

Evaluating the Use of a Portable Spirometer in a Study of Pediatric Asthma*

Kathleen M. Mortimer, ScD, MPH; Andre Fallot, MD, MPH;
John R. Balmes, MD, FCCP; and Ira B. Tager, MD, MPH

Study objectives: Laboratory-based spirometry is the “gold standard” for the assessment of lung function, both in clinical and research protocols. These spirometers, however, are neither practical nor affordable for home-based monitoring or studies that collect data in multiple locations. Traditionally, peak flowmeters have been used, but they have important limitations.

Design: Based on data from a cohort of 92 children with asthma, we evaluated the agreement between a portable spirometer and a office-based spirometer, using an in-line technique to evaluate measures from the same effort. We compared a range of pulmonary function parameters collected during office-based tests, and also evaluated whether adequate adherence and data quality could be achieved in a home-based study of children with asthma.

Results: The agreement between the devices for the actual values of peak expiratory flow, FEV₁, and forced expiratory flow at 25% of FVC was excellent. The portable device was programmed with customized software to grade each curve using revised American Thoracic Society acceptability and reproducibility criteria. For 74% of the curves, quality grade agreed with a grade assigned by physician review of the curve from the office-based spirometer. During 2 weeks of twice-daily monitoring at home, children completed an average of 23 of 28 possible sessions (83%). Of these, 84% had at least two acceptable and two reproducible curves. Although children ≥ 8 years old were not more adherent, they were significantly more likely to achieve acceptable and reproducible curves.

Conclusions: Portable spirometers can provide measurements that are highly comparable to those obtained from “gold standard” laboratory spirometers, and high-quality tracings can be achieved both at home and in the office setting. Visual inspection of the curves by experienced reviewers identified unacceptable curves that were not rejected by the quality control software. Portable spirometers are an important contribution to epidemiologic and clinical studies that require frequent measures of a more broad range of pulmonary function parameters than can be provided by peak flowmeters. (CHEST 2003; 123:1899–1907)

Key words: pediatric asthma pulmonary function testing; spirometry panel studies

Abbreviations: ATS = American Thoracic Society; FACES = Fresno Asthmatic Children’s Environment Study; FEF_{25–75} = forced expiratory flow between 25% and 75% of FVC; FEF₇₅ = forced expiratory flow at 75% of FVC; PEF = peak expiratory flow

Laboratory-based spirometry is the “gold standard” for the assessment of lung function in children with asthma, both in clinical and research protocols. Due to technician and equipment costs,

however, peak flowmeters often are used for home monitoring of lung function of children with asthma in clinical settings and epidemiologic studies. Such use of peak flow measurement has been advocated by the National Asthma Education and Prevention Program. The value of these measurements is limited, however, because peak expiratory flow (PEF) is effort dependent and only reflects flows of the large airways in contrast to FEV₁ and forced expiratory flow between 25% and 75% of FVC (FEF_{25–75}), which characterize the flows in both the large and small airways. It has been shown that peak flowmeter recordings are not highly reproducible, and are no better at predicting asthma exacerbations than monitoring symptoms alone.^{1–4} Portable spirometers

*From the Division of Public Health Biology and Epidemiology (Drs. Mortimer, Fallot, and Tager), University of California, Berkeley; and Division of Occupational and Environmental Medicine (Dr. Balmes), University of California at San Francisco, San Francisco, CA.

The study was funded by the California Air Resources Board, Contract 99-322.

Manuscript received April 30, 2002; revision accepted December 17, 2002.

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Correspondence to: Kathleen Mortimer, ScD, MPH, 1918 University Ave, #3C, Berkeley, CA 94704; kmort@uclink.berkeley.edu

have the ability to collect a wide range of pulmonary function parameters that are more clinically and epidemiologically useful, in that they are more sensitive to changes in functional status in asthma.⁵

Two studies^{6,7} have evaluated the practicality and validity of home spirometry in children with asthma. Unfortunately, neither study validated the device used by comparison with a "gold standard," laboratory-based spirometer. Although both studies examined adherence and reproducibility of efforts in the home setting, neither study mentions the use of quality control measures to ensure acceptability of efforts prior to evaluation of their reproducibility.

We performed a direct comparison of a portable spirometer (EasyOne; ndd Medical Technologies; Andover, MA) with an office-based volume spirometer (model RS232; Morgan Scientific; Winchester, MA), based on an in-line technique to simultaneously measure forced expiratory maneuvers from both instruments. The acceptability of each curve was determined independently for each device. Customized quality control software was used to determine the acceptability of curves obtained by the portable spirometer. The acceptability of curves generated on the office-based spirometer was initially determined by the technician and underwent further independent review by three physicians experienced in the interpretation of spirometry (A.F., J.R.B., I.B.T.). Volume-time and flow-volume curves were reviewed. The curves from each effort in a given session were considered during the review. Any differences in interpretation were resolved by consensus. The agreement between the two methods of acceptability grading was compared. Additionally, a 2-week home study using only the portable spirometer was performed with the same children to assess adherence and the acceptability and reproducibility of efforts.

MATERIALS AND METHODS

Study Population

This report includes a subset of 92 children enrolled in the Fresno Asthmatic Children's Environment Study (FACES), a longitudinal study of the effect of air pollution and other environmental agents on the health of asthmatic children aged 6 to 11 years. The study was approved by the Committee for the Protection of Human Subjects of the University of California, Berkeley, and the Committee on Human Research at University of California at San Francisco.

The FACES design consists of longitudinal and panel components with > 4 years of follow-up. Every 6 months, each child will undergo lung function testing. For the panel component, children will be observed for three 2-week panels per year for up to 4 years. During panel periods, daily data will be obtained on the following: twice-daily forced expiratory volumes, symptoms, and medication use. For both the panel and longitudinal components,

lung function is the primary health outcome of interest. Given that it is not feasible to do office-based testing on a daily basis for several weeks, it was desirable to obtain an affordable and portable device that would give comparable measurements to the office spirometer. Key requirements included the following: (1) the ability to record and store full flow-volume curves and answers to a series of medication and symptom questions; (2) inclusion of quality control software and prompts to obtain acceptable and repeatable efforts; (3) time and date stamping of all records; (4) easy transfer of specific flows and volumes to a personal computer database; (5) ability, with minimal cleaning, to be reused to test multiple children; (6) easy calibration; (7) inclusion of an incentive program to improve adherence; (8) reminder alarm and limitations on the times of day that entries can be collected; and (9) compliance with American Thoracic Society (ATS) criteria for spirometer performance. Because FACES is not an intervention study, we wanted to mask the results to avoid influencing the children's behavior with respect to their asthma, based on pulmonary function readings. The EasyOne device met all of these criteria.

Equipment and Setup

The EasyOne portable spirometer is a small, portable device that uses ultrasound flow sensors to measure airflow through a hollow disposable mouthpiece (thin-walled spirette). The ultrasonic flow measurement is independent of gas composition, pressure, temperature, and humidity, and eliminates errors due to these variables. Since the disposable spirette has no sensor elements, it does not perform a measurement function and does not require calibration. Hundreds of sessions of spirometric data can be stored in memory, and later can easily be uploaded to a computer database. All sessions are time and date stamped. The device has a screen that can display up to 40 characters of text as well as flow-volume curves. A numeric keypad allows the user to answer yes/no questions that are displayed on the screen. The device has no moving parts requiring calibration. The office-based volume spirometer used in this study is a 12-L dry rolling seal spirometer. The spirometer is attached to a monitor that displays flow-volume curves to assist the technician in the evaluation of acceptability and reproducibility.

Due to the inherent variability of pulmonary function parameters in children with asthma due to bronchial reactivity, we used reproducibility criteria that are less stringent than those proposed by ATS. The ATS criteria were established for more general testing, and do not account for the particular difficulties faced in testing children and asthmatics.⁸ Based on our criteria that were developed specifically for asthmatic children (Table 1) the technician can decide whether the data from each curve should be saved.

Office-Based Testing

Prior to testing each child, both machines underwent verification of calibration at multiple flow rates with the same 3-L syringe. Ambient temperature, barometric pressure and humidity were entered into the software for the volume spirometer to calculate a body temperature and pressure, saturated, correction factor. Because the flow sensors of the portable spirometers are insensitive to humidity and ambient temperature, the only correction factor used was for an estimated temperature drop of 4°C between the mouth of the child and the flow sensors (as recommended by the manufacturer). The distal end of the portable spirometer mouthpiece was attached via a standard ventilator adapter to steel-reinforced tubing that led to the inlet of the volume spirometer (Fig 1). To ensure proper posture and

Table 1—Acceptability and Reproducibility Criteria

Acceptability Criteria	Reproducibility Criteria
Back-extrapolated volume must be < 150 mL or 5% of the FVC	The current PEF and the previous largest PEF from an acceptable effort must be within 20%
Time to peak flow must be \leq 120 ms	The current FEV ₁ and the previous largest FEV ₁ from an acceptable effort must be within 10%
No abrupt ending (abrupt ending occurs when > 100 mL of volume is accumulated in the 0.5-s interval preceding end of test)	The current FVC and the previous largest FVC from an acceptable effort must be within 10%

to avoid motion during a maneuver, the portable spirometer was clamped in place in a stand that was adjusted to each child's sitting height.

At the start of the baseline office visit, children were taught to perform a forced expiratory maneuver with the portable spirometer. The same portable unit was used to test all children. Training included demonstration and coaching by an experienced technician and was limited to three efforts to avoid tiring the children prior to actual testing. A parent was present during the training. Parents and children were then instructed verbally on the use of the other features of the portable spirometer, including the following: (1) the coaching messages displayed by the quality control software, (2) the timer and alarm to remind the children to complete sessions during the specified time windows, (3) how to answer the yes/no questions on symptoms and medication use at the end of a session, and (4) the incentive point scoring system. After the training, standing height (in stocking feet) and sitting height were measured with a wall-mounted stadiometer. Weight measurements were also obtained.

Children were coached through a prebronchodilator session of forced expiratory maneuvers and were seated, wearing nose-clips. The children were allowed up to eight attempts to achieve three

acceptable efforts with at least two that met reproducibility criteria (Table 1). Each effort was measured simultaneously by both machines with the in-line setup. Two puffs of albuterol were then administered via a metered-dose inhaler and spacer with facemask, and children were allowed to rest for 20 min. A postbronchodilator session was then performed. Children again were permitted up to eight efforts to achieve three acceptable maneuvers with at least two of them meeting reproducibility criteria. For participation in the baseline visit, children were given gift packages that included approximately \$50 worth of coupons from local vendors and food establishments.

Home Panel Measurements

Within 1 month of completion of the baseline spirometry measurements, children were given an EasyOne portable spirometer with the customized FACES quality control software to perform twice-daily spirometry at home for 2 weeks. Prior to home delivery, new batteries were installed and each unit underwent verification of calibration at varying flow rates with the same 3-L syringe that is used in the laboratory.⁹ Children were given a set of photographic instructions accompanied with

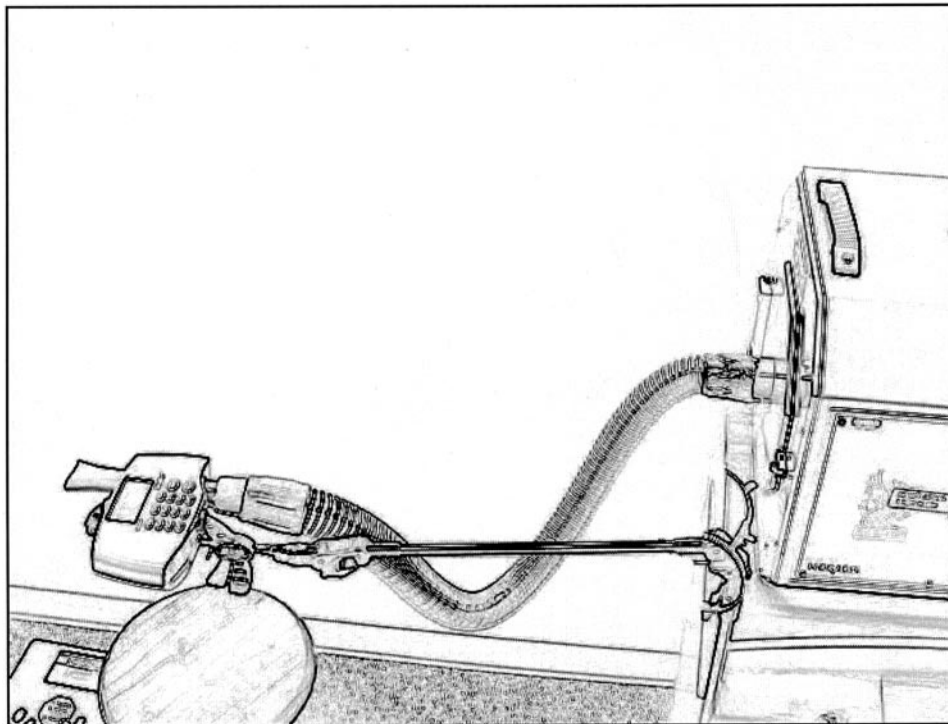


FIGURE 1. In-line configuration for office-based and portable spirometers.

text instructions in both English and Spanish. The serial number of each unit was recorded in each child's chart. The portable spirometers were programmed with an alarm that activated during the time windows of 7 to 9 AM and from 7 to 10 PM to remind children to perform the tests. The spirometers operate only within these time windows, and the units only allow one session of up to six attempts during each time window. The spirometers used the same acceptability and reproducibility criteria noted previously (Table 1) to evaluate each effort. If a criterion was not met, the message prompted the child on how to improve the subsequent effort, such as "Blow out longer." Children were allowed six attempts to achieve three acceptable efforts with two of them meeting all of the reproducibility criteria. Data were saved for each of the three best efforts even if the acceptability and reproducibility criteria were not satisfied during the session. The curve with the largest sum of FEV₁ plus FVC was chosen as the best. The only exception was when an unacceptable curve had the greatest sum, but the session included an acceptable curve with a smaller sum of FEV₁ plus FVC. All sessions were time and date stamped. At the end of each session, children were prompted to answer a series of questions about asthma symptoms and medication use by entering "yes" or "no" on the spirometer keypad. After the completion of the 2-week home panels, a \$25 gift certificate to a toy store was mailed to each child.

After answering all the questions at the end of each session, the cumulative point total defined by the FACES incentive scoring system was displayed. The incentive system was designed to balance the need to reward children for performing daily readings, yet not discourage children who were unable to achieve acceptable or reproducible tracings. For each session, 500 points were awarded if three acceptable and at least two reproducible efforts were obtained and all questions were answered. If six attempts were made and all questions were answered but the efforts failed to meet either the acceptability or reproducibility criteria, the session was awarded 200 points. Over a 14-day period, a total of 14,000 points could be obtained. The number of points was stored in the software and children were allowed to pick out various prizes during their next visit, based on the total number of points.

Agreement Between Physician and Quality Control Software Grading

To assess the ability of the customized FACES quality control software to determine whether a forced expiratory maneuver was acceptable, the three physicians independently reviewed the office-based maneuvers stored by the volume spirometer, based on the same acceptability criteria applied to the portable spirometer. The reviewers included one additional criterion that was not programmed into quality control software. Efforts were declared unacceptable if the middle portion of the time-volume curves displayed any deviation as outlined by the ATS 1994 update of spirometry standardization.⁵ The reviewer's assessment for each effort obtained from baseline sessions on the volume spirometer was then compared to the determination of acceptability for that effort of the portable spirometer. Because the quality control software was not programmed to evaluate the entire curve, the physicians' visual review takes priority throughout this report.

For the 2-week home panel testing, the child's identifying information, time and date, pulmonary function testing measures, acceptability status, and answers to the questions for each session were uploaded to a single database for evaluation (Access 97 for Windows; Microsoft; Redmond, WA). Adherence during the 2-week panels was calculated as a percentage of sessions out of a total possible 28 sessions completed by a child. We also calculated the percentage of sessions with at least three acceptable

efforts and with at least two curves that met all three of the reproducibility criteria (FEV₁, FVC, and PEF). Additional reproducibility measures were calculated separately for FEV₁, FVC, and PEF. The panel data included in this report have not yet undergone expert visual review to determine if they meet our more stringent acceptability and reproducibility criteria. This will be done in future health-effects analyses, in which case we can "override" the determination of the software of the quality of the data if necessary.

Statistical Methods

For each effort and several lung function parameters, the measured difference between the two devices (office-based minus portable device value) was plotted against the mean of the values measured by both instruments.^{10,11} Only efforts that were determined acceptable by both the reviewers and the portable spirometer were used in the plots. Due to the differing abilities of the children, the number of maneuvers contributed by each child to the plots was variable. A repeated-measures analysis using a random-effects model (lme routine of Splus; Insightful; Seattle, WA) was used to calculate a 95% confidence interval for each of the plots.¹⁰ The Shapiro-Wilk test and normal probability plots were used to test the normality of the differences observed between the devices for each of the spirometric indexes. Confidence intervals were also obtained nonparametrically using a bootstrap technique. Ten thousand bootstrap samples were generated to estimate the 2.5% and 97.5% quantiles of the distribution of the measurement differences between the two devices.

"Completeness" and "reproducibility" of the 2-week panel data were continuous variables that were compared across various demographic characteristics. Testing across dichotomous variables was done using PROC TTEST (SAS Institute; Cary, NC) and tests for categorical variables with more than two levels were assessed using PROC ANOVA (SAS Institute), with a significance level of $p < 0.05$; SAS version 6.12 was used for these analyses.¹²

RESULTS

Office-Based Spirometry

The characteristics of the first 92 children who completed the in-line testing and who completed the

Table 2—Characteristics of Study Group (n = 92)*

Characteristics	Data
Mean age at office visit (SD), yr	8.7 (1.42)
Mean height (SD), cm	133.3 (11.2)
Male gender	57
Race	
African American	15.2
Hispanic	39.1
White	33.7
Other	12.0
Ever hospitalized for asthma	23
Hospitalized or had an emergency department visit in 12 mo prior to baseline	64
Ever prescribed oral steroids	66
Prescribed controller medications in 12 mo prior to baseline	85
Mean FEV ₁ (SD), L†	1.80 (0.42)
Mean FVC (SD), L†	2.07 (0.49)

*Data are presented as % unless otherwise indicated.

†Calculated as the mean of up to three acceptable curves obtained during the in-office postbronchodilator session.

Table 3—In-Office Comparison of Acceptability Grading for Each Device

Variables	Software/Portable Spirometer		Total
	Acceptable	Not Acceptable	
Physician/office spirometer	369	18	387
Acceptable	122	21	143
Not acceptable	491	39	530

2-week panel can be found in Table 2. Table 3 presents the curve-by-curve evaluation from each method for determining acceptability. Among the 530 curves from 180 sessions, the overall agreement between the physician and software acceptability scores was 74%. Based on the slightly more stringent criteria (eg, mid-curve review by a physician), significantly more curves from the office-based spirometer (27%) were rejected than from the portable spirometer (7%) [$p < 0.001$]. The physicians rejected 25% of the curves that were coded as acceptable by the portable spirometer. Nearly all of the rejections were due to problems at the end of the test, such as small leaks or coughs. The majority of those curves, however, can be included in analyses limited to PEF or FEV₁, which are not influenced by what happens at the end of the test.

Based on physician review of the curves and using the reproducibility criteria for three pulmonary function parameters (FEV₁, FVC, and PEF), 43% of the office-based sessions had at least three acceptable and at least two reproducible curves, and 66% had at least two acceptable and reproducible curves. According to the quality control software of the portable spirometer, > 97% of the sessions included at least one acceptable curve, but only 67% had at least three acceptable and two reproducible curves. Because it is harder for asthmatic children to perform a series of acceptable efforts due to bronchoconstriction, we examined the number of times that at least two (rather than three) reproducible efforts were

achieved. When we relaxed the criteria, we found that 85% of sessions had at least two curves that met all of the acceptability and reproducibility criteria. The results based on reproducibility criteria for each individual parameter are presented in Table 4. As would be expected, when the reproducibility criteria were based only on one parameter (ie, FEV₁ or FVC or PEF), the percentage of sessions with three acceptable and at least two reproducible curves improved.

These comparisons between the pulmonary function values from each device are limited to curves that were determined to be acceptable by both methods of evaluation, and include 87 children. Figure 2 presents a curve-by-curve comparison of the difference vs the mean for each of several key pulmonary function parameters. The confidence intervals presented in Figure 2 were obtained from the random-effects model. Although the Shapiro-Wilks test suggested that the differences between the devices for nearly all the measures were normally distributed, the confidence intervals obtained from the bootstrap method are also presented in Table 5, which summarizes the magnitude of the differences for each measure.

The best agreement was seen for FEV₁ and PEF. For these measures, there does not appear to be any systematic difference between readings obtained from the two devices and only one outlier was identified (for PEF). The agreement for parameters influenced by the end of the curve, such as FEF₂₅₋₇₅ and FVC, was less strong. The volume spirometer uses a “zero flow” criterion, where as the portable spirometer uses a finite flow plateau. Detailed examination of the relationship between machine differences in FVC (as a measure machine differences in end-of-test identification) was most consistent with subtle differences in the actual algorithms used by the manufactures to implement the criteria or differences in the sensitivity of the measure devices at very low flow rates (data not shown). When the devices were evaluated separately (not in-line) within

Table 4—Office-Based Sessions With Acceptable and Reproducible Curves*

Reproducibility Criteria	At Least Three Acceptable and Two Reproducible Curves		At Least Two Acceptable and Two Reproducible Curves	
	Office Spirometer and Physician Review	Portable Spirometer	Office Spirometer and Physician Review	Portable Spirometer
	FEV ₁ , FVC, PEF	43	67	66
FEV ₁ only	45	86	68	90
FVC only	46	83	69	88
PEF only	46	86	71	91

*Data are presented as %.

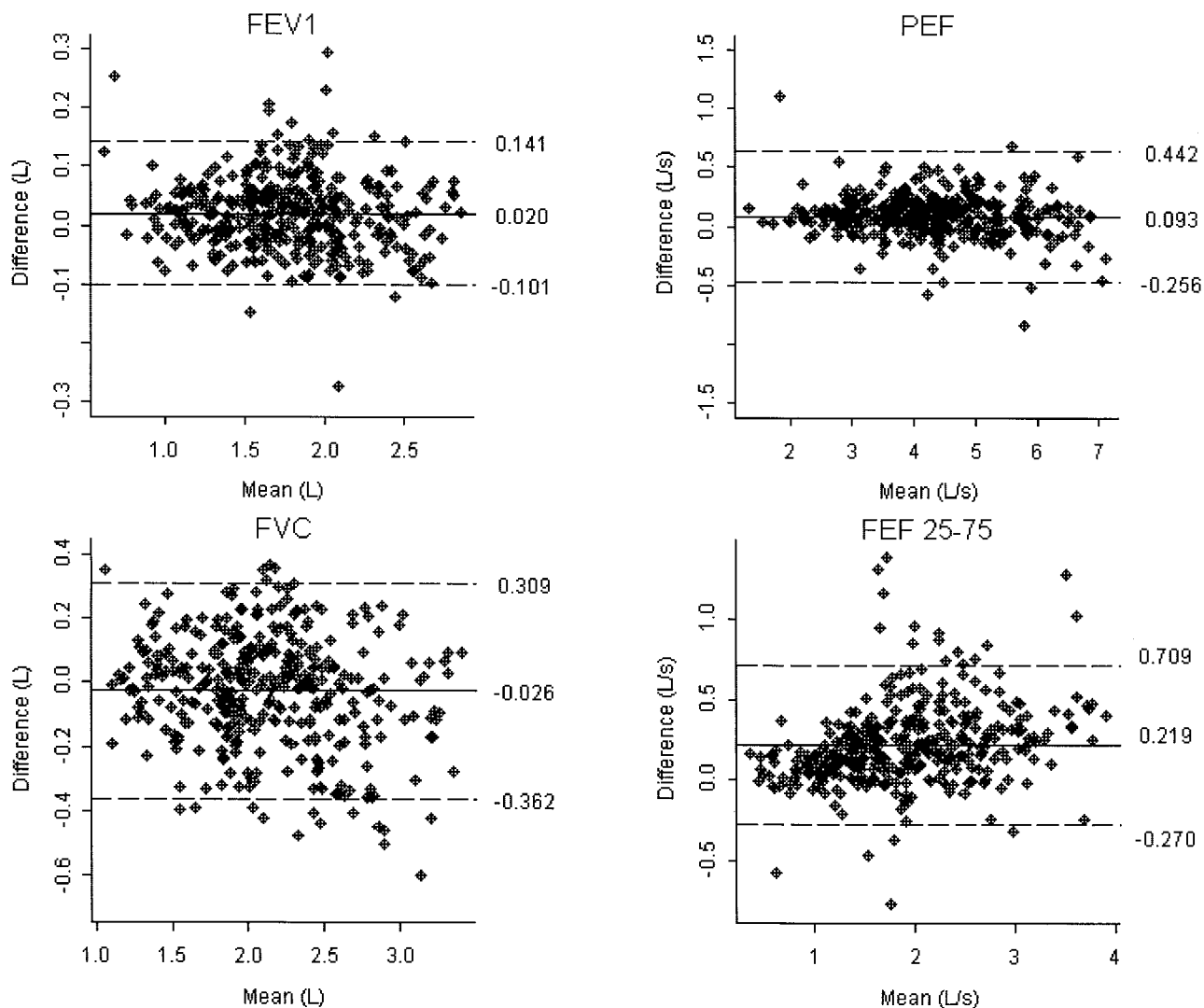


FIGURE 2. Office-based spirometer value minus portable spirometer value vs mean of two values.

a group of several adults, the agreement between the FEF₂₅₋₇₅ value from each device improved (data not shown).

To obtain an additional quantitative measure of agreement, we also evaluated the devices using reproducibility criteria across devices, rather than within devices. The “best curve” from the session on the office-based spirometer was identified as the one with the maximum sum of FEV₁ and FVC. We then calculated whether the portable spirometer data from the same effort met the reproducibility criteria using the best curve from the office-based device. For 72% of the sessions, all three reproducibility criteria were met. The reproducibility based on individual parameters was 97%, 75% and 98% for FEV₁, FVC, and PEF, respectively.

Adherence During the Home Panels

The adherence information from the 2-week home panels is presented in Table 6. All 92 children in this analysis were doing 2-week panels for the first time. On average, the children attempted 23 of 28 possible sessions (83%). Adherence was only slightly lower for morning vs evening sessions. Adherence was similar for the first and second weeks of monitoring, 82% and 85%, respectively. According to the grading of the quality control software, at least one acceptable effort was obtained during 94% of the sessions. Three acceptable and two reproducible curves were obtained in 1,271 of 2,151 sessions (59%) [Table 5]. The median number of sessions per child that met these criteria was 16 (range, 0 to 28). When the reproducibility criteria were based only on one pa-

Table 5—Between-Device Agreement for Various Pulmonary Function Measures*

Measures	Mean Value	Mean Difference (Office – Portable)	% Difference	95% CI†
FEV ₁ , L	1.75	0.02	1.1	– 0.08–0.15
FVC, L	2.12	– 0.02	– 0.9	– 0.40–0.28
PEF, L/s	4.27	0.07	1.6	– 0.27–0.45
FEF ₂₅ , L/s	3.66	0.08	2.2	– 0.40–0.50
FEF ₅₀ , L/s	2.24	0.07	3.1	– 0.37–0.66
FEF ₇₅ , L/s	0.94	0.08	8.5	– 0.35–0.69
FEF _{25–75} , L/s	1.90	0.22	11.6	– 0.18–0.84

*Includes only curves coded as acceptable by reviewers. FEF₂₅ = forced expiratory flow at 25% of FVC; FEF₅₀ = forced expiratory flow at 50% of FVC; CI = confidence interval.

†Obtained from bootstrap method and differ from the random effects confidence intervals presented in Figure 2.

parameter, the median number of sessions per child that met these criteria was 74%, 75%, and 82% for FEV₁, FVC, and PEF, respectively.

As described in “Materials and Methods,” the incentive point system takes into consideration both the completion and quality of the readings. Of 14,000 possible incentive points, the average number of points was 8,816 (range, 200 to 14,000 points).

Neither adherence nor the number of points received were significantly different according to age, race, or gender. The percentage of sessions with three acceptable and two reproducible tracings was

significantly higher in the children who were > 8 years old, but did not significantly differ by race or gender. More frequent medication use was associated with increased adherence but decreased ability to achieve acceptable and reproducible tracings. Similarly, children who were more symptomatic (*ie*, reported more symptoms in the 12 h prior to testing) had similar adherence, but were less likely to achieve acceptable and reproducible tracings. There was only one battery failure during these panels, and all of the devices were in working order when retrieved from the families.

Table 6—Adherence During the 2-Week Home Panels*

Variables	% Completion†	Completed Sessions With Three Acceptable and at Least Two Reproducible Curves‡	Completed Sessions With Two Acceptable and at Least Two Reproducible Curves‡
Overall	87	59	62
Morning	87	56	61
Evening	87	62	64
Week 1 (morning and evening, n = 1,288)	82	60	63
Week 2 (morning and evening, n = 1,288)	85	58	61
Gender			
Male	83	54	58
Female	83	66	67
Age, yr			
6–8	83	47§	52§
9–11	82	65§	68§
Rescue medication in past 12 h			
< 35% of sessions (<i>ie</i> , less than median)	79	64	68
≥ 35% of sessions	87	55	58
Cough or wheeze in past 12 h			
< 14% of sessions (<i>ie</i> , less than median)	83	63	66
≥ 14% of sessions	83	55	58
Race			
African American	89	65	68
Hispanic	79	52	56
White	83	69	71
Other	92	47	50

*Data are presented as %.

†A session is “complete” if the child attempted to do the pulmonary function test and completed the symptom and medication questions.

‡Reproducibility is based on FEV₁, PEF, and FVC (Table 1). Acceptability was determined by the quality control software.

§p < 0.05 for age comparison. No other within-block comparisons (*eg*, week 1 vs week 2, etc.) were significant.

DISCUSSION

The first goal of this study was to evaluate whether pulmonary function data from a portable spirometer are comparable to those obtained from an office-based spirometer. Comparability was determined in two ways. First we compared acceptability scores (yes/no) for the data from each device. In addition, we graphically compared the magnitude of a range of pulmonary function measures. Although we could not find any references of comparable in-line evaluations, we found the agreement between the devices to be reassuring, across nearly all the key parameters, in particular FEV₁ and PEF. In addition, for the parameters with larger differences between devices, such as FEF₂₅₋₇₅, the differences are most likely explained by end-of-test criteria, (*ie*, “zero flow” vs “no abrupt end”) or subtle differences in the sensitivity of the flow detection software at very low flows that can be considered in the analyses of those data. Small differences in FVC can have large effects on measured values of FEF₂₅₋₇₅, which is, in part, dependent on the shape of the time-volume curve location of the 75% volume point in relation to the shoulder of the curve. In addition, differences in FVC will lead to differences in instantaneous flows at specific lung volumes (*eg*, forced expiratory flow at 75% of FVC [FEF₇₅]), since the actual volume points at which the flows are measured will be different. Most importantly for the purposes of the large epidemiologic study of which this analysis is only one small part, these differences will not affect day-to-day variations in each measurements obtained from the same device and same patient. Because these differences are independent of exposure, they will not bias the analysis of the longitudinal data.

The second goal was to demonstrate whether a substantial portion of the asthmatic children in this age range (6 to 11 years) were able to provide good quality data, both in the office and home settings. When supervised, the percentage of sessions with two acceptable and two reproducible efforts was 66% in the office setting. In the unsupervised panel data, 62% of the sessions had at least two acceptable and reproducible tracings. We propose that requiring three rather than two acceptable tracings may be too stringent a requirement for young children with asthma.

The third goal was to provide a comparison of the physician review vs quality control software. Our experience indicates that visual inspection of curves by a qualified reviewer will identify unacceptable curves that would be classified differently by the criteria of the software. Although the agreement between the two methods of assessment was high, the software was not programmed to identify prob-

lems in the midportion of the curve, and 25% of the curves that were coded as acceptable by the software were rejected by physician review. In the subset of 56 children who had at least one discordant scoring (*ie*, the physicians rejected curves that the software accepted), the mean FEV₁ of curves accepted by the physicians was 1.59 L vs 1.56 L for the curves accepted by the software. The mean FEV₁ for the curves that were accepted only by the software was 1.50 L. This indicates the curves that the physicians rejected and the software accepted have lower FEV₁s, leading to a lower mean. The extent to which the inclusion of those curves in a longitudinal analysis would impact the findings will be evaluated as we collect more data.

The final goal was to evaluate adherence during the 2-week panels. Adherence was as good and often better than that reported in other panel studies, which range from 60 to 85% over a similar time period.^{6,13,14} As more children complete the 2-week panels, we will examine additional characteristics that are predictive of good adherence. It is clear that some children were not able to produce acceptable and reproducible tracings, either on their own or with coaching; however, they were able to provide valuable symptom and medication information. While the older children were not more adherent, they were more likely to achieve reproducible curves. Future analyses will evaluate the improvement in children's performance over the course of the study.

Clinical and epidemiologic studies often have been limited to measurements derived from peak flowmeters. This study suggests that it will be feasible to expand the range of pulmonary function measures that can be captured in these settings. These devices are substantially more expensive than peak flowmeters (approximately \$600 vs \$25); however, they are approved for multiple users (with disposable mouthpieces). The need for more sensitive and physiologically relevant measures may warrant that expense. For example, in a clinical setting, the accurate monitoring of pulmonary function may help avoid the use of expensive health-care services such as diagnostic testing or hospitalization. The ability of epidemiologic studies, such as those focused on air pollution, to observe evidence of functional alterations could be greatly improved if a wider range of parameters of pulmonary function were measured. Most studies of air pollution and asthma have found statistically significant, but clinically small effects on PEF rate and FEV₁. One of the goals of FACES is to determine whether changes in FEF₂₅₋₇₅ and FEF₇₅ are more sensitive indicators of air pollution health effect than FEV₁ and PEF rate. Larger percentage effects of air pollution on lung

growth already have been observed for FEF₂₅₋₇₅ and FEF₇₅ compared to PEF and FEV₁ in population samples of children.¹⁵ For that reason, we feel that it is essential that epidemiologic and clinical evaluations of lung function evaluate a wider range of pulmonary function measures than has been the case up to now. Evaluating the cost-effectiveness of such a device is not within the scope of this report.

In general, electronic devices provide many benefits over paper diaries or manual recording of pulmonary function measures. The data values and timing of collection cannot be fabricated and are easily transferred to a personal computer, eliminating the cost and errors associated with manual data entry of paper diaries. This device also provides immediate suggestions to improve technique as well as displays an incentive scoring system to improve adherence.

This adherence component of this study allows only for the evaluation of a portable spirometer as a data collection tool. Children were blinded to the results, and monitoring was not performed in conjunction with a clinical or case-management program; therefore, the results may not be generalizable to those settings. The findings of this study are based on 2-week panels with twice-daily readings and therefore cannot assess adherence with longer-term monitoring.

CONCLUSION

We conclude that this portable spirometer accurately and reliably measures pulmonary function, relative to a "gold standard" office-based device. Although there was good agreement across key lung function measures, physician review of the curves revealed some limitations in our current quality control software. We achieved a high degree of compliance during 2-week intervals, even among the youngest children who had difficulty producing reproducible tracings. The compliance was substantially higher than has been reported in other studies using peak flowmeters, which may be due to the user-friendly nature of the device and the incentive scoring system. Devices that improve compliance and precision are particularly useful in epidemiologic

studies such as this, which focus on small changes in day-to-day measurements.

ACKNOWLEDGMENT: The authors thank Romain Neugebauer for statistical analysis; Paul Enright, MD, for suggesting the incentive scoring system; and the FACES staff and the FACES families, whose hard work and cooperation made this study possible.

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