Indian J Otolaryngol Head Neck Surg
(November 2019) 71(Suppl 3):S1935–S1939; https://doi.org/10.1007/s12070-018-1349-9

ORIGINAL ARTICLE

The Reliability of Polyvinylidene Fluoride Sensor for Intra- and Intersession Measurements

Roopa G. Manjunatha[1] · Surya Prakash[2] · Konandur Rajanna[1]

Received: 5 December 2017 / Accepted: 6 April 2018 / Published online: 16 April 2018

Abstract A new nasal sensor has been designed using Polyvinylidene fluoride (PVDF) film using its piezoelectric property to measure nasal patency. The aim of this study is to determine the intra- and intersession reliability of the new PVDF nasal sensor measurement of unilateral and combined nasal parameters in a group of healthy subjects. Two identical nasal sensors: for right nostril (RN) and left nostril (LN) were designed using piezoelectric natured PVDF films. Twenty subjects were studied. To evaluate the repeatability, total three sets of PVDF sensor measurements were recorded, two sets were taken 5 min apart during same session without repositioning the PVDF nasal sensors and two more sets were taken during 1 h apart successively, by repositioning the PVDF nasal sensor. Intraclass correlation coefficients (ICC) of PVDF sensor measurements for intra- and intersession showed a high and greater repeatability over time for all the combined (mean) and unilateral (RN and LN) values. In both healthy and patients, ICC values for both intra- and intersession measurements were ≥ 0.80 confirming strong reliability and also almost all of the coefficients of variation for the same parameters were low (below 10%). PVDF sensor measurements showed good intra- and intersession repeatability and can be recommended for the objective monitoring of nasal patency during diagnosis and follow-up of conditions.

✉ Roopa G. Manjunatha
roopa.bme@gmail.com

[1] Department of Instrumentation and Applied Physics, Indian Institute of Science, Bangalore 560012, India

[2] Department of Ear, Nose and Throat, M. S. Ramaiah Medical College and Hospital, Bangalore 560054, India

Keywords PVDF nasal sensor · Nasal patency · Intra- and intersession repeatability · Reliability

Introduction

The subjective methods and objective methods used in evaluation of nasal patency eases clinician effort to recognize and accurately diagnose the nasal disease. In general clinical setup, ENT clinician evaluates nasal patency subjectively, by inspection of the nose and face, both during inspiration and expiration. Major anomalies like deviated nasal septum, alar collapse during inspiration can be visualized directly. Other than visual inspection, a very simple, rapid, easy technique called cold spatula test is also used to examine the nasal obstruction [1]. By holding a cold spatula (metal plate) under the nostrils, the airflow during nasal expiration can be assessed. A lack of uniform fogging indicates an inadequate nasal flow, or major asymmetrical fogging indicates unilateral obstruction. Other than subjective method, the objective methods like acoustic rhinometry, rhinomanometry, and peak nasal inspiratory flow meter (PNIF) are most commonly used to assess nasal patency objectively. Acoustic rhinometer assess the nasal patency in each nasal cavity separately by measuring echoes of sound impulses sent into one nostril [2]. Rhinomanometry measures the nasal airflow and pressure during normal inspiration and expiration and it is considered as the standard technique for the evaluation of nasal airflow [3], whereas PNIF also measures the nasal flow through both nasal cavities during forced inspiration and/or expiration [4]. The main disadvantages of Acoustic rhinometer and rhinomanometry are, they are expensive, require trained operator and cannot be portable easily, and also PNIF may be inaccurate because it relies on the

patient's cooperation and correct instruction by the investigator [5]. Therefore, there is a need of instruments which can be easily portable, reliable, need minimal co-operation from patients and low-cost instrument to evaluate nasal obstruction objectively. Besides, its repeatability is also essential, which is the test resource to produce the reliable and consistent results when they are independently repeated [6].

The reliability of any objective technique depends upon the nature of the method and their positioning while recording serial measurements over consecutive sessions. The intra- and intersession repeatability of objective method is very important aspect in clinical evaluation, particularly for patients with nasal obstruction, when these methods are used for the follow-up purpose. Correlation and/or reliability of the objective diagnostic methods like rhinomanometry, acoustic rhinometry, optical rhinometry, and magnetic resonance imaging are studied extensively in both clinical and experimental settings [7–10].

Polyvinylidene fluoride (PVDF) film is a bio-compatible polymer which as a strong piezoelectric property [11]. Piezoelectric property of the material is the ability to generate voltage whenever a mechanical stress/strain is applied on them. PVDF nasal sensor used in this study has already been successfully evaluated for measuring nasal obstruction when compared to peak nasal inspiratory flow meter (PNIF) [12]. In the present study, the reliability of developed PVDF nasal sensor is being accessed.

The aim of this study is to examine the intra and intersession repeatability of PVDF nasal sensor in assessing the nasal patency of healthy subjects and as well as patients with nasal obstruction.

Materials and Methods

Subjects

Twenty subjects (11 male and 9 female) were participated in the study. The age (mean ± SD) of healthy subjects was 34 ± 5.06 years and the age of (mean ± SD) of patients was 39 ± 7.10 years. Healthy volunteers were taken from hospital staff without any complaints of nasal blockage and patients were taken from ENT OPD. The study was conducted at M. S. Ramaiah Medical College and Hospital, Bangalore, India after the institutional review board approved the study protocol. Written consent was obtained from all the subjects before participation in the study.

Measurement Procedure

ENT clinician visually examined the nose with the aid of bright light source and a nasal speculum (an instrument that gently spreads open nostril) carefully in each nostril of individual subject. Further nasal visual examination was supplemented by the cold spatula test. By holding a cold metal spatula under the nostrils, every subject was asked to breathe normally and exhale air on the spatula. There was a uniform fogging on the spatula from both the nostrils for healthy volunteers. Based upon the subject's history, clinician visual nasal examination and cold spatula test 20 healthy subjects were taken.

After cold spatula test, PVDF nasal sensor measurements were performed in a well-ventilated room with normal room temperature and humidity. The PVDF nasal sensor setup consists of a PVDF nasal sensor mounted on headphone, signal conditioning box and a computer for data recording as shown in Fig. 1. He/she was asked to wear headphone and then a researcher adjusts the position of the PVDF nasal sensor in such a way that the nasal airflow during their usual inspiration and expiration will fall on them. The detailed design of the PVDF nasal sensor has been explained in our previous paper [13]. The PVDF nasal sensors were placed 5 mm below the nose. After positioning of the PVDF nasal sensor, he/she was instructed to do normal breathing. While recoding the breathing signal/data, an initial signal/data for 30 s was truncated to avoid possible artifact which might have been caused due to wearing head phones and then the voltage signal resulted due to breathing of a subject was recorded for 1 min and stored in the computer for further analysis.

Study Design for Repeatable Measurements

The first set of PVDF nasal sensor measurements were taken on all twenty subjects individually during their first visit. After taking first set of measurements, without removing the PVDF nasal sensors, the second set of measurements were taken after 5 min for evaluation of intra-session repeatability. After taking second set of measurements, the PVDF nasal sensors were removed from subject. Again after 1 h, the third set of PVDF nasal sensor measurements were taken on same subjects individually by again putting back the PVDF nasal sensors precisely in the same position as previous recording for evaluation of intersession repeatability.

Breathing Signal

The voltage output of PVDF nasal sensor as function of time gave nasal breathing cycle of a subject with inspiration and expiration peaks. The peaks above the 0-axis were the inspiration peaks and the peaks below the 0-axis were the expiration peaks. This peak-to-peak amplitude (V_{p-p}) of the inspiration and expiration peaks, gave a correlated magnitude of a nasal airflow. The average peak-to-peak

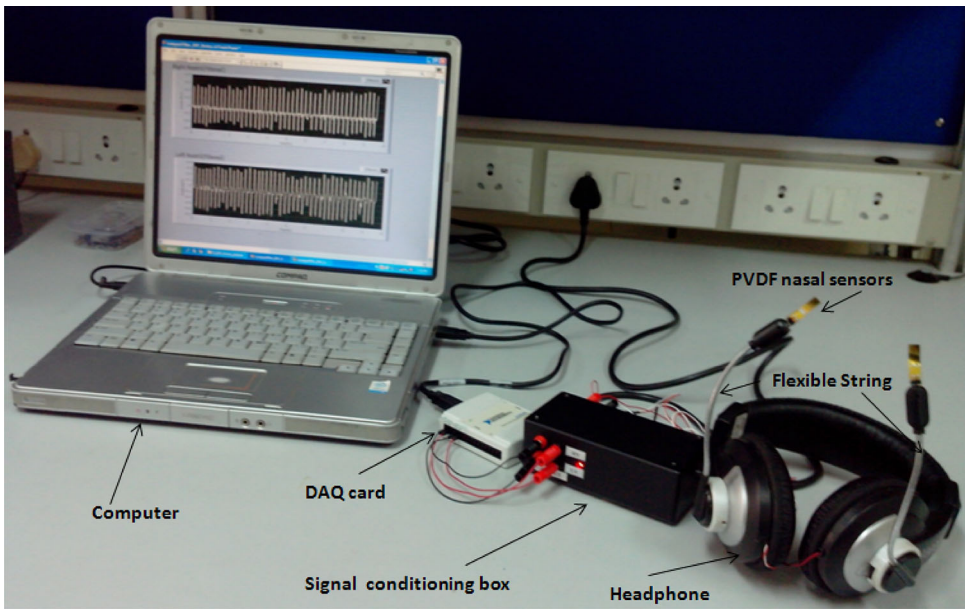

Fig. 1 PVDF nasal sensor along with signal conditioning box and computer for measuring nasal airflow

amplitude of breathing cycle recorded for 1 min long is calculated for both the nasal cavities separately in each subject, using MATLAB software (version R2007b).

Statistics

Data were expressed as mean ± SD. A value of $p < 0.05$ was considered as statically significant.

The intra- and intersession repeatability of PVDF nasal sensor measurement parameter (peak-to-peak amplitude of breathing cycle, V_{p-p}) were expressed as, intraclass correlation coefficient (ICC; for interpretation, good repeatability was defined as an ICC of ≥ 0.8 [14] and Coefficient of Variation (CV) for unilateral and total (combined right and left) values. Statistical analysis was carried out using SPSS 18 (Statistical Package for Social Sciences version 18.0 for windows).

Results

Figure 2 shows the sample tracing of a breathing cycle obtained from PVDF nasal sensor for RN and LN simultaneously, separately. The signal above 0-axis represents the inspiration phase and below 0-axis represents the expiration phase. One peak-to-peak inspiration phase and expiration phase represents one complete nasal cycle. For healthy subjects without complaints of nasal blockage, the peak-to-peak amplitude (V_{p-p}) of both nostrils breathing signal was same as shown in Fig. 2. The peak-to-peak amplitude variable gives the measurement of nasal patency objectively. The mean (SD) peak-to-peak amplitude of healthy subjects for all three set of PVDF nasal measurements were: 0.67 ± 0.11 V_{p-p} for RN, 0.62 ± 0.16 V_{p-p} for LN and 0.65 ± 0.14 V_{p-p} for combined nostrils.

The repeatability of combined (mean of left and right), RN and LN values for the PVDF nasal measurements, for both intra- and intersession are given in Table 1. Intraclass correlation coefficients (ICC) for both sessions indicated excellent agreement with ≥ 0.80 confirming almost perfect agreement. All intraclass correlations were associated with p values < 0.001. The mean CVs expressed in % were $< 10\%$ for all intrasession and intersession measurements in healthy subjects. There was no much difference between the combined values and unilateral values of ICC and CV.

Discussion

Repeatability, sometimes also known as reliability is one of the very important parameter for any objective method. The repeatability of any objective method is to produce the reliable and consistent results when they are independently repeated [6]. The repeatability of PVDF sensor measurements during intra- and intersession was examined in this study. This degree of repeatability can have very good clinical implications with regard to the utilization of this rapid and easy-to-use technique in the follow-up of conditions associated with impaired nasal patency.

The value of peak-to-peak amplitude of the breathing signal from both nostrils for healthy subjects were almost same as seen in Fig. 2. Therefore, by computing the average of peak-to-peak amplitude of the breathing signal from each nostril obtained from PVDF nasal sensor, one can assess the nasal patency. In order to use PVDF nasal

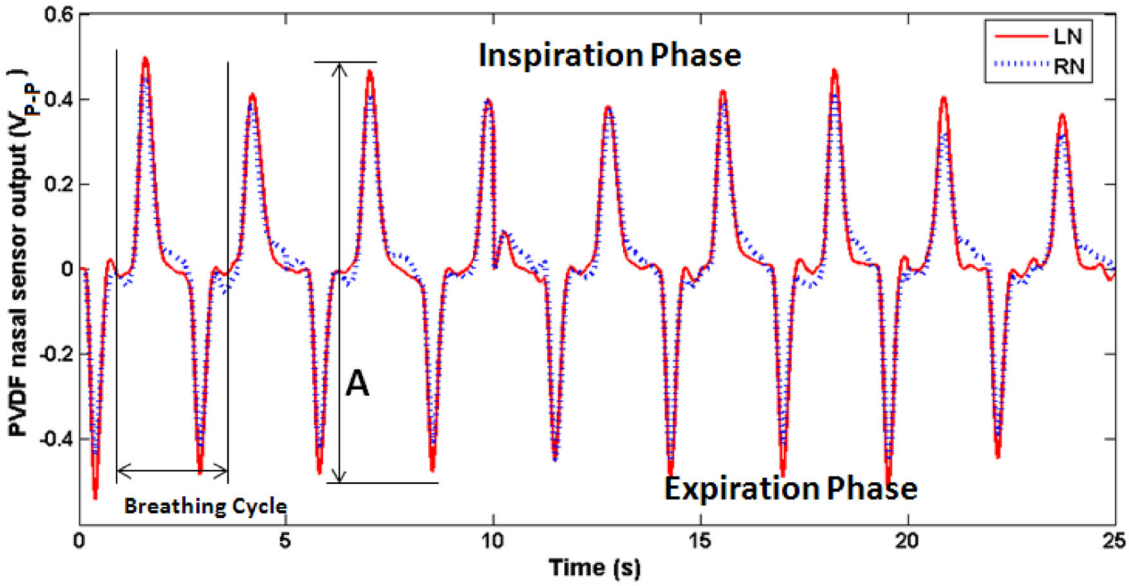

Fig. 2 Sample tracing of breathing signal recorded using PVDF RN and LN nasal sensors for healthy subject (A—peak-to-peak amplitude of inspiration and expiration phases of both the nostrils are same)

Table 1 Repeatability for the combined (mean of left and right) and separate nostril values of PVDF nasal sensor over intra and inter-session measurements

Variables	Intra-session			Inter-session		
	V_{p-p} (mean ± SD)	CV (%)	ICC	V_{p-p} (mean ± SD)	CV (%)	ICC
Normal subjects (n = 20)						
Right nostril	0.57 ± 0.04	7.1	0.98	0.62 ± 0.07	11.7	0.88
Left nostril	0.68 ± 0.05	8.3	0.93	0.64 ± 0.05	8.8	0.84
Combined	0.62 ± 0.04	7.2	0.95	0.63 ± 0.06	9.5	0.86

sensor in general clinical setting routinely, it is very important that PVDF nasal sensor technique should give consistent repeatable readings for both healthy and patients, when the measurements were repeated as a function of time. And also the PVDF nasal sensor repeatability should be good when they are repeated for different sessions as a function of their positioning on subjects. Therefore, in the present study, we have examined the repeatability for PVDF RN sensor, PVDF LN sensor as a function of time and positioning of sensor and computed PVDF RN sensor, PVDF LN sensor and combined (mean of RN and LN) values in both healthy group and patients. As can be seen in Table 1, the ICC values for healthy and patients in both sessions were greater than 0.80 showing a very strong repeatability. The ICC value of intra-session was greater than intersession ICC in both the case, may be because the sensor were not removed from subjects and the measurement technique was repeated perfectly.

For intersession, the time interval between 2 measurements was 1 h and the PVDF sensors were removed and placed back precisely in the same position as previous recording, while taking measurements in order to assess whether the repeatability were affected by re-positioning of sensors. The results of intersession measurements also showed that the PVDF sensor measurements were repeatable with good ICC values. And also the CV values for healthy was less than 10% for intra-session, but for intersession, the CVs were slightly higher than 10% due to repositioning of PVDF nasal sensor. But this may not significantly affect the PVDF nasal sensor measurements when taken during intersession because the ICC were still higher than 0.80 showing strong repeatability during intersession also. Our results show that PVDF nasal sensor is a method with good intra- and inter-session repeatability. These results are comparable with that obtained by other objective methods for nasal obstruction. In the previous studies, Starling et al., measured the repeatability of PNIF

as ICC 0.92 on 283 subjects with rhinitis [15]. Similarly, Silkoff also measured ICC 0. 96 for rhinomanometry and ICC 0.86 for acoustic rhinomanometry for 6 normal people [8], and Al Ahmari et al. [10] measured ICC 0.85 for repeatability of acoustic rhinometry measurement in 12 healthy subjects.

This study serves as pilot study to examine the intra and intersession repeatability of PVDF nasal sensor for using ICC and CV on averaged combined and separate nostril peak-to-peak amplitude of breathing signal. We showed that PVDF nasal sensor measurements provide excellent repeatable results, best taken over different session's within same day for both healthy and patients with nasal obstruction. However, We propose that this new technique, PVDF nasal sensor might benefit from further investigations, perhaps with greater numbers of healthy and patient populations and measurements taken over between different days.

Conclusion

This study showed that PVDF nasal sensor measurements for intra- and intersession were repeatable in healthy subjects. This technique is simple, inexpensive and can be easily portable, and hence can be recommended for the objective measurement of nasal patency unilaterally or bilaterally during routine clinical checkups as well during follow-ups.

Acknowledgements Authors also thank Prof. NS Murthy and Ms. Radhika, Department of Biostatistics, M. S. Ramaiah Medical College, Bangalore, India for their valuable inputs and contributions.

Authors' Contributions RGM carried out the design and coordinated the study, participated in most of the experiments and prepared the manuscript. SP provided assistance for clinical data and expertise. All authors have read and approved the content of the manuscript. KR provided expertise in the design of the study, coordinated all the experiments and participated in manuscript preparation.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interests.

References

1. Scadding G, Hellings P, Alobid I, Bachert C, Fokkens W, van Wijk RG et al (2011) Diagnostic tools in Rhinology EAACI position paper. Clin Transl Allergy 1:2
2. Hilberg O, Jackson AC, Swift DL, Pedersen OF (1989) Acoustic rhinometry: evaluation of nasal cavity geometry by acoustic reflection. J Appl Physiol 66(1):295–303
3. Kern EB (1981) Committee report on standardization of rhinomanometry. Rinology 19(4):231–236
4. Fairley JW, Durham LH, Ell SR (1993) Correlation of subjective sensation of nasal patency with nasal peak flow rate. Clin Otolaringol 18(1):19–22
5. Chaaban M, Jacquelynne PC (2011) Assessing nasal air flow: options and utility. Proc Am Thorac Soc 8:70–78
6. Pallanch JF, Mccaffrey TV, Kern EB (1993) Evaluation of nasal breathing function. In: Cummings CW, Fredrickson JM, Harher LA, Krause CJ, Shuller DE (eds) Otolaryngology—head and neck surgery, 2nd edn. Mosby-Year Book, St Louis, pp 1–59
7. Corey JP, Gungor A, Nelson R, Fredberg J, Lai V (1997) A comparison of the nasal cross-sectional areas and volumes obtained with acoustic rhinometry and magnetic resonance imaging. Otolaryngol Head Neck Surg 117(4):349–354
8. Silkoff PE, Chakravorty S, Chapnik J, Cole P, Zamel N (1999) Reproducibility of acoustic rhinometry and rhinomanometry in normal subjects. Am J Rhinol 13(2):131–135
9. Cheung EJ, Citardi MJ, Fakhri S, Cain J, Batra PS, Luong A (2010) Com-parison of optical rhinometry to acoustic rhinometry using nasal provocation testing with Dermatophagoides farinae. Otolaryngol Head Neck Surg 143(2):290–293
10. Al Ahmari MD, Wedzicha JA, Hurst JR (2012) Intersession repeatability of acoustic rhinometry measurements in healthy volunteers. Clin Exp Otorhinolaryngol 5(3):156–160
11. Kawai H (1969) The piezoelectric of polyvinylidene fluoride. Jpn J Appl Phys 8(7):975–976
12. Manjunatha RG, Rajanna K, Mahapatra DR, Prakash S (2014) Evaluation of polyvinylidene fluoride nasal sensor to assess deviated nasal septum in comparison with peak nasal inspiratory flow measurements. Am J Rhinol Allergy 28(1):e62–e67
13. Manjunatha RG, Rajanna K, Mahapatra DR, Nayak MM, Krishnaswamy UM, Srinivasa R (2013) Polyvinylidene fluoride film based nasal sensor to monitor human respiration pattern: an initial clinical study. J Clin Monit Comput. https://doi.org/10.1007/s10877-013-9486-x
14. Landis JR, Koch GG (1977) The measurement of observer agreement for categorical data. Biometrics 33(1):159–174
15. Starling-Schwanz R, Peake HL, Salome CM, Toelle BG, Ng KW, Marks GB, Lean ML, Rimmer SJ (2005) Repeatability of peak nasal inspiratory flow measurements and utility for assessing the severity of rhinitis. Allergy 60(6):795–800