Balloon Sinuplasty: An Effective, Disruptive Technology

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Sinusitis Overview

Statistics

- 37 million afflicted in the US alone\(^1,2\)
- $8.6 billion in healthcare costs\(^3\)
- Over 58 million days of restricted activity/year\(^3\)
- Accounts for 1 in 5 antibiotic Rx\(^4,5\)
- 525,000 sinus surgeries per year in the US\(^6\)

Common Symptoms

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

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\(^6\) Thomson Reuters Outpatient Procedure Database.
Medication used to treat bacterial infection and allergies and provide symptomatic relief to the patient.

**Limitations:**
- Does not address underlying anatomy
- Side effects

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

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

**Limitations:**
- Requires general anesthesia
- Longer recovery
Balloon Sinuplasty

- Idea taken from interventional cardiology
- Cleared by FDA in 2005
- Concern: technology finding a disease to Tx
- Less invasive
- Quicker recovery
- ? Outcomes
Any technology which displaces current technology leading to a transformation of that field

- Clayton Christensen

*Disruptive Technologies*

1995
Functional Endoscopic Sinus Surgery (FESS)

- 1985 - Introduced to US - David Kennedy MD
- Allowed intranasal endoscopy
- Minimized tissue disruption
- Now broadly accepted
- Moved to tissue sparing

Technology: advanced our understanding of pathophysiology of sinusitis
Limitations of FESS

• Tissue damage---scarring
• Involves general anesthesia
• High failure: asthma, nasal polyps, allergies, Samter’s- 10-15%
• Still with severe complications-orbital injury, CSF leak- 1-3%
Critical Site: Ostiomeatal Complex OMC
-Junction of middle turbinate/ethmoid/uncinate process (mucosal contact)

-Place where antigens are deposited

-Critical area for common sinus flow

-Necessary to expand patency with balloon dilation
Technique

Intended Use
Treatment of frontal recesses, sphenoid sinus ostia, maxillary ostia
How Office Balloon Sinus Dilation Works
Multiple studies (CLEAR, ORIOS I/II, Patient Registry) reveal safety of maxillary balloon with up to 2 year f/u

- Frontal sinuses (PLAZA study)
- Children (INTACT) study

Consistent safety among a variety of sinuses addressed and patients
Clinical Data

- **Balloon only data** demonstrates significant reduction of symptoms (SNOT-20)
- **Hybrid procedures** (balloon + surgery) - significant level of symptom reduction
- **Low revision** surgery rates within 12 months
- **High patient satisfaction** and fast return to normal activities
NEW Clinical Data:

Randomized Evaluation of Maxillary Antrostomy Versus Ostial Dilation Efficacy Through Long-Term Follow-Up
Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial.

Jeffrey Cutler, M.D., Nadim Bikhazi, M.D., Joshua Light, M.D., Theodore Truitt, M.D., Michael Schwartz, M.D., and the REMODEL Study Investigators


Published electronically on Aug 5, 2013

In-print publication expected in Sept-Oct 2013
Patient Selection (Inclusion)

- Adults ≥ 18 years
- Maxillary and anterior ethmoid sinuses
- Uncomplicated rhinosinusitis
- Met 2007 Adult Sinusitis Guidelines for CRS or RARS
  - (CRS) > 12 weeks duration of symptoms and evidence of inflammation
  - (RARS) ≥ 4 episodes/year of acute bacterial rhinosinusitis
- Met 2011 coverage guidelines for medically necessary FESS
  - Anthem or BCBS of North Carolina coverage policies
  - Specified failure of optimal/maximal medical therapy
  - Does not specify nor require CT evidence of mucosal thickening
Patient Selection (Exclusion)

- Disease in the frontal, posterior ethmoid or sphenoid sinuses that requires surgery
- Fungal disease
- Gross polypoid disease
- Require concurrent nasal surgery or have had previous sinus surgery
- Nasal surgery within 3 months prior to enrollment
- Severe septal deviation causing obstruction of the OMC
- Primary ciliary dysfunction
- Hemophilia
- Samter’s Triad
Primary Study Endpoints

1. Long-term symptom improvement
   - Assessed by mean change in overall Sino-Nasal Outcome Test (SNOT-20) score between Baseline and 6-Month follow-up

2. Mean number of postoperative debridements
   - Transnasal removal of dead, contaminated or adherent tissue or foreign material that may promote infection or impede healing throughout the study period
Secondary Study Endpoints

1. **Post-discharge recovery outcomes**
   - Nausea
   - Nasal bleeding
   - Duration of analgesic use
   - Recovery time (time to return to baseline level of activity before surgery)

2. **Short-term symptom improvement**
   - Combined one-week & one-month changes in SNOT-20 scores

3. **Complication rate**
   - Serious device-related or procedure related adverse event

4. **Revision rate**
## Baseline Characteristics & Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Balloon Dilation (n = 50)</th>
<th>Control (FESS) (n = 42)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD or n (%)</td>
<td>Mean ± SD or n (%)</td>
<td></td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td>47.0 ± 14.6</td>
<td>47.9 ± 14.5</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>34 (68.0%)</td>
<td>23 (54.8%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>42 (84.0%)</td>
<td>36 (85.7%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Smoking History</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never smoked</td>
<td>29 (58.0%)</td>
<td>27 (64.3%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Allergies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All year</td>
<td>21 (42.0%)</td>
<td>17 (40.5%)</td>
<td>NS</td>
</tr>
<tr>
<td>Seasonal</td>
<td>13 (26.0%)</td>
<td>12 (28.6%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Asthma/bronchitis</strong></td>
<td>8 (16.0%)</td>
<td>8 (19.0%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Previous Nasal Surgery</strong></td>
<td>7 (14.0%)</td>
<td>8 (19.0%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Septal Deviation</strong></td>
<td>30 (60.0%)</td>
<td>25 (59.5%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Lund-MacKay Score</strong></td>
<td>3.2 ± 3.2</td>
<td>3.6 ± 3.5</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Sinuses Affected</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxillary only</td>
<td>31 (62.0%)</td>
<td>26 (61.9%)</td>
<td>NS</td>
</tr>
<tr>
<td>Maxillary and anterior ethmoid</td>
<td>19 (38.0%)</td>
<td>16 (38.1%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Chronic Rhinosinusitis Diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic (&gt; 12 weeks duration)</td>
<td>34 (68.0%)</td>
<td>29 (69.0%)</td>
<td>NS</td>
</tr>
<tr>
<td>Recurrent acute (≥ 4 episodes in 1 yr)</td>
<td>16 (32.0%)</td>
<td>13 (31.0%)</td>
<td>NS</td>
</tr>
<tr>
<td><strong>No. of Sinusitis episodes past yr</strong></td>
<td>4.5 ± 1.8</td>
<td>5.2 ± 2.8</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Duration of Sinusitis (yrs)</strong></td>
<td>12.4 ± 13.0</td>
<td>12.7 ± 13.9</td>
<td>NS</td>
</tr>
</tbody>
</table>
Procedure Summary

• **Balloon Dilation (50 patients)**
  – 52 patients randomized / 50 underwent balloon dilation
    • 1 did not want to undergo in-office balloon dilation
  – 99% technical success rate
  – 97 of 98 dilations of the maxillary ostia/ethmoid infundibula were successfully completed

• **FESS (42 patients)**
  – 53 patients randomized / 42 underwent FESS
    • *8 did not want to undergo FESS*
  – 99% technical success rate
  – 80 of 81 attempted maxillary antrostomies with uncinectomies were successfully completed
    • 41 concomitant anterior ethmoidectomies in 22 patients

Summary: 91/92 patients treated (99%) completed 6-Month follow-up
Results: SNOT-20 (Primary)

Mean SNOT-20 Score

Balloon Dilation
Control (FESS)

Δ = -1.7
Δ = -1.6

Baseline 6 Months
Baseline 6 Months

p<0.001

Conclusion: Balloon dilation is **not inferior** to FESS for symptom improvement
Results: Debridement Rate (Primary)

Mean /patient

Balloon Dilation

Control (FESS)

Total # of Debridements

p<0.0001

Mean /patient

Balloon Dilation

Control (FESS)

Conclusion: Balloon dilation results in less post-op debridements than FESS
### Results: Recovery Outcomes (Secondary)

**Post-discharge nausea**
- Balloon Dilation: 6%
- Control (FESS): 17%
- Comparison: p=NS

**Discharged with nasal bleeding**
- Balloon Dilation: 28%
- Control (FESS): 55%
- Comparison: p=0.011

**Conclusion:** Post-op nasal bleeding is **less** for balloon dilation versus FESS.
Conclusion: Recovery time and duration of Rx pain medications are **significantly better** for balloon dilation versus FESS.
### Results: Short-Term SNOT-20 (Secondary)

<table>
<thead>
<tr>
<th>Follow-Up Interval</th>
<th>Balloon Dilation (BD)</th>
<th>Control (FESS)</th>
<th>Difference BD-FESS (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>Mean Change ± SD</td>
<td>n</td>
<td>Mean Change ± SD</td>
<td></td>
</tr>
<tr>
<td>1 Week</td>
<td>48</td>
<td>-1.5 +/-0.9</td>
<td>41</td>
<td>-1.0 ± 1.1</td>
</tr>
<tr>
<td></td>
<td>1.5 ± 0.9</td>
<td>40</td>
<td>-1.6 ± 1.0</td>
<td>-0.3</td>
</tr>
<tr>
<td>1 Month</td>
<td>49</td>
<td>-1.7 ± 1.0</td>
<td>40</td>
<td>-0.5, -0.1</td>
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<tr>
<td></td>
<td>-1.7 ± 1.0</td>
<td></td>
<td>0.014</td>
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</tr>
</tbody>
</table>

**Conclusion:** Short-term symptom improvement is **significantly better** for balloon dilation versus FESS.
Secondary Study Endpoints

- **Complications:**
  - No complications occurred in balloon dilation arm or FESS arm

- **Revision Surgeries:**
  - Balloon dilation: 2% (1 patient)
  - FESS: 2.4% (1 patient)
## Results: Subgroup Analyses (SNOT-20)

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Balloon Dilation</th>
<th>Control (FESS)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean Change ± SD</td>
<td>n</td>
</tr>
<tr>
<td>Diseased Sinuses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maxillary only</td>
<td>30</td>
<td>-1.6 ± 1.1</td>
<td>25</td>
</tr>
<tr>
<td>Maxillary &amp; anterior ethmoid</td>
<td>18</td>
<td>-1.7 ± 1.0</td>
<td>16</td>
</tr>
<tr>
<td>Accessory Ostium</td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>17</td>
<td>-1.8 ± 1.4</td>
<td>9</td>
</tr>
<tr>
<td>No</td>
<td>31</td>
<td>-1.6 ± 0.9</td>
<td>32</td>
</tr>
<tr>
<td>Septal Deviation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>28</td>
<td>-1.7 ± 1.2</td>
<td>24</td>
</tr>
<tr>
<td>No</td>
<td>20</td>
<td>-1.7 ± 1.0</td>
<td>17</td>
</tr>
<tr>
<td>Chronic Rhinosinusitis Diagnosis</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>CRS</td>
<td>32</td>
<td>-1.7 ± 1.1</td>
<td>28</td>
</tr>
<tr>
<td>RARS</td>
<td>16</td>
<td>-1.6 ± 1.1</td>
<td>13</td>
</tr>
</tbody>
</table>

Conclusion: Results are similar within and between study arms for all subgroups.
• Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial with 1-year follow-up (Am. J Rhinol Allergy)
Nadim Bikhazi, MD¹, Joshua Light, MD², Theodore Truitt, MD³, Michael Schwartz, MD⁴, Jeffrey Cutler, MD⁵ and for the REMODEL Study Investigators

- 1 year data that balloon sinuplasty was non-inferior to FESS for reductions in sinusitis (decrease in sinusitis episodes 4.2/3.5)

- Improvements in daily activity and overall work productivity in both

- Revision surgery rates 2% in both groups
Conclusions

• **Standalone balloon dilation** and **FESS** are both **safe** and **effective** treatments for treating medically refractory uncomplicated rhinosinusitis in the maxillary/anterior ethmoid sinuses.

• Post-operative debridement after balloon dilation is **lower** versus FESS (p<.05).

• Balloon dilation recovery outcomes are **better** versus FESS (p<.05):
  - Frequency of nasal bleeding
  - Duration of Rx pain medication
  - Time to return to normal daily activities
  - Short-term and Long-term symptom improvement
Clinical Data Overview
Conclusion: Revision rates for standalone and hybrid balloon procedures are within the ranges for FESS.
Symptomatic Improvement (SNOT 20) Through 2 Years

- Sustained statistically significant (p<0.0001) & clinically meaningful (Δ ≥ 0.8) improvement
- Patients treated in the office [19] reported an average pain of 2.7 (0=no pain; 10=severe).
- Sinus symptoms improved approximately 70%.
- Approximately 92% of patients were satisfied with the balloon procedure.
- **Patients with maxillary and anterior ethmoid disease improved as much as those with only maxillary disease.**
Post-Op Healthcare Utilization (Rhinosinusitis Symptom Inventory)

- Statistically significant ($p<0.0001$) reduction in number of MD/nurse visits due to nasal problems for CRS and RARS patients
- Statistically significant ($p \leq 0.001$) reduction in antibiotic use for CRS and RARS patients

**Average No. MD/Nurse Visits for Nasal Problems**

- Pre-Op: 1-Yr interval before procedure
- Post-Op: 1-Yr interval after procedure

**Average No. of Antibiotic Courses**

- Pre-Op: 1-Yr interval before procedure
- Post-Op: 1-Yr interval after procedure

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In-office standalone balloon dilation in adults with chronic or recurrent acute rhinosinusitis: a prospective, multi-institutional study with 1-year follow-ups. Publication pending.
Summary of Balloon Dilation Results

- Proven safety in OR and in office-setting
- Well-tolerated by patients using local anesthesia only
- High rate of technical success (access and dilate targeted ostia)
- Durable improvement in sinus symptoms through minimum of 2 years that is both significant and meaningful (SNOT 20)
- Demonstrated low rate of revision sinus surgery in range acceptable for ESS
- High rate of patient satisfaction
- Significant reduction in post-operative health care utilization

Data and references included on previous slides.
**Recurrent Sinusitis**

- Spikes of sinusitis resolving in between
- May respond to medical therapy during each episode of symptoms
- Patient/physician is frustrated with the cycle of infections and medications

**Chronic Sinusitis**

- Patients who have continual sinusitis symptoms despite lengthy rounds of medication
- Patients for office based balloon treatments:
  - Co-morbidities that prevent surgery
  - Those who are opposed to traditional sinus surgery
Comparing Balloon Sinus Dilation/Endoscopic Sinus Surgery

Why consider in-office balloon sinus dilation vs. endoscopic sinus surgery?

• Convenient in-office procedure
• Quick recovery
• May reduce healthcare costs

BALLOON SINUS DILATION VS ENDOSCOPIC SINUS SURGERY

<table>
<thead>
<tr>
<th></th>
<th>BALLOON</th>
<th>FESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptom Improvement After Six Months</td>
<td>66%</td>
<td>63%</td>
</tr>
<tr>
<td>Symptom Improvement After One Week</td>
<td>59%</td>
<td>38%</td>
</tr>
<tr>
<td>Days Prescription Pain Medicine Needed</td>
<td>&lt;1</td>
<td>2.8</td>
</tr>
<tr>
<td>Days to Return to Normal Activity</td>
<td>1.6</td>
<td>4.8</td>
</tr>
<tr>
<td>Require Follow-Up Debridements*</td>
<td>8%</td>
<td>74%</td>
</tr>
</tbody>
</table>

5 2013 National Average Cost to Medicare for FESS using CPT 31254-50, 31256-50, 31237-50:
   ASC Procedure Surgeon fee of $563 + Anesthesiologist fee of $408 + ASC payment of $2,843 + bilateral post-op debridement fee of $504
   HOPD Procedure Surgeon fee of $563 + Anesthesiologist fee of $408 + HOPD payment of $5,068 + bilateral post-op debridement fee of $504
2013 National Average Cost to Medicare for Office Procedure using CPT 31295-50, 31231:
   Office Procedure Surgeon fee of $3,345 + bilateral post-op nasal endoscopy fee of $219
   Medicare office reimbursement fee covers all costs to perform a procedure performed in the office setting (supplies, equipment, labor, time & overhead)
   Medicare shows the unilateral rate on their website and the bilateral rate is calculated based on the 50% rule for multiple procedures.