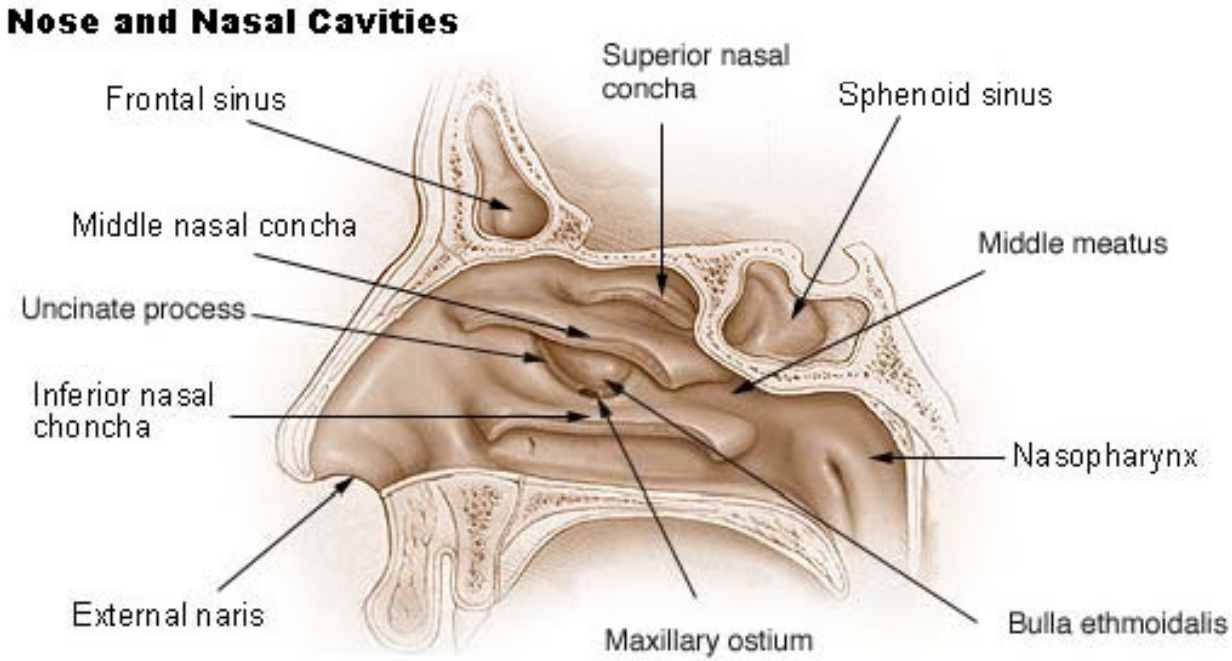
- Early sinus surgery was done through external approaches
  - Incisions in the skin or under the lip
- Today this is reserved for more complicated cases
  - Trauma
  - Tumors
  - Severe infections



http://www.otorrinomarbella.com

History

- Technical advances – flexible/rigid endoscopes – 1950s/60s
- Dr. Kennedy describes “FESS” – 1985



http://www.training.seer.cancer.gov

Functional Endoscopic Sinus Surgery

- Less invasive than external approaches
- Goal is to create controlled openings into the sinuses
- Incorporate natural drainage pathways
- Remove inflammatory tissue
- Preserve normal landmarks, mucosa, and functional structures (turbinates) as much as possible

Functional Endoscopic Sinus Surgery

- Technological advances
  - High definition cameras
  - Refinement of surgical tools
- Image guided surgery
  - Mapping a CT scan to instruments used during surgery
- Dramatic changes over the past 10 – 15 years
- **But** – still a surgery in the operating room with general anesthesia and extended recovery

Sinus Balloon Dilation

- Part of the overall evolution in medicine toward less-invasive approaches
- FDA approval 2005
- Tool has expanded our ability to treat sinus disease safely, effectively, less invasively
- Able to care for patients in the office setting, using local anesthesia
- Lower risks, less pain, faster recovery

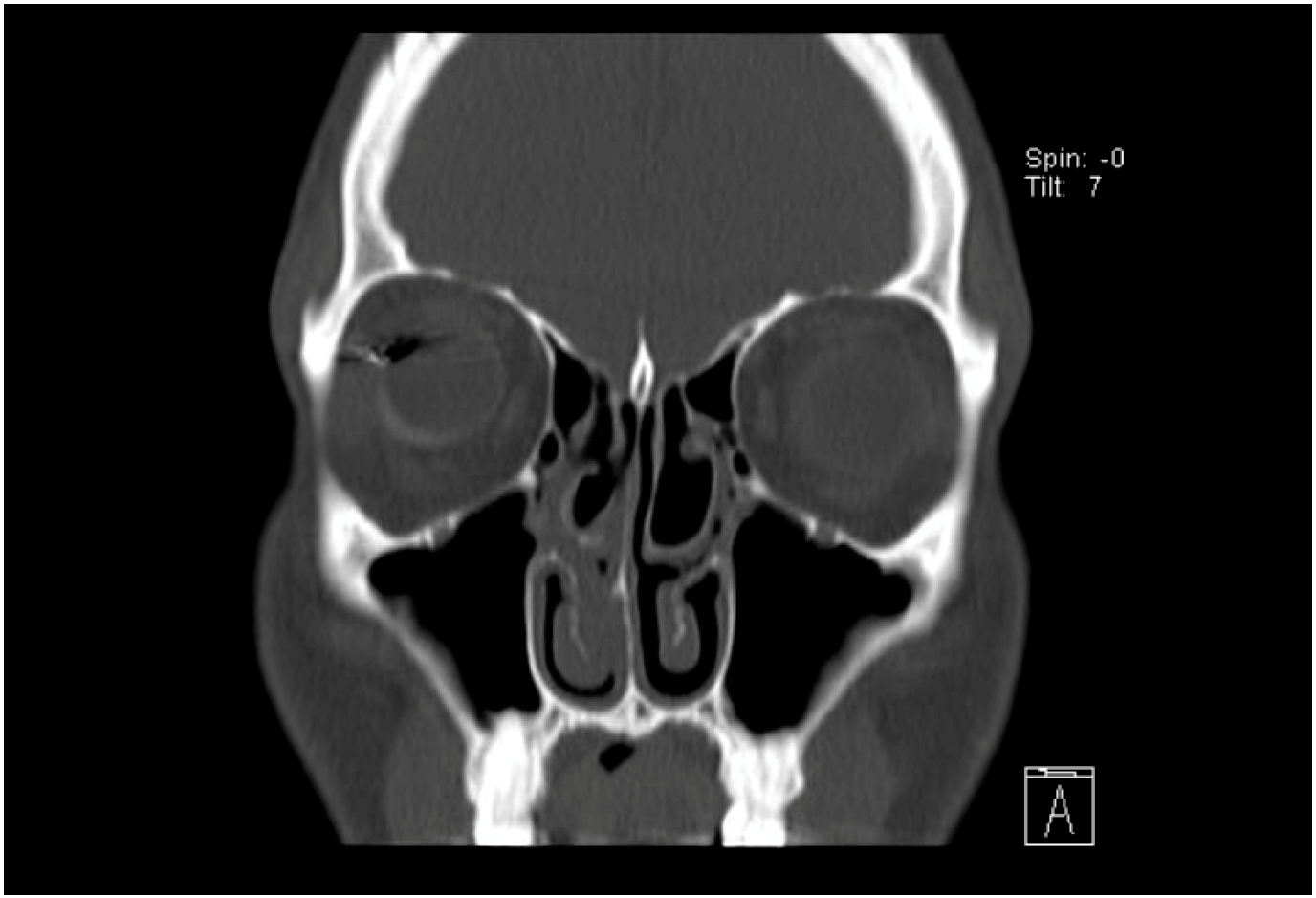
Case Presentation

- 35 year old male with 6 months of nasal congestion, post nasal drip, sinus pressure
- His symptoms worsen several times per year
- Sometimes diagnosed with an acute infection and given antibiotics
- Has tried nasal steroids (flonase, nasonex), antihistamines (claritin, allegra, zyrtec) without relief
- Referred to ENT by his primary care physician

Case Presentation

- Exam in ENT office shows severe nasal congestion but otherwise not remarkable
- Optimize medical management
  - Nasal steroid sprays
  - Nasal saline
  - Longer course of antibiotics, possibly oral steroids
  - Consider allergy testing
- CT scan of the sinuses obtained after “maximal medical therapy”

Case Presentation



Case Presentation

- What are the options for this patient?

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- Continued medical management?

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- Sinus surgery in the operating room?

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- What are the options for this patient?
- Continued medical management?
- Sinus surgery in the operating room?
- Office-based intervention?

Evidence

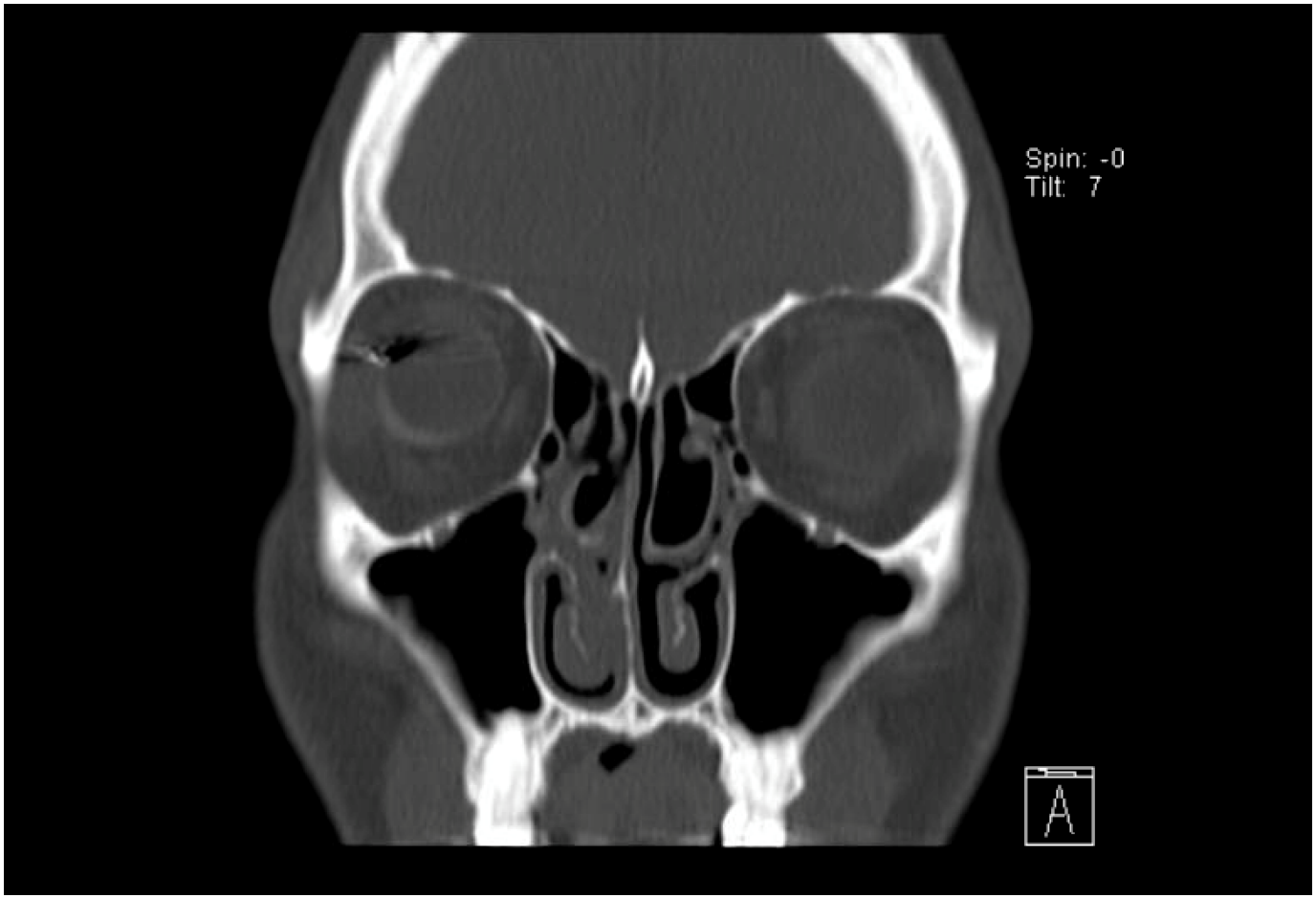
- Comparing outcomes, cost, safety of balloon dilation vs. traditional sinus surgery (FESS)

Balloon Sinus Dilation Data - Summary

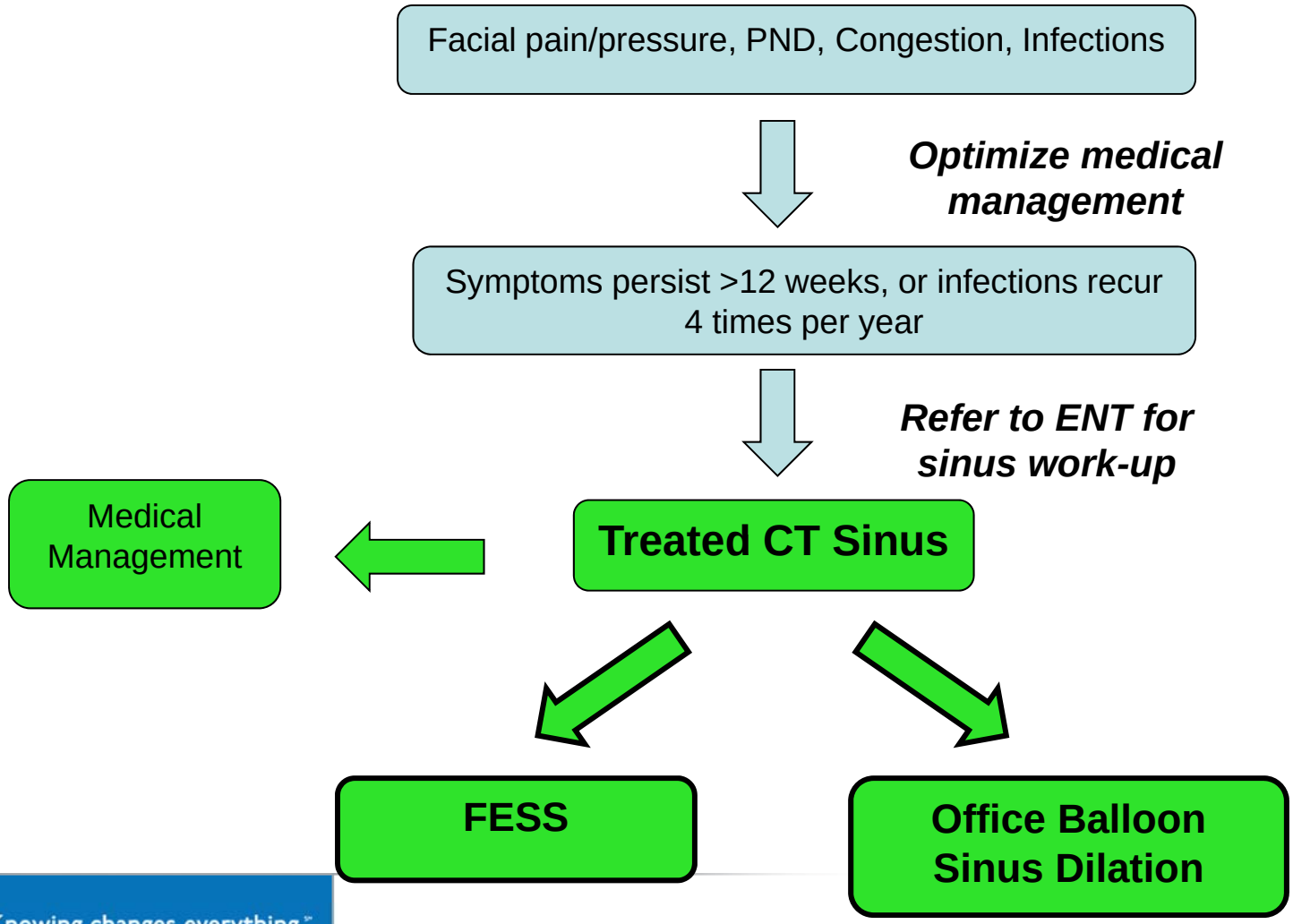
- High patient satisfaction, well tolerated in office setting
- Significant reduction in symptoms (similar to FESS)
- Low revision surgery rates (~ 5%)
- Faster return to normal activities (24-48 hours)
- Decreased costs to health care system
- Consistently good results across numerous clinical studies

Data courtesy of Entellus Medical

What would you do?



Chronic Sinusitis Treatment Flow



Sinusitis: Treatment options

Medical Therapy

Medicines commonly used to treat bacterial infection and allergies and provide symptomatic relief to the patient.

Limitations:

- Does not address underlying anatomy
- Side effects

Office Sinus Dilation

Ideal for patients who fail medical therapy but do not need, want, or are unable to have sinus surgery.

Limitations:

- May not be able to treat some complex sinus disease

Sinus Surgery

For patients who fail medical management and suffer from complex sinus disease. More invasive than balloon dilation.

Limitations:

- Requires general anesthesia
- Longer recovery

Courtesy of Entellus Medical

How does it work?

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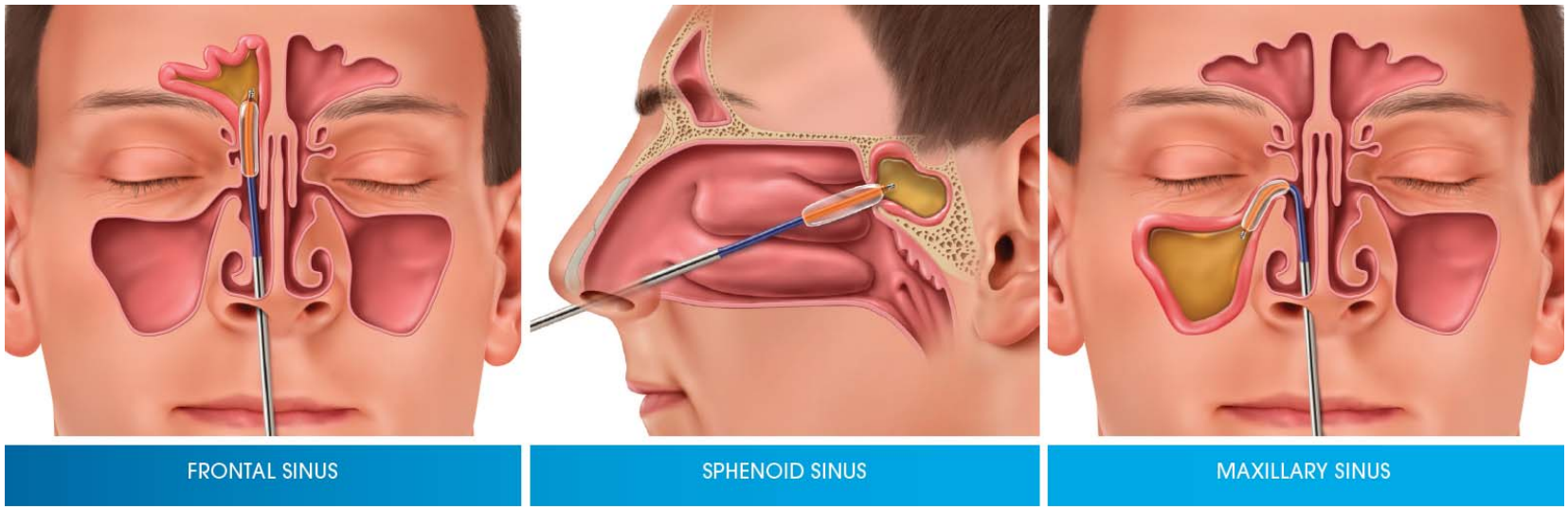
Courtesy of Entellus Medical

How does it work?

Treat frontal (forehead), maxillary (cheek), sphenoid and front part of the ethmoid sinuses



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Procedure overview

- Office procedure – 60 minutes
- Pain medication, anti-anxiety medication, topical/local anesthesia
- Balloon gently inserted into natural drainage pathways of affected sinuses
- Expanded to dilate and remodel drainage pathways of the sinuses

Office sinus dilation

- Syracuse Channel 9 News Story

Conclusions

- Balloon sinus dilation is a tool that allows a less invasive, office-based treatment for chronic sinusitis
- Has been shown to be safe and effective
- Part of the progression in medicine toward minimally invasive surgery and office-based procedures
- Decreased costs to the health care system

References

- Kennedy DW (Oct 1985). "Functional endoscopic sinus surgery. Technique". *Arch Otolaryngol* **111** (10): 643–9.
- Chandra RK, Kern RC, Cutler JL, Welch KC, Russell PT. “REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies.” *Laryngoscope*. 2015 Jul 30.
- Bikhazi N, Light J, Truitt T, Schwartz M, Cutler J; REMODEL Study Investigators. “Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial with 1-year follow-up.” *Am J Rhinol Allergy*. 2014 Jul-Aug;28(4):323-9.
- Chandra RK, et al. „REMODEL Larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies.” *Laryngoscope.* 2015 Jul 30.
- Levine SB, et al. ”In-office stand-alone balloon dilation of maillary sinus ostia and ethmoid infundibula in adults with chronic or recurrent acute rhinosinusitis: A prospective, multi-institutional study with 1-year follow-up.” *Annals of Otology, Rhinology & Laryngology* 2013; 122(11):665-671.
- Gould J, Alexander I, Tomkin E, Brodner D. ”In-office, multisinus balloon dilation: 1-year outcomes from a prospective, multicenter, open label trial. *Am J Rhinol Allergy* 2014 Mar-Apr;28(2):156-63.
- Benninger, M. et al. “Adult chronic rhinosinusitis: Definitions, diagnosis, epidemiology, and pathophysiology.*” Otolaryngol Head Neck Surg.* 2003; 129S: S1-S32.
- Lusk R, Bothwell MR, Piccirillo J. “Long-term follow-up for children treated with surgical intervention for chronic rhinosinusitis.” *Laryngoscope*. 2006; 116:(12) 2099-2107.
- Ray, N., et al. “Healthcare expenditures for sinusitis in 1996: Contributions of asthma, rhinitis, and other airway disorders.” *J Allergy Clin Immunol* 1999; 103: 408-414. (Inflation Adjusted as per CPI to 2010 dollars.)
- Gill JM, Fleischut P, Haas S, Pellini B, Crawford A, Nash DB. “Use of antibiotics for adult upper respiratory infections in outpatient settings: a national ambulatory network study.” *Fam Med*. 2006;38(5):349-354
- Rosenfeld RM, Andes D, Bhattacharyya N, et al. “Clinical practice guideline: adult sinusitis.” *Otolaryngol Head Neck Surg.* 2007;137(3):(suppl) S1-S31
- Rosenfeld RM, Piccirillo JF, et al. “Clinical Practice Guideline (Update): Adult Sinusitis.” *Otolaryngol Head Neck Surg.* 2015; 152(25): (suppl) S1-S35.
- Thomson Reuters Outpatient Procedure Database.

QUESTIONS?