Office-Based Balloon Sinus Dilation
52+ week follow-up of a prospective multicenter study

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## Investigators

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<thead>
<tr>
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<th>Center</th>
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<tbody>
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Disclosure: Acclarent, Inc. (Menlo Park, CA) provided financial and logistic sponsorship for the study, data monitoring and data analysis.
Background

- Balloon Sinus Dilation (BSD) instruments afford the opportunity for office-based sinus procedures in properly selected Chronic Rhinosinusitis (CRS) patients, offering potential advantages over OR-based surgery:
  - Avoidance of general anesthesia
  - Potential for significant cost savings
  - Patient convenience

- We have previously reported 24-week safety & efficacy for a large group of CRS patients refractory to medical therapy who underwent office-based BSD using transnasal instrumentation under local anesthesia.\(^1\)

This report describes 52+ week outcomes following office-based surgery, including outcomes for patients with mild to moderate ethmoid disease who were treated with BSD without ethmoidectomy.

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## Study Design – 52+ Week Follow-Up

<table>
<thead>
<tr>
<th>Design</th>
<th>Prospective, multi-center, single arm, IRB-approved</th>
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<tbody>
<tr>
<td>Centers</td>
<td>13</td>
</tr>
<tr>
<td>Intervention/Location</td>
<td>Trans-nasal balloon sinus dilation (BSD) in an office setting for all peripheral sinuses</td>
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<tr>
<td>Anesthesia</td>
<td>Local (without IV sedation)</td>
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<tr>
<td>Follow-up</td>
<td>2, 8, 24, 52 weeks post-procedure</td>
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<tr>
<td>Primary Outcome Measures</td>
<td>QOL (SNOT-20)&lt;sup&gt;2&lt;/sup&gt;, Radiographic (Lund-MacKay)&lt;sup&gt;3&lt;/sup&gt;</td>
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<tr>
<td>Secondary Outcome Measures</td>
<td>Safety, Technical Success, Return to Normal Activity, Need for Revision Procedure</td>
</tr>
<tr>
<td>Subgroup Analysis</td>
<td>Patients with ethmoid disease entering the study + no office ethmoidectomy</td>
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Results: Demographics and Disposition

- 203 subjects enrolled originally into a 24 week study.
- Follow-up interval extended to 52 weeks or greater (“52+ weeks”)
- Comparison of subjects who returned for 52+ weeks vs those who did not showed no difference in baseline characteristics except for gender and prior sinus surgery

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<tr>
<th></th>
<th>52+ weeks</th>
<th>Exit prior to 52 weeks</th>
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<tbody>
<tr>
<td>Patients</td>
<td>60.0% (122/203)</td>
<td>40.0% (81/203)</td>
</tr>
<tr>
<td>Mean Age (range)</td>
<td>50.0 (19.8-88.4)</td>
<td>46.2 (20.8-90.5)</td>
</tr>
<tr>
<td>Male</td>
<td>40.1%†</td>
<td>55.6%</td>
</tr>
<tr>
<td>Prior sinus surgery</td>
<td>47.5%†</td>
<td>24.7%</td>
</tr>
<tr>
<td>Polyps</td>
<td>10.7%</td>
<td>4.9%</td>
</tr>
<tr>
<td>Baseline SNOT-20</td>
<td>2.1</td>
<td>2.1</td>
</tr>
<tr>
<td>Baseline LMK</td>
<td>6.8</td>
<td>7.2</td>
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† Statistically different between groups
Results: Technical Success

- 551 sinuses successfully dilated out of 592 attempted (93.1%)
- Average of 2.7 sinuses dilated/patient
Results: 52+ Week Quality of Life

- SNOT-20 decreased from 2.1 @ baseline to 1.0 @ 52+ weeks (n=122).
- This change is similar previous reports for OR-based balloon dilation\(^1\) and ‘traditional’ ESS procedures\(^2,3\).
- Mean follow-up for the 122 subjects was 1.4 years

Results: SNOT-20 Subscores

- Facial pain/pressure
- Wake up tired
- Fatigue
- Lack of a good night's sleep
- Reduced productivity
- Reduced concentration
- Wake up at night
- Frustrated
- Post-nasal discharge
- Ear fullness
- Difficulty falling asleep
- Thick Nasal Discharge
- Cough
- Need to blow nose
- Runny nose
- Dizziness
- Embarrassed
- Ear pain
- Sad
- Sneezing

Baseline – 52+ weeks
SNOT-20 subscore change

-1.8
-1.8
-1.5
-1.4
-1.4
-1.4
-1.3
-1.2
-1.1
-1.1
-1.0
-0.9
-0.8
-0.8
-0.8
-0.7
-0.6
-0.6
-0.6

• All SNOT-20 subscore changes statistically significant (P < 0.0001) at 52+ weeks post procedure (after multiplicity correction)
• Top ranking changes in fatigue-related symptoms consistent with prior studies of effects of traditional FESS

Results: Safety

No device or procedure-related adverse events between 24 and 52+ weeks

Previously reported at 24 weeks:
• 1 serious non-device related event: Pneumonia requiring hospitalization approximately two months post-procedure

• 1 procedure-related adverse event: Self-limiting periorbital swelling that resolved shortly after the procedure without further sequelae.
Results: Ethmoid CT at 24 weeks

- Ethmoid disease was not an exclusionary criterion for the study
- At 24 weeks, 87% of subjects with ethmoid disease showed radiographic improvement in ethmoid LMK without an ethmoidectomy

Baseline

24 weeks post-procedure

Figure: Subject demonstrating radiographic clearance of ethmoid disease without an ethmoidectomy. Mild mucosal thickening and an asymptomatic right maxillary sinus cyst required no additional intervention through 52+ weeks (Image courtesy of Dr Jacob Johnson).
Results: Ethmoid Subgroup-52+ Week QOL

• 61 patients in the ethmoid subgroup 52+ week analysis, defined as:
  – Ethmoid disease entering study, no ethmoidectomy during study, 52+ week SNOT-20

• Subjects entering study with or without ethmoid disease had similar QOL improvement
Results: Revision Rates

- 87% of patients with ethmoid disease successfully treated with office-based balloon dilation only; no additional intervention required.
- Low revision rate for subjects without ethmoid disease.
- 4/8 revisions in ethmoid subgroup did not include ethmoidectomy.
- No baseline characteristics predictive of revision in the ethmoid subgroup.

<table>
<thead>
<tr>
<th></th>
<th>All Subjects</th>
<th>w/ Ethmoid Disease</th>
<th>w/o Ethmoid Disease</th>
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<tbody>
<tr>
<td>n</td>
<td>9/122</td>
<td>8/61</td>
<td>1/59</td>
</tr>
<tr>
<td>Revision Rate</td>
<td>7.4%</td>
<td>13.1%</td>
<td>1.7%</td>
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Conclusions

• This study of over 100 subjects demonstrates that office-based transnasal BSD can result in significant symptom improvement maintained through 52+ weeks (average 1.4 years)

• Patients with mild to moderate ethmoid disease can be treated in an office setting with an acceptable rate of required re-intervention

• Viable option for properly selected patients who have failed maximal medical therapy and are candidates for ESS