

In-vitro Validation Of A Novel Handheld Oscillometry Device

D. Bizzotto¹, P. P. Pompilio², A. Gobbi², R. L. Dellacà¹

Rationale

The forced oscillation technique (FOT), or oscillometry, uses the flow-response to high-frequency, low-amplitude pressure oscillations applied at the airway opening to evaluate respiratory mechanics during spontaneous breathing. It requires minimal patient cooperation, making this technique ideal for home monitoring [1] and in-field lung function testing. However, current oscillometry devices are too complex, cumbersome, and expensive for large scale applications. Recently, a new small handheld FOT device based on a miniaturized fan for generating a sinusoidal forcing waveform has been developed. This study aims to evaluate the performances of this novel technology on an in-vitro setting.

Methods

The accuracy of oscillatory parameters measured by the handheld FOT device (FOT HH, see Figure 1, RESTECH SRL, Milano, Italy) using 5 Hz pressure waveforms was evaluated against a commercially-available oscillometric device for ambulatory use (FOT PRO, Resmon PRO FULL, RESTECH SRL, Milano, Italy).

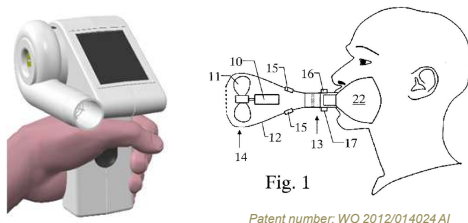


Figure 1: Handheld FOT device

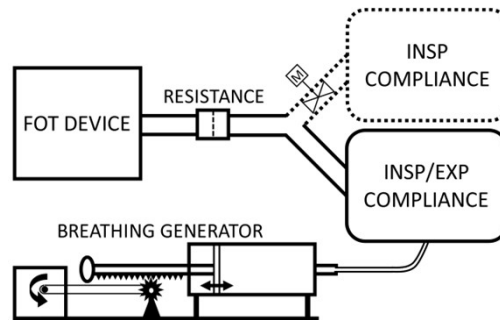


Figure 2: Experimental setup

The comparison was done in vitro by using a specifically-developed breathing test lung. It consisted of mesh-type resistances (Hans Rudolph, Shawnee, KS, USA) connected to glass bottles and a piston-type servocontrolled volume generator used to reproduce human pre-recorded breathing patterns (Figure 2).

The tests were performed on several combinations of two resistances (5 and 15 cmH₂O*s/l) and three glass bottles (3, 5 and 15 l, leading to a reactance of approximately -10.5, -6.9 and -2.3 cmH₂O*s/l, respectively) to simulate different degrees of lung disfunction. Each condition was measured under two different breathing patterns (1: Vt 0.4 l, RR 17 bpm, Ti 1.60 s; 2: Vt 0.28 l, RR = 23.5 bpm, Ti 1.19 s). Within-breath changes of Xrs, hallmark of patients with tidal Expiratory Flow Limitation [2], were simulated by using an electrically-controlled valve activated synchronously with the breathing phase to close the connection of an additional gas bottle during expiration, leading to a decreased expiratory compliance.

Results

The performance of the novel device is reported in the Table I as linear regression parameters and average errors. The correlation coefficient was always > 0.99.

Table I: Linear regression parameters and relative errors between FOT HH and FOT PRO.

	Linear Regression (FOT HH vs. FOT PRO)			Error (FOT HH vs. FOT PRO)		
	R ²	Slope (CI 95%)	Intercept (CI 95%)	mean (%)	std (%)	Range max-min (%)
R _{insp}	1.000	0.98 (0.97;1.00)	-0.28 (-0.48;-0.07)	-4.4	1.7	7.2 - 2.8
R _{exp}	1.000	0.92 (0.90;0.95)	0.24 (-0.16;0.65)	-5.5	1.6	8.0 - 2.9
R _{tot}	1.000	0.95 (0.94;0.96)	-0.01 (-0.18;0.17)	-5.0	0.3	5.5 - 4.6
X _{insp}	1.000	1.11 (1.09;1.12)	0.31 (0.24;0.39)	2.3	5.3	7.4 - 4.3
X _{exp}	0.999	0.99 (0.92;1.05)	-0.01 (-0.47;0.46)	-1.9	3.3	5.4 - 1.7
X _{tot}	1.000	1.04 (1.00;1.08)	0.14 (-0.13;0.41)	0.1	3.8	5.6 - 0.9
ΔX	0.999	1.04 (0.94;1.15)	0.07 (-0.41;0.54)	5.5	5.5	13.9 - 1.5

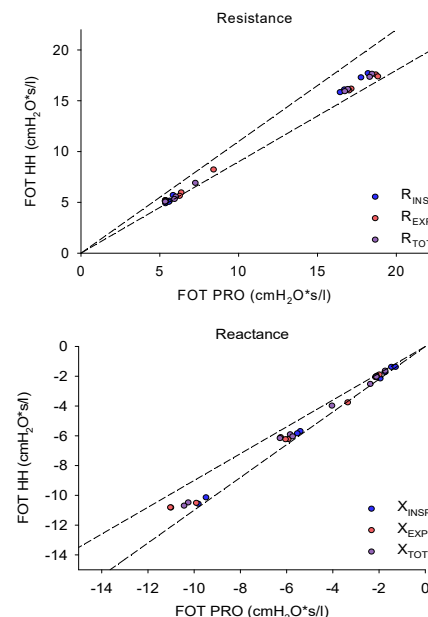


Figure 3: Comparison of resistance and reactance measured by the FOT HH and FOT PRO. Dashed lines represent ± 10% error.

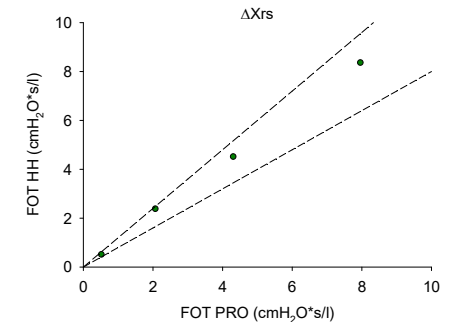


Figure 4: ΔXrs measured by the FOT HH and FOT PRO. Dashed lines represent ± 20% error.

Discrepancies of Rrs and Xrs were always within the 10% limit of agreement (Figure 3), satisfying current FOT technical standards [3]. The maximum error for ΔXrs was lower than the limit of 20% (Figure 4).

Conclusions

The novel fan-based approach allows accurate measurements of oscillatory mechanics with a handheld compact, portable and more accessible device, opening new applications for the diagnosis and management of respiratory conditions outside the lung function test laboratory.

References

1. Walker et al, AJRCCM 2018
2. Dellacà et al, ERJ 2004
3. King et al, ERJ 2020

Disclosures

P.P., A.G. and R.D. are co-founders and serve as board members of RESTECH s.r.l.