Overview

- Overview of the technology
- Safety studies and clinical trials
- The buzz…
- Where will this fit in?
- Conclusion
Overview of the Technology

- Balloon dilation catheters similar to angioplasty

Overview of the Technology

- Endoscopic placement of guiding sheath
Overview of the Technology

- Seldinger technique - thread balloon over guide wire

Overview of the Technology

- Dilation balloon threaded over wire into sinus
Overview of the Technology

• Balloon inflated with dye for visualization

Overview of the Technology

• Lateral view of dilation
Safety Studies

3 Initial Studies performed
1. In lab **cadaver** study
2. Single site **patient** study – initial 10 patients
3. Multisite **patient** study – 115 patients

Safety and Feasibility Study #1 - Design

- Feasibility, mechanics, evaluation
  - endoscopy, CT, dissection
  - 12 cadaver heads used
  - 9 max, 11 sph 11 frontal
- All attempted sinuses cannulated
- No damage to surrounding structures
  - orbital bone / skull base / carotid / optic nerve
- CT dilated osteum size comparable to balloon size
- Achieved expected results
- Appropriate to proceed with patient study

Bolger AJR 2006
Safety and Feasibility Study #2

- Initial determination of safety in patients
- End points - catheterize sinus, dilate osteum, safety
- Inclusion - Failed medical therapy for sinusitis
- Exclusion - Nasal polyps, osteoneogenesis, previous surgery
- Maxillary, frontal, sphenoid only

<table>
<thead>
<tr>
<th>Maxillary</th>
<th>Sphenoid</th>
<th>Frontal</th>
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</thead>
<tbody>
<tr>
<td>10 / 10 *</td>
<td>5 / 5</td>
<td>3 / 3</td>
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Successful cannulation and dilatation

No complications

* 6 hybrid procedures

Brown Annals ORL 2006

Safety and Feasibility Study #3

- Multi-site study, 10 investigators, safety / feasibility
- Endpoints
  - Any complication
  - Osteal patency at 1, 12, 24 weeks by endoscopy
  - Evaluate patients using patient questionnaire (SNOT-20)

- 115 patients enrolled
- 356 sinuses dilated
- 45% sinuplasty only, 55% hybrid procedures
- No procedure related complications
- 7 balloon ruptures, 4 kinked catheter tips, 1 slow deflation

Bolger Oto-HNS 2007
Safety and Feasibility Study #3 - Results

<table>
<thead>
<tr>
<th>Week</th>
<th>Patent</th>
<th>Non-Patent</th>
<th>Indeterminate</th>
<th>F/U</th>
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<tbody>
<tr>
<td>24</td>
<td>82.8%</td>
<td>.80%</td>
<td>16.4%</td>
<td>79%</td>
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<table>
<thead>
<tr>
<th>Visit</th>
<th>Average Score</th>
<th>Difference from Baseline</th>
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<tbody>
<tr>
<td>QOL Score</td>
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<td></td>
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<tr>
<td>Baseline</td>
<td>2.20</td>
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<tr>
<td>Week 1</td>
<td>1.41</td>
<td>0.80</td>
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<tr>
<td>Week 12</td>
<td>1.07</td>
<td>1.13</td>
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<tr>
<td>Week 24</td>
<td>1.38</td>
<td>0.82</td>
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</table>

Safety and Feasibility Study #3

- Appears that sinus dilation using guide wire technology with fluoroscopy guidance is feasible and it appears to be safe
- Sinus osteum patency is >83%
  - Some sinus ostea not visualized on office endoscopy may be patent (16%)
- Patients realized improvement in QOL scores, though it is difficult to say to what degree this is related to sinuplasty

Bolger Oto-HNS 2007
1 and 2 year follow up studies

- 92% patency at 1 year  
  - Direct visualization 85%  
  - CT, additional 7%  

- Results maintained at 2 years  

Radiation Exposure

- Median radiation  
  - Average 3.1 sinuses per patient  
  - Fluoro time per sinus: 0.81 minutes  
  - Mean dose per patient: 730 mrem

- Head CT scan: 200 mrem  
- Natural background: 300 mrem  
- Chest CT: 800 mrem  
- Coronary angiogram: 460-1580 mrem  
- Angioplasty: 750-5,700 mrem
Need for Fluoroscopy?

• Techniques being developed to eliminate need for intraoperative fluoro

• Use of light wand to transilluminate sinuses

• Use of image guidance to navigate

• Dilation with endoscope only  Citardi ARS 2007

Other Balloon Dilation methods

• Transantral dilation of maxillary sinus  Stankiewicz 2009
  – Local or local with IVS
  – 95% patency at 3 months by CT
  – 95% completion rate

• Dilation of frontal sinus with Fogarty  Lanza 1994

• Dilation of frontal sinus with DCR balloon  Luong 2008
Reported Complications in Early Experience

- One report of CSF leak  
  Stringer ARS 2007

- FDA Website  
  http://www.fda.gov/cder/aers/default.htm

- One report of contrast in the “left lower quadrant of the eye” after balloon rupture
- One report of orbital entry with guidewire
- One other report of CSF leak reviewed by independent Otolaryngologist not seen as related to balloon sinuplasty

Comparison of Pain with FESS

- Patients undergoing FESS or Sinuplasty
  - Less pain with Sinuplasty in week following surgery
  - Use of pain medicine more in FESS patients
  - Return to normal activity 2 days longer in FESS

Vaughn and Wynn AAOHNS 2006
The Controversy…

"This is a wonderful, wonderful advantageous technology for patients," said Dr. Peter Catalano of the Lahey Clinic in Burlington, Mass.

- ABC World News Tonight, 4/6/06

"It allows for no incisions or cutting. There's no bruising or swelling," said Dr. Howard Levine of the Cleveland Nasal/Sinus Center.

- ABC World News Tonight, 4/6/06

The Controversy…

“It’s really the most exciting thing that’s happened in our specialty in probably 15 years.”

- Dr. Michael Friedman, Associated Press, 4/10/06

“How well does it work? There’s no research to tell,” Even Kennedy acknowledges that sinuplasty, with less pain and scar tissue, may prove useful for milder sinusitis cases or to buy time for people hoping to postpone surgery.

- Dr. David W. Kennedy Associated Press, 4/10/06
ARS Position Statement - September 2006

• … may have some potential application …
• … limited surgical indications …
• The majority of patients … may still require conventional ESS
• In a small group of very selected patients … may eliminate the need for other surgical techniques.

AAOHNNS coding position - March 19, 2007

Use of existing codes for endoscopic sinus surgery are appropriate if:

• A sinus endoscope is used to position the balloon prior to and during the cannulation of the ostia and confirming the dilatation with the balloon
• Bone and mucosa must be moved in such a fashion to significantly enlarge the ostia of the sinus addressed
Based on currently available scientific medical evidence, endoscopic balloon dilation technology is acceptable and safe …

Endoscopic balloon dilation technology is a tool, not a procedure, available to the operating surgeon at his/her discretion for the surgical management of sinus disease.

Patients … may require concurrent conventional endoscopic sinus surgery especially in the ethmoid sinuses …

In a group of selected patients … dilation alone may eliminate the need for other surgical techniques.

Endoscopic balloon catheter dilation … is not investigational or experimental and should not be viewed as such.

Position Statement removed from Website
ARS position statement is “no longer consistent with AMA CPT Editorial Panel”

Announcement
– As of January 20, 2010, Acclarent, Inc. will operate as a business unit of Ethicon, Inc., a J & J company

Just in time?
Future opportunities and obstacles

• Opportunities
  – Desire to reduce morbidity, debridements
  – Ability to advertize “newest technology”

• Obstacles
  – Need for fluoroscopic guidance or illumination
  – Hospital resistance to investment
  – Uncertain reimbursement

Resistance from insurance companies/hospitals

• Empire Blue Cross
  – Investigational/Not Medically Necessary:
    The use of balloon sinuplasty for the treatment of *any* sinus condition, including, but not limited to sinusitis, is considered investigational/not medically necessary.
Resistance from insurance companies/hospitals

Blue Cross/Blue Shield of Florida

POSITION STATEMENT:
…experimental or investigational. No studies have been published in the peer-reviewed literature addressing safety, efficacy, and long-term outcomes of balloon sinuplasty.

BILLING/CODING INFORMATION:
There is no specific CPT code to report balloon sinuplasty.

HCPCS Coding
S2344 Nasal/sinus endoscopy, surgical; with enlargement of sinus ostium opening using inflatable device (i.e., balloon sinuplasty)

ICD-9 Diagnoses Codes That Support Medical Necessity
All diagnoses for balloon sinuplasty are considered investigational.

Resistance from insurance companies/hospitals

• Blue Cross/Blue Shield of Tennesee

The cost of a balloon sinuplasty may range from $5,000 to $10,000 or more.

*The cost may or may not be covered by insurance*
Is it being used???

• >2000 US physicians trained
• >500 international physicians trained
• Sales numbers from Acclarent, Inc estimate 10s of thousands of patients treated

Where will this fit in?
Where does balloon dilation fit it?

- Single osteum sinuses
  - Frontal, Maxillary, Sphenoid
- All appear to have persistent dilation
- All appear to be safe

Maxillary Sinus?

- Not a difficult sinus to perform antrostomy
- Takedown of uncinate helpful in ethmoid surgery
- Larger antrostomy helpful in orientation to orbital floor, medial orbital wall, posterior maxillary sinus wall
- Perhaps as a less invasive option for isolated maxillary sinus disease
Sphenoid Sinus?

• Sphenoid sinusotomy rarely needed
• Sphenoid sinus pathology that needs surgery often requires a larger opening
  – Hyperplastic disease
  – mycetoma

Frontal Sinus?

• Minimally invasive approach to technically challenging sinus
• May be helpful for experienced and less experienced surgeons to avoid iatrogenic stenosis
• Light wand is an effective tool to localize in the frontal sinus without fluoroscopy
Conclusion

• Balloon Sinuplasty appears to be safe for dilation of the maxillary, frontal, and sphenoid sinuses

• The absence of a treatment for the ethmoid sinus necessitates hybrid procedures for most patients who undergo sinus surgery

• It has yet to be determined where this technology will ultimately fit into our treatment algorithm

• Reimbursement uncertainties and cost may hinder continued acceptance of this technology