ORIGINAL ARTICLE

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 improve-

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

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M any 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.[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.[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 Polyps 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.[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.[7,8]

A recent study examined rates of sinus surgical procedures across a large administrative database for children with CRS.[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.[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.[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).[11–13] The SN-5 is a validated,

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).[11] 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.[12] 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.[13] 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

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)
Uncinectomy	0 (0.0)	1 (5.9)	1 (2.0)
Other procedures[a]	4 (12.1)	2 (11.8)	6 (12.0)
Method to control postoperative bleeding			
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.
[a]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.

(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

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

TABLE 2. SN-5 outcomes*

Quality of life item	n	Baseline	6-Months	Change from baseline	Percent improvement	p^a
SN-5 overall score	50	4.6 ± 1.2	1.7 ± 0.8	−2.9 ± 1.4	60.7 ± 20.3	<0.0001
SN-5 sinus infection	50	5.5 ± 1.3	1.7 ± 1.1	−3.8 ± 1.9	64.3 ± 32.7	<0.0001
SN-5 nasal obstruction	50	5.5 ± 1.5	1.9 ± 1.2	−3.6 ± 1.8	58.4 ± 44.1	<0.0001
SN-5 allergy symptoms	50	4.5 ± 1.9	2.2 ± 1.5	−2.3 ± 2.0	45.5 ± 34.0	<0.0001
SN-5 emotional distress	50	4.2 ± 1.9	1.5 ± 1.1	−2.7 ± 2.1	52.9 ± 43.4	<0.0001
SN-5 activity limitations	50	3.5 ± 1.7	1.3 ± 0.7	−2.2 ± 1.8	50.7 ± 32.2	<0.0001
Overall quality of life	50	4.8 ± 1.7	8.9 ± 1.4	4.2 ± 2.2	120.3 ± 107.0	<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).
aValue of p from paired t tests for the change from baseline.
SD = standard deviation; SN-5 = Sinus and Nasal Quality of Life Survey.

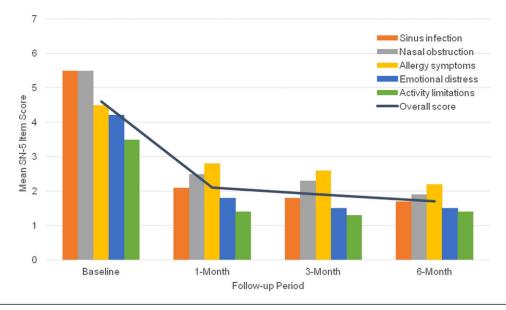**FIGURE 1.** Mean change from baseline in overall and subscale SN-5 scores over time. SN-5 = Sinus and Nasal Quality of Life Survey.

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.

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).

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

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

Parameter	n	Baseline	6 Months	Change from baseline	Percent improvement	p^a
SNOT-22 overall score	17	42.2 ± 19.2	10.4 ± 9.7	−31.9 ± 20.7	71.7 ± 29.9	<0.0001
Rhinologic symptoms	17	15.2 ± 5.1	3.8 ± 4.5	−11.4 ± 7.0	72.6 ± 34.2	<0.0001
Extranasal rhinologic symptoms	17	6.0 ± 3.4	1.5 ± 2.3	−4.5 ± 3.8	75.8 ± 40.1	<0.001
Ear/facial symptoms	17	7.5 ± 5.1	1.8 ± 1.6	−5.8 ± 5.3	67.5 ± 26.5	<0.001
Psychological symptoms	17	11.9 ± 8.8	3.2 ± 4.8	−8.8 ± 9.5	66.6 ± 58.1	0.002
Sleep dysfunction	17	10.7 ± 7.3	2.6 ± 4.0	−8.1 ± 8.0	67.2 ± 41.8	<0.001

*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.
aValue of p from paired t tests for the change from baseline.
SD = standard deviation; SNOT-22 = 22-item Sino-Nasal Outcome Test.

TABLE 9. Mean RSI symptom scores[*]

RSI symptoms	n	Baseline	6-Months	Change from baseline	Percent improvement	p^a
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).
[a]Value of p from paired t tests for the change from baseline.
RSI = Rhinosinusitis Symptom Inventory; SD = standard deviation.

feasibility of balloon dilation of pediatric sinuses, with a technical success rate of 100%, including maxillary, frontal, and sphenoid sinuses. Most importantly, there were no serious adverse events associated with the procedure and the minor adverse events reported were not considered device-related. The safety and feasibility of performing balloon dilation in children is also supported by other studies that have reported high technical success rates and the absence of significant complications.[14–17] Strengths of this study include a prospective and registered design that minimizes publication bias, review and oversight by the FDA, and multicenter involvement including both tertiary referral and community practice settings. Data from this study was used to obtain FDA clearance for the expanded indication for treating maxillary sinuses in children 2 years and older and treating frontal and sphenoid sinuses in children 12 years and older. This suggests that technical success and safety data may be generalizable beyond an individual surgeon or center; however, it should be stated that all providers were trained and experienced in both balloon dilation and traditional techniques.

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 SN-5 scores differently than has been reported by others.[14–18] We defined the MCID at the level of moderate improvement or better (change ≥1.0). Therefore, in our report, participants with mild improvements (change 0.5 to 0.9) 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 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.[7,8] 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.[18] 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,

TABLE 11. Mean recovery time in the presence or absence of concomitant procedures[*]

Subgroup	Return to normal activities (days)		
	Child (2–11 years)	Adolescent (12–21 years)	All participants
Balloon + concomitant procedure	2.3 ± 2.2 (22)	5.3 ± 4.1 (8)	3.1 ± 3.0 (30)
Balloon only	0.9 ± 0.5 (11)	1.3 ± 0.9 (9)	1.1 ± 0.7 (20)
p[a]	0.010	0.028	0.002

[*]Data are displayed as mean ± SD (n).
[a]Value of p from 2-sample t test.
SD = standard deviation.

diverse centers. Most importantly, validated patient-reported outcome measures (PROMs) were used from both patient and parent perspectives, with improvements that can be considered both statistically significant and clinically relevant. There are some limitations worth pointing out. Although all patients were required to have failed medical management before considering surgery, a standardized medical treatment protocol was not utilized as an inclusion requirement. Additionally, although study criteria required objective findings on CT scan indicating disease in the sinuses, the results were not reported using a standardized score such as the Lund-Mackay. Although this type of protocol likely reflects real-world practice, it also limits the ability to clearly delineate which children might be best served by a balloon procedure. Opportunities remain to design studies meant to explore the ideal pediatric patient population for balloon dilation vs those better served with other techniques.

This study does not offer insight as to how outcomes of balloon dilation compare to traditional sinus surgical techniques in a pediatric population. Certainly, this study excluded patients with ciliary disease, fungal disease, and altered anatomy wherein traditional techniques might be favored. The ability to offer balloon dilation to adolescents might prove to be an attractive option to some patients wishing to avoid the general anesthesia that is often necessary for traditional surgery, but sample size was not large enough to reliably compare outcomes from in-office and operating room procedures. Last, the study does not allow for conclusions beyond 6 months and studies with longer duration will be necessary to determine if results are durable.

Conclusion

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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References

1. Smith TL, Batra PS, Seiden AM, Hannley M. Evidence supporting endoscopic sinus surgery in the management of adult chronic rhinosinusitis: a systematic review. *Am J Rhinol*. 2005;19:537–543.
2. Hengerer AS. Embryologic development of the sinuses. *Ear Nose Throat J*. 1984;63:134–136.
3. Neff L, Adil EA. What is the role of the adenoid in pediatric chronic rhinosinusitis? *Laryngoscope*. 2015;125:1282–1283.
4. Lusk R. Pediatric chronic rhinosinusitis. *Curr Opin Otolaryngol Head Neck Surg*. 2006;14:393–396.
5. Mahdavinia M, Grammer LC 3rd. Chronic rhinosinusitis and age: is the pathogenesis different? *Expert Rev Anti Infect Ther*. 2013;11:1029–1040.
6. Sedaghat AR, Gray ST, Chambers KJ, et al. Sinonasal anatomic variants and asthma are associated with faster development of chronic rhinosinusitis in patients with allergic rhinitis. *Int Forum Allergy Rhinol*. 2013;3:755–761.
7. Fokkens WJ, Lund VJ, Mullol J, et al. EPOS 2012: European position paper on rhinosinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. *Rhinology*. 2012;50:1–12.
8. Brietzke SE, Shin JJ, Choi S, et al. Clinical consensus statement: pediatric chronic rhinosinusitis. *Otolaryngol Head Neck Surg*. 2014;151:542–553.
9. Ference EH, Schroeder JW Jr, Qureshi H, et al. Current utilization of balloon dilation versus endoscopic techniques in pediatric sinus surgery. *Otolaryngol Head Neck Surg*. 2014;151:852–860.
10. Levy JM, Marino MJ, McCoul ED. Paranasal sinus balloon catheter dilation for treatment of chronic rhinosinusitis: a systematic review and meta-analysis. *Otolaryngol Head Neck Surg*. 2016;154:33–40.
11. Kay DJ, Rosenfeld RM. Quality of life for children with persistent sinonasal symptoms. *Otolaryngol Head Neck Surg*. 2003;128:17–26.
12. Hopkins C, Gillett S, Slack R, et al. Psychometric validity of the 22-item Sinonasal Outcome Test. *Clin Otolaryngol*. 2009;34:447–454.
13. Bhattacharyya N. Symptom outcomes after endoscopic sinus surgery for chronic rhinosinusitis. *Arch Otolaryngol Head Neck Surg*. 2004;130:329–333.
14. Ramadan HH, Bueller H, Hester ST, Terrell AM. Sinus balloon catheter dilation after adenoidectomy failure for children with chronic rhinosinusitis. *Arch Otolaryngol Head Neck Surg*. 2012;138:635–637.
15. Ramadan HH. Safety and feasibility of balloon sinuplasty for treatment of chronic rhinosinusitis in children. *Ann Otol Rhinol Laryngol*. 2009;118:161–165.
16. Ramadan HH, McLaughlin K, Josephson G, et al. Balloon catheter sinuplasty in young children. *Am J Rhinol Allergy*. 2010;24:e54–e56.
17. Ramadan HH, Terrell AM. Balloon catheter sinuplasty and adenoidectomy in children with chronic rhinosinusitis. *Ann Otol Rhinol Laryngol*. 2010;119:578–582.
18. Wang F, Song Y, Zhang X, Tan G. Sinus balloon catheter dilation in pediatric chronic rhinosinusitis resistant to medical therapy. *JAMA Otolaryngol Head Neck Surg*. 2015;141:526–531.