Balloon Sinuplasty™ Technology

Presenter’s information place here
Balloon Sinuplasty™ Technology
Further Evolving Sinus Surgery

- The Relieva Balloon Sinuplasty™ devices are endoscopic tools and may be used with other medical therapies or FESS techniques.
Marry Endoscopic Techniques with New Technologies

Advancements In Surgical Devices Continues

- **Relieva Balloon Sinuplasty™ devices**
  - Designed for customized access
    - Sinus Guidewire
    - Sinus Guide Catheter
  - Engineered for sinus dilation
    - Sinus Balloon Catheter
  - Developed for controlled inflation
    - Sinus Balloon Inflation Device
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 Relieva™ Sinus Balloon Catheter

Sinus Guide Catheter
Access under endoscopic guidance

Sinus Guidewire
Sinus Balloon Catheter
Sinus Guide Catheter

Images provided by Frederick Kuhn, MD
Step Two – Fluoroscopic view

Relieva™ Sinus Balloon Catheter inflated to gently remodel the ostium

Images provided by Frederick Kuhn, MD
Step Three
Deflate and remove the Relieva Balloon Sinuplasty™ devices

Frontal Sinus Dilation
Final endoscopic image

Frontal sinus
Post-procedure CT scan

Images provided by Frederick Kuhn, MD
Balloon Sinuplasty™: A Clinical Review

Catheter-Based Dilation of the Sinus Ostia: Initial Safety & Feasibility Analysis in a Cadaver Model

William Bolger, MD, F.A.C.S.
Bethesda, MD

Winston Vaughan, MD
Palo Alto, CA
Catheter-based Dilation of the Sinus Ostia
Initial Safety and Feasibility Analysis in a Cadaver Model

☐ Study objective
   ■ Explore safety and feasibility of catheter-based technology to relieve sinus ostial obstruction

☐ Primary end points
   ■ Success or failure of ostial dilation
   ■ Absence or presence of adverse effects associated with balloon dilatation

Catheter-based Dilation of the Sinus Ostia
Initial Safety and Feasibility Analysis in a Cadaver Model

Methods

- Sinuses dilated in 6 cadaver specimens
  - 7mm Relieva Sinus Catheter, 16 atm

- Multi-angled endoscopy & CT scans
  - Comprehensive CT protocol
  - Performed before and after sinus balloon dilation

- Gross anatomic dissection for any evidence of catheter-induced trauma

Relieva™ Sinus Guide Catheter
Relieva™ 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
Catheter-based Dilation of the Sinus Ostia
Initial Safety and Feasibility Analysis in a Cadaver Model

- Results
  - Procedural success and feasibility
    - The devices easily cannulated and dilated the sinus ostia
      - 9 maxillary
      - 11 sphenoid
      - 11 frontal
  - Sinus dilatation was successful in all 31 sinuses
  - Endoscopy and CT scans showed the dilated sinus ostia size achieved was comparable to the maximum balloon diameter

Catheter-based Dilation of the Sinus Ostia
Initial Safety and Feasibility Analysis in a Cadaver Model

- Results
  - Device safety
    - No trauma to surrounding “vital structures” by CT scan, endoscopy, and gross anatomical dissection
    - Mucosal trauma imparted by catheter dilation appeared to be much less than that seen with standard endoscopic instruments

Safety & Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia: A Preliminary Investigation

William Bolger, MD, F.A.C.S.
Bethesda, MD

Christopher Brown, MD
Melbourne, Australia

Catheter-Based Dilation of the Sinus Ostia: Initial Safety & Feasibility Analysis in a Cadaver Model
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

- **Methods**
  - Ethics committee approval
  - Maximum of 2 sinus dilations / patient per protocol
  - ‘Hybrid’ allowed per surgeon’s discretion
  - Sinus dilation was conducted in 10 patients
    - Endoscopy and CT performed
    - Fluoroscopic verification of balloon position

- **Inclusion criteria**
  - Medical therapy for chronic rhinosinusitis had failed
  - FESS candidate

- **Exclusion criteria**
  - < 18 years old
  - Pregnant or at risk of pregnancy
  - Cystic fibrosis
  - Prior sinus surgery
  - Significant nasal polyposis / osteoneogenesis

Safety and Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia

<table>
<thead>
<tr>
<th></th>
<th>Maxillary</th>
<th>Sphenoid</th>
<th>Frontal</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 sinuses targeted</td>
<td>10</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Successful cannulation &amp; dilatation</td>
<td>10/10</td>
<td>5/5</td>
<td>3/3</td>
</tr>
<tr>
<td>Balloon diameters (mm)</td>
<td>5, 7</td>
<td>5, 7</td>
<td>5</td>
</tr>
<tr>
<td>Mean Inflation pressure (atm)</td>
<td>13</td>
<td></td>
<td>10 - 16</td>
</tr>
<tr>
<td>Fluoro time / patient (mins)</td>
<td>9:18</td>
<td></td>
<td>3:15 – 17:29</td>
</tr>
</tbody>
</table>

Safety and Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia

Right Sphenoid Sinus - Patient

2-weeks Post-op

6-weeks Post-op

Safety and Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia

- Results
  - Procedural success
    - Sinus dilatation was successful in all 18 treated sinuses
      - 100% procedural success
  - Procedural safety
    - High degree of mucosal preservation, minimal blood loss
    - No complications occurred at 1 and 6 weeks and all subsequent follow-up visits

Initial Safety & Feasibility Analysis in a Cadaver Model

Safety & Feasibility of Balloon Catheter Dilation of Paranasal Sinus Ostia: A Preliminary Investigation

Clinical Evaluation to Confirm Safety & Efficacy of Sinuplasty in the Paranasal Sinuses (CLEAR)

William Bolger, MD
Bethesda, MD

Christopher Brown, MD
Melbourne, Australia

Christopher Church, MD
Loma Linda, CA

Andrew Goldberg, MD
San Francisco, CA

Boris Karanfilov, MD
Columbus, OH

Frederick Kuhn, MD
Savannah, GA

Howard Levine, MD
Cleveland, OH

Michael Sillers, MD
Birmingham, AL

Winston Vaughan, MD
Palo Alto, CA

Andrew Goldberg, MD
San Francisco, CA

Boris Karanfilov, MD
Columbus, OH

Frederick Kuhn, MD
Savannah, GA

Howard Levine, MD
Cleveland, OH

Michael Sillers, MD
Birmingham, AL

Winston Vaughan, MD
Palo Alto, CA
CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)

- A multi-center, non-randomized, prospective evaluation of 115 patients/358 sinuses treated with balloon dilation

- Study objectives
  - Confirm safety in a larger patient cohort
  - Evaluate efficacy of balloon catheter dilation in achieving and maintaining sinus ostia patency
  - Gain insight into balloon catheter technology to relieve patient’s symptoms

As reported at the AAO-HNS Annual Meeting 2006
CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)

- **Site selection**
  - 9 sites - US and Australia
  - Independent IRB-approvals

- **Study design**
  - Safety
    - Assessed by the rate of adverse events
  - Efficacy
    - Ability to cannulate and dilate ostia
    - Endoscopic patency examination: 1, 12, 24 weeks
  - QOL / Patient outcomes
    - SNOT-20: Baseline, 1, 12, 24 weeks
    - Standardized patient questionnaire: 1, 12, 24 weeks

As reported at the AAO-HNS Annual Meeting 2006
CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)

Methods

- A prospective, multi-center, non-randomized evaluation was conducted in patients with chronic sinusitis.

- Patients for whom endoscopic sinus surgery was recommended were offered treatment with the balloon catheter devices.

- Balloon instrumentation used for maxillary, frontal, sphenoid sinuses at discretion of the investigator.

- Ethmoid treated with current endoscopic forceps and microdebrider concurrently if indicated.

As reported at the AAO-HNS Annual Meeting 2006.
Clinical Evaluation to Confirm Safety & Efficacy of Sinuplasty in the Paranasal Sinuses (CLEAR)

- **Inclusion Criteria**
  - 18 years of age or older
  - Diagnosed with chronic sinusitis that is not responsive to medical management.
  - Planned endoscopic sinus surgery (recommended by physician and consented to by patient)

- **Exclusion Criteria**
  - Extensive sinonasal polyps
  - Previous extensive sinonasal surgery
  - Extensive sinonasal osteoneogenesis
  - Diagnosed with Sampter’s Triad
  - Sinonasal tumors or other obstructive lesions
  - History of facial trauma that distorts sinus anatomy and precludes access to the sinus ostium
  - Ciliary dysfunction
  - Cystic fibrosis
  - The patient is pregnant

As reported at the AAO-HNS Annual Meeting 2006
CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)

- Patient Demographics & Flow
  - Age: Average = 47.8 years (range of 21-76)
  - Gender: 41 male, 74 female
  - Patients with a history of prior FESS: 21 patients (18.3%)

- ENTERED STUDY
  - 115 patients / 358 sinuses

- SUCCESSFULLY TREATED
  - 109 patients / 342 sinuses
  - 1 sinus exited (personal decision)

- 24 WK. FOLLOW-UP COMPLETED
  - 95 patients / 307 sinuses (90%)

As reported at the AAO-HNS Annual Meeting 2006
The CLEAR Study

- Results Summary
  - Safety
    - No serious adverse events occurred during study
  - Efficacy
    - Overall patency at 24-weeks - 81%
    - Observed patency at 24-weeks - 98%
  - Patient outcomes
    - SNOT-20 scores demonstrated clinically and statistically significant difference from baseline at all time points

As reported at the AAO-HNS Annual Meeting 2006
CLinical Evaluation to Confirm SAffety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)

Observed Ostial Patentcy Rate
Out to 24 weeks

<table>
<thead>
<tr>
<th></th>
<th>24 weeks</th>
<th>12 weeks</th>
<th>1 week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-patent</td>
<td>3%</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>Patent</td>
<td>97%</td>
<td>97%</td>
<td>98%</td>
</tr>
</tbody>
</table>

Observed patency: Patency rate of the ostia technically able to be visualized endoscopically

As reported at the AAO-HNS Annual Meeting 2006
CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)

SNOT-20

*p<.0001

Clinically^1 and statistically significant difference demonstrated at all time points.


As reported at the AAO-HNS Annual Meeting 2006
### Type of Event

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

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

As reported at the AAO-HNS Annual Meeting 2006
CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR)

- Additional study data
  - 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)
  - Annual natural background radiation in the US (300 mrem)
  - Chest CT (800 mrem)
  - Coronary angiogram (460-1580 mrem)
  - Angioplasty (750-5,700 mrem)

As reported at the AAO-HNS Annual Meeting 2006
Clinical Evaluation to Confirm Safety & Efficacy of Sinuplasty 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

As reported at the AAO-HNS Annual Meeting 2006
Clinical Evaluation to Confirm Safety & Efficacy of Sinuplasty in the Paranasal Sinuses (CLEAR)

Balloon Sinuplasty™ Case Experience
Frederick A. Kuhn, MD, FACS, FARS

As reported at the AAO-HNS Annual Meeting 2005
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

As reported at the AAO-HNS Annual Meeting 2005
Case Study: Right frontal sinus
Relieva™ Sinus Balloon Catheter

As reported at the AAO-HNS Annual Meeting 2005
Case Study: Right frontal sinus

- Relieva™ Sinus Guidewire & un-inflated sinus balloon placement

As reported at the AAO-HNS Annual Meeting 2005
Case Study: Right frontal sinus
10 weeks post-op

As reported at the AAO-HNS Annual Meeting 2005
Catheter-Based Dilation of the Sinus Ostia: Initial Safety & Feasibility Analysis in a Cadaver Model

Safety & Feasibility of Balloon Catheter Dilatation of Paranasal Sinus Ostia: A Preliminary Investigation (CLEAR)

Clinical Evaluation to Confirm SAFety & Efficacy of Sinuplasty in the PaRanasal Sinuses

Postoperative Recovery: FESS with Balloon Sinuplasty™ Devices

Winston Vaughan, MD
Palo Alto, CA

Rhoda Wynn, MD
Palo Alto, CA
Post-Operative Recovery after FESS with Balloon Sinuplasty™ Devices

- **Study Goal**
  - To assess post-operative pain, usage of analgesics, epistaxis and length of time to return to regular activity for patients undergoing FESS with the Balloon Sinuplasty™ devices vs. conventional cutting instrumentation

- **Study Results**
  - Patients with comparably-matched sinus disease undergoing sinus surgery with the balloon sinuplasty device reported less pain as measured by change scores during the first week after surgery compared to those undergoing conventional FESS
  - *Balloon Sinuplasty™* device patients required narcotic pain medication for shorter periods during the post-operative period and many required none.
  - *Balloon Sinuplasty™* patients needed an average of a little more than two days less time to return to full activity compared to conventional FESS.

As reported at the AAO-HNS Annual Meeting 2006
Catheter-Based Dilation of the Sinus Ostia: Initial Safety & Feasibility Analysis in a Cadaver Model

Safety & Feasibility of Balloon Catheter Dilation of Paranasal Sinus Ostia: A Preliminary Investigation

CLinical Evaluation to Confirm SAfety & Efficacy of Sinuplasty in the Paranasal Sinuses (CLEAR)

Postoperative Recovery: FESS with Balloon Sinuplasty™ Devices

Functional Endoscopic Dilatation of the Sinuses: Quality of Life, Pt Satisfaction, Postoperative Pain, and Cost

Michael Friedman, MD
Chicago, IL

Paul Schalch, MD
Irvine, CA
Functional Endoscopic Dilatation of the Sinuses (FEDS): QOL, Patient Satisfaction, Postoperative Pain, and Cost

☐ Study Goal

- Compare a group of patients treated with Balloon Sinuplasty™ devices to similar group who underwent classical FESS:
  - Short-term postoperative quality of life improvement
  - Patient satisfaction with the procedure
  - Post-op narcotic usage
  - Cost of procedures

As reported at the AAO-HNS Annual Meeting 2006
Functional Endoscopic Dilatation of the Sinuses (FEDS): QOL, Patient Satisfaction, Postoperative Pain, and Cost

Results

- FEDS patients reported a significantly improved post-op QOL compared to FESS patients.
- FEDS had favorable results when compared to FESS regarding patient satisfaction and post-op narcotics usage.
- Cost was no different for primary procedures, but significantly lower for FEDS in revision cases.
- Although long-term clinical results are needed, FEDS devices compare favorably to conventional FESS in short-term QOL, patient satisfaction and cost.

As reported at the AAO-HNS Annual Meeting 2006
Clinical Program Summary

- The Balloon Sinuplasty™ technology has undergone vigorous development and clinical validation.
- The technology is shown to be safe, effective and a viable alternative for widening ostia currently targeted for classic FESS instrumentation.
  - One-year follow-up on CLEAR patients is ongoing.
- Clinical assessment ongoing through surgeon initiated trials.
- Surgeon training and patient care continues to expand.