Comparison of Eupnoos, a smartphone-based platform for the measurement of spirometry parameters, with spirometry conducted using conventional spirometer

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Background

The NHS Long Term Plan was published in January 2019 and set the plan for the NHS for the next 10 years, where Respiratory disease was identified as a national clinical priority. The NHS Long Term Plan commits to improving the quality and reducing variation of spirometry testing.

Spirometry plays an integral role in the diagnosis and monitoring, primarily for respiratory conditions. Currently, purchasing and maintaining spirometers is costly; in addition, operating such a device requires a dedicated computer and trained personnel able to perform the spirometry and subsequently interpret the reported results. For these reasons, spirometers are largely underused in primary care. Many primary care clinicians therefore refer patients to hospital for spirometric evaluation, thereby not only significantly increasing financial burden, but also time to diagnoses/management.

There are important advantages to developing a smartphone-based solution as compared to current commercial spirometers (5, 10). Firstly, the low-cost and inherent portability of the smartphone allows much greater uptake of home spirometry. The relative low cost of smartphones as compared to spirometers can also help in lowering access barriers to medical devices in the developing world (1, 6, 10). Secondly, a smartphone spirometer can have built-in coaching and feedback—mechanisms to maximise measurement acceptability that are critically lacking in current home spirometers. Thirdly, smartphones provide the capability of easy data uploading, enabling longitudinal tracking of results and instantaneous alerts. Finally, with the smartphone, spirometry can easily be coupled with evaluations such as symptom scores, cough sensing, or oximetry to provide a comprehensive disease self-management tool.

The Eupnoos Spirometry module is used to perform Spirometry using just a smartphone microphone. It requires a person to hold their smartphone at a specific distance from their body, and then breathe in their full lung volume and forcefully expires towards the smartphone microphone. The phone's microphone records the exhalation and sends the audio data to a server, which calculates the exhaled flow rate by considering both the user's vocal tract and the reverberation of sound near the user. Flow rate is estimated by calculating a few envelope functions of the sound in the time/frequency domain. These uncalibrated flow rates are then converted into real air flow spirometry curves based on a data-driven machine learning regression. The most prominent flow rate metrics (PEF, FEV_1, FVC, FEV_1/FVC Ratio) are computed, while the graphs found in clinical spirometers (Flow Volume Loop and Volume-Time Curve) are also produced (Figure 1).

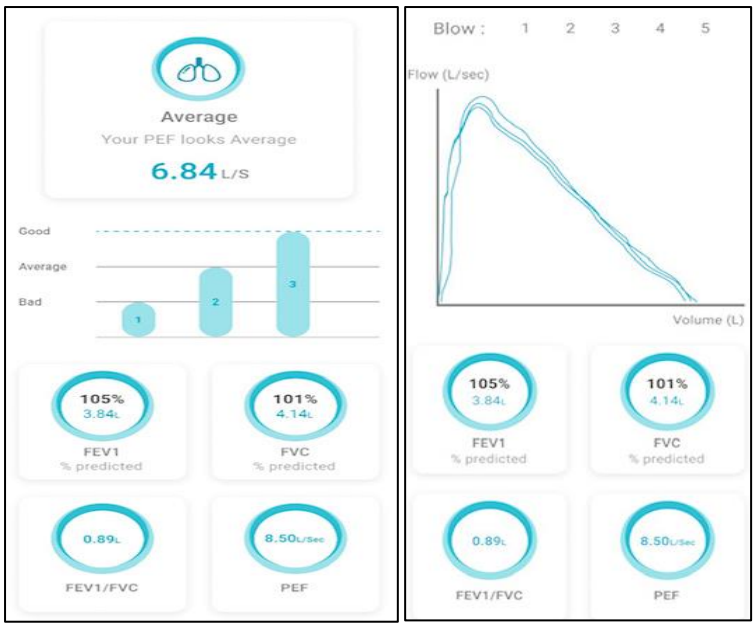


Fig. 1 The Eupnoos Platform and the reported spirometric parameters

The objective of this study was to assess the accuracy and validity of Eupnoos Platform measurements by comparing them with gold standard spirometer.

Materials & Methods

Twenty-two healthy subjects, aged between 19-59 years of age, were enrolled in the study. The patient demographic included mixed ethnicities and genders (7 Male: 15 Female). We excluded patients that had any contraindication to perform spirometry: recent hemoptysis of unknown origin, pneumothorax, pulmonary embolism, recent myocardial infarction or unstable angina, aneurysm (cerebral, thoracic, and abdominal) or recent eye surgery.

All patients performed spirometry both with a conventional gold standard spirometer, and with the Eupnoos Platform. The Eupnoos software measures the spirometry lung volumes via the phone's built-in microphone (i.e., a complete software-enabled solution). The audio data is converted into flow rates and flow volume loops.

The gold standard spirometer was calibrated according to the manufacturer's manual, while the Eupnoos Platform does not need calibration. The order in which each of the spirometers were used was randomised in order to avoid bias. Measurements with both devices were carried out by trained personnel, according to the ATS/ERS guidelines.

A spirometry effort was considered acceptable if the following apply: i) starts from full inhalation, ii) shows minimal hesitation at the beginning of forced expiration, iii) exhibits an explosive start of the forced exhalation, iv) shows no evidence of cough in the first second of forced exhalation and v) meets one of the following criteria that define a valid end-of-test (1 - smooth curvilinear rise of the volume-time tracing to a plateau of at least 1 s's duration; 2 - if a test fails to exhibit an expiratory plateau, a forced expiratory time of 15 seconds; or 3 - when the patient cannot or should not continue forced exhalation for valid medical reason). From each spirometry the following metrics were recorded: FEV1 (absolute value in L), FEV1% predicted, FVC (absolute value in L), FVC% predicted and PEF (L/sec).

Descriptive statistics are presented as mean with standard deviation (SD). The agreement and relation between the aforementioned spirometric parameters for the module and device was assessed by calculating the Pearson correlation coefficient. Pearson correlation was calculated with IBM SPSS statistics, version 24. Moreover, Bland and Altman plots were created to depict the bias between the mean differences for the values obtained by the spirometric device and the Eupnoos platform.

Results

In this study, 22 healthy subjects performed spirometry with a conventional spirometer and with the Eupnoos platform. The following spirometric parameters were recorded for all patients and with both spirometers: FEV1, FVC, and PEF. Table 1 contains the key spirometric parameters with both spirometers.

Table 1 Key spirometric parameters across all 22 subjects, with both spirometers: (1) conventional spirometer and (2) Eupnoos Platform.

	Conventional Spirometer			Eupnoos Platform		
	FEV_1 (L)	FVC (L)	PEF (L/sec)	FEV_1 (L)	FVC (L)	PEF (L/sec)
Mean	3.07	3.73	482	3.03	3.69	471
95% CI	(2.63-3.49*)	(3.22-4.26*)	(440-546*)	(2.64-3.36*)	(3.22-4.14*)	(436-523*)
Minimum	1.84	2.44	300	1.97	2.58	320
Maximum	4.62	5.68	719	4.31	5.21	644
Std. Deviation	0.80	1.01	116	0.69	0.89	95

** p < 0.005 for CI (Confidence Intervals)*

Table 2 Pearson correlation coefficients between the spirometric values obtained with using a spirometer and Eupnoos Platform

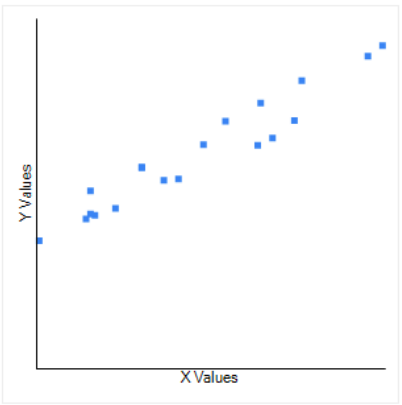
	Pearson correlation
FEV_1 (L)	0.9643
FVC (L)	0.9554
PEF (L/sec)	0.9791

**for all metrics p < 0.001*

In order to evaluate agreement and concordance between the two methods of spirometry measurement, we calculated the Pearson correlation for all the key spirometric parameters, between the two spirometers (Table 2). The Pearson correlation for all spirometric parameters considered was high (greater than 0.9), and for certain key spirometric parameters (FEV_1, FVC, PEF) was greater than 0.95. All calculated correlations the corresponding p-values < 0.001.

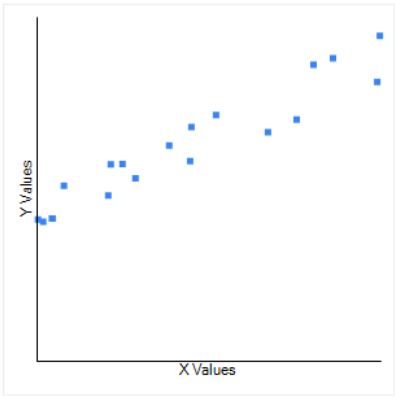
(A)

X Values	Y Values
2.92	2.72
3.71	3.55
3.48	3.8
2.35	2.2
3.46	3.2
2.32	2.55
2.67	2.88
2.29	2.15
2.82	2.7
2.67	2.89
3.09	3.21
2.49	2.3
1.97	1.84
3.76	4.12
3.56	3.3
4.21	4.47
3.24	3.54
4.31	4.62
2.32	2.22



(B)

X Values	Y Values
3.75	3.5
5.19	4.88
3.95	4.3
2.69	2.5
4.35	4
2.78	3.07
3.14	3.44
2.69	2.5
3.33	3.2
3.23	3.45
3.59	3.77
3.12	2.9
2.62	2.44
4.7	5.18
4.57	4.22
5.21	5.68
3.76	4.09
4.85	5.29
2.58	2.48



(C)

X Values	Y Values
320.1	300
448.4	430
376	350
361.2	350
621	600
552	580
382.8	400
597.7	640
497.9	546
384.8	400
448	480
562.7	613
415.2	429
468.4	478
488	468
348.9	327
574.8	609
644	719.4
443.9	418
463.5	490

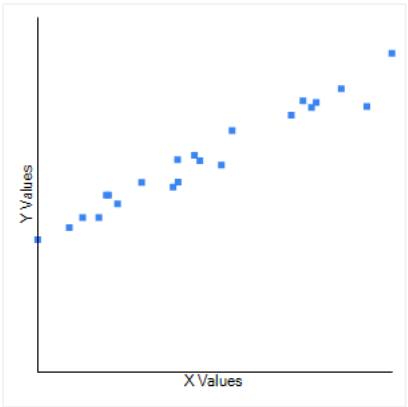
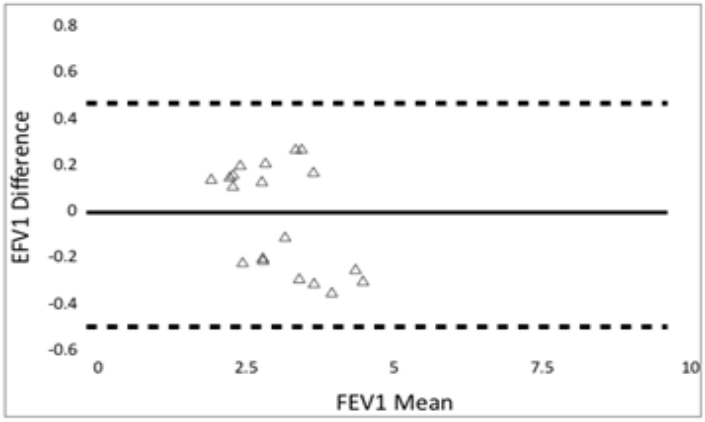


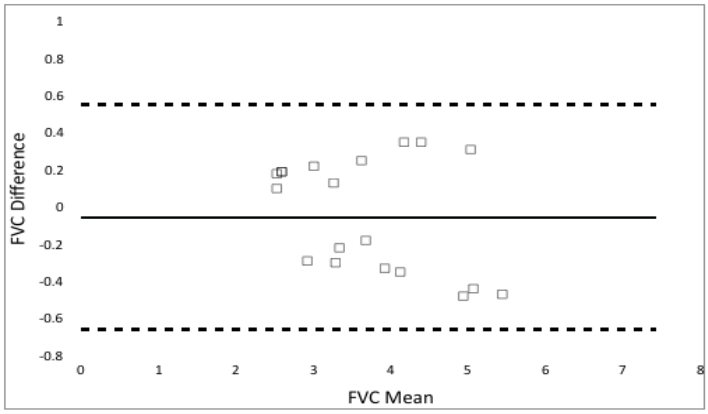
Fig. 2 Correlation plots between the values obtained from the Eupnoos Module (X Values) and spirometer (Y Value), for spirometric parameters considered (A) FEV_1, (B) FVC, (C) PEF.

The correlation plots for these parameters presented in Fig. 2 visually depict the high concordance between the two methods of spirometry measurement. As exhibited in the plots are significant agreement between the two spirometers, for all spirometric parameters, FEV1, FVC and PEF, which are primarily useful for the interpretation of spirometry. In the plots, the X axis values refer to the values obtained from the Eupnoos Module, whereas the Y axis is the values obtained from the conventional spirometer.

(A)



(B)



(C)

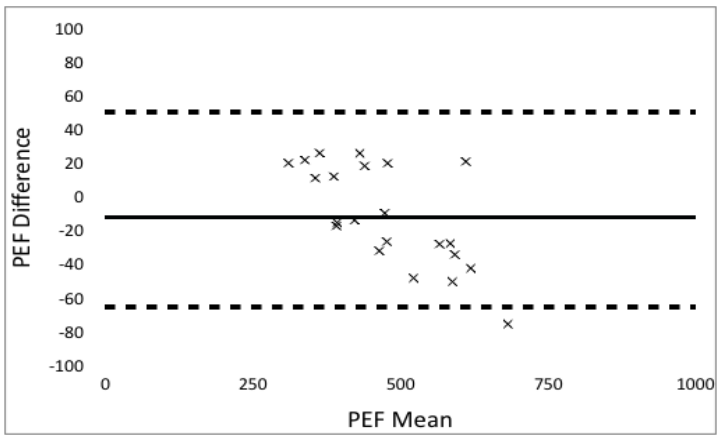


Fig. 3 Bland-Altman plots for the evaluated spirometric parameters: (A) FEV1, (B) FVC, (C) PEF. Black lines represent the mean difference between measurements and dashed lines the 95% limits of agreement

In order to further evaluate the reproducibility of the measurements with the Eupnoos Platform vs. the conventional spirometer, we have developed Bland-Altman plots (Fig. 3). In these plots, we provide visualisation of the mean difference of the evaluated spirometric parameters between the two methods of measuring spirometry. In all cases we observed a small mean difference between the two devices, with the majority of measurements being well within the limits of agreement.

Conclusion

In this study, we have shown that spirometric measurements with the Eupnoos Software and conventional spirometry results present very good agreement (as expressed by Pearson's > 0.95 for evaluated parameters) and reproducibility (in Bland-Altman plots) with a standard spirometer.

Mobile App spirometers feature a multitude of characteristics that makes them an ideal solution for extensive adoption in several medical and non-medical settings. Specifically, this Eupnoos Module can be used as a spirometer that does not need calibration and can be operated via a user-friendly smartphone application. After careful validation study, the results yielded by the Eupnoos Module and a conventional spirometer exhibit very good agreement and reproducibility. Our results support the use of Eupnoos Module as a reliable spirometer for the screening and diagnosis of various spirometric patterns in clinical practice.

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