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# *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

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

# Background

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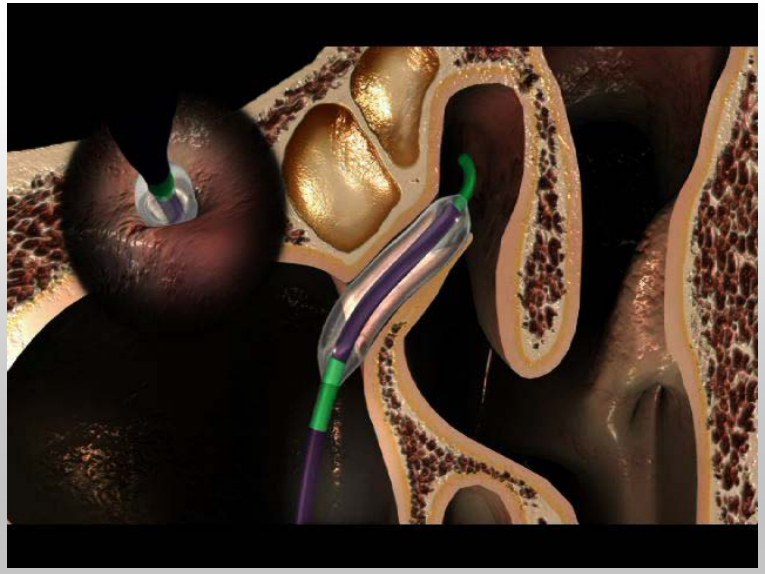
- FinESS released April 2008

- "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

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## 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

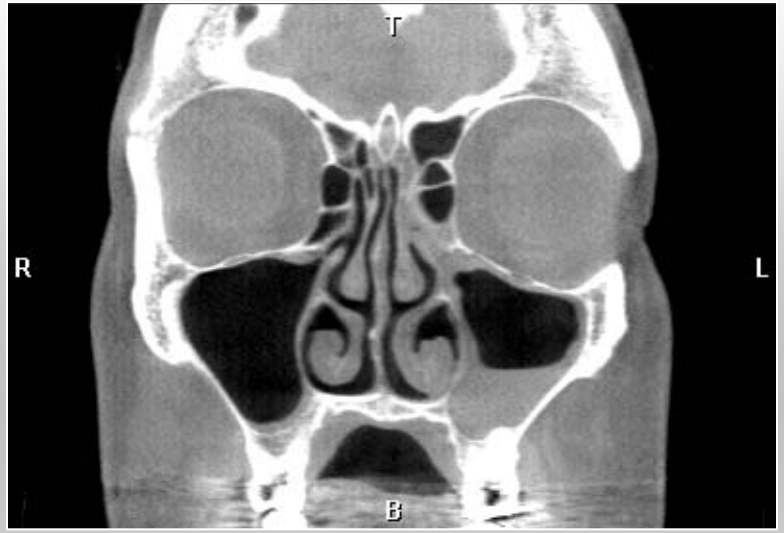
## Case Study

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

## Follow-Up

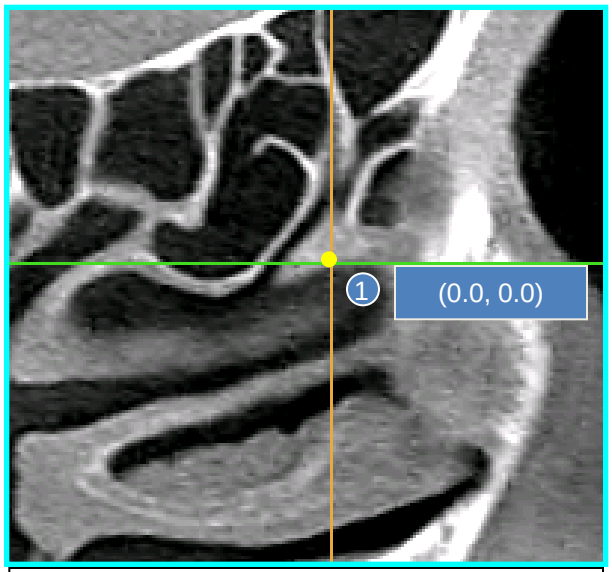
- CT Scan : 1 Month
- SNOT-20 Qol:
  - Baseline = 2.5
  - 6-Mo. = 1.5
  - 12-Mo. = 1.0

## Baseline Evaluation CT Scan



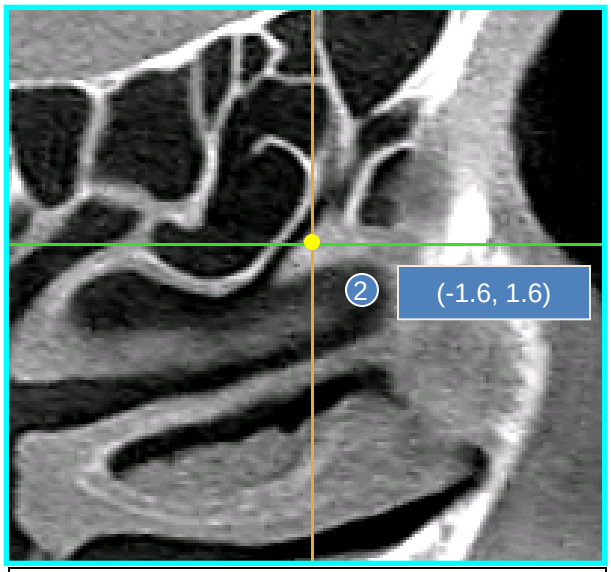
# Methodology

## Pre-Procedure CT: Left Maxillary Sinus & OMU



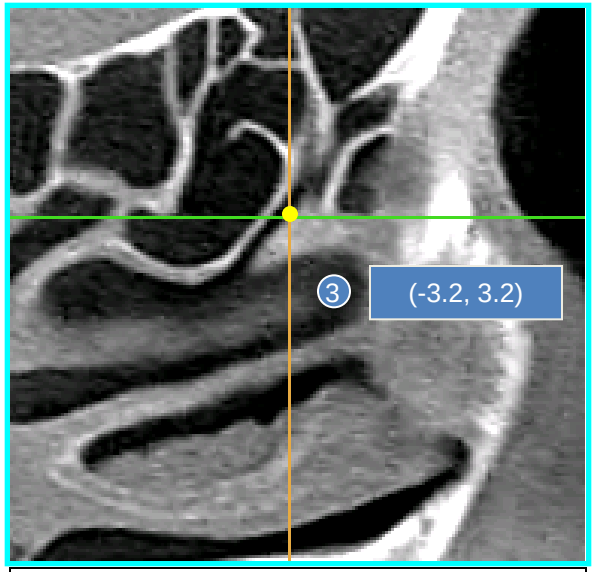

**OMU Position #1**

- 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

Pre-Op

Post Op

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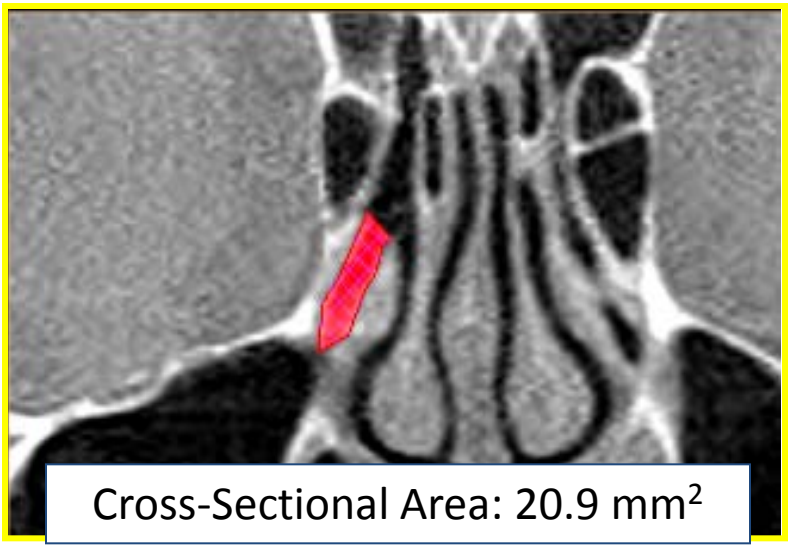
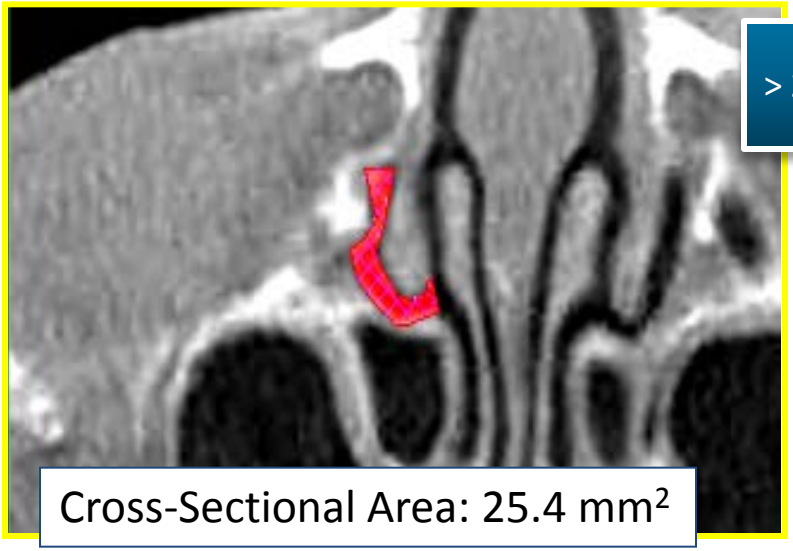
Cross-Sectional Area: 11.4 $mm^2$



Cross-Sectional Area: 20.9 $mm^2$

Cross-Sectional Area: 9.3 $mm^2$



Cross-Sectional Area: 25.4 $mm^2$

> 2X Increase

# Left Side - OMU Position #1

Pre-Op

Post Op

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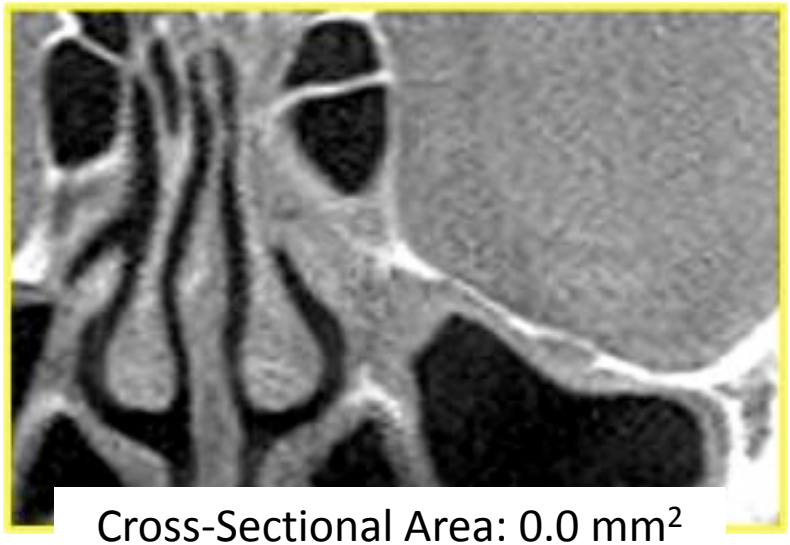
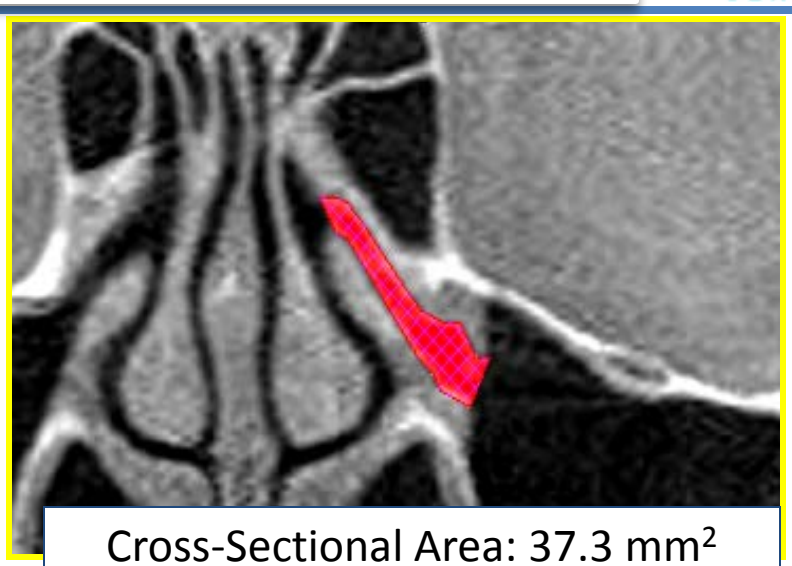
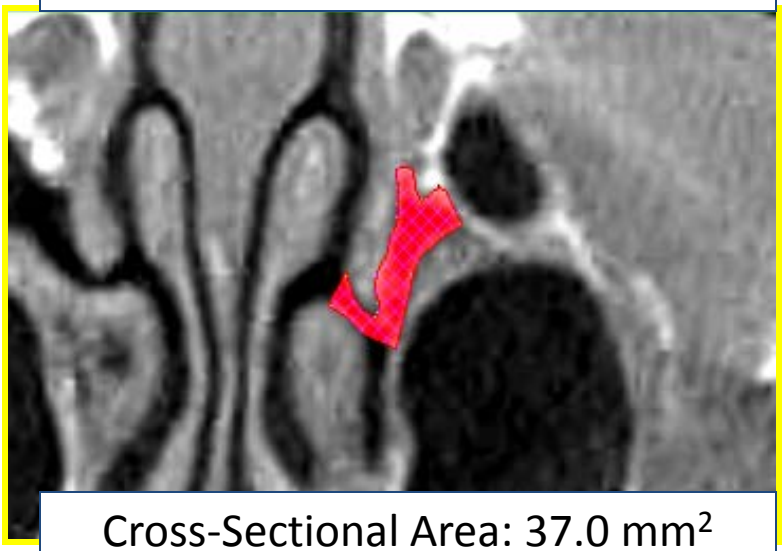


Cross-Sectional Area: 0.0 mm$^2$



Cross-Sectional Area: 37.3 mm$^2$

Cross-Sectional Area: 0.0 mm$^2$



Cross-Sectional Area: 37.0 mm$^2$

# Average Results Over 3 Different Locations

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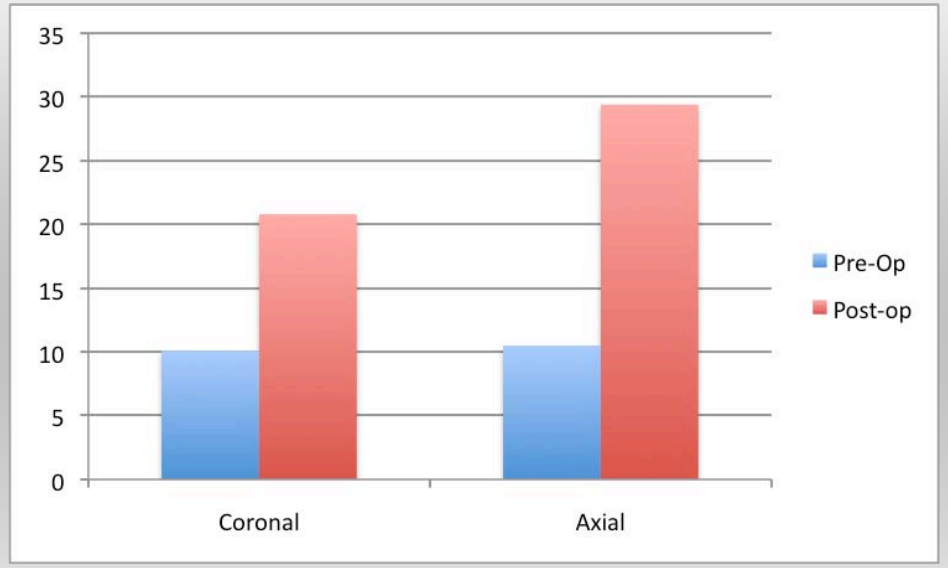
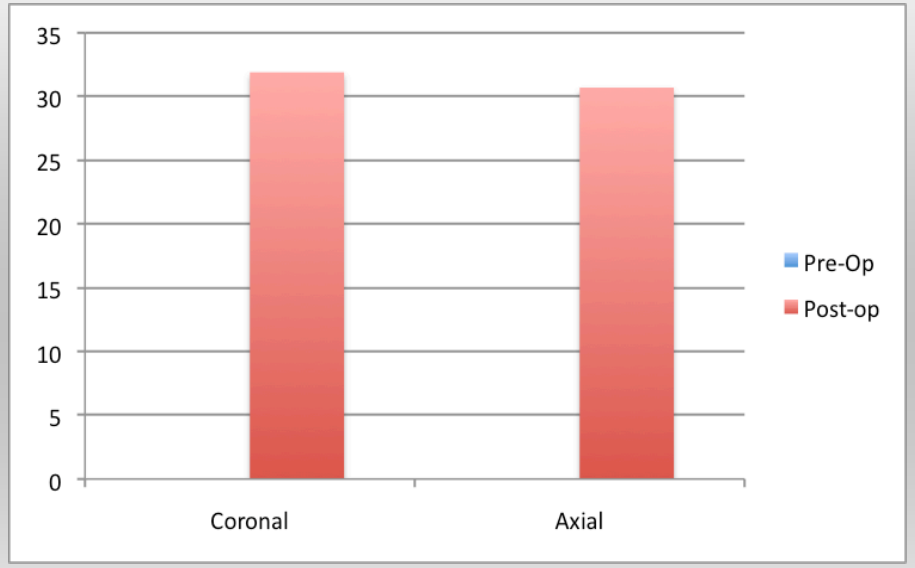
Right ($mm^2$)




Left ($mm^2$)



## Discussion

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- 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

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- 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.