Case Study:
Mechanisms of Action for Balloon Dilation of the Ostiomeatal Unit (OMU) in Patients with Chronic Rhinosinusitis

Jim Atkins, M.D.
Texas Sinus Center
San Antonio, TX
Financial Disclosures

- Paid Consultant: Entellus Medical, Inc. (Scientific Advisory Board)
- Stock Shareholder: Entellus Medical, Inc.
Background

- FinESS released April 2008
- “How are you getting any benefit just dilating the ostia?”
- Ostial dilation is not the only component of the procedure
- Infundibular remodeling is also a large component

How Did We Know This?

- Intra and postoperative visualization of the medialized uncinate
- Intra-operative inspection of the infundibulum
Goal and Methodology

**Goal**
- To radiographically quantify the magnitude of the remodeling

**Methodology**
- Xoran MiniCAT™ CT; 0.4-mm slice spacing
- Visually and digitally aligned the pre/post op CT scans
- Three locations in the infundibulum were selected and compared pre and post op
- Cross-sectional area at each location was calculated using commercial software\(^1\)

\(^1\) *Universal Desktop Ruler v3.2.3231 – Evaluation Version.*
Methodology

Case Study

- 53-Year Old Female
- Bilateral FinESS™ in Nov. 2007
- 5mm Balloon
- Local Anesthesia with IV Sedation

Follow-Up

- CT Scan : 1 Month
- SNOT-20 Qol:
  - Baseline = 2.5
  - 6-Mo. = 1.5
  - 12-Mo. = 1.0
Methodology

Pre-Procedure CT: Left Maxillary Sinus & OMU

OMU Position #1
- Anterior, inferior slice (i.e. anterior maxillary ostium)
- Coronal and axial measurements

OMU Position #2
- 4 slices (1.6 mm) Superior from #1
- 4 slices (1.6 mm) Posterior from #1
- Coronal and axial measurements

OMU Position #3
- 8 slices (3.2 mm) Superior from #1
- 8 slices (3.2 mm) Posterior from #2
- Coronal and axial measurements
### Right Side - OMU Position #1

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op</th>
<th>Post Op</th>
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</thead>
<tbody>
<tr>
<td>Cross-Sectional Area</td>
<td>11.4 mm²</td>
<td>20.9 mm²</td>
</tr>
<tr>
<td>Cross-Sectional Area</td>
<td>9.3 mm²</td>
<td>25.4 mm²</td>
</tr>
</tbody>
</table>

> 2X Increase
Left Side - OMU Position #1

Pre-Op

Cross-Sectional Area: 0.0 mm²

Cross-Sectional Area: 0.0 mm²

Post Op

Cross-Sectional Area: 37.3 mm²

Cross-Sectional Area: 37.0 mm²
Average Results Over 3 Different Locations

Right (mm$^2$)

<table>
<thead>
<tr>
<th>Location</th>
<th>Pre-Op</th>
<th>Post-op</th>
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<tbody>
<tr>
<td>Coronal</td>
<td>10</td>
<td>20</td>
</tr>
<tr>
<td>Axial</td>
<td>15</td>
<td>25</td>
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Left (mm$^2$)

<table>
<thead>
<tr>
<th>Location</th>
<th>Pre-Op</th>
<th>Post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronal</td>
<td>30</td>
<td>35</td>
</tr>
<tr>
<td>Axial</td>
<td>25</td>
<td>30</td>
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Discussion

- Radiologic –
  
  CT scanning has limitations for visualizing and quantifying changes to the infundibulum after balloon dilation
  
  3-D Imaging may offer a alternative

- Clinically –
  
  2D comparison suggests a 2 fold increase in cross-sectional area within the infundibulum after 5mm balloon dilation.
Conclusion

- Sustained expansion of the infundibulum is identifiable and measurable after FinESS.
- Optimal infundibular size post balloon dilation will need to be determined to assure proper mucociliary flow.
- Sustained expansion combined with uncinate preservation are likely two of the key factors contributing to the success of this procedure.