Prospective, multicenter evaluation of balloon sinus dilation for treatment of pediatric chronic rhinosinusitis
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Background: Although balloon sinus dilation is a treatment option for adults with chronic rhinosinusitis (CRS), there have been few studies performed in pediatric patients.

Methods: This study was designed as a prospective, multicenter, single-arm investigation. Children (2 to 21 years old) with CRS who had failed medical management were treated with balloon sinus dilation and followed to 6 months postprocedure.

Results: Fifty children were treated at 4 centers; 33 participants were 2 to 12 years old (mean ± standard deviation age: 6.6 ± 2.2 years) and 17 participants were >12 to 21 years (mean age: 15.7 ± 2.5 years). A total of 157 sinus dilations were attempted (98 maxillary, 30 frontal, and 29 sphenoid sinuses) and all were successful with no complications. Significant improvement in the Sinus and Nasal Quality of Life Survey (SN-5) was seen for all children between baseline and 6 months (4.6 ± 1.2 vs 1.7 ± 0.8; p < 0.0001) and 92% improved by a minimal clinically important difference (MCID) of 1.0 or more. Those children aged 2 to 12 years with standalone balloon dilation also showed significant SN-5 improvements between baseline and follow-up (4.5 ± 1.0 vs 1.9 ± 0.8; p < 0.0001). Multivariate regression analysis showed no differences or associations of SN-5 improvement at 6 months with the presence of allergy, asthma, or concomitant procedures. For adolescents, overall 22-item Sino-Nasal Outcome Test (SNOT-22) mean scores were also significantly improved at 6 months (42.2 ± 19.2 vs 10.4 ± 9.7; p < 0.0001).

Conclusion: Balloon sinus dilation is safe and appears effective for children with CRS aged 2 years and older. © 2016 The Authors International Forum of Allergy & Rhinology, published by ARSAAOA, LLC. This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

Key Words: sinusitis; chronic, rhinosinusitis; adolescent; child; quality of life; balloon; sinuplasty; surgery; therapy; outcome

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Many prior studies have evaluated treatment outcomes in patients with chronic rhinosinusitis (CRS), particularly with regard to surgical procedures. However, the majority of these studies exclude pediatric patients.1 Several prominent differences between adult and pediatric populations are often cited as reasons for exclusion. The first reason is embryologic, namely that only the maxillary and ethmoid sinuses are present at birth and relatively premature compared to an adult.2 During childhood, progressive expansion and pneumatization occurs with subsequent

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development of the sphenoid and then frontal sinuses. Children also typically have prominent adenoid tissue, which can play both an obstructive role and serve as a reservoir for microbes.\textsuperscript{3} Perhaps most important, the pathophysiology of pediatric CRS does not necessarily mirror that present in the adult population. Although heterogeneity and overlap exists in both populations, pediatric CRS may be more impacted by sinus ostial obstruction, bacterial infection, allergic rhinitis, gastroesophageal reflux disease (GERD), and adenoid hypertrophy.\textsuperscript{4–6}

Children with CRS often respond to medical therapy with adequate control of symptoms. Those children with ongoing symptoms and impaired quality of life (QOL) despite medical treatment may be offered a surgical procedure. The European Position Paper on Rhinosinusitis and Nasal Polyposis 2012 (EPOS12) suggested that the surgical algorithm for pediatric CRS begin with adenoidectomy and that consideration could be given to concurrent balloon dilation of the maxillary sinus or antral irrigation.\textsuperscript{7} Traditional endoscopic sinus surgery (ESS) would be reserved for treatment failures, patients without enlarged adenoids, or disorders that directly impact mucociliary function. However, both the EPOS12 and a recent Clinical Consensus Statement did not find conclusive evidence regarding the effectiveness of balloon dilation in children and suggested that future research is necessary.\textsuperscript{7,8}

A recent study examined rates of sinus surgical procedures across a large administrative database for children with CRS.\textsuperscript{9} Overall, balloon dilation was utilized in 11.9% of pediatric CRS cases as compared with traditional ESS. Although data supporting safety and efficacy of balloon dilation in adult patients are developing, few studies have addressed similar outcomes in pediatric patients.\textsuperscript{10} As discussed, differences in development, anatomy, and possibly pathophysiology are sufficient enough that direct extrapolation of balloon dilation results from adult studies to the pediatric population should not be done. With these issues in mind, the objectives of this study were to evaluate the procedural success, safety, and effectiveness of balloon sinus dilation in pediatric patients with CRS.

**Patients and methods**

**Population**

This study was a prospective, multicenter, single-arm investigation. Patients aged 2 through 21 years were enrolled after satisfying diagnostic criteria for CRS as defined by EPOS12.\textsuperscript{7} A computed tomography (CT) scan within 6 months prior to the procedure date demonstrating mucosal thickening, air-fluid level, and/or obstruction of the sinus outflow tract was required. Each patient must have failed initial medical management as determined by the treating physician. Failure was defined as ongoing sinonasal symptoms despite prior medical therapy, but medical therapy was not standardized across patients or centers. Patients must not have had prior sinus surgery, head or neck surgery within the previous 3 months (adenoidectomy, septoplasty, turbinate surgery), fungal sinus disease, cystic fibrosis, severe asthma, known immunodeficiency, anatomic conditions that would prevent transnasal access, hypoplastic/atelectatic maxillary sinus, or craniofacial deformity. The study was conducted under an Investigational Device Exemption (IDE) and approved by the U.S. Food and Drug Administration (FDA). Institutional Review Board approval was obtained by each participating investigational center before study enrollment. All participants/caregivers provided informed consent and assent was obtained, when applicable. The study was registered on the www.clinicaltrials.gov website with the unique identifier of NCT02278484.

**Procedure**

All study participants underwent transnasal balloon sinus dilation with the XprESS Multi-Sinus Dilation System (Entellus Medical, Plymouth, MN) according to the manufacturer’s instructions. The balloon dilation device is available in a variety of lengths and diameters and selection was based on the surgeon’s preference and the participant’s anatomy. The PathAssist LED Light Fiber (Entellus Medical, Plymouth, MN) was used to illuminate and confirm placement in all maxillary and frontal sinuses. Fluoroscopy was not used for device placement confirmation in any participant. Selection of anesthesia (local or general) and the location of the procedure (office or surgical center) were at the discretion of the treating surgeon. After completion of the balloon sinus dilation, concomitant procedures such as adenoidectomy, inferior turbinate reduction, and ethmoidectomy were allowed, based on individual participant needs. Additionally, the time required for each participant to return to normal activities (recovery time) was documented.

**Outcome measures**

The primary outcomes were technical success and procedure complication rate. Technical success was defined as the percent of successful dilations, wherein the balloon was delivered to the target location, inflated, deflated, and withdrawn from the treated sinus. The outcome is calculated per sinus ostium attempted to be treated. The minimum a priori sample size of 50 treated sinuses was based on an assumed 90% technical success rate, alpha of 0.05, and precision of 11.8% or less. Complications were defined as serious adverse events that were related to the balloon device or procedure during the initial 3 months.

Secondary outcomes were the surgical revision rate and changes in disease-specific QOL. Participants were followed at 1, 3, and 6 months postprocedure. Revision surgery was defined as surgery on any sinus initially treated during the study procedure or surgery on a previously untreated sinus. QOL assessments included the Sinus and Nasal Quality of Life Survey (SN-5), 22-item Sino-Nasal Outcome Test (SNOT-22), and Rhinosinusitis Symptom Inventory (RSI).\textsuperscript{11–13} The SN-5 is a validated,
Balloon sinus dilation for pediatric CRS

5-item CRS-specific QOL instrument specifically designed for use in children. The survey is filled out by parents and includes questions related to sinus infections, nasal obstruction, allergy symptoms, emotional distress, and activity limitations. Each item is scored from 1 (none of the time) to 7 (all of the time) based on the preceding 4 weeks, and averaged to generate an overall SN-5 score. Improvements in overall SN-5 scores can be classified as large (>1.5), moderate (1.0 to 1.5), small (0.5 to 0.9), and no change/worsening (<0.5). A change of 1.0 or more was considered the minimal clinically important difference (MCID). The SN-5 also includes a global score that is based on a faces visual analog scale of 0 (worst) to 10 (best). The SNOT-22 is a well-established, validated CRS-specific QOL questionnaire. Total SNOT-22 scores can range from 0 to 110 (higher scores indicate worse QOL) and a change of 8.9 is considered the minimal clinically important difference. In this study, the SNOT-22 was only completed by participants 12 years or older because the questionnaire has not been validated for completion by young children or their caregivers. The RSI questionnaire was also completed by all participants, in conjunction with their parents. The RSI rates 12 sinus-related symptoms on a scale of 0 (symptom absent) to 5 (very severe) based on the preceding 12 weeks. The symptoms can be further categorized into 4 symptom domain scores of nasal, facial, oropharyngeal, and systemic, with scores ranging from 0 (no symptoms) to 100 (maximum severity).

**Statistical analysis**

Categorical variables were summarized using frequency distributions and continuous variables were summarized with means and standard deviations. Changes in QOL measures from baseline to follow-up were evaluated using paired t tests. All statistical tests were 2-sided, with p values <0.05 considered statistically significant. Multivariate linear regression was performed to determine the association of selected covariates with the change from baseline for SN-5 overall scores at 6 months postprocedure. The following covariates were included in the model: sex, age (continuous), asthma vs no asthma, allergies vs no allergies, maxillary only vs other sinuses treated, previous sinonasal procedures vs none, and concomitant sinonasal procedures vs none.

**Results**

**Study population**

Fifty children (157 sinuses) were treated at 4 centers between October 2014 and June 2015; each center enrolled between 9 and 15 participants. Thirty-three participants were 2 to 12 years old (mean 6.6 ± 2.2 years) and 17 participants were >12 to 21 years old (mean 15.7 ± 2.5 years). Males made up 66% of the total population, and allergies and asthma were comorbid conditions in 70% and 30% of participants, respectively. The most prevalent symptoms experienced at baseline were nasal congestion (94%), nasal discharge (86%), cough (86%), and nasal obstruction (78%). Overall follow-up visit compliance was 99% (198 visits completed/200 visits expected), with all participants (50/50, 100%) completing the 6-month follow-up.

**Primary outcomes: technical success and complications**

A total of 157 sinus dilations were attempted (98 maxillary, 30 frontal, and 29 sphenoid sinuses) and all were successful, for a technical success rate of 100%. Image guidance was used in 1 participant to confirm placement in a frontal

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**TABLE 1. Procedural characteristics**

| Characteristic                          | Child (2–12 years) n = 33 | Adolescent (>12 to 21 years) n = 17 | All participants n = 50 |
|----------------------------------------|----------------------------|-------------------------------------|-------------------------|
| Procedure location                      |                            |                                     |                         |
| Surgical center                        | 33 (100.0)                 | 9 (52.9)                            | 42 (84.0)               |
| Office                                 | 0 (0.0)                    | 8 (47.1)                            | 8 (16.0)                |
| Anesthesia type                        |                            |                                     |                         |
| General                                | 33 (100.0)                 | 9 (52.9)                            | 42 (84.0)               |
| Local                                  | 0 (0.0)                    | 8 (47.1)                            | 8 (16.0)                |
| Pain assessment (n = 8)                | NA                         | 1.5 ± 1.2                           | NA                      |
| Concomitant procedures                 |                            |                                     |                         |
| None                                   | 11 (33.3)                  | 9 (52.9)                            | 20 (40.0)               |
| Adenoidectomy                          | 19 (57.6)                  | 2 (11.8)                            | 21 (42.0)               |
| Inferior turbinate reduction           | 6 (18.2)                   | 7 (41.2)                            | 13 (26.0)               |
| Tonsillectomy                          | 5 (15.2)                   | 2 (11.8)                            | 7 (14.0)                |
| Ethmoidectomy                          | 4 (12.1)                   | 2 (11.8)                            | 6 (12.0)                |
| Myringotomy with ear tube placement    | 5 (15.2)                   | 0 (0.0)                             | 5 (10.0)                |
| Concha bullosa resection               | 0 (0.0)                    | 3 (17.6)                            | 3 (6.0)                 |
| Uncinctomy                             | 0 (0.0)                    | 1 (5.9)                             | 1 (2.0)                 |
| Other procedures*                      | 4 (12.1)                   | 2 (11.8)                            | 6 (12.0)                |
| Method to control postoperative bleeding | 4 (12.1)                   | 2 (11.8)                            | 6 (12.0)                |
| None                                   | 31 (93.9)                  | 16 (94.1)                           | 47 (94.0)               |
| Packing, removed before discharge      | 2 (6.1)                    | 0 (0.0)                             | 2 (4.0)                 |
| Gel film                               | 0 (0.0)                    | 1 (5.9)                             | 1 (2.0)                 |

*Data are displayed as mean ± SD or n (%), as shown.
*Other concomitant procedures include: cauterization of nasal vessels (2), out-fracture of inferior turbinate (2), resection of agger nasi cell (1), and septoplasty (1).
NA = not applicable; SD = standard deviation.
sinus. Nearly all of the sinus dilations, 92% (144/157), included bilateral treatment of the affected sinuses. Most of the procedures (84%) were conducted in surgical centers under general anesthesia; however, 8 of the 17 adolescent participants (47.1%) were successfully treated in the office under local anesthesia only. Twenty participants (40%) underwent balloon sinus dilation with no concomitant procedures, 21 underwent concurrent adenoidectomy (42%), 13 underwent concurrent inferior turbinate reduction (26%), and 6 had concurrent ethmoidectomy (12%) (Table 1). There were no serious adverse events reported through the 6-month follow-up period for all participants. Two adolescents reported non-serious adverse events postprocedure: 1 patient had an ulcer along the uvula related to airway device and 1 patient had night sweats on postoperative day 3.

Secondary outcomes: revision surgery and QOL

There were no revision surgeries performed during the 6-month follow-up period for any participants. Across the entire cohort there was a mean improvement in overall SN-5 scores from baseline to 6 months (4.6 ± 1.2 vs 1.7 ± 0.8; \( p < 0.0001 \)). Significant mean improvement was seen in each individual item of the SN-5, as well as the overall QOL score (Table 2; Fig. 1). Significant improvements were similarly seen for all children age 2 to 12 years (Table 3), as well as those ages 2 to 12 years with standalone balloon dilation (Table 4). At the 6-month follow-up, 82% of participants had achieved large improvement in SN-5 overall scores (change >1.5), 10% achieved moderate improvement (1.0 to 1.5), 2% achieved slight improvement (0.5 to 0.9), and 6% did not experience a clinical change (<0.5). Overall, 92% of the participants achieved an MCID (change ≥1.0) (Table 5). Qualitatively similar MCID changes were seen for all children age 2 to 12 years and those ages 2 to 12 years with standalone balloon dilation (Tables 6 and 7).

The mean changes in SNOT-22 overall and subscale scores from baseline to 6-month follow-up for the adolescent participants are shown in Table 8. Mean overall SNOT-22 scores significantly improved over baseline at all follow-up time periods (\( p < 0.0001 \)). The mean change from baseline to 6 months (42.2 ± 19.2 vs 10.4 ± 9.7; \( p < 0.0001 \)) was greater than the MCID (change of at least 8.9). In addition to overall SNOT-22 scores, significant improvements were seen for each subscale score and for all individual items except the symptoms “embarrassed” and “sad.”

The mean change in sinus symptoms between baseline and 6 months was also evaluated using the RSI. There were statistically significant improvements in all of the major and minor symptom measures as well as the 4 domain measures (Table 9).

Multivariate regression analysis was done at the 6-month follow-up period to explore the impact of various factors on SN-5 change scores. Notably, there was no difference in SN-5 outcomes when comparing those with and
Balloon sinus dilation for pediatric CRS

FIGURE 1. Mean change from baseline in overall and subscale SN-5 scores over time. SN-5 = Sinus and Nasal Quality of Life Survey.

TABLE 3. SN-5 outcomes for ages 2 to 12 years*

| Quality of life item       | n   | Baseline       | 6-Months    | Change from baseline | Percent improvement | p    |
|---------------------------|-----|----------------|-------------|----------------------|---------------------|------|
| SN-5 overall score        | 33  | 4.8 ± 1.2      | 1.7 ± 0.8   | −3.1 ± 1.4           | 62.4 ± 18.3         | <0.0001 |
| SN-5 sinus infection      | 33  | 5.6 ± 1.3      | 1.7 ± 1.1   | −3.8 ± 1.7           | 65.9 ± 24.4         | <0.0001 |
| SN-5 nasal obstruction    | 33  | 5.5 ± 1.4      | 1.9 ± 1.2   | −3.6 ± 1.9           | 57.5 ± 51.5         | <0.0001 |
| SN-5 allergy symptoms     | 33  | 4.5 ± 1.9      | 2.2 ± 1.6   | −2.4 ± 2.0           | 46.1 ± 35.8         | <0.0001 |
| SN-5 emotional distress   | 33  | 4.6 ± 1.9      | 1.5 ± 1.1   | −3.1 ± 2.1           | 59.2 ± 32.1         | <0.0001 |
| SN-5 activity limitations | 33  | 3.8 ± 1.7      | 1.2 ± 0.6   | −2.5 ± 1.7           | 58.0 ± 27.5         | <0.0001 |
| Overall quality of life   | 33  | 4.3 ± 1.5      | 8.8 ± 1.5   | 4.5 ± 2.0            | 139.5 ± 113.7       | <0.0001 |

*Data are displayed as mean ± SD. SN-5 survey responses for each item can range from 1 (none of the time) to 7 (all of the time). The overall quality of life assessment ranges from 0 (worse possible) to 10 (best possible).

SD = standard deviation; SN-5 = Sinus and Nasal Quality of Life Survey.

TABLE 4. SN-5 outcomes for ages 2 to 12 years with balloon-only treatment*

| Quality of life item       | n   | Baseline       | 6-Months    | Change from baseline | Percent improvement | p    |
|---------------------------|-----|----------------|-------------|----------------------|---------------------|------|
| SN-5 overall score        | 11  | 4.5 ± 1.0      | 1.9 ± 0.8   | −2.6 ± 1.2           | 56.5 ± 19.2         | <0.0001 |
| SN-5 sinus infection      | 11  | 5.6 ± 0.8      | 2.0 ± 1.1   | −3.6 ± 1.4           | 63.6 ± 21.8         | <0.0001 |
| SN-5 nasal obstruction    | 11  | 5.3 ± 1.1      | 1.8 ± 1.0   | −3.5 ± 1.7           | 62.9 ± 23.5         | <0.0001 |
| SN-5 allergy symptoms     | 11  | 4.0 ± 2.1      | 2.6 ± 1.8   | −1.4 ± 1.5           | 29.4 ± 35.4         | 0.013 |
| SN-5 emotional distress   | 11  | 4.1 ± 1.6      | 1.9 ± 1.5   | −2.2 ± 2.1           | 47.8 ± 40.2         | 0.007 |
| SN-5 activity limitations | 11  | 3.7 ± 1.7      | 1.2 ± 0.4   | −2.5 ± 1.8           | 60.1 ± 25.5         | 0.001 |
| Overall quality of life   | 11  | 4.1 ± 1.4      | 8.9 ± 0.9   | 4.8 ± 1.7            | 149.0 ± 111.0       | <0.0001 |

*Data are displayed as mean ± SD. SN-5 survey responses for each item can range from 1 (none of the time) to 7 (all of the time). The overall quality of life assessment ranges from 0 (worse possible) to 10 (best possible).

SD = standard deviation; SN-5 = Sinus and Nasal Quality of Life Survey.
TABLE 5. SN-5 minimal clinically important difference for all ages

| Improvement | 1 Month | 3 Months | 6 Months |
|-------------|---------|----------|----------|
| > 1.5: Large | 77.6 (38/49) | 79.6 (39/49) | 82.0 (41/50) |
| 1.0–1.5: Moderate | 10.2 (5/49) | 10.2 (5/49) | 10.0 (5/50) |
| 0.5–0.9: Mild | 2.0 (1/49) | 8.2 (4/49) | 2.0 (1/50) |
| <0.5: No change | 10.2 (5/49) | 2.0 (1/49) | 6.0 (3/50) |

*Data are displayed as % (n/N). A change ≥1.0 was considered to be clinically meaningful for the purposes of this analysis.
SN-5 = Sinus and Nasal Quality of Life Survey.

TABLE 6. SN-5 minimal clinically important difference for ages 2 to 12 years

| Improvement | 1 Month | 3 Months | 6 Months |
|-------------|---------|----------|----------|
| > 1.5: Large | 75.8 (25/33) | 75.0 (24/32) | 84.8 (28/33) |
| 1.0–1.5: Moderate | 6.1 (2/33) | 12.5 (4/32) | 9.1 (3/33) |
| 0.5–0.9: Mild | 3.0 (1/33) | 9.4 (3/32) | 3.0 (1/33) |
| <0.5: No change | 15.2 (5/33) | 3.1 (1/32) | 3.0 (1/33) |

*Data are displayed as % (n/N). A change ≥1.0 was considered to be clinically meaningful for the purposes of this analysis.
SN-5 = Sinus and Nasal Quality of Life Survey.

TABLE 7. SN-5 minimal clinically important difference for ages 2 to 12 years with balloon-only treatment

| Improvement | 1 Month | 3 Months | 6 Months |
|-------------|---------|----------|----------|
| > 1.5: Large | 72.7 (8/11) | 63.6 (7/11) | 81.8 (9/11) |
| 1.0–1.5: Moderate | 9.1 (1/11) | 18.2 (2/11) | 9.1 (1/11) |
| 0.5–0.9: Mild | – | 9.1 (1/11) | – |
| <0.5: No change | 18.2 (2/11) | 9.1 (1/11) | 9.1 (1/11) |

*Data are displayed as % (n/N). A change ≥1.0 was considered to be clinically meaningful for the purposes of this analysis.
SN-5 = Sinus and Nasal Quality of Life Survey.

Discussion

Balloon dilation of the sinuses in children has been proposed as a treatment option for those failing prior medical management, usually in conjunction with or following adenoidectomy. Data from this study supports the use of balloon dilation without concurrent sinonasal procedures (eg, adenoidectomy, turbinate surgery, ethmoidectomy) or between those with and without previous sinonasal procedures. Additionally, there were no associations of the change in SN-5 score with age, allergic rhinitis, or asthma (Table 10).

Last, an analysis of recovery times showed that participants who underwent concomitant procedures had significantly longer recovery times (3.1 ± 3.0 days) than participants undergoing standalone balloon dilation (1.1 ± 0.7 days; p = 0.002) (Table 11).

**TABLE 8. Mean SNOT-22 overall score and subscales scores for adolescent participants

| Parameter | Baseline | 6 Months | Change from baseline | Percent improvement | p* |
|-----------|----------|----------|----------------------|--------------------|----|
| SNOT-22 overall score | 42.2 ± 19.2 | 10.4 ± 7.4 | −31.9 ± 20.7 | 71.7 ± 34.9 | 0.0001 |
| Rhinologic symptoms | 15.2 ± 5.1 | 3.8 ± 4.5 | −11.4 ± 7.0 | 72.6 ± 34.9 | 0.0001 |
| Extranasal rhinologic symptoms | 6.0 ± 3.4 | 1.5 ± 2.3 | −4.5 ± 3.8 | 75.8 ± 40.1 | 0.0001 |
| Ear/facial symptoms | 7.5 ± 1.6 | 1.8 ± 1.6 | −5.8 ± 3.9 | 67.5 ± 26.9 | 0.0001 |
| Psychological symptoms | 11.9 ± 8.8 | 3.2 ± 4.8 | −8.8 ± 9.5 | 66.6 ± 56.1 | 0.0002 |
| Sleep dysfunction | 10.7 ± 7.3 | 2.6 ± 4.0 | −8.1 ± 6.0 | 67.2 ± 41.8 | 0.0001 |

*Data are displayed as mean ± SD. Overall SNOT-22 scores can range from 0 to 110 with higher scores indicating worse symptoms. Only the adolescent participants completed the SNOT-22 assessment. SD = standard deviation; SNOT-22 = 22-item Sino-Nasal Outcome Test.
Clinical efficacy was a secondary but nonetheless important outcome measure of this study. Robust improvements in QOL were seen in parent-reported (SN-5), patient-reported (SNOT-22), and mixed QOL outcome measures (RSI) from baseline to 6-month follow-up. These improvements were not only statistically significant, but achieved the MCID in the vast majority of patients. It should be noted that we defined the MCID for the change in RSI symptom scores differently than has been reported by others. We defined the MCID at the level of moderate improvement or better (change ≥0.5) are not considered successes with regard to overall SN-5 symptom scores. These data demonstrate the vast majority of children undergoing balloon dilation experienced meaningful improvement and did not require revision surgery through 6 months postprocedure.

It is important to point out that 60% of patients had adjunctive procedures, most commonly adenoidectomy. Adenoidectomy is currently recommended as an initial procedure except in those with prior adenoid removal or

### TABLE 9. Mean RSI symptom scores

| RSI symptoms                              | n   | Baseline | 6-Months | Change from baseline | Percent improvement | p*  |
|-------------------------------------------|-----|----------|----------|----------------------|---------------------|-----|
| **Major symptoms**                        |     |          |          |                      |                     |     |
| Facial pain/pressure                      | 49  | 2.4 ± 1.3| 0.2 ± 0.7| −2.1 ± 1.4           | 91.3 ± 24.1         | <0.0001 |
| Facial congestion/fullness                | 50  | 3.3 ± 1.3| 0.4 ± 0.8| −2.9 ± 1.4           | 87.8 ± 25.1         | <0.0001 |
| Nasal obstruction/blockage                | 50  | 3.5 ± 1.3| 0.6 ± 1.1| −2.8 ± 1.6           | 79.1 ± 40.6         | <0.0001 |
| Discolored or pus nasal discharge or postnasal drip | 50  | 2.9 ± 1.5| 0.5 ± 0.9| −2.4 ± 1.7           | 82.1 ± 31.7         | <0.0001 |
| Decreased sense of smell                 | 47  | 2.3 ± 1.7| 0.2 ± 0.6| −2.1 ± 1.6           | 91.9 ± 22.2         | <0.0001 |
| **Minor symptoms**                        |     |          |          |                      |                     |     |
| Headache                                  | 49  | 2.5 ± 1.5| 0.7 ± 1.1| −1.8 ± 1.4           | 78.7 ± 30.3         | <0.0001 |
| Fever                                     | 50  | 1.4 ± 1.3| 0.2 ± 0.8| −1.1 ± 1.3           | 83.1 ± 40.4         | <0.0001 |
| Halitosis (bad breath)                    | 50  | 1.6 ± 1.4| 0.4 ± 0.9| −1.2 ± 1.5           | 75.5 ± 45.6         | <0.0001 |
| Fatigue (tiredness)                       | 50  | 2.3 ± 1.5| 0.4 ± 0.9| −1.9 ± 1.5           | 87.1 ± 27.1         | <0.0001 |
| Dental pain                               | 50  | 0.5 ± 1.0| 0.0 ± 0.1| −0.5 ± 1.0           | 97.2 ± 9.6          | <0.001 |
| Cough                                     | 50  | 2.9 ± 1.3| 0.8 ± 1.1| −2.1 ± 1.4           | 73.5 ± 38.6         | <0.0001 |
| Ear pain/pressure                         | 49  | 2.2 ± 1.7| 0.6 ± 1.2| −1.6 ± 1.6           | 75.1 ± 40.8         | <0.0001 |
| **Domains**                               |     |          |          |                      |                     |     |
| Nasal                                     | 50  | 58.1 ± 21.9| 9.3 ± 15.5| −48.8 ± 23.7         | 84.7 ± 25.3         | <0.0001 |
| Facial                                    | 50  | 54.8 ± 22.8| 9.2 ± 12.4| −45.6 ± 22.3         | 82.3 ± 31.7         | <0.0001 |
| Oropharyngeal                              | 50  | 35.9 ± 18.6| 8.9 ± 13.1| −27.0 ± 18.2         | 75.0 ± 34.8         | <0.0001 |
| Systemic                                  | 50  | 36.8 ± 22.4| 6.2 ± 12.9| −30.6 ± 21.4         | 87.2 ± 26.2         | <0.0001 |
| Total                                     | 50  | 46.1 ± 15.9| 8.6 ± 10.3| −37.4 ± 15.6         | 82.0 ± 20.9         | <0.0001 |

*Data are displayed as mean ± SD. Individual RSI symptom scores can range from 0 to 5 with higher scores indicating worse symptoms. Domain symptom scores can range from 0 (no symptoms) to 100 (maximum severity).

*Value of p from paired t tests for the change from baseline.

RSI = Rhinosinusitis Symptom Inventory; SD = standard deviation.
TABLE 10. Overall SN-5 score improvement: multivariate regression analysis

| Covariate                                      | 6-Month change | Estimate | p      |
|------------------------------------------------|----------------|----------|--------|
| Age (1-unit increase, linear relationship)    |                | 0.05     | 0.363  |
| Allergies vs none                             |                | −0.07    | 0.894  |
| Asthma vs none                                |                | −0.19    | 0.717  |
| Male vs female                                |                | −0.06    | 0.896  |
| Maxillary only vs other                       |                | 0.34     | 0.429  |
| No concomitant surgeries vs any               |                | 0.52     | 0.277  |
| No previous procedures vs any                 |                | 0.01     | 0.977  |

*Linear regression model at 6 months adjusting for all the covariates listed.
SN-5 = Sinus and Nasal Quality of Life Survey.

older children whose adenoids are minimally present. For those children requiring adjunctive procedures such as adenoidectomy, the relative contributions of each procedure (ie, balloon dilation vs other procedures) is not discernible with this study design. For those patients not requiring adjunctive procedures (40%), significant improvements in QOL occurred after standalone balloon dilation and recovery times were faster. The multivariate regression analysis showed that improvements in SN-5 scores were maintained despite controlling for numerous factors, including the performance of adjunctive procedures. These findings suggest that balloon dilation in and of itself contributes to efficacy. However, it remains imperative for the clinician to determine the degree to which adjunctive procedures (adenoidectomy, turbinate reduction, ethmoidectomy) are necessary for any individual case.

This study was designed as a single-arm study without a control group; therefore, it is not possible to conclude with certainty that surgery itself was responsible for the entirety of QOL improvement seen. This is a similar limitation to most sinus surgery outcomes studies without control groups. Obviously, a randomized, blinded, controlled clinical trial would be required to prove causality, which is unlikely to be performed on children, given problems with blinding, sham surgery, enrollment, and equipoise. However, a nonrandomized, controlled study was recently performed in China comparing balloon dilation to ongoing medical management in children failing medical therapy. The control group improved over time, suggesting efficacy of ongoing medical management or perhaps some degree of regression to the mean from the natural history of the disease. However, the improvement in the balloon dilation group remained superior at all time points. This suggests, as expected, that most but not all improvement is likely related to the procedure.

As discussed, strengths of the study include its prospective design, oversight by FDA, and the involvement of multiple, International Forum of Allergy & Rhinology, Vol. 7, No. 3, March 2017
Balloon sinus dilation has high procedural success rates and is safe for children with CRS aged 2 years and older. Significant improvements in QOL were seen up to 6 months after surgery on both parent-reported and patient-reported outcome measures. Future studies should evaluate outcomes beyond 6 months and further refine the role of balloon dilation within the treatment algorithm for pediatric CRS.

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