



Clinical Validation of the Tremoflo C2 *Versus* Tremoflo C100 in Asthmatic Patients 2-7 Years of Age

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ABSTRACT

Background: Tremoflo C2 is an effort-independent oscillometer successor to C100 and measures resistance and reactance. Our objectives are to assess the reliability between two devices, compare Small Airway Dysfunction (SAD) identification in young asthmatic children, and evaluate device acceptance, feasibility and usability in this age group.

Methods: In 53 asthmatic children 2-7 years, three sets of valid measurements were obtained for R7, R7-19, AX, and X7. SAD was defined as z-scores exceeding 1.645 residual standard deviations. After completion, patients and operators provided feedback. Single measure Intraclass Correlation Coefficient (ICC) determined whether C2 was as acceptable as C100. Bland-Altman analyses examined agreement and proportional bias. The McNemar test evaluated whether the proportion of SAD patients differed significantly between the two tools.

Results: In our study population, 84.9% had mild asthma and 86.8% were well-controlled. Overall ICC indicated good device reliability, and proportional bias was seen only for R7-R19 ($\beta=0.214$ (95% CI .039, .388), $p=.017$). SAD was identified in 47.2% using the C2 device, 49.1% with the C100, ($p=1.00$). Patients and operators preferred C2 over C100.

Conclusion: In our young, predominantly well-controlled, mild asthmatics, the C2 and C100 devices showed good agreement, usability, and preferability of C2 to identify SAD.

Keywords: Airwave oscillometry system; Small airway disease; Uncontrolled asthma; Children; Resistance; Reactance

Abbreviations: AOS-Airwave Oscillometry System; IOS-Impulse Oscillometry System; SAD-Small Airway Disease; FEV1-Forced Expiratory Volume in 1 Second; R-Resistance; X-Reactance; AX-Reactance Area; ICS-Inhaled Corticosteroids; ICC-Intraclass Correlation Coefficients; Hz-Hertz

INTRODUCTION

The National Asthma Education and Prevention Program (NAEPP) guidelines recommend that spirometry be a critical part of asthma diagnosis and management [1]. Using spirometry in young children is difficult due to its effort-dependent cooperation and thus, decreasing data quality with younger age [2,3]. Spirometry values are affected by resistance in the large airways so a markedly reduced Forced Expiratory Volume in One Second (FEV1) is required for prediction of asthma exacerbations, which may be late in detecting early onset symptoms [3]. Oscillometry is a non-invasive, effort-independent device that measures resistance and reactance from a range of frequencies, effective in assessing the central and peripheral airways [4,5]. It is estimated that spirometry becomes abnormal and symptoms appear when 75% of the peripheral airways become obstructed, known as Small Airway Dysfunction (SAD), which may be an early event [6]. Oscillometry is easy to use due to its maneuvers and less execution time compared to spirometry [7]. Several studies have demonstrated its effectiveness in identifying early pediatric asthma and predicting loss of control and exacerbations in children [8-10]. Overall, oscillometry provides a valuable alternative for assessing lung function in very young children and serves as complementary tool alongside spirometry in older children.

As children grow, baseline lung mechanics change, which is especially important in preschool children and those with underlying developmental delay as it is impossible to know their underlying lung function, putting them at risk for significant pulmonary morbidities [11]. Given the limitations with spirometry, asthma control is determined by clinical symptoms and short-acting beta agonist use reported by parents per NAEPP guidelines [1]. Many studies have shown benefits of oscillometry in asthma management and SAD detection in children. Peripheral airways were found to be the major site for airway obstruction, which contribute to poor outcomes in asthmatic children [12,13]. Galant et al. used standardized oscillometry reference values to demonstrate that children with uncontrolled asthma had higher levels of SAD [14]. Another study identified SAD in children with well-controlled asthma by using both spirometry and oscillometry but found oscillometry to be superior in identifying SAD [13]. Therefore, oscillometry should be utilized alongside spirometry as it can be used to identify asthma in young children and predict risk of uncontrolled asthma and exacerbations through detection of SAD [5,9].

Recently, Thorasys developed a new Airwave Oscillometry System (AOS), Tremoflo C2 (Thorasys Inc., Montreal, Canada), which is a successor to Tremoflo C100. Tremoflo C2 is smaller

in size and weight, works wirelessly, and generates the same parameters as Tremoflo C100. Currently, Tremoflo C100 is approved by the Food and Drug Administration for children 4 years and up, but Ducharme et al. suggest that it is feasible to perform oscillometry in children as young as 3 years old and has published reference equations using Tremoflo C100 [15]. With the updated features, we propose that Tremoflo C2 can be utilized in children as young as 2 years old, which may be valuable for early lung function screening [16]. Currently, numerous oscillometry devices exist, but there have been concerns about their comparability and absence of uniform reference values. Previous studies comparing different devices showed good Intraclass Correlation Coefficients (ICC), but proportional bias was seen, particularly when using one set of reference values [17-20]. Ducharme, et al. found proportional bias and recommended specific normative data for each device [18]. The primary objectives of this study are to assess the reliability between two devices (C2 and C100) and identify the percentage of children 2-7 years of age with levels of asthma severity and control aged 2-7 who have SAD. The secondary objective is to evaluate the usability and feasibility of the two devices from both patient and operator perspectives.

MATERIALS AND METHODS

Study population and design

This single-site cross-sectional, prospective study enrolled 60 children with specialist diagnosed asthma, aged 2 to 7 years in the Allergy and Immunology outpatient clinic at Children's Hospital of Orange County (CHOC) located in Orange, California. This study was approved by the CHOC Institutional Review Board (IRB #2209143) and the ethics committee. Tremoflo AOS (Thorasys Inc., Montreal, Canada) C100 and C2 were used. Patient data were collected from September to November 2023. Children with respiratory infections, fever within 14 days, and craniofacial abnormalities were excluded. Potential participants with asthma, ages 2 to 7 years were identified by reviewing future appointments and existing clinical databases. If the participant showed interest, the study's purpose, procedures, voluntariness, and benefits *versus* risks were reviewed. After agreement, informed consent and HIPAA documents were signed. Finally, to be enrolled in the study the patient had to demonstrate the ability to adequately perform oscillometry with both AOS devices. Demographics including age, gender, ethnicity, height, and weight were documented. Asthma severity and control were based on the 2020 NAEPP guideline criteria [1]. Exacerbation was defined as emergency department or urgent care visit, oral steroid use, or

hospitalization 12 months prior to AOS testing. Devices were calibrated daily using a different Tremflo-supplied calibrator for each device and the automated software system, and their sequence of use randomized, depending on odd or even order of the patient. AOS was performed as previously described [5,8]. For the in vivo analysis, three sets of valid measurements were obtained for each device at mutually prime frequencies from 7-41 Hz. Up to 8 trials were permitted to achieve the coefficient of variability of <15%. To avoid interference from increased breathing frequency in young children, a standardized frequency was changed to 7 and 19 Hz, rather than 5 and 20 Hz in older children and adults [18]. Four primary oscillometry metrics (R7, R7-R19, AX, and X7) were measured. Reference equations by Ducharme et al. were used, although their study did not include patients aged 2 years old [15]. SAD was defined as z-scores exceeding 1.645 Residual Standard Deviations (RSD) [14]. After measurements, feedback of each device was obtained from the patients and operators. Survey questionnaires were derived from a previous study and an example is shown in the online supplement [21].

Statistical analysis

The characteristics of the study population were described using counts and percentages for categorical traits and means with standard deviations for age and step of therapy distributions. The mean difference in average oscillometry values between the C2 and C100 was reported, and single measure ICC calculated to evaluate whether the new device was comparable to the older version. Bland-Altman analysis examined agreement between the two devices, including plots of agreement and the

assessment of proportional bias through the significance of the slope in a regression model predicting the difference in oscillometry measurements (C2 vs. C100) based on their average scores. The reliability of the C2 compared to the C100 in identifying SAD based on the ULN threshold (LLN for X7) was described using percentage agreement and disagreement across unique combinations, along with the overall percentage agreement [15]. This analysis was further stratified to examine reliability across potential confounders, testing for significant differences in the percentage of patients identified with SAD within each subgroup using the McNemar test. This test procedure was also applied to compare the percentage of patients and operators strongly agreeing with each question on the satisfaction survey. Analyses were conducted using SPSS v 29.0.

RESULTS

Characteristics of the study population

The population size was reduced from 60 to 53 children due to guardian consent issues (three patients) and their inability to adequately perform both devices in a complete oscillometry data collection (four patients). The patients who were excluded due to poor performance, included a 3 and 6-year-old, and two 2-year-olds. Average age of patients was 4.9 years (SD=1.5) with 37.7% 2-4 years of age, 73.6% were male, and average BMI was 17.0 kg/m² (SD=2.7), Table 1. The majority (84.9%) had mild asthma severity (mild intermittent or persistent asthma), and 86.8% were well-controlled (Table 1). The average step of therapy was 2.3 (SD=1.3), and 44.2% experienced an asthma exacerbation in the past 12 months.

Table 1: Characteristics of the study population, n=53.

mean (SD) or n (valid %)	N=53
Age (years)	4.9 (1.5)
2-4 years	20 (37.7%)
5-7 years	33 (62.3%)
Sex:	
Female	14 (26.4%)
Male	39 (73.6%)
BMI (kg/m ²)	17.0 (2.7)
Asthma Severity:	
Mild Intermittent	27 (50.9%)
Mild Persistent	18 (34.0%)
Moderate Persistent	6 (11.3%)
Severe Persistent	2 (3.8%)
Asthma Control (NAEPP):	

Controlled	46 (86.8%)
Uncontrolled	7 (13.2%)
Step of Therapy:	2.3 (1.3)
Step 1	21 (39.6%)
Step 2	9 (17.0%)
Step 3	10 (18.9%)
Step 4	12 (22.6%)
Step 5	1 (1.9%)
Exacerbation (prior 12 months):	
No	29 (55.8%)
Yes	23 (44.2%)

Comparison of absolute oscillometry metrics between C2 and C100 (Table 2) and (Supplemental Figure 1).

Table 2: Comparison of absolute oscillometry metrics between C2 and C100.

IOS metrics:	C2 mean (SD)	C100 mean (SD)	ICC (95% CI)^a	CCC (95% CI)
R7	8.8 (2.6)	8.7 (2.5)	.787 (.658, .871)*	.788 (.656, .872)*
R7-19^b	2.3 (1.6)	2.6 (1.3)	.809 (.689, .886)*	.791 (.660, .875)*
X7	-4.5 (2.0)	-4.8 (2.2)	.865 (.777, .920)*	.859 (.767, .917)*
AX^b	53.4 (28.3)	47.2 (24.7)	.848 (.855, .953)*	.825 (.710, .897)*

Note: *p<.05; ^a-Single measure Intraclass Correlation (ICC) coefficient was utilized to focus on whether the new version is as acceptable as the older version. This produces a more conservative estimate of ICC than the average measure ICC; ^b-For AX, three extreme values, and for R7–R19, one extreme value, were excluded from the Reported mean (SD) to avoid undue influence of non-representative outliers on the descriptive statistics. All observations were retained for the ICC and CCC calculations; All oscillometry metrics are in cmH₂O/L/s.

To evaluate the acceptability of C2 to replace the older device C100, single-measure ICCs were calculated for each oscillometry metric, Table 2. ICC values suggested reliability between devices across all four metrics: R7 (0.787), R7-19 (0.809), X7 (0.865) and AX (0.848). Lin's concordance correlation coefficients (CCC) indicated strong agreement between devices across all metrics: R7 = 0.787, R7–R19 = 0.791, X7 = 0.859, and AX = 0.825. Bias-correction factors were near 1 (0.92–0.99), suggesting minimal systematic shift between devices and reinforcing interchangeability alongside the ICC results. Of the four major metrics, R7, R7-19, X7, and AX, proportional bias was only seen for R7-R19 (p= 0.017), Supplemental Figure 1. As the average R7-R19 metric increased, the difference between C2 and C100 also increased. The coefficient (β = 0.214; 95% CI 0.039, 0.388) indicates that for every one unit increase in the

average R7-R19 value, the difference between the two devices increases by 0.214 units. Although notable is that only two observations fell outside the limits of agreement, as shown in Supplemental Figure 1, panel b, suggesting the overall agreement between the two devices (Supplemental Figure 1).

Reliability of C2 in comparison to C100 across metrics evaluated as dichotomy (abnormal vs normal value)

Overall comparisons of oscillometry metrics between the two devices in terms of abnormal (SAD identified) vs normal values showed general agreement ranging from 79.3% to 96.2% for the four metrics (Supplemental Table 1). Examination of SAD identification by abnormal value for any of the four metrics showed no significant differences in SAD percentage between the C2 device at 47.2% compared to the C100 device at 49.1% (p=1.00),

(Table 3). In addition, there was 79.2% agreement between devices. Agreement was not significantly affected by age, gender, asthma severity, step of therapy, or history of an exacerbation. Although a slightly higher percentage of patients were identified with SAD using the C100 device compared to the C2 (47.8% vs. 43.5%, respectively, $p < .001$), the overall

agreement between the two devices was 82.6%. For the seven non-well-controlled asthmatics, the percent SAD for the C2 device was 71.4%, compared to 57.1% for the C100 device with percent agreement of 57.1%, but limited interpretation by small sample size (Figure 1).

Table 3: Reliability of C2 in comparison to original C100 tool for identifying SAD by abnormal value on any of four measures (R7, X7, R7-19, or AX) within strata, n=53.

Characteristic	n	C2 % SAD	C100 % SAD	P-value	% Agree
Overall	53	47.2%	49.1%	1.00	79.2%
Age (years)					
2-4 years	20	50.0%	55.0%	1.00	85.0%
5-7 years	33	45.5%	45.5%	1.00	75.8%
Sex:					
Female	14	35.7%	28.6%	1.00	78.6%
Male	39	51.3%	56.4%	.727	79.5%
Asthma Severity:					
Intermittent	27	40.7%	55.6%	.219	77.8%
Persistent	26	53.8%	42.3%	.375	80.7%
Step of Therapy:					
1-2	30	43.3%	53.3%	.453	76.7%
3 or higher	23	52.2%	43.5%	.625	82.6%
Exacerbation (prior Yr):					
No	29	51.7%	51.7%	1.00	65.5%
Yes	23	39.1%	43.5%	1.00	95.7%
Asthma Control Status:					
Well Controlled	46	43.5%	47.8%	<.001*	82.6%
Uncontrolled	7	71.4%	57.1%	1.00	57.1%
Note: * $p < .05$; ^a p-value based on McNemar test of difference in percentage of patients in whom SAD detected by each tool. No significant difference between factor levels in percentage with SAD was detected for either tool based on Chi-square test, $p > .05$. Percentage with SAD evaluated by asthma control status for each tool using Fisher's exact test (C2 43.5% vs. 71.4%, $p = .234$; C100 47.8% vs. 57.1%, $p = .704$)					

Patient reaction to device

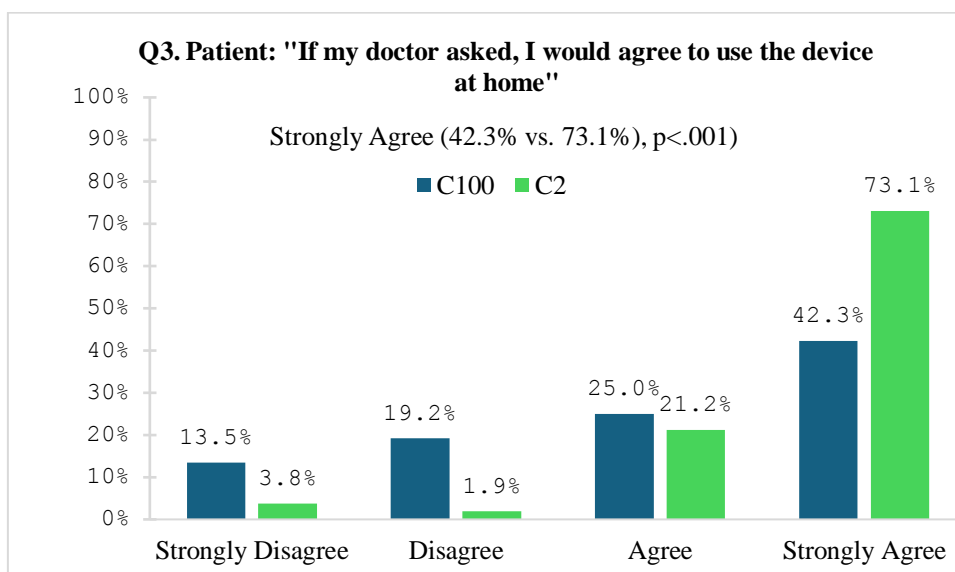
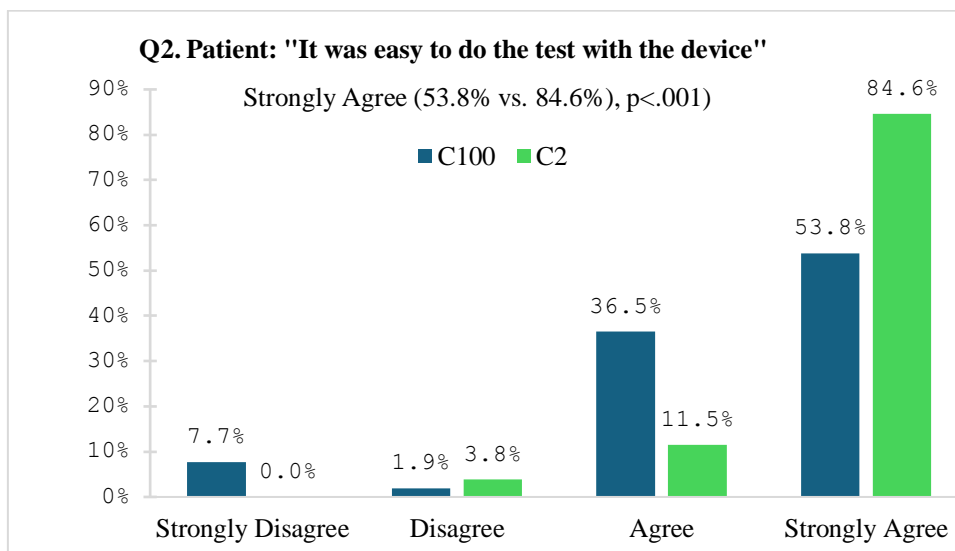
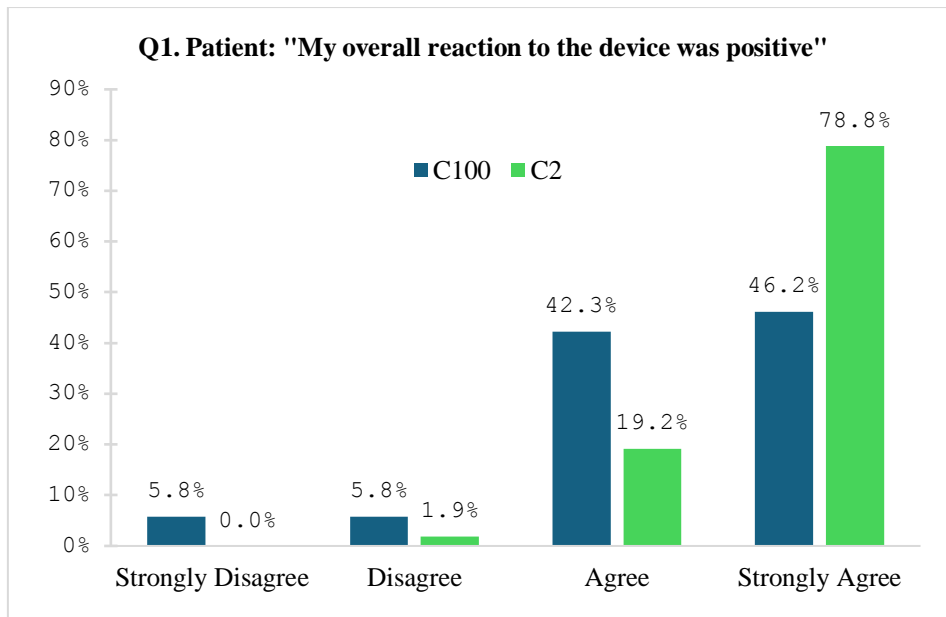


Figure 1: Patient reaction to device, whether they found easy to use, and their willingness to use at home comparing C100 to the newer C2 version (p-value based on McNemar test), N=52 with responses.

A greater proportion of patients strongly agreed that they had an overall positive reaction to the C2 device (78.8%) *versus* the C100 device (46.2%), greater ease of performance to the C2 device (84.6%) *versus*

the C100 device (53.8%), and increased willingness to use the device at home if recommended by their doctor in the C2 device (73.1%) *versus* the C100 device (42.3%) (Table 4).

Table 4: Operator perception regarding the C100 compared to newer C2 device across 52 patients.

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
Q1. My overall work experience with the device was positive:					
C100	2 (3.8%)	1 (1.9%)	8 (15.4%)	12 (23.1%)	29 (55.8%)
C2	0 (0.0%)	1 (1.9%)	2 (3.8%)	2 (3.8%)	47 (90.4%)
Q2. It was easy to perform the test with the device:					
C100	1 (1.9%)	2 (3.8%)	3 (5.8%)	12 (23.1%)	34 (65.4%)
C2	0 (0.0%)	1 (1.9%)	0 (0.0%)	3 (5.8%)	48 (92.3%)
Q3. The software interface was easy to use:					
C100	4 (7.7%)	16 (30.8%)	7 (13.5%)	7 (13.5%)	18 (34.6%)
C2	0 (0.0%)	2 (3.8%)	3 (5.8%)	2 (3.8%)	45 (86.5%)

Operator perception to C100 vs C2: Table 4

A higher proportion strongly agreed that their overall work experience with the device was positive (90.4% *vs.* 55.8%, $p < 0.001$), that performing the test was easy (92.3% *vs.* 65.4%, $p < 0.001$), and that the software interface was user-friendly (86.5% *vs.* 34.6%, $p < 0.001$) compared to the C100.

DISCUSSION

Our clinical data show that C2 and C100 are interchangeable and comparable in all metrics. In our predominately well-controlled population with mild asthma, good agreement between the C2 and C100 was observed for resistance and reactance values, based on mean measurements, classification of value as abnormal *versus* normal for each metric, and proportion of patients identified with SAD by any metric. Proportional bias was seen in R7-R19, although only two patients were outside the limits of agreement and ICC values remained for this metric high throughout most frequencies. As Wong, et al. suggests, there may be fluctuations in the measurements from underlying airway instability in pediatric asthmatics [22]. Some variability and bias seen between the two devices may be attributed by the physiologic heterogeneity of the asthmatic lungs rather than the devices themselves.

Previous studies have compared different oscillometry devices and their measurement outcomes. Using a ventilator to stimulate breathing, Dandurand et al. compared several commercially

available and custom-built devices including the Tremoflo C100 and found a large degree of variability in resistance and reactance [17]. In pediatric subjects from 3-7 years of age with asthma, Ducharme et al. compared several commercially available devices including the Tremoflo C100 and found high ICC in resistance and reactance but significant proportional bias in most within breath parameters at 5 *vs* 7 Hz [18]. Kuo et al. compared the Tremoflo C100 AOS and Jaegar Impulse Oscillometry System (IOS) in adults with asthma and chronic obstructive pulmonary disease and found small to high degree of comparative bias between AOS and IOS for resistance and reactance respectively with higher R5 and R20 in IOS and higher X5 and AX in AOS [19]. Similarly, Lundblad et al. demonstrated a difference between the Tremoflo C100 and the Jaeger IOS that tended to increase with the severity of COPD, using a phantom with different impedances; also showing that the IOS underestimated the impedance compared with the Tremoflo C100 in a similar way as in the patients [20]. These studies suggested the importance of using specific reference values for each device. However, our data suggested good agreement and comparability using the same reference equation between the two different models of the Thorasys Tremoflo device. Hence, we conclude that any variability or difference between the devices is likely to emanate from the test subjects and not from the devices.

Although most patients were diagnosed by asthma specialists as mild and well-controlled, over 50% had an exacerbation in the previous 12 months, and

both C2 and C100 detected SAD in approximately 50% of patients, the latter a proven exacerbation risk factor. SAD could be an explanation for the higher risk of exacerbations in the future despite the physician diagnosis of well-controlled asthma, particularly in the young asthmatic. This potentially explains why some children have difficult-to-control asthma and exacerbations despite treatment. Future studies should explore SAD in this population using oscillometry devices to determine if these children would be at risk for future exacerbations despite their diagnosis of mild and well-controlled asthma.

Survey results from both the patients and operators were overall positive for both portable devices, with a preference for C2 over C100 due to its smaller size and user-friendly design. Operators commented that C2's size and weight made it easier to hold while collecting data from the patients. The program interface for C2 was quicker to use compared to C100. In some patients, C100 required more trials to obtain measurements despite similar efforts with both C2 and C100. With the new updates, C2 will be versatile at various clinical and potentially home-based settings and applicable at ages from 2 years and up.

Study limitations

Our study had a small sample size of 53 patients, resulting in reduced power. There was less diversity in the patient population in asthma control and severity. Compared to previous studies, our study used different frequency of 7 Hz to avoid interference from the increased breathing frequency seen in young children [18]. Additionally, the reference equations adapted from Ducharme et al. were based on the C100 device in children 3 years and above, being unable to enroll children less than 3 years of age [15]. However, we used the same equation to establish SAD for our patients who are 2 years of age and for the new C2 device. In our study, we had four children aged 2 years old with the youngest being 2 years and 1 month. Although this could potentially be a limitation, this may be a strength as we were able to successfully demonstrate good agreement on both devices and detect SAD in that population, especially as this cannot be done using spirometry alone.

CONCLUSION

In conclusion, there was good agreement for resistance and reactance between the Tremoflo C2 and C100. Therefore, these equations might prove appropriate for the new C2 model starting at age of 2 years to identify SAD, pending more data in this age cohort. Although both C2 and C100 oscillometers are effective in identifying SAD,

especially in younger population, C2 might be preferable, given the feedback.

DECLARATION

Conflict of interest

No conflict of interest declared.

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Author contribution statement

Drs. Stanley P. Galant and Lennart K. A. Lundblad designed the study. Dr. Yela Jung, Dr. Sarah S. Field, and Zarah Chhoet screened patients and collected patient data. Dr. S. P. Galant, Dr. Y. Jung, and Tricia Morphey analyzed the patient data. Dr. Y. Jung wrote the manuscript with input from Drs. S. P. Galant and L. K. A. Lundblad. T. Morphey wrote the statistical method and analysis. Dr. S. P. Galant is the main principal investigator. All authors approved the final version and agreed to be accountable for the work.

Ethical approval

This study was approved by the CHOC Institutional Review Board (IRB #2209143) and the ethics committee.

Data availability

Not applicable.

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