Balloon Sinuplasty™ Technology
A minimally invasive option for pediatric patients

- Recent publications demonstrate the safety of Balloon Sinuplasty Technology and positive clinical outcomes for children\(^1\)\(^2\)
- In the United States, pediatric patients make up 22% of all office visits for chronic sinusitis\(^3\)
- Balloon Sinuplasty Technology enables ostial dilation with minimal mucosal trauma and does not require bone or tissue removal

Products specifically designed for pediatric maxillary sinuses include:

**Relieva Luma® Sinus Illumination System**
- Enables confirmation of sinus access while eliminating the need for fluoroscopy

**Relieva Solo Pro™ Sinus Balloon Catheter**
- Smallest balloon (3.5 × 12 mm) specifically designed for pediatric anatomy

**Maxillary Sinus Guide Catheters**
- Small profiles enable sinus access with minimal mucosal trauma

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Balloon Catheter Sinuplasty in Young Children

Hassan Ramadan, MD; Kevin McLaughlin, MD; Gary Josephson, MD; Frank Rimell, MD; John Bent, MD; Sanjay Parikh, MD; American Journal of Rhinology & Allergy, 24(1) 2010: e54 - e56.

Study Overview

Study Design  Multi-center, prospective study
Study Size    32 children, aged 2-11
Follow Up     1, 12, 24, and 52 weeks
Endpoints     Safety at the time of surgery
               Outcomes evaluated using the clinically validated SN-5 test which assesses symptom burden

Results

> Mean SN-5 scores decreased from 4.9 at baseline to 2.95 at 52-week follow up, representing a clinically and statistically significant 40% reduction in symptom burden
> 0 adverse events
> 87% of patients showed sustained improvement in SN-5 score at 1-year follow-up

<table>
<thead>
<tr>
<th>Change in symptom burden</th>
<th>Change in SN-5 Scores at 52-week follow-up</th>
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</thead>
<tbody>
<tr>
<td>Significant Improvement</td>
<td>50%</td>
</tr>
<tr>
<td>Moderate Improvement</td>
<td>29%</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>8%</td>
</tr>
<tr>
<td>No Change</td>
<td>4%</td>
</tr>
<tr>
<td>Worsened</td>
<td>8%</td>
</tr>
</tbody>
</table>

% of patients

Conclusions

This study concludes that sinus ostial dilation using Balloon Sinuplasty Technology in children may be an effective minimally invasive treatment option to relieve sinus ostial obstruction in the maxillary sinus, and improve patient quality of life.

For more information on Balloon Sinuplasty Technology and Acclarent, Inc., please call your Acclarent representative or visit www.acclarent.com.

Balloon Sinuplasty System is intended for use by or under the direction of a physician that is trained in the use of Balloon Sinuplasty Technology. Prior to use, it is important to read the Instructions for Use and to understand the contraindications, warnings, and precautions associated with this device.