Piezoelectric sensing: Evaluation for clinical investigation of deviated nasal septum

Roopa G. Manjunatha, M.E.,[1] Konandur Rajanna, Ph.D.,[1] Roy D. Mahapatra, Ph.D.,[2] and Srinivas Dorasala, M.D.[3]

ABSTRACT

Noninvasive objective evaluation of nasal airflow is one of the important clinical aspects. The developed polyvinylidene fluoride (PVDF) sensor enables measurement of airflow through each side of the nose using its piezoelectric property. This study was designed to evaluate the diagnostic capability of the PVDF sensor in assessing the deviated nasal septum (DNS). PVDF nasal sensor uses its piezoelectric property to measure the peak-to-peak amplitude (V_{p-p}) of nasal airflow in both of the nostrils: right nostril (RN) and left nostril (LN), separately and simultaneously. We have compared the results of PVDF nasal sensor, visual analog scale (VAS), and clinician scale for 34 DNS patients and 28 healthy controls. Additionally, the results were further analyzed by receiver operating characteristic curve and correlation between PVDF nasal sensor and VAS in detecting DNS. We found a significant difference in the peak-to-peak amplitude values of the test group and the control group. The correlation between the PVDF nasal sensor measurements and VAS (RN and LN combined) for test group was statistically significant (-0.807; $p < 0.001$). Sensitivity and specificity of the PVDF nasal sensor measurements in the detection of DNS (RN and LN combined) was 85.3 and 74.4%, respectively, with optimum cutoff value ≤ 0.34 V_{p-p}. The developed PVDF nasal sensor is noninvasive and requires less patient efforts. The sensitivity and specificity of the PVDF nasal sensor are reliable. According to our findings, we propose that the said PVDF nasal sensor can be used as a new diagnostic tool to evaluate the DNS in routine clinical practice.

The word piezoelectricity means electricity resulting from electrical polarization by mechanical stress.[1] Certain materials such as zinc oxide, lead zirconate titanate, aluminum nitride, *etc.*, when subjected to mechanical stress, develop surface electric charges. Thus, when suitable electrodes are provided, these charges will appear on these electrodes and hence a measurable voltage will be developed across them. Piezoelectric transducers find numerous applications in the medical instrumentation field. For example, they are used in ultrasonic scanners for imaging, blood flow measurements, detection of Korothoff sounds in noninvasive pressure measurement, and in external and internal phonocardiography.[1] Piezoelectric materials are also available as polymeric films such as polyvinylidene fluoride (PVDF).[2] It is a semicrystalline polymer consisting of the repeated molecule $-CH_2-CF_2-$. It is superior compared with other piezo materials in many ways: it exhibits high fidelity across a broad frequency range (nearly direct current [DC] to 1 GHz); it is very thin, light weight, flexible, and durable. PVDF has been used already in many medical applications related to cardiac activity and respiration.[3–5]

Human respiration is highly dependent on the structure of the nose. A congested nose severely affects the respiration. Therefore, it becomes very much important to measure the obstruction of the nose by rhinologists and respiratory physiologists. Deviated nasal septum (DNS) is one of the major causes of nasal blockage in many cases. The nasal septum is a osseous-cartilaginous structure in the center of the nose that separates the nasal cavity into two symmetrical nostrils.[6] A "DNS" occurs when the septum is shifted away from the midline. It is most frequently caused by impact nasal trauma, such as by a blow to the face. It can also be a congenital disorder, caused by compression of the nose during childbirth. In some cases, this deviation will be so severe that it will be symptomatic, causing nasal obstruction.[7] Hence, it becomes very important to study the DNS objectively to evaluate the nasal obstruction.

Usually, the diagnosis of DNS is based on patient's symptoms and clinician physical nasal examinations, which are subjective in nature. Choi *et al.* have performed a nasal sound spectral analysis to evaluate DNS and compared the results with a peak nasal inspiratory flowmeter.[8] In this method, forced respiration may cause the shifting of sound to a high level and peak nasal inspiratory flowmeter measurements may be influenced with an incompletely closed mouth and

different sizes of face masks. Computed tomographies (CT) of the nose and acoustic rhinometry (AR) are the other diagnostic tools that are often used to evaluate DNS objectively.[9,10] Although, CT shows bony and cartilaginous anatomic abnormalities of the septum quite reliably, this method should be used rarely because it is expensive and exposes patients to unnecessary radiations. AR is performed by analyzing the sound wave reflections from the interior of the nose. If there are any anatomic obstructions, such as nasal polyposis or septal deviations, it results in the distortions of the sound waves. It is a rapid and noninvasive technique. The disadvantages of this technique are not easily portable, creates interference with the breathing, and exhibits low correlation with patients' symptoms.[11–13] Hence, AR is unreliable to be used in the clinic. Therefore, it becomes a primary concern while using objective evaluation instruments for nasal blockage caused by DNS that the use of such instruments should be comfortable to patients, accurate, clinically applicable, and easily portable.

Other than the aforementioned objective methods, the nasal patency can also be measured subjectively by using visual analog scale (VAS).[14] VAS is the subject-stated perception or experience about his/her nasal blockage; hence, VAS is a well validated and reliable parameter.[15] Similar to VAS, by making a thorough visual investigation of the external structures of the nose, such as the position of the nasal septum with the use of nasal speculum in bright light by the ear, nose, and throat (ENT) clinician, the clinician can subjectively judge the deviation of nasal septum on a clinician scale (CS).

In the present article, we report a new method using the piezoelectric property of PVDF to measure the nasal blockage caused by DNS objectively. Nasal airflow generates an aerodynamic pressure. When this pressure acts on the surface of PVDF used in the sensor, electrical charges are developed on the surface of the PVDF film. These surface charges are then measured as voltage using the electrodes on both of the surfaces. Therefore, the voltage developed on the surface of a PVDF is directly correlated to the nasal airflow.

The aim of this study is to investigate the use of PVDF nasal sensor in diagnosing DNS. We have compared the results of the PVDF nasal sensor, VAS, and CS in patients with DNS with those of a nondeviated control group.

MATERIALS AND METHODS

Subjects

The study was conducted at M.S. Ramaiah Medical College and Hospital, Bangalore, India, after the approval of the study protocol by the Institutional Review Board. Written consent was obtained from all of the subjects before their participation in the study. We involved 62 subjects and divided them into two groups. The first group was a nondeviated control group consisting of 28 (19 male and 9 female subjects) subjects aged 32 ± 9 years. The second group was a case group consisting of 34 (20 male and 14 female) DNS patients aged 28 ± 10 years. Healthy subjects were chosen from hospital staff, nurses, and interns without any complaints of nasal blockage and symptoms. The criterion requested for enrollment of patients in the study was the presence of nasal obstruction without additional pathology. Mainly, patients diagnosed with DNS by clinician were taken as the case group for this study from ENT outpatient department (OPD).

PVDF Nasal Sensor Device Setup

The complete device setup consisting of a PVDF nasal sensor is shown in Fig. 1. The PVDF film (obtained from Precision Acoustic, Dorset, U.K.) is designed in the cantilever beam configuration with dimensions 10 mm $\times$ 5 mm $\times$ 28 μm. One end was attached on a plastic base by leaving the other end to deflect freely whenever nasal airflow impinges on it. Two separate PVDF films in the cantilever configuration together form the sensors. The two identical PVDF sensing elements were mounted on either side of the flexible strings of a headphone. When a subject wears this headphone, the sensing elements will be placed just below his/her nostrils in such a way that while breathing, the aerodynamic pressure exerted on the sensing elements causes deflection of these cantilever beams resulting in a corresponding voltage. The voltage signal from each of the sensing elements is the potential difference between the top electrode and the bottom electrode and is given by[16]

$$\Delta V \approx \frac{l^3 e_{31} b}{C_P C_{11} h^2} p(z) \qquad (1)$$

where ΔV is the total differential voltage output from a sensing element; $p(z)$ is the aerodynamic force on the cantilever beam caused by nasal airflow; C_{11} denotes the elastic modulus of the piezoelectric sensing element; e_{31} denotes the piezoelectric constant; C_p is the effective capacitance; and l, b, and h are the length, breadth, and thickness, respectively, of the sensing element in the form of cantilever beam. The output signals from the two sensing elements are given to signal conditioning circuitry for filtering (low pass filter) and further amplification (with a gain of 10). The final output signals are recorded and stored in the computer using a data acquisition card (NI 6008).

Measurement Methodologies

The subjects' noses were not decongested before the test. With the aid of a bright light source and a nasal
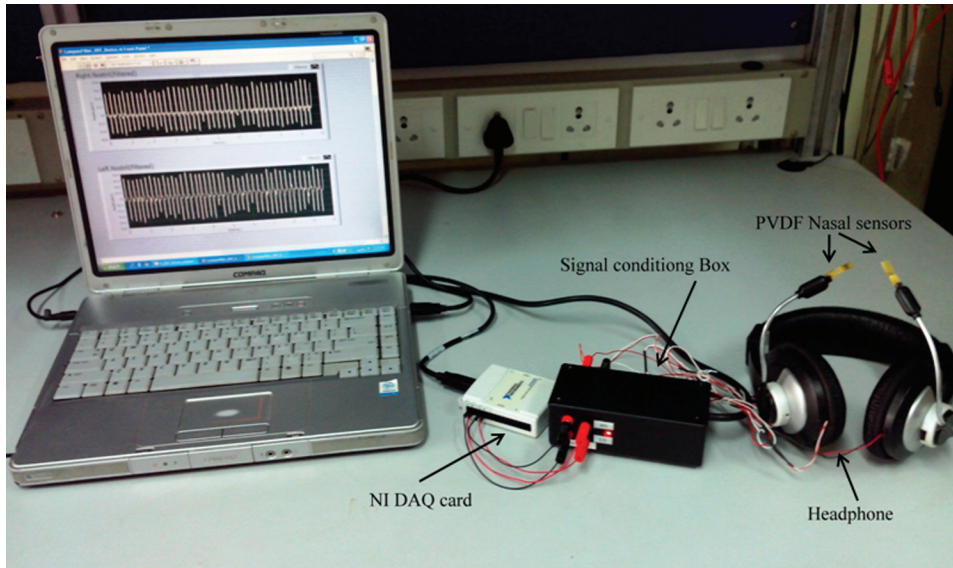
Figure 1. Polyvinylidene fluoride (PVDF) nasal sensor setup for measuring nasal airflow from both of the nostrils separately and simultaneously.

speculum (an instrument that gently spreads open the nostril), a detailed physical examination was performed by the ENT clinician to evaluate the side of the septum deviation carefully in each nostril of the individual subject. The side of the deviated septum is rated on a CS by the clinician as 0, no deviation; 1, deviation toward right nostril (RN); and 2, deviation toward left nostril (LN). Along with the CS, VAS was also used to determine the nasal obstruction experienced by the subject. Each subject was asked to answer the standardized questionnaire and mark their nasal patency on a 0–10 VAS scale: from totally clear (1) to complete blockage (10).

After recording CS and VAS, each subject was made to sit on a chair comfortably in a well-ventilated room with normal room temperature and humidity. He/she was asked to wear headphones and then a researcher/examiner positioned the PVDF nasal sensor 5 mm below the nose bottom/base and perpendicular to the direction of the nasal airflow. After positioning of the PVDF nasal sensor as shown in Fig. 2, he/she was instructed to do normal breathing. While recording the breathing signal/data, an initial signal/data for 30 seconds was truncated to avoid possible artifacts, which might have been caused because of wearing of the headphones. In addition, the voltage signal resulted due to breathing of a subject was recorded for 1 minute and stored in the computer for analysis.

Breathing Signal Analysis

The voltage output of PVDF nasal sensor as a function of time gave the nasal breathing cycle of the 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 ($V_{P\text{-}p}$) of the inspiration and
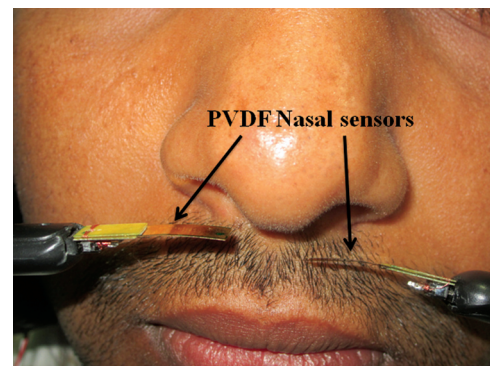

Figure 2. Nasal airflow measurement using polyvinylidene fluoride (PVDF) nasal sensor.

expiration peaks gave a correlated magnitude of a nasal airflow. The average peak-to-peak amplitude of the breathing cycle recorded for 1 minute is calculated for both the nasal cavities separately for each subject, using MATLAB software (version R2007b, Mathworks, Inc., Natick, MA).

Statistics

Data were expressed as mean ± SD. A value of $p < 0.05$ was considered statistically significant. The age of control and test groups was tested using Student's *t*-test. Correlation coefficients and *p* values are determined between PVDF nasal sensor and VAS. Receiver operating characteristic (ROC) curve plots sensitivity versus 100 specificity and it was used to compare the reliability of PVDF nasal sensor in determining DNS relative to VAS. The sensitivity and specificity are determined by applying the diagnostic test to one group of diseased persons and to a reference group of non-diseased (normal) persons (Table 1).[17]

Table 1 2 × 2 Tables for calculation of sensitivity and specificity

Prediction by the Diagnostic Test	Truth		Total
	Disease Present	Disease Absent	
Disease Present	a (true positive)	b (false positive)	a + b (predicted as diseased)
Disease Absent	c (false negative)	d (true negative)	c + d (predicted as nondiseased)
Total	a + c (truly diseased)	b + d (truly nondiseased)	

From Table 1, sensitivity of the diagnostic test is the probability of picking up the disease when it is truly diseased, *i.e.*,

sensitivity (expressed as percentage)

$$= \frac{a}{a + c} \times 100 \quad (2)$$

Specificity of the diagnostic test is the probability of picking up the nondisease (normal) when it is truly nondiseased (normal), *i.e.*,

specificity (expressed as percentage)

$$= \frac{d}{b + d} \times 100 \quad (3)$$

The optimum cutoff value (*J) is the best possible predicted value that represents maximum of sensitivity and specificity and is expressed as[17]

$$*J = \text{Max} [SE_i + SP_i - 1] \quad (4)$$

where SE_i and SP_i are the sensitivity and specificity, respectively, for all measured/observed cutoff values.

Plotting sensitivity on the *y*-axis and its corresponding 100 specificity on the *x*-axis for each cutoff gives the ROC curve. In the ROC curve, the diagonal line, also known as diagnostic/reference line, divides the ROC space. We have chosen the diagnostic line based on CS, 0 as negative (without nasal blockage) and 1 as positive (with nasal blockage).

RESULTS

We have collected the data using the PVDF nasal sensor, CS, and VAS in 28 (9 female and 19 male patients) healthy controls with the mean age of 28 ± 10 years and 34 (14 female and 20 male patients) septum-deviated patients with mean age of 32 ± 9 years. There was no significant difference found in the ages of control group and test group ($p > 0.05$). The age of healthy controls ranged from 20 to 58 years and age of the test group ranged from 21 to 56 years. The ENT clinician did a thorough nasal examination of each individual and scored the position of nasal septum as RN and LN deviation. Twelve (35%) of the patients had RN septum deviation and 22 (65%) of the patients had LN septum deviation.

The voltage output (V_{p-p}) of PVDF nasal sensor provides a nasal breathing cycle of a subject with inspiration and expiration phase as shown in Fig. 3 As can be seen in Fig. 3 *A*, when there was no septal deviation, the magnitude of nasal airflow was equal in both the nostrils. In the case of a nasal septum deviation toward any side, the magnitude of the nasal airflow decreases in that corresponding side. The output response of the PVDF nasal sensor recorded for the subjects with LN and RN deviations are shown in Fig. 3, *B* and *C*, respectively. The data of the magnitude of the nasal airflow of each nostril measured by the PVDF nasal sensor is given in Table 2. VAS and CS gives the scoring of the septum deviation, but does not give any information about nasal airflow. When the CS score was 0, indicating no deviation, the PVDF nasal sensor measured relatively equal amounts of airflow in both of the nostrils (RN, 0.576 ± 0.18 V_{p-p}; LN, 0.60 ± 0.19 V_{p-p}). When the CS scores were 1 for patients with RN deviation, PVDF nasal sensor measured less airflow in the RN (0.37 ± 0.14 V_{p-p}) compared with the LN. Similarly, for patients with LN deviation, the CS scores were 2 and the PVDF nasal sensor also measured less airflow in the LN (0.31 ± 0.14 V_{p-p}) compared with the RN. Similarly, VAS for nasal obstruction was between 5 and 9 (6.6 ± 3.2 for LN and 7.6 ± 2.2 for RN) for the deviation group and between 1 and 3 (1.5 ± 0.4 for LN and 1.6 ± 0.6 for RN) for the control group. There was a good negative linear correlation between the PVDF nasal sensor and VAS in the test group. Table 3 shows the correlation r_s analysis for patients with RN deviation as −0.737 ($p < 0.001$) and r_s value for patients with LN deviation as −0.856 ($p < 0.001$). Figure 4 shows the scatterplot of correlation between PVDF nasal sensor (for combined RN and LN DNS) and VAS ($r_s = -0.807$; $p < 0.001$).

The PVDF nasal sensor measurements and VAS scores were compared by means of ROC analysis as shown in Fig. 5. Sensitivity and specificity (using Eqs. 2 and 3) were calculated for the PVDF nasal sensor and VAS (for combined right and left nasal cavities) by taking each measured value as a cutoff point as shown in Table 4. The optimum cutoff value was calculated using Eq. 4 and found to be ≤0.34 V_{p-p} and >4 for PVDF nasal sensor and VAS, respectively. At this optimum cutoff value, the sensitivity and specificity for
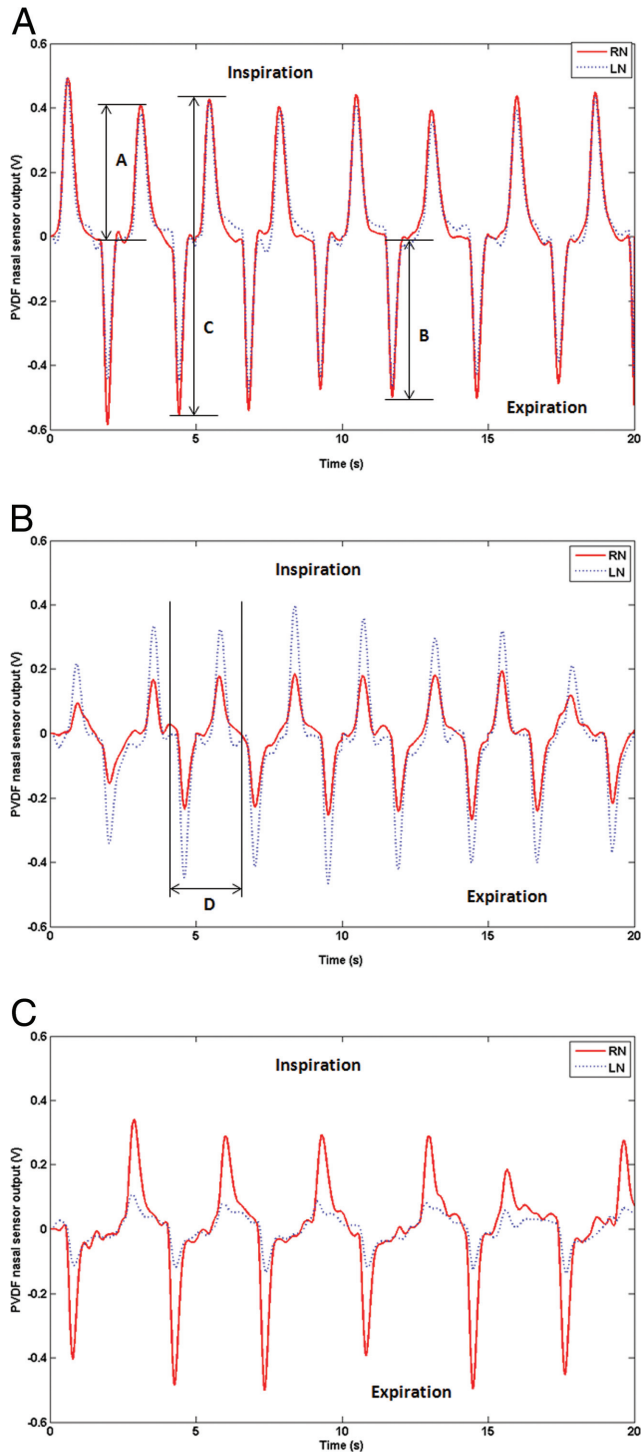
Figure 3. Breathing cycle traced by polyvinylidene fluoride (PVDF) nasal sensor in (A) control subject (peak-to-peak amplitude of both the nostrils right nostril [RN] and left nostril [LN] are equal), (B) patient with right-side deviation (peak-to-peak amplitude of RN is smaller than LN showing septum deviation toward right), and (C) patient with left-side deviation (peak-to-peak amplitude of LN is less than LN showing septum deviation toward left). Panel A indicates inspiration peak, panel B indicates expiration peak, panel C indicates peak-to-peak amplitude of inspiration and expiration, and panel D indicates breathing cycle.

the PVDF nasal sensor were found to be 85.3 and 74.4%, respectively, whereas the sensitivity and specificity for VAS were 94.1 and 92.9%, respectively. When compared with clinical diagnosis as gold standard, PVDF nasal sensor measurements were reasonably close to the VAS score in terms of sensitivity and specificity as shown in Table 5. Also, the sensitivity and specificity of PVDF nasal sensor measurements in the detection of RN deviations were 76.9 and 72.3%, respectively, with a cutoff value ≤ 0.36 V$_{p-p}$ and in the detection of LN deviations were 81 and 82.8%, respectively, with a cutoff value ≤ 0.31 V$_{p-p}$. The cutoff value was chosen as the value that maximized sensitivity and specificity. For PVDF nasal sensor, the values below optimum cutoff value ≤ 0.34 V$_{p-p}$ indicates that the subject will have DNS, whereas for the VAS, the score of >4 will have DNS.

DISCUSSION

In the past several years, researchers have used the usefulness of the PVDF in various biomedical applications. The efficiency of PVDF polymer is high in converting mechanical energy into electrical signals, when compared with its other counterparts such as lead zironate titanate (PZT) (also not biocompatible), zinc oxide, *etc.*[18] Because PVDF has a wide frequency bandwidth (near DC to 1 GHz) and is nonreactive, flexible, light-weight, biocompatible, and available in various thickness and size, it becomes efficient in sensing biomedical signals such as heart rate, respiration, and other physiological signals.[19]

Fraden[20] has used PVDF films in babies to detect apnea and cardiac irregularities for the prevention of sudden infant death syndrome. Siivola *et al.*[5,21] have used a piezoelectric transducer (PVDF) for recording heart rate and body movements and, furthermore, they have attached a piece of PVDF film on a human belly to record the respiration at the level of diaphragm. Carlos *et al.*[22] have fabricated PVDF film-based pressure sensor that can measure a very low pressure in the order of millimeters of mercury and they have used it to measure intraocular pressure in the ophthalmological unit. Berry *et al.*[23] and Dodds *et al.*[24] have made use of PVDF to detect sleep apnea and measure respiration rate, respectively. All of the aforementioned studies have shown the potential usage of the PVDF film in the biomedical field.

In our present study, we have used the piezoelectric property of PVDF film to detect nasal blockage objectively, caused by DNS. The nasal septum divides the nose into the right and left nasal cavity. The deviation in the nasal septum toward RN or LN (sometimes with a spur or with no spur) causes asymmetries in the nasal cavities, because of which there will be less airflow from the deviated nostril. Most of the time deviation

Table 2 Measurements of peak-to-peak amplitude of nasal airflow using PVDF nasal sensor, VAS, and CS based on nasal septum deviation

Subjects	Nasal Cavity	PVDF Nasal Sensor Measurement (V_{p-p})	CS Score	VAS
Controls	RN	0.576 ± 0.18	0	1.5 ± 0.4
	LN	0.60 ± 0.19	0	1.6 ± 0.6
Patients with RN deviation	RN	0.37 ± 0.14	1	6.6 ± 3.2
	LN	0.63 ± 0.1	0	1.4 ± 1.1
Patients with LN deviation	RN	0.72 ± 0.11	0	1.8 ± 0.5
	LN	0.31 ± 0.14	2	7.6 ± 2.2

PVDF = polyvinylidene fluoride; VAS = visual analog scale; CS = clinical scale; RN = right nostril; LN = left nostril.

Table 3 Correlation analysis (PVDF nasal sensor vs VAS) for patients with RN and LN deviation

Test Group	Correlation Coefficient (r_S)	Significance (p)
Patients with RN deviation	-0.737	<0.001
Patients with LN deviation	-0.856	<0.0001
Complete nose (including both RN and LN)	-0.807	<0.0001

PVDF = polyvinylidene fluoride; VAS = visual analog scale; RN = right nostril; LN = left nostril.
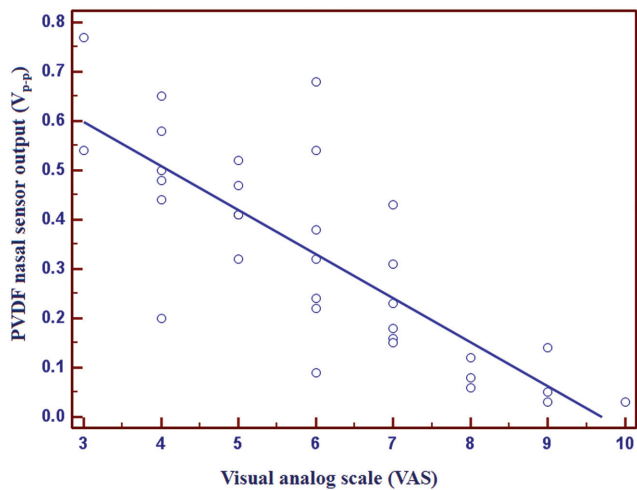

Figure 4. Correlation between polyvinylidene fluoride (PVDF) nasal sensor (for combined right nostril [RN] and left nostril [LN] deviated nasal septum [DNS]) versus visual analog scale (VAS). The solid line is the regression line ($r = 0.86$; $p < 0.001$).
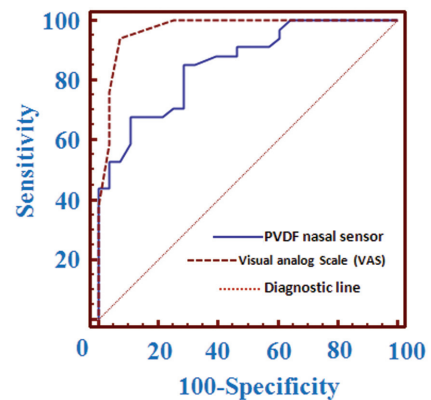

Figure 5. Receiver operating characteristic (ROC) curve for the polyvinylidene fluoride (PVDF) nasal sensor measurements and visual analog scale (VAS). The diagnostic line is drawn based on clinician scale (CS).

will be not symptomatic, but sometimes it becomes symptomatic depending on the degree of deviation (mild, moderate, and severe). PVDF film generates voltage whenever they are subjected to the nasal airflow (which is a form of mechanical energy). When there is no septum deviation, the airflow from symmetrical nasal cavities are equal in magnitude and, hence, they give rise to the same amount of voltage (peak-to-peak amplitude, V_{p-p}) from the PVDF nasal sensor, as shown in Fig. 3 *A*. The amplitude of the PVDF nasal sensor output depends on the severity of

deviation, *i.e.*, the more the deviation, the less the amplitude, as shown in Fig. 3, *B* and *C*. An increase in the severity of nasal septum deviations leads to decreased airflow; hence, the PVDF nasal sensor can detect severe and moderate DNS more precisely.

In most of the clinical setups, DNS is detected by the physical examination of the nasal cavity by a clinician and subjects' symptoms of nasal blockage. The clinician visually analyzes the position of the nasal septum and recommends septoplasty depending on the severity of the deviation. It will be very helpful for a clinician if DNS can be objectively measured. AR, CT scan, and rhinomanometry are the few instruments that will measure DNS objec-

Table 4 ROC analysis of PVDF nasal sensor and VAS		
Cutoff Value (V_{p-p})	Sensitivity (%)	Specificity (%)
PVDF nasal sensor		
<0.03	0	100
≤0.04	20.59	100
≤0.05	23.53	98.89
≤0.06	29.41	98.89
≤0.08	32.35	97.78
≤0.09	44.12	97.78
≤0.1	44.12	95.56
≤0.12	47.06	95.56
≤0.15	52.94	91.11
≤0.17	52.94	90
≤0.18	58.82	88.89
≤0.19	58.82	86.67
≤0.21	67.65	84.44
≤0.23	67.65	81.11
≤0.24	70.59	80
≤0.26	70.59	76.67
≤0.28	82.35	76.67
≤0.31	82.35	75.56
≤0.34*	85.29	74.44
≤0.39	85.29	73.33
≤0.42	88.24	68.89
≤0.47	88.24	65.56
≤0.52	91.18	62.22
≤0.56	91.18	55.56
≤0.58	94.12	53.33
≤0.61	94.12	51.11
≤0.62	97.06	47.78
≤0.64	97.06	43.33
≤0.65	100	38.89
≤0.66	100	34.44
≤0.7	100	33.33
≤0.71	100	30
≤0.72	100	28.89
≤0.73	100	27.78
≤0.74	100	26.67
≤0.76	100	24.44
≤0.77	100	23.33
≤0.79	100	20
≤0.8	100	18.89
≤0.81	100	16.67
≤0.84	100	15.56
≤0.85	100	12.22
≤0.87	100	11.11
≤0.88	100	8.89
≤0.89	100	6.67
≤0.9	100	5.56
≤0.94	100	4.44
≤0.96	100	2.22
≤1.01	100	1.11
≤1.2	100	0

Table 4 Continued		
Cutoff Value (V_{p-p})	Sensitivity (%)	Specificity (%)
VAS		
≥1	100	0
>1	100	64.29
>2	100	75
>3	98.18	84.20
>4*	94.12	92.96
>5	76.47	96.43
>6	38.24	100
>7	20.59	100
>8	11.76	100
>9	2.94	100
>10	0	100

*The optimum cutoff chosen.
PVDF = polyvinylidene fluoride; VAS = visual analog scale; ROC = receiver operating characteristic.

tively.[10,25] But these methods are not commonly used in clinical setup because of their high cost and complexity in handling them, because they require a trained operator. Therefore, a practical, swift, portable, reliable, and low-cost method is needed to evaluate nasal blockage caused by DNS objectively.

To optimize the PVDF nasal sensor positioning with respect to nostrils, before going for clinical validation of the PVDF nasal sensor at a hospital, a detailed experiment was conducted in 10 subjects (six male and four female subjects) for optimizing the sensor position with respect to nostrils. Initially, a ruler was used to position the sensors at various distances such as 1, 3, 5, 7, 9, 12, and 15 mm. After positioning the sensors, parallel to nasal bottom (taken as reference line) and perpendicular to the direction of nasal airflow (as illustrated in Fig. 6), voltage signals were recorded for each subject at different sensor position. Figure 7 shows the voltage signals of all 10 subjects for each distance of sensor position. Table 6 gives the average peak-to-peak amplitude of PVDF nasal sensors for different distances from the reference line. As can be seen from Fig. 7, the PVDF nasal sensor gives maximum peak-to-peak amplitude at 1-mm distance; however, the main disadvantage of this position is that the sensors will be in very close proximity with the nostrils; hence, there will be a chance that sensors might touch the nostril/inner portion of nostril because of deflection by nasal airflow. This might cause irritation for the subject or sometimes initiate itching/sneezing, because the inner portion of nostril is very sensitive. From Table 6 it can be seen that the PVDF nasal sensors provide almost constant voltage responses for the distances in the range of 3–7 mm; beyond 7-mm distance, the

Table 5   ROC curve values with their significance for both of the methods (PVDF nasal sensor and VAS)

Parameter	Sensitivity (%)	Specificity (%)	Cutoff Value (V_{p-p})	AUC	Significance (p)
PVDF nasal sensor					
a. RN deviated patients vs control group	76.9	72.3	≤0.36	0.808	<0.001
b. LN deviated patients vs control group	81.0	82.8	≤0.31	0.830	<0.001
c. Combined (RN + LN) DNS vs control group	85.3	74.4	≤0.34	0.867	<0.001
VAS					
a. RN deviated patients vs control group	92.3	95.8	>5.2	0.900	<0.0001
b. LN deviated patients vs control group	94.6	98.2	>6.1	0.902	<0.0001
c. Combined (RN + LN) DNS vs control group	94.1	92.9	>4	0.907	<0.0001

AUC = area under the curve; PVDF = polyvinylidene fluoride; VAS = visual analog scale; RN = right nostril; LN = left nostril.
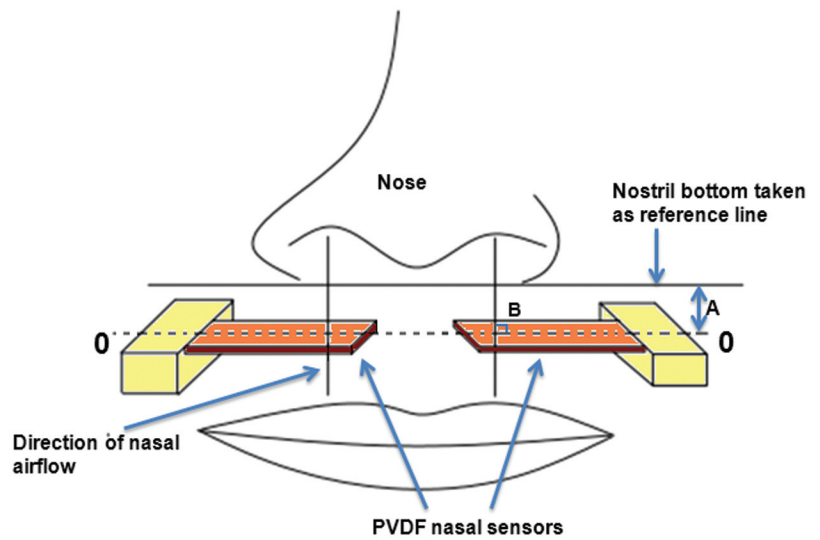

Figure 6. Illustration of position of polyvinylidene fluoride (PVDF) nasal sensor with respect to nose (A is the distance between PVDF nasal sensor and reference line, B is the angle (90°) between direction of nasal airflow and PVDF nasal sensor, "00" represents neutral axis of PVDF cantilever).
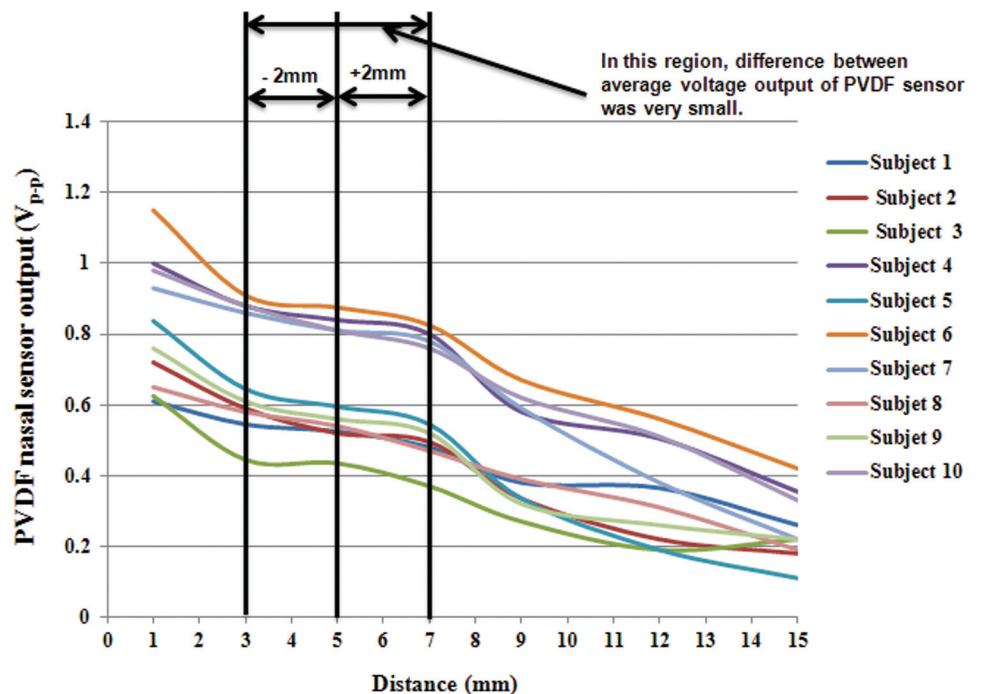

Figure 7. Plot of the measurement obtained from a polyvinylidene fluoride (PVDF) nasal sensor as a function of the distance from reference line for 10 subjects.

Table 6 Average PVDF nasal sensor output (V_{p-p}) expressed as mean ± SD for different distance of the PVDF nasal sensor from reference line

	Distance (mm)						
	1	**3**	**5**	**7**	**9**	**12**	**15**
PVDF nasal sensor output (V_{p-p})	0.82 ± 0.18	0.69 ± 0.17	0.65 ± 0.16	0.60 ± 0.16	0.44 ± 0.14	0.34 ± 0.13	0.25 ± 0.09

PVDF = polyvinylidene fluoride.

peak-peak amplitude (output) of the sensor reduced noticeably. Hence, from the aforementioned detailed experiment, the position of the PVDF nasal sensor was optimized to 5 mm; however, in realistic usage, if the sensor is placed above or below 5 mm (±2 mm) also, there will not be much difference in the sensitivity of the sensor output. Table 6 shows the difference between average peak-to-peak amplitude corresponding to 3- and 5-mm distances was 0.04 V_{p-p}, whereas for the distances of 5 and 7 mm amplitude was 0.05 V_{p-p}, which are very less when compared with the difference in output response between the normal subjects and DNS patients which is ≈0.3 V_{p-p} (Table 2). Visually, one can position PVDF sensors parallel with respect to the reference line (nostril bottom taken as reference line) and perpendicular to the direction of the nasal airflow easily without the need of any special instrument/extra care. Also, at the hospital, we repeated the aforementioned experiment for a group of 10 DNS patients and found that there was not much difference in the PVDF nasal sensor output response for the distances in the range of 3 to 5 mm. One important thing we observed while doing the experiment for DNS patients was that there was always less nasal airflow from the blocked nostril (deviated side) compared with the other nonblocked (normal) nostril at all measured distances. As an example for this observation, the responses recoded for the distances of 5 and 12 mm are shown in Fig. 8. It is evident that although the peak-to-peak amplitude of the PVDF sensor output reduced at 12-mm distance compared with the 5-mm distance; nevertheless, the difference between the peak-to-peak amplitude for the deviated nostril and the normal nostril is significant and can be seen clearly. This makes the PVDF nasal sensor robust and reliable, irrespective of precise positioning.

The PVDF nasal sensor proposed in this article has several advantages as follows: (1) it is easy to use and quick (it takes a minute to perform), (2) it is noninvasive and requires minimal patient cooperation (as the measurement is done in natural breathing form and no forced breathing is needed), (3) it is portable and does not require a trained operator, and (4) it is not expensive and data can be recorded in a routinely used computer.

PVDF nasal sensor measurements and VAS score showed a negative linear correlation in the test group for patients with RN and LN deviation ($r_s = -0.807$; $p < 0.001$). Based on the CS score obtained from the clinician (both control and test groups), we have set a diagnostic line from which results are considered positive and negative (0 as negative, without nasal blockage, and 1 as positive, with nasal blockage).

ROC analysis assesses the accuracy of a diagnostic tool by calculating sensitivity and specificity. The sensitivity and specificity of VAS in the detection of DNS were >90% because CS and VAS scores matched strongly. For VAS, the score above 4 on a 0–10 VAS will be considered a DNS case. The sensitivity and specificity of our PVDF nasal sensor—85.3 and 74.4%, respectively—were reasonably close to the clinical diagnosis in detecting DNS. The peak-to-peak amplitude values of a subject below the optimum cutoff point—0.34 V_{p-p} for combined RN and LN—was considered to have DNS and above these values are considered to be normal. However, there is always a chance of false positive and false negative cases. The area under curve predicts the overall discriminating ability of the diagnostic criteria.[17] Therefore, as shown in Table 5, 86 and 90% of the total subjects have been diagnosed correctly by the PVDF nasal sensor and VAS, respectively.

Perhaps the specificity of the PVDF nasal sensor <100% could be a result of nasal cycle, which is a confounding factor that may have altered the nasal airflow during measurement. The nasal cycle is an alternate fluctuation (congestion and decongestion) of the nasal airflow between right and left nasal cavities found in 80% of the population.[26] However, if healthy individuals had reduced unilateral airflow due to the presence of nasal cycle in either of the nostrils, from the results (Table 2) it can be seen that the average peak-to-peak voltage corresponding to airflow in controls was still much higher than patients.

In this study, we have evaluated the usefulness of piezoelectric property of PVDF to detect nasal obstruction caused by DNS in a limited number of
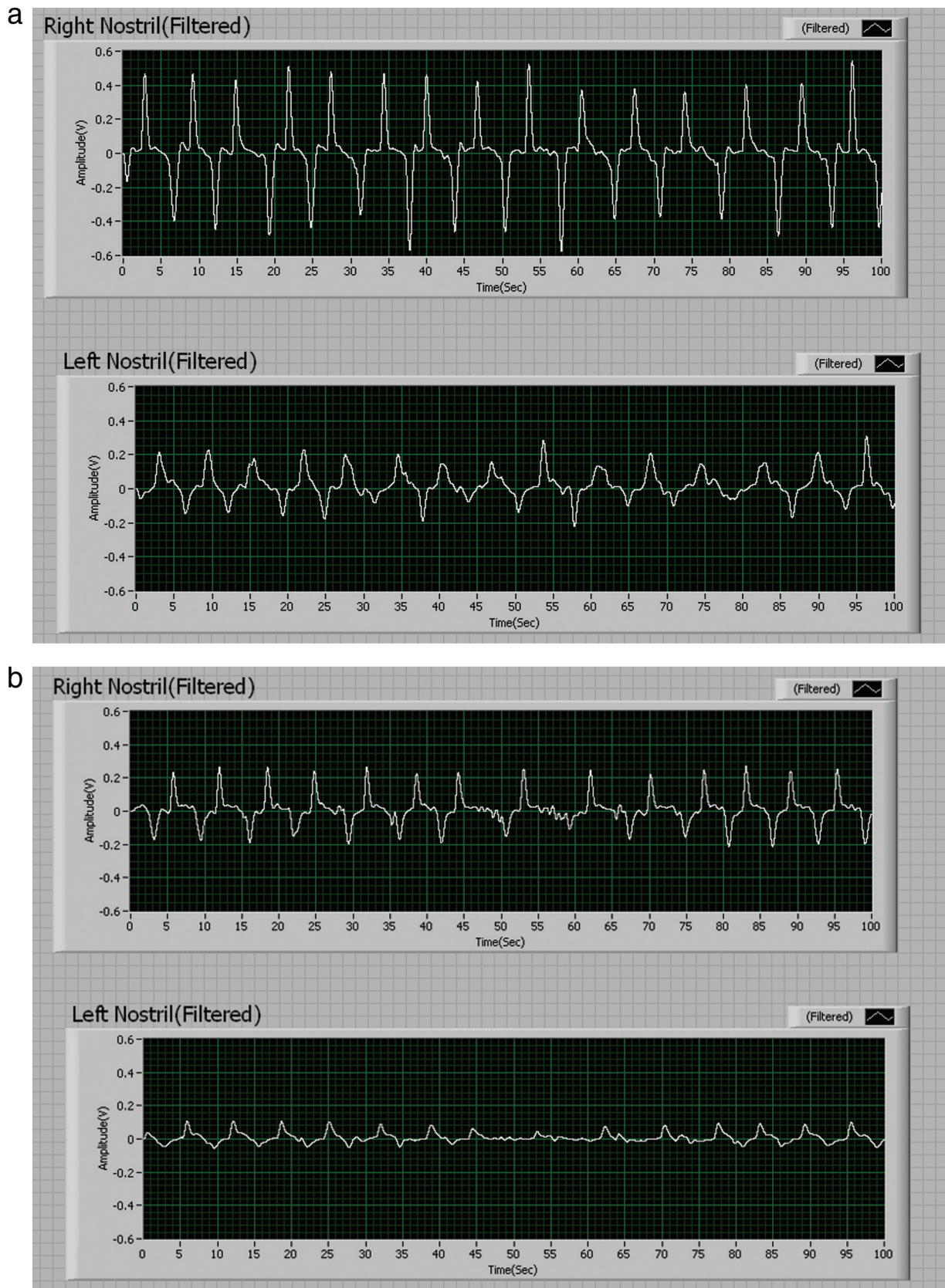
Figure 8. Output of the polyvinylidene fluoride (PVDF) nasal sensor for left nostril (LN) deviated patient (a) PVDF nasal sensor was positioned at 5 mm from the nasal reference line (b) positioned at 12 mm from the nasal reference line.

patients (34) and healthy control (28). However, additional studies with larger patient populations are required to determine the validity of the PVDF nasal sensor.

CONCLUSION

The piezoelectric natured PVDF nasal sensor successfully differentiated the normal nasal cavity from the deviated nasal cavity. The PVDF nasal sensor is a noninvasive, simple, portable, and inexpensive technique that requires minimal patient cooperation for testing nasal blockage. The present study showed that the PVDF nasal sensor exhibited good correlation with VAS. From the ROC analysis the sensitivity and specificity of the PVDF nasal sensor matched reasonably well with clinical diagnosis. Thus, we speculate that the PVDF nasal sensor could be used as a novel diagnostic tool to evaluate nasal obstruction objectively rather than relying on subjective perception. However, additional studies with larger patient populations are required to determine the validity of the PVDF nasal sensor.

REFERENCES

1. Khandpur RS. Handbook of Biomedical Instrumentation. Chapter 3: Physiological Transducers, Second Edition. New Delhi: Tata McGraw-Hill Education, 78–79, 2003.
2. Kawai H. The piezoelectric of poly(vinylidene fluoride). Jpn J Appl Phys 8:975–976, 1969.
3. Dario D, Bedini R, Francesoni R, and Trivella MG. PVF2 catheter tip transducer for pressure, sound and flow measurements. Ferroelectrics 60:149–162, 1984.
4. F Wang, Tanaka M, and Chonan S. Development of a PVDF piezoplymer sensor for unconstrained in sleep cardio respiratory monitoring. J Intell Mater Syst Struct 14:185–190, 2003.
5. Siivola J, and Lang AH. Non-invasive piezoelectric transducer for recording of respiration at the level of diaphragm. Electroencephalogr Clin Neurophysiol 106:552–553, 1998.
6. Dunning WM. The Submucous Resection of the Nasal Septum. Chapter 2: Breathing and Smelling, Surgery Publishing Co., NY 99–110, 1921.
7. Sam A, Deshmukh PT, Patil C, et al. Nasal septal deviation and external nasal deformity: A correlative study of 100 CASES. Indian J Otolaryngol Head Neck Surg 64:312–318, 2012.
8. Choi H, Park IH, Yoon HG, and Lee HM. Diagnostic accuracy evaluation of nasal sound spectral analysis compared with peak nasal inspiratory flow in nasal septal deviation. Am J Rhinol Allergy 25:e86–e89, 2011.
9. Kimbell JS, Garcia GJ, Frank DO, et al. Computed nasal resistance compared with patient-reported symptoms in surgically treated nasal airway passages: A preliminary report. Am J Rhinol Allergy 26:e94–e98, 2012.
10. Mamikoglu B, Houser S, Akbar I, et al. Acoustic rhinometry and computed tomography scans for the diagnosis of nasal septal deviations, with clinical correlation. Otolaryngol Head Neck Surg 123:61–68, 2000.
11. Tomkinson A, and Eccles R. Comparison of the relative abilities of acoustic rhinometry, rhinomanometry and the visual analogue scale in detecting change in the nasal cavity in a healthy adult population. Am J Rhinol 10:161–165, 1996.
12. Castano R, Trudeav C, and Ghezzo H. Correlation between acoustic rhinometry and subjective nasal patency during nasal challenge test in subjects with suspected occupational rhinitis; a prospective controlled study. Clin Otolaryngol 35(6):462–467, 2010.
13. Reber M, Rahm F, and Monnier P. The role of acoustic rhinometry in the pre- and post-operative evaluation of surgery for nasal obstruction. Rhinology 36:184–187, 1998.
14. Lam DJ, James KT, and Weaver EM. Comparison of anatomic, physiological, and subjective measures of the nasal airway. Am J Rhinol 20:463–470, 2006.
15. Bousquet PJ, Combescure C, Neukirch F, et al. Visual analog scales can assess the severity of rhinitis graded according to ARIA guidelines. Allergy 62:367–372, 2007.
16. Roopa Manjunatha G, Rajanna K, Mahapatra DR, et al. Polyvinylidene fluoride film based nasal sensor to monitor human respiration pattern: An initial clinical study. J Clin Monit Comput 27:647–657, 2013.
17. Zweig MH, and Campbell G. Receiver-operating characteristic (ROC) plots: A fundamental evaluation tool in clinical medicine. Clin Chem 39:561–577, 1993.
18. Scott W, and Bloomfield P. Durable lead attachment techniques for PVDF polymer transducers with application to high voltage pulses ultrasonics. Ferroelectrics 32:79–83, 1981.
19. Sessler GM. Piezoelectricity in polyvinylidene fluoride. J Acoust Soc Am 70:1596–1608, 1981.
20. Fraden J. Application of piezo/pyroelectric films in medical transducers. J Clin Eng 13:133–138, 1998.
21. Siivola J. New noninvasive piezoelectric transducer for recording of respiration, heart rate and body movements. Med Biol Eng Comp 27:423–425, 1989.
22. González Moran CO, González-Ballesteros R, and Suaste-Gómez E. Polivinylidene difluoride (PVDF) pressure sensor for biomedical applications. International Conference in Electrical and Electronics Engineering ICEEE, 473–475, 2004.
23. Berry RB, Koch GL, Trautz S, and Wagner MH. Comparison of respiratory event detection by polyvinylidene fluoride film airflow sensor and a pneumotachograph in sleep apnea patients. Chest 128:1331–1338, 2005.
24. Dodds D, Purdy J, and Moulton C. The PEP transducer: A new way of measuring respiratory rate in the non-intubated patient. J Accid Emerg Med 16:26–28, 1999.
25. Szucs E, and Clement PA. Acoustic rhinometry and rhinomanometry in the evaluation of nasal patency of patients with nasal septal deviation. Am J Rhinol 12:345–352, 1998.
26. Kayser R. Die exakte messung der luftdurchgängigkeit der nase. Arch Laryngol Rhinol (Berl) 8:101–102, 1895. □