Advances in Endoscopic Sinus Surgery: FESS/BSD

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“Practice Makes Perfect”

• Answer to Bulletin Article
• Fellowship in Rhinology (Sinus and Skull Base at Cleveland Clinic Foundation
  – 1 of 20 in US in 2002 (0.003% of US hospitals)
  – Now 1 of 120 (0.02% of hospitals)
  – Academic research on Central Skull Base
  – Teach Skull base surgery at State and National Conferences
  – Statewide Tertiary Care revision sinus surgery

Endoscopic Pituitary Resection

• Few hundred resections
  – No catastrophic bleeding
  – No surgical induced visual loss
  – Average hospital stay 1-2 days
  – No delayed CSF leaks except in one expected extended skull base resection

Central Oregon ENT

• Only fellowship trained surgeon in….
  – Head and Neck Cancer
  – Laryngology
  – Pediatric ENT
  – Rhinology - Sinus and skull base
  – Neurootology
  …… East of Cascades

Endoscopic Skull Base Surgery

Endoscopic Skull Base Resection:
Esthesioneuroblastoma
Left Olfactory Fossa
T2N0M0

Endoscopic Juvenile Angiofibroma Resection
OBJECTIVES

- To discuss new techniques (advanced and minimally invasive surgical techniques) for patients with rhinosinusitis and skull base lesions
- Differentiate between acute and chronic sinusitis.
- Identify key aspects of the history and physical exam and interpret diagnostic studies.
- Discuss the indications for endoscopic sinus surgery.
- Discuss outcomes and comparison of standard functional endoscopic sinus surgery vs. functional endoscopic dilatation of the sinuses.
- Discuss management of post-operative care.
- Triple Aim— with an aim toward improving the health of the population, the patient’s experience (outcomes, safety, satisfaction), and reducing of controlling health care costs.
Mucociliary Clearance

Rhinosinusitis Overview

- Inflammation of the sinus lining caused by:
  - Bacterial, viral and/or microbial infections
  - Structural issues
  - Ostial blockage

- Common symptoms:
  - Nasal congestion
  - Facial discomfort
  - Nasal discharge
  - Headache
  - Fatigue

- Acute rhinosinusitis
  - Symptoms < 4 weeks

- Subacute rhinosinusitis
  - Symptoms > 4 weeks and < 3 months

- Chronic rhinosinusitis
  - Symptoms > 3 months


Acute Bacterial Rhinosinusitis: Diagnosis
(requires at least 2 major factors, or 1 major & 2 minor factors)

Symptoms worsening after 5–7 days, persistence of major symptom(s) >10 days, or symptoms out of proportion to typical URI

Symptoms

- Nasal / Post-nasal drainage*
- Facial pain / pressure*
- Nasal obstruction / congestion*
- Hyposmia / anosmia
- Cough not due to asthma (in children)

* = most common symptoms


Viruses Cause Mucosal Edema/Inflammation, with Ostiomeatal Obstruction

Acute Viral URI 2 Weeks Later, No Treatment


Chronic Rhinosinusitis Defined

Debilitating

Definitive


Chronic Rhinosinusitis: Population Health Toll

- 900,000 patients not successfully treated
- 7M seek prescriptions
- 1.4M fail medications annually
- Only 35% of these undergo surgery
- Prevalence: Afflicts estimated 37M U.S. More common than heart disease or asthma
- Results in 18-22M physician office visits annually
- Quality of Life: More debilitating than congestive heart failure or chronic back pain
Common Medical Therapy for Acute and Chronic Rhinosinusitis

- Oral and/or intranasal antihistamines
- Oral and/or intranasal steroids
- Oral decongestants
- Intranasal saline
- Oral antihistamine/decongestants
- Oral leukotriene blockers
- Oral antibiotics

Medical therapy typically consists of varying combinations of these agents.

Medical Treatment: Chronic Rhinosinusitis

No FDA approved medications for treatment of Chronic Rhinosinusitis… ...

- Oral antibiotics based on endoscopic culture
- Extended maximal medical therapy: 3-4 weeks of ABX +/- oral steroids
- Nebulized Medications (Steroids, Antibiotics, Antifungals)
- Nasal Surfactant (Pending Recall)
- Medication in Vertex-Down Position (Polyps or hyposmia)
- Intranasal Pulmicort, Tobradex, Pred forte
- Aspirin desensitization (Per allergist for Aspirin Exacerbated Respiratory Disease)

Structural Problems
- Deviated nasal septum
- Abnormal turbinates
  - Hypertrophic, paradoxical, concha bullosa
- Hypertrophic adenoids
- Evidence of eustachian tube dysfunction

Mucosal Problems
- Edema
- Hyperemia
- Purulence
- Polyps or polypoid mucosa

Physical Examination of RS Patients

Enlarged, bluish-red inferior turbinate of patient with allergic rhinitis

Septal Deviation Can Impinge on Ostiomeatal Region


Diagnostic Nasal Endoscopy Can Be Performed with Rigid (0, 30, 70 degree, Rotatable) or Flexible Endoscopes

Endoscopic Nasal Examination and Obtaining Culture for Diagnosis

Small culturette obtaining mucopus sample from hiatus semilunaris
Sterile Sinus Secretion Collector
Pathogenesis of CRS: Role of Bacteria

No prior surgery

Aerobes – 75–100%
- Coag. neg. Staphylococci
- Staph. Aureus
- Strep. Pneumonia
- Strept. viridans
- H. influenza
- Corynebacterium
- Moraxella catarrhalis

Anaerobes – 0–25%
- Fusobacterium sp.
- Peptostreptococcus sp.
- Propionibacterium sp.

Prior Surgery

Anaerobes – 0–25%
- Fusobacterium sp.
- Peptostreptococcus sp.
- Propionibacterium sp.


Plain Sinus Radiography

- Limited utility for ethmoids
- Can document acute maxillary, frontal, or sphenoid RS
- Can follow progress if baseline films obtained
- Air / fluid levels documented on plain films during prior episodes of RS merit proceeding directly to nasal endoscopy & CT scan
- Plain films are not recommended in chronic RS


Sinus Anatomy
(as depicted by normal coronal CT scan)

[Image of sinus anatomy]

- M = maxillary sinus
- I = inferior turbinate
- M = middle turbinate
- S = septum
- U = uncinate process

CT Scans for Rhinosinusitis

- Should not be used as the sole diagnostic criteria
- Indicated for:
  - questions of diagnosis &/or therapy
  - strong history not responding to therapy
  - prior to sinus surgery
- Timing of CT scan
  - in chronic RS, after 4 weeks or more of appropriate therapy
  - in recurrent acute RS, in search of origin of problem
  - in acute disease, if extranasal spread of infection; note in acute viral URIs that 87% of sinus CTs are positive, & 21% remain so 2 weeks after clinical resolution


Relative Indications for Surgery for Rhinosinusitis
(and reasons for most sinus surgery)

- Recurrent acute rhinosinusitis in which a persisting obstruction to sinus aeration (e.g., polyp, concha, septum) or a specific area of recurring disease has been identified
- Chronic rhinosinusitis that has failed to clear on appropriate medical therapy

Absolute Indications for Surgery for Rhinosinusitis

- Rhinosinusitis causing
  - Brain abscess or meningitis
  - Subperiosteal orbital abscess, cavernous sinus thrombosis
  - Other contiguous infection (e.g., Pot’s tumor, facial cellulitis)
- Fungal sinusitis (all varieties)
- Sinus mucocele or pyocele
- Massive polyposis (all varieties)
- Neoplasm or suspected neoplasm (causing sinus obstruction)
FESS/BSD: Definitions

FESS = Functional Endoscopic Sinus Surgery

FEDS = Functional Endoscopic Dilation of the Sinuses
  = BSD (Balloon Sinus Dilatation)
  = BSP (Balloon Sinuplasty)

Preservation of Natural Ostium

• “The natural drainage and ventilation paths should be restored, the anatomy changed as little as possible, and the mucosa preserved to the greatest extent.”
  - Prof. Heinz Stammberger, M.D.

F.E.S.S. Endoscopic Diagnosis and Surgery of the Paranasal Sinuses and Anterior Skull Base. The Messerklinger Technique and Advanced Applications from the Graz School, 2003. pg. 22.

Mucociliary Clearance

Evolution of Sinus Surgery Techniques

1893 - 1985
Caldwell-Luc

• Good access to maxillary sinus
• Standard of care for 80 years
• Risk of nerve damage
• Largely replaced by endoscopic techniques


Evolution of Sinus Surgery Techniques

1985 - Present
FESS (Functional Endoscopic Sinus Surgery)

• Precise visualization of cavity
• Physiology-driven approach
  - Restore normal sinus drainage and function
  - Preserve normal anatomy and mucosal tissue
• Significant reduction in trauma
• Mucosal/anatomic preservation sometimes difficult with available tools


Evolution of Sinus Surgery Techniques

2005 - Present
FESS with BSD (Balloon Sinus Dilatation)

• Drainage via natural ostia can be restored in a minimally invasive manner
• No bone resection or mucosal stripping
• Physiology-driven approach
• Restore normal sinus drainage and function
• Preserve normal anatomy and mucosal tissue

Keys for Successful FESS

- Knowledge and understanding of Anatomy
- More precise instrumentation
- Visualization/Optics
- Image-Guided Navigation

Recurrent Sinonasal Polyposis with Skull Base Defect: Encephalocele

Balloon Catheter Sinuplasty

- Originally released in 2005 by Acclarent
- Safety and feasibility studies published in 2006
- Originally utilizing fluoroscopy guidance
- Now performed with transillumination
- Entellus allows for Image Guidance

Controversy 2006

COMMENTARY: Balloon Sinuplasty: Not Ready for Prime Time

Donald C. Lanza, David W. Kennedy. The Annals of Otology, Rhinology & Laryngology; Oct 2006; 115, 10; ProQuest Nursing & Allied Health Source
ARS position statement on balloon sinuplasty (2006)

- Balloon dilation technology may have potential where surgical management of sinus disease is required.
- The technology has limited surgical indications at this time.
- Patients treated with balloon dilatation 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.

FESS with flexible, atraumatic instrumentation

- Balloon catheters allow dilation of sinus drainage pathways without resorting to tissue removal during FESS
  - Minimize bleeding and scarring associated with use of rigid and powered instrumentation
  - Preserve nasal mucosa, allowing for undisturbed mucociliary clearance and immune response

Balloon Sinus Dilatation

1. Advance and inflate balloon
2. Deflate balloon
3. Retract balloon
4. Dilated sinus ostium

FESS

- Left FESS: Ethmoidectomy
- Maxillary Sinus BSP

Balloon Catheter Sinuplasty Manufacturers

- Acclarent
- Entellus

Stairstep Approach: Maxillary Sinusitis

- Most Invasive
- Medial Maxillectomy
- Caldwell-Luc
- Mega-Antrostomy
- Antrostomy
- Uncinctomy
- Balloon Sinuplasty

- Least Invasive
Standard Antrostomy or BSD?

Stairstep Approach: Frontal Sinusitis

- Most Invasive
  - Obliteration
  - Modified Lothrop (Endo Drill-Out)
  - Frontal Sinus Rescue
  - Endo. Frontal Sinusotomy - FESS
  - Balloon Catheter Sinuplasty

- Least Invasive

Right Frontal Balloon Sinuplasty

Frontal Sinus: Confirmation by Transcutaneous Illumination

Right Frontal Recess
In-Office
Balloon Sinus Dilatation

Outcomes measurements in FESS/BSD

- QOL Survey
  - SNOT-20, RSDI, CSS
- Nasal endoscopy to look for ostia patency
- Lund-Mackay CT scores
Outcomes Based Chronic Rhinosinusitis Treatment: Data Driven

New patient: Nasal and Sinus Questionnaire

SNOT-20 Sino-Nasal Outcomes Test

RSDI Rhinosinusitis Disability Index

Determinants of Outcomes of Sinus Surgery: A Multi-Institutional Prospective Cohort Study

- Objectives:
  - To quantify proportion of patients who experience improved QOL post ESS
  - To identify preop clinically predictive characteristics
- Design: Prospective, multi-institutional cohort study
- Setting: Academic tertiary care centers
- Subjects and Methods: 302 CRS pts
  - Pt characteristics, CT scores, Endoscopy scores and QOL scores were obtained
- Results:
  - Poor baseline QOL pts
    - 71.7% improvement on RSDI
    - 76.1% on CSS
  - Primary patients
    - 2.1 times more likely for improved RSDI
    - 1.8 times more likely for improved CSS
- Conclusion:
  - FESS results in improved QOL in majority of patients
  - Predictor of disease-specific QOL improvement post FESS: Primary patients more likely to improve than revision patients


Determinants of Outcomes of Sinus Surgery: A Multi-Institutional Prospective Cohort Study

BSP CLEAR Series & PatiENT Registry

- CLEAR 6 Mo: Proven Safe
- CLEAR 1yr: Effective and Durable
- CLEAR 2yr: Improved in QOL SNOT-20 Reproducible
- 1036-pt Registry: Results are reproducible in 1036 patient registry across at 27 practice sites.

CLEAR Two-Year Study Patient Quality of Life Outcomes

- Symptom Assessment SNOT-20
  - Preop: 2.17
  - 2 Year: 0.87
  - (1) Statistically significant (p <0.001)
  - (2) Clinically meaningful change (>0.8)
  - (3) Improvement reported at every time point

- Lund-MacKay CT Score
  - Preop: 9.66
  - 2 Year: 2.89
  - No serious adverse events reported between one year and two years (n=65)
  - Revision rates at two years: 3.6% sinus revision rate (7/195), 9.2% patient revision rate (6/65)

CLEAR Two-Year Study Conclusions

- Balloon catheter sinusotomy achieves a statistically significant and clinically significant improvement in SNOT-20 symptom scores at each time point through two years.
- Patients reported clinical symptom improvement across the two-years period supporting the changes in the SNOT-20 scores.
- Resolution of disease on CT Scan previously observed at one year is also sustained in this two year analysis.

PED BSP Literature

- Rhamadan: Balloon Catheter Sinuplasty and Adenoidectomy in Children with Chronic Rhinosinusitis
  - Pilot: Nonrandomized, controlled, prospective pediatric CRS patients
  - BCS 80% (24 of 30 pts) with 12 month improvement in SN-5 QOL scores
  - Adenoidectomy 52.6% (10 of 19 pts) with 12 month improvement in SN-5 QOL scores
  - Flaws undefined: It was BCS and Lavage – What really improved the patients? BCS or Lavage Can this be addressed?
  - Study limitations:
    - 17/30 underwent ADX with BCS
    - 9/30 previous ADX
    - Low numbers
    - Sinus lavage and cultures in HOW MANY?

Outcome of adenoidectomy versus adenoidectomy with maxillary sinus wash for chronic rhinosinusitis in children

- **OBJECTIVES:**
  - To compare postoperative outcomes of adenoidectomy versus adenoidectomy with maxillary sinus wash as surgical treatment of chronic rhinosinusitis (CRS) in children.

- **STUDY DESIGN:** retrospective review of prospectively collected data.

- **METHODS:** CRS patients
  - adenoidectomy alone or adenoidectomy with a maxillary sinus wash.

- **RESULTS:** 60 Children.
  - 87.5% (28/32) wash/A improved SN-5 Scores
  - 68.7% (23/34) Adenoidectomy with improved SN-5 Scores
  - 93% improvement with higher CT scores
  - 60% improvement with higher CT scores

- **CONCLUSIONS:** Children with more severe sinus disease as evidenced by a high CT score had a higher success rate if a maxillary sinus wash was performed at the time of adenoidectomy. Children with a low CT score did not have that benefit.


Balloon Catheter Technology in Rhinology: Reviewing the Evidence

- BCT/BCS/BSP has been most extensively studied to date (At present 66 peer reviewed articles)

- Selection criteria not clearly defined
  - Can the data be extrapolated to the general population????
  - Is BCT equivalent or superior to standard FESS devices?
  - Will use of BCT translate into improve QOL, better outcomes?
  - Need prospective randomized trials to compare BCT to standard FESS

Balloon Dilation of the Frontal Recess: A Randomized Clinical Trial

- **Design/Objectives:** Double-blinded randomized trial FESS with BCS vs. Conventional FESS in CRS treatment

- **Methods:** 40 pts enrolled, 34 randomized, 32 competed 1 year follow-up
  - All with CRSwNCP
  - BCS or FESS (Draf I or Ila)
  - Outcomes: CT & Endoscopic improvement

- **Results**:
  - Lund-Mackay statistically sig reduction in both groups
  - BCS 81% resolution of frontal disease vs. 75% for FESS (not statistically significant)
  - Endoscopic FR permeability: BCS 73% vs. FESS 63%
  - 4 patients needed revision surgery
  - 0 complications


Past and Present Controversies in CRS Surgical Management

- **FESS**
- **Soft Tissue Shavers in 1990s**
- **Image guidance Navigation**
- **Transnasal CSF leak repair**
- **Endoscopic pituitary surgery**
- **Balloon Sinuplasty**
**Success in CRS Surgical Management**

- Pediatric and FESS/BSP. Is doing less, more?
- Stair-step graduated approach to surgery?
- 3 Dimensional understanding of Anatomy
- Utilizing angled scopes (30, 45, 70, 90 degree or rotatable – Cyclops)
- Tissue preservation
- Surgical treatment with LONG TERM MEDICAL THERAPY
- Post op Care
  - Continuation of surgery in clinic
  - Debridements aid would healing
  - Prevent and release synechia

**Why BSP is Forcing ENTs to BE BETTER SINUS Surgeons:**

- BSP challenges ENTs to be better sinus surgeons
  - For a stepwise approach to CRS surgery
  - Focuses on minimally invasive technique
- FACT: BSP
  - Stimulating discussion and FESS/BSP research resulting in better outcomes data.

**My Predictions**

- Less pediatric surgical iatrogenesis
- Less frontal sinus iatrogenic disease/stenosis
- Less maxillary sinus iatrogenic disease (biofilm patients)
- Less frontal revision surgery by Tertiary Care Rhinologists
- Rotatable scopes: Improvement general ENTs understanding of and ability to operate in frontal recess
- Forcing better FESS outcomes studies

**Final thoughts…**

- BSD is not Panacea for Treatment of CRS
- Balloon Sinus Dilatation refers to a set of instruments and technique to be used in FESS
- When Goal is to open blocked Ostia
- BSD In-Office (Cost Saving) or general anesthesia
  - Endoscopic catheter-based approach
    - Minimally invasive
    - Safe and effective
    - Reduced bleeding
    - Fast recovery time
    - Does not limit treatment options
    - Clinically established

**CAN WE AVOID?**

- Nasal Antral Window
- Frontal Sinus Mucocele: Frontal Recess Stenosis
Bilateral Frontal Recess Stenosis

Frontal Sinus Mucocele: Frontal Recess Stenosis

FESS is not going away!!!!

Nasal Polyps and Pansinusitis from Cystic Fibrosis (s/p 7 sinus operations & lung transplant, chronic pseudomonas)

Allergic Fungal Ethmoiditis & Associated Nasal Polyps Causing Partial Maxillary Obstruction

Inverting Papilloma

36 y/o male s/p 4 prior operations for “nasal polyps” and chronic rhinosinusitis (no biopsies taken); inverting papilloma on right and allergic polyps on left
Surgical Resection of Polyps
Obstructing Nose & Sinuses

Balloon Sinus Dilatation

Chronic Frontal and Maxillary Rhinosinusitis
FESS or BSP?

Left Frontal Sinus Chronic Opacification with Localizing Pain

Pediatric CRS: FESS ↔ BSD?

Pediatric CRS: FESS ↔ BSD?
Thank You