

Design Criteria to Miniaturize the Single Use Functional Respiratory Air Flow Tube

Kyung Ah Kim, Tae Soo Lee, Eun Jong Cha

Biomedical Engineering Department, School of Medicine, Chungbuk National University, Cheongju, Korea
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Abstract: Respiratory tubes with a length of 35mm and diameters of 10, 15, and 20mm were made for experimental purpose, and both the static(P_s) and dynamic(P_D) pressures were simultaneously measured for steady flow rates ranging 1-12/sec. Least squares analysis resulted successful fitting of P_s and P_D data with quadratic equations with correlation coefficients higher than 0.99($P < 0.0001$). The spirometric measurement standards of the American Thoracic Society(ATS) were applied to P_s data, which demonstrated the smallest tube diameter of 15mm to satisfy the ATS standards. The maximum P_D value of the velocity type transducer(the functional single use respiratory air flow tube) with the diameter of 15mm was estimated to be approximately 75cmH₂O, implying more than 7 times larger sensitivity than the widely used pneumotachometers. These results showed that the velocity type respiratory air flow transducer is a unique device accomplishing miniaturization with the sensitivity increased, thus would be of great advantage to develop portable medical devices.

Key words: Respiratory air flow transducer, Air velocity measurement, Miniatured transducer, Portable medical device.

INTRODUCTION

Respiratory air flow rate is an important biological variable to evaluate pulmonary function[1]. The most widely applied techniques are pneumotachography[2] and turbinometry[3], both of which require sensor element located on the flow plane converting the respiratory air flow rate into a measurable physical variable. However, the sensor element could apply excessive load against breathing, which in turn masks measurement reliability. When screening test is performed for a number of subjects, cross-infection could also occur. The authors recently proposed a new technique converting the respiratory air flow rate into dynamic pressure with no respiratory load[4]. The "functional single use respiratory tube", one of the velocity-type respiratory air flow transducers, was developed and successfully tested for accuracy. In particular, this device is free from cross-infection owing to its single use design[5].

Chronic respiratory diseases such as asthma should

be managed by self test on a daily basis[6]. The peak expiratory flow(PEF) meter provides handy and convenient measurement of PEF[7], however, works by simple spring mechanism, thus incapable of evaluating more important spirometric parameters such as the forced expiratory volume at 1 second (FEV1.0) and/or the forced vital capacity(FVC). FEV1.0 and FVC measurements require continuous air flow signal acquired by an electronic spirometer. Unfortunately, the currently available spirometers adapt large and expensive respiratory air flow transducers hard to carry and self test for personal use.

The device must be down sized for portable personal application in self home care. The air flow resistor(mesh screen or capillary tubes) employed by pneumotachography is difficult to manufacture small enough due to its structural design. The propeller or turbine of the turbinometer keeps the same structural problem. Furthermore, cleaning and sterilization should be done every test to prevent cross-infection. The functional single use respiratory tube previously developed by the authors is a disposable paper tube, in which a narrow rod shaped plastic element(called a "sensing rod") converting air velocity into dynamic pressure is placed on the diameter of the flow plane[5]. The sensing rod is narrow enough to have almost no resistance to breathing, thus the length and diameter of the respiratory tube can be minimized. Therefore, the present study aimed to establish the design criteria, i.e., the minimal length and diameter

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Corresponding Author: Eun Jong Cha

Department of Biomedical Engineering, School of Medicine,
Chungbuk National University, 12 Gaeshin, Heungduk,
Cheongju, Chungbuk 361-763, Korea

Tel. 043-261-2856 Fax. 043-273-0848

HP. 011-468-6331 E-mail. ejcha@chungbuk.ac.kr

of the functional single use air flow tube meeting the internationally accepted standards of the American Thoracic Society(ATS).

MATERIALS AND METHODS

Dynamic Pressure Measurement

The sensing rod of the functional single use flow tube is basically dual symmetric Pitot tubes measuring differential pressure[8]. Energy conservation principle by Bernoulli makes possible to convert bi-directional respiratory air velocity(u) into dynamic pressure(P_D) since the static pressure(P_S) components applied on both tubes closely adjacent to each other are cancelled out(Fig. 1).

$$u = S \cdot \sqrt{P_D} \tag{1}$$

where S=sensitivity coefficient

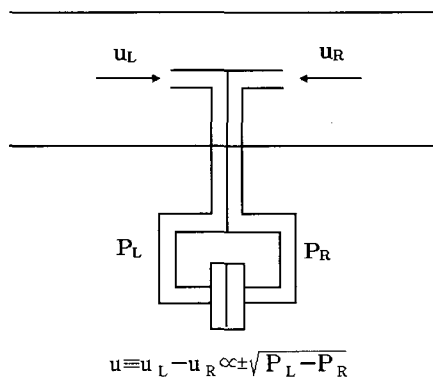


Fig. 1. Bi-directional velocity measurement principle.

Uni-directional Sensor Element

Although clinical spirometers measure bi-directional respiratory air flow rates, we decided to design the sensing rod for uni-directional measurement only for miniaturization. Most spirometric parameters are obtained from the expiratory air flow signal only, enough for personal self care(refer to the Discussion section). The next consideration was the length of the flow tube. Since the patient should breathe through the mouth, the tube must be long enough for the entrance to be put within the mouth. We arbitrarily decided a length of 35mm, long enough to connect to the patient's mouth but the shortest to attach to the electronic device. The tube diameter is a major

determinant of flow resistance, and 3 tubes with diameters of 10, 15, and 20mm were specially made for experiments. Fig. 2 shows the flow tube incorporated with the newly designed uni-directional sensing rod. The sensing rod had a small and narrow cylindrical shape with the inner diameter of 1mm.

The sensing rod needs to have sensing holes converting flow rate into dynamic pressure. The authors previously reported a systematic way to determine the optimal locations of multiple sensing holes[13]. Although more holes would provide more accurate measurements, technical as well as cost problems occur especially in the smallest tube of diameter, 10mm. For manufacturing consideration and experimental consistency, we decided to make 3 sensing holes(the rationale described in the Discussion section) at the same locations, on each sensing rod of all 3 experimental flow tubes. The three sensing holes with a diameter of 0.5mm were made on the mid-point and ±2.5mm upper and lower from the mid-point of the sensing rod, i.e., the center±2.5mm on the flow plane. Through these sensing holes, air velocities were converted into dynamic pressure according to eq.(1), then averaged physically within the sensing rod. The averaged dynamic pressure was transmitted to the pressure transducer connected to the sensing rod. This newly designed sensing rod works as a uni-directional Pitot tube measuring the sum of both the static and dynamic pressure components. To minimize the static pressure component, the sensing rod was located near the outside air, where the static pressure was considered zero(5mm toward the inside from the end of the tube). By this way, the sensing rod was considered to measure the dynamic pressure component(P_D) only in eq.(1).

In Fig. 2, an additional pressure tap was placed 5mm inside from the entrance of the tube to simultaneously measure the static pressure component(P_S), which reflected air flow resistance against the patient's exhalation. P_S increases with a decrease in the tube diameter increasing air flow resistance, thus the diameter becomes a major limit in the tube design. Since P_S is described as air flow rate(F) multiplied by resistance(R),

$$P_S = R \cdot F \tag{2}$$

R generally depends on F, and can be approximated by a linear function of F as follows(Rohrer's equation)[2].

$$P_S = R(F) \cdot F = (R_0 + R_1 F) \cdot F = R_0 F + R_1 F^2 \tag{3}$$

where R₀ and R₁ are constants.

Since it is obvious that R(F) increases with smaller diameter, R₀ and R₁ take larger values. Given air flow rate, P_S increases for smaller

diameter and longer length of the tube. To establish the design criteria, the length was first shortened as much as possible to 35mm, just long enough to put the entrance of the tube in the mouth. This was arbitrarily determined, since no standard way was available, but considered valid from the practical point of view. As a next step, P_s was measured given diameter, and the ATS standards were introduced to determine the smallest tube diameter(details described in the Results section).

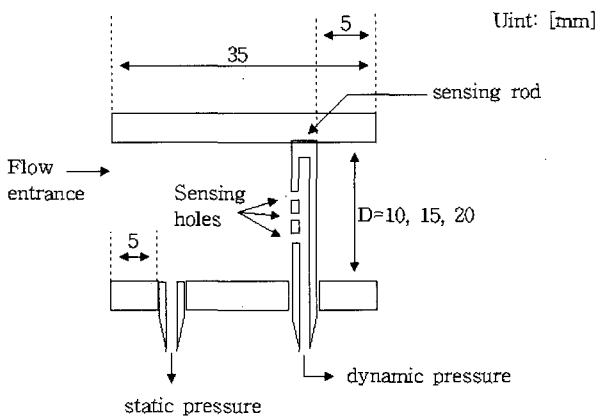


Fig. 2. Uni-directional flow tube design.

Experiments

The experimental respiratory tubes were tested by a set-up shown in Fig. 3.

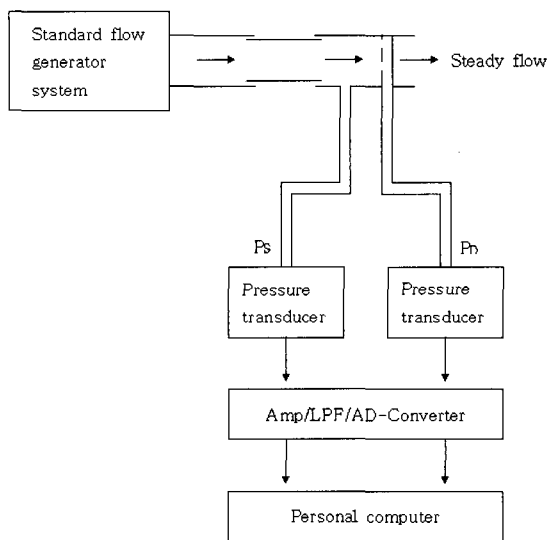


Fig. 3. Block diagram of the experimental set-up.

The flow tube was connected to the standard air flow generator system(SVSyr6.0, CKInternational, Korea), which applied steady flows ranging 1-12l/sec with steps of 1l/sec. Each flow lasted for 5sec, and P_s and P_D were simultaneously measured by differential pressure transducers(MPX2010DP, Motorola, U. S. A.). Both pressure signals were sampled at 100Hz with 12bits, then averaged at each flow level. The experiments were repeated for the three tubes with diameters of 10, 15, and 20mm.

RESULTS

P_s -F Relationship

Fig. 4 demonstrates quadratic relationship having two constants(R_0 and R_1 in eq.(3)) between P_s and F with correlation coefficients higher than 0.99 ($P < 0.0001$). It can be seen that P_s increased to a large degree with smaller diameter as has been expected since P_s reflects air flow resistance to a given flow rate in eq.(3). Therefore, the tube diameter can only be reduced to such a degree that the patient's breathing is not disturbed. Least squares analysis was done to form the fitting equations for each diameter.

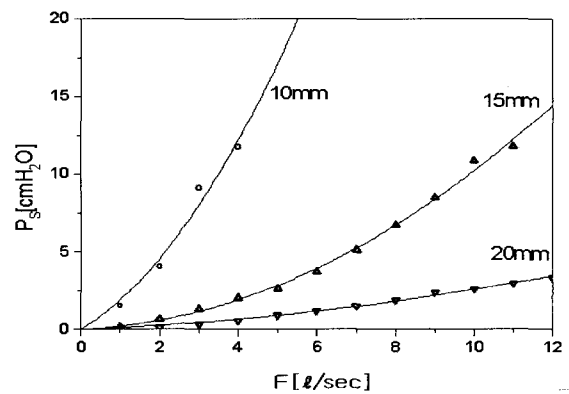


Fig. 4. P_s -F relationship with different tube diameters.

P_D -F Relationship

Eq.(1) can be rewritten as

$$P_D = S_D \cdot u \quad (4)$$

where $S_D = 1/S^2$

By introducing the continuity principle of flow,

$$F = A \cdot u \tag{5}$$

$$A = \pi D^2 / 4 \tag{6}$$

where A=cross-sectional area and
D=tube diameter

The above eqs.(4, 5, 6) give the below P_D -F relationship

$$P_D = \frac{16S_D F^2}{\pi^2} \cdot \frac{1}{D^4} \propto \frac{1}{D^4} \tag{7}$$

Fig. 5 demonstrates a squared relationship of F to P_D as expected by eq.(7) for given D. Regression equations were also obtained for each D with high enough correlation coefficients >0.99 (P<0.0001). When comparing Figs. 4 and 5, P_D increases faster than P_S with F increased for given D, because the regression equation of P_D has a second order coefficient only (eq.(7)) while P_S equation has both the second and the first order coefficients (eq.(3)). Note in Fig. 2 that P_D is the sensing variable measured through the sensing rod to estimate F. Smaller tube generated much larger P_D according to eq.(7) as shown in Fig. 5 through the same sensing rod, demonstrating enhanced sensitivity of F measurement. Therefore, smaller diameter is of great advantage in flow measurement by the present functional single use respiratory air flow tube technique, and no further considerations need to be made for tube miniaturization.

Design Criteria

As aforementioned, P_D does not disturb breathing, and is even advantageous for smaller tube to enhance the flow measurement sensitivity. On the other hand, smaller tube increases P_S according to eq.(3) reflecting the resistance to flow, and D becomes a major determinant of miniaturization. Thus, given length of 35mm, the minimum diameter (D_{min}) of the tube should be determined based on reasonable criteria. The ATS recommends the standards of spirometric measurement [9], in which the upper limit of flow resistances need to be 1.5 and 2.5 cmH₂O/l/sec for the diagnostic and the self-monitoring devices, respectively, corresponding to P_D values of 21 and 35 cmH₂O at the upper limit of F=14l/sec also recommended by ATS. Since P_S -F data for given D are available in Fig. 4, these allowable P_S upper limits were inserted into all three curves to obtain maximum flow rates (F_{max}) measurable by each tube. F_{max} values calculated for both the diagnostic and self-monitoring devices standards are shown in Fig. 6. F_{max} data in Fig. 6 defines flow measurement range for given tube diameter, satisfying the ATS standards. Since the flow measurement range of 14l/sec is recommended by ATS, the diameter giving F_{max} =14l/sec was estimated by interpolation on the data shown in Fig. 6, resulting in the possible minimum diameter of D_{min} =14.7 and 12.8mm for the diagnostic and the self-monitoring devices, respectively. These D_{min} values defines the lower limits of the tube diameter, and we determined approximately 15mm since these two values differ only by 1.9mm.

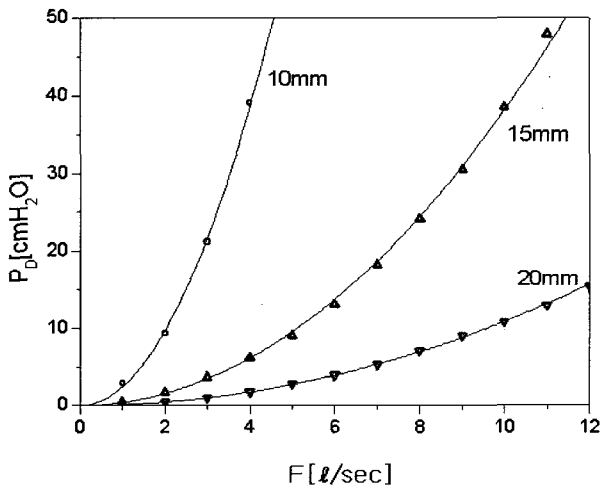


Fig. 5. P_D -F relationship with different tube diameters.

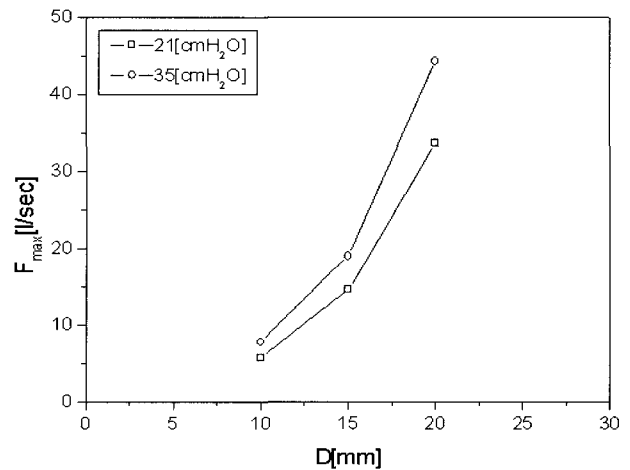


Fig. 6. The maximum flow rate (F_{max}) data plotted against the tube diameter (D).

Therefore, the functional single use respiratory flow tube previously developed by the authors can be miniaturized such that expiratory flow measurement only, the length of 35mm, and the diameter of 15mm, satisfying the ATS standards of both the diagnostic and self-monitoring spirometric devices. The total volume of the tube was estimated to approximately 6.2cm^3 , small enough to be incorporated with portable devices.

Measurement Sensitivity

Fig. 5 describes the measurement characteristics of the tube, resulting in $P_D=472, 75, 21\text{cmH}_2\text{O}$ at $F_{\text{max}}=14\text{l}/\text{sec}$ for $D=10, 15, 20\text{mm}$, respectively. These P_D values represent the maximum pressures ($P_{D\text{max}}$) defining the dynamic pressure measurement range corresponding to the flow range of $14\text{l}/\text{sec}$. Since P_D inversely correlates with D^4 in eq.(7), P_D is expected to be proportional to $1/D^4$ as demonstrated in Fig. 7. For graphic convenience, the unit of D was cm in Fig. 7. The $P_{D\text{max}}$ data estimated for 3 tubes of $D=10, 15, 20\text{mm}$ closely fell on the regression line supporting the validity of eq.(7). Since D_{min} was determined to be 15mm, this value was inserted into the regression line of Fig. 7, giving $P_{D\text{max}}$ of approximately $75\text{cmH}_2\text{O}$, which is at least 7 times large pressure of at most $10\text{cmH}_2\text{O}$ obtainable by the widely used pneumotachometers[10, 11]. Larger $P_{D\text{max}}$ implies enhanced flow measurement sensitivity, thus very much advantageous from the manufacturing point of view in terms of cost as well as technical convenience.

DISCUSSION

The present study was performed to establish design criteria for miniaturization of the respiratory air flow sensor tube. More specifically, the minimum diameter for given length of 35mm was estimated based on the internationally accepted ATS spirometric measurement standards[9]. The functional single use respiratory air flow tube previously developed by the authors[5] was demonstrated to be made as small as 15mm in diameter. The worldwide ATS standards were satisfied, thus the present estimation of D_{min} was considered valid.

To develop the smallest tube, the sensing rod converting air velocity into dynamic pressure was first simplified in structure to operate uni-directionally (expiratory flow measurement only). FVC test is the most important and frequently performed spirometric test. Most diagnostic parameters are evaluated from the expiratory flow rate signal based on the well-known expiratory flow

limitation phenomenon[12]. This physiological phenomenon describes that the airways narrow to limit the expiratory flow while increased expiratory muscular efforts tend to increase the flow during the forced expiratory maneuver. Once maximal expiratory effort has been made, an equilibrium is reached to represent the pure mechanical properties of the respiratory apparatus. Therefore, most clinically valuable parameters are obtained from the forced expiratory air flow signal with little information added from the inspiratory flow signal. Furthermore, self-management of the chronic respiratory diseases requires at most 5 parameters estimated from the forced expiratory flow signal only. Some spirometers even for hospital use are manufactured to acquire only the expiratory flow signal during the FVC maneuver[3]. Thus, the uni-directional flow measurement design of the present study limits neither practical nor clinical applications.

The flow tubes made for experiment had a pressure tap to measure P_S unnecessary in real flow measurement situation. P_S reflects flow resistance disturbing the patient's breathing, thus considered a major determinant of the design criteria. With smaller diameter, increased resistance is resulted. The ATS recommends to keep the air flow resistance lower than 1.5 and $2.5\text{cmH}_2\text{O}/\text{l}/\text{sec}$ for the diagnostic and the self-monitoring spirometric devices, respectively. Introducing the ATS standards, the possible D_{min} was 15mm corresponding to a tube volume of 6.2cm^3 , small enough to adapt for portable devices.

The functional single use respiratory air flow tube is equipped with small and narrow sensing rod placed on the diameter of the flow plane to generate dynamic pressure proportional to squared flow rate[5]. The sensing rod shows virtually no airway resistance regardless of the size of dynamic pressure which is a flow sensing variable. The most widely applied pneumotachography, however, picks up differential static pressure across a flow resistor against the patient's breathing, obviously adding significant flow resistance[10, 11]. This flow resistance works as an additional source of static pressure inside the tube, accordingly cannot be manufactured as small as our functional tube with sensing rod. In other words, the functional single use respiratory air flow tube is a unique technique enabling the smallest design.

The sensing rod had 3 sensing holes through which air velocities were sampled and converted into dynamic pressure. Since only finite number of sensing holes can be made, sampling error must exist. We previously suggested a systematic way to distribute multiple sensing holes minimizing the sampling error[13]. The sensing holes were unequally spaced on the sensing rod considering the non-linear velocity profile, and computer simulation demonstrated the validity of this technique. When N holes are made on the upper half of the sensing rod, the optimal location (r_n) of the n -th hole is

$$r_n = R \sqrt{\frac{2n-1}{2N}}, \quad n=1, 2, \dots, N \quad (8)$$

where R=tube radius

On the lower half of the sensing rod, N holes are also made on the symmetric locations, resulting in the total number of holes, 2N. For the smallest experimental tube of the diameter, 10mm, let us consider 4 holes, then $R=10/2=5\text{mm}$ and $N=4/2=2$. By substituting these values into eq.(8), $r_1=2.5$ and $r_2=4.3\text{mm}$. Since the diameter of the sensing hole is 0.5mm, the circumference of the second hole is apart from the tube wall only by 0.45mm ($=5-4.3-0.5/2$), which is practically difficult to make. Also, since the air velocity on the wall is zero(boundary condition), the second hole very close to the wall may not contribute significantly to the whole flow rate. Thus, we decided to make only 2 holes on the locations of $\pm r_1=\pm 2.5\text{mm}$. Since only two holes are practically possible, another consideration was introduced. It is clear that more sensing holes would make more reliable measurement. But since too many holes cannot be made, we decided to add just one more hole on the center of the flow plane where the velocity was the largest. With these 3 sensing holes, the dynamic pressure data well fitted the theoretical quadratic equation(eq. (4)) as demonstrated in Fig. 5 for all 3 experimental tubes. Therefore, we assured that 3 holes were enough to accomplish the purpose of the present study by making accurate enough flow measurement. Although more than 3 holes could be made in larger tubes of diameters, 15 and 20mm, the same sensing rod was used to keep experimental consistency.

Expiratory air flow rate is converted into dynamic pressure in the sensing rod followed by pressure measurement. As mentioned above, the sensing rod is merely small and narrow rod shaped adding virtually no resistance against breathing independent of the measured dynamic pressure level, i.e., flow resistance does not exist due to the sensor element. Keeping this in mind, note that the dynamic pressure increased to a large degree only with small decrease in tube diameter(eq.(7) and Fig. 5).

Increased dynamic pressure implies enhanced sensitivity, guaranteeing more reliable flow measurement. It is usually the case in most sensor techniques that smaller sensors have lower measurement sensitivity. On the contrary, the present flow tube with the sensing rod shows much better sensitivity with smaller diameter and, as a result, tube miniaturization leads to great technical advantages. Most of all, less sensitive and cheaper pressure transducer can be employed to measure dynamic pressure. The signal extraction circuitry could also be simplified, leading to lowered manufacturing cost. The diameter of 15mm gave a maximum pressure of 75cmH₂O as estimated in Fig. 7, corresponding to at least 7 times of the pressure obtained in usual pneumotachometers. These results demonstrate that the functional single use

respiratory air flow tube provides superiority in both measurement quality and manufacturing convenience to other air flow measurement techniques.

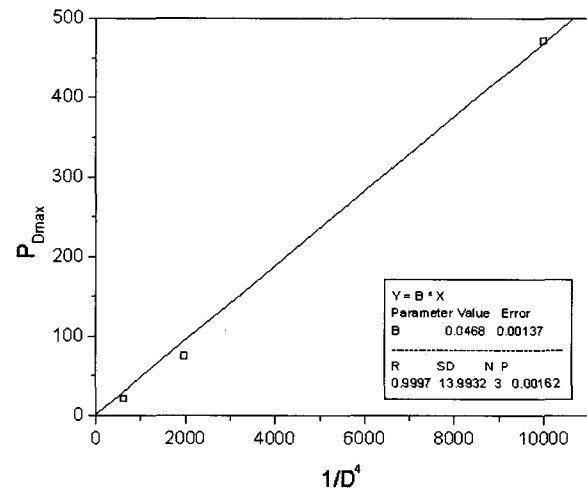


Fig. 7. Relationship between the maximum dynamic pressure(P_{Dmax}) and the tube diameter(D).

CONCLUSION

The present study performed experiments to obtain both static and dynamic pressures over a wide range of steady flow with different flow tube diameters. The resultant pressure-flow relationships demonstrated that the previously developed functional respiratory air flow tube technique provided the smallest design of the tube diameter, 15mm, satisfying the ATS standards. Furthermore, it took a great technical advantage in that smaller tube resulted enhanced sensitivity, allowing to employ less sensitive and of course cheaper and smaller pressure transducer. Recent social needs of portable medical devices for self home care could make the present technique the most appropriate as a small and handy respiratory air flow sensor tube. In particular, portable spirometer may be the best application example in self management of chronic respiratory diseases such as asthma.

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