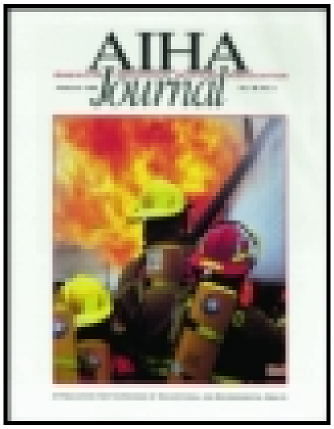

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Noninvasive, Quantitative Respirator Fit Testing through Dynamic Pressure Measurement

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Noninvasive, Quantitative Respirator Fit Testing through Dynamic Pressure Measurement

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A new method has been invented for the noninvasive and quantitative determination of fit for a respirator. The test takes a few seconds and requires less expensive instrumentation than presently used for invasive testing. In this test, the breath is held at a negative pressure for a few seconds, and the leak-induced pressure decay inside the respirator cavity is monitored. A dynamic pressure sensor is attached to a modified cartridge of an air-purifying respirator or built into the respirator body or into the air supply line of an air-supplied respirator. The method is noninvasive in that the modified cartridge can be mounted onto any air-purifying respirator. The pressure decay during testing quantifies the airflow entered through the leak site. An equation has been determined which gives the air leakage as a function of pressure decay slope, respirator volume and the pressure differential during actual wear—all of which are determined by the dynamic pressure sensor. Thus, the ratio of air inhaled through the filters or via the air supply line to the leak rate is a measure of respirator fit, independent of aerosol deposition in the lung and aerosol distribution in the respirator cavity as found for quantitative fit testing with aerosols. The new method is shown to be independent of leak and sensor locations. The concentration and distribution of aerosols entered through the leak site is dependent only on the physical dimensions of the leak site and the air velocity in it, which can be determined independently. Thus, the new method measures the leakage exactly, noninvasively, very quickly and inexpensively. The volume of the respirator cavity is determined by the same technique. This new method does not meet the current Occupational Safety and Health Administration (OSHA) and American National Standards Institute (ANSI) standards.

Introduction

Respirators are worn throughout industry and the armed forces to provide respiratory protection to the wearer. To ensure that respirators fit adequately, quantitative fit testing usually is performed by comparing the aerosol concentration inside to that outside the respirator cavity.[1-5] The considerable expense of buying and operating an aerosol generator, an aerosol exposure chamber or tent, and an aerosol detection and recording instrument has led to the development of qualitative, less expensive techniques.[6-8] In search of a less expensive but quantitative technique, K. Willeke of the University of Cincinnati discovered in 1980 that the aerosol generator and exposure facility become redundant if the aerosol detector counts ultrafine particles,[5] of which ten thousand to several hundred thousand are generally present per cubic centimeter of air space in most air environments.[9] Since most of these ultrafine particles are optically invisible in their natural state, he used a continuous-flow condensation nuclei counter to record them. The Willeke Particle Count Test has been confirmed independently[10,11] and recently has become available commercially (Portacount®, TSI, Inc., St. Paul, Minn.).

Several factors may cause the leakage measured in a quantitative aerosol fit test to be different from the actual leakage which occurs under working conditions. Factors such as measurement method and aerosol-size distribution in the work environment relative to the laboratory test may have considerable influence on the recorded fit factor.[12] The locations of leak sites and sampling probe may affect significantly the recorded fit factor.[13,14] In addition, work activity, work rate, minute volume, heat and body movements, and air current velocity and direction have been suggested as possible sources of variation.[13] The major disadvantage of every presently available aerosol method is the necessity of an invasive sampling probe. Thus, a surrogate mask is used for fit testing, and the actual mask worn is assumed to have the same shape, pliability and workmanship resulting in the same fit. No accommodation is made for change in shape and pliability during aging nor for contamination of the respirator during wear.

In search of a technique that is noninvasive and can be used before and after field use of the actual mask—similar to radioactive monitoring before and after potential radioactive exposure—the fundamental question to be answered first is this: which physical parameter does not significantly vary throughout the respirator cavity while the complex airflows in the mask distribute the aerosols in an uneven manner during the short inhalation and exhalation periods? It was concluded that pressure equalizes much faster than the aerosol concentration, since air accommodates a pressure change faster than it can mix the entire air space for uniform aerosol distribution.

The use of pressure as a qualitative means of assessing the respirator fit is common practice. The wearer covers the air inlets, inhales to create a negative pressure inside the respirator, and holds the breath. The subject determines, by sensation, if the negative pressure is maintained, indicating a good fit. Similar testing is done at a positive pressure when the exhalation valve is covered. Since the 1930s, this method occasionally has been extended to include a U-tube manom-

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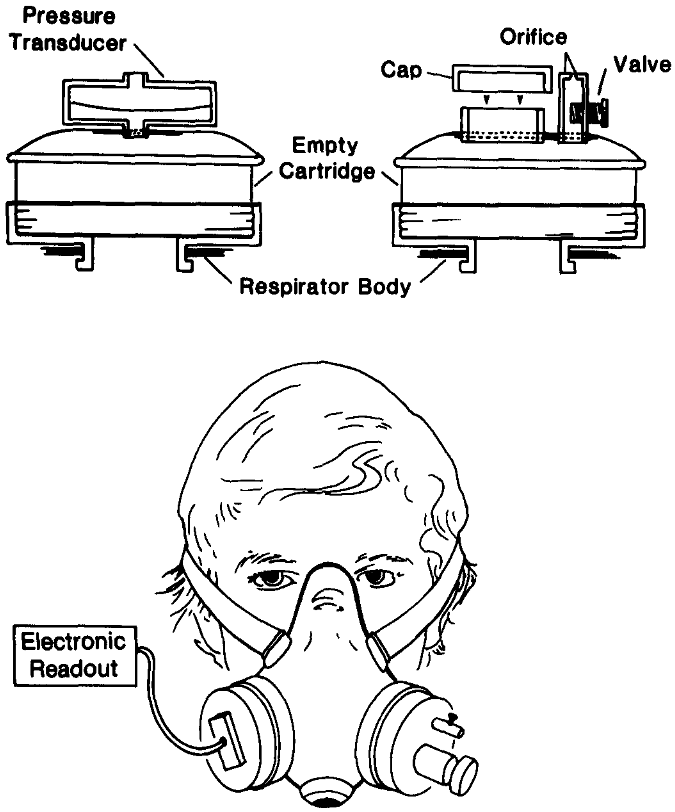

Figure 1—Schematic representation of the dynamic pressure test.

eter connected to the respirator cavity. Since the response time for pressure changes through the tubing and the inertia of the fluid in the manometer do not permit an instantaneous, dynamic recording of the pressure inside the respirator cavity, this method has been used only as a pass-fail test.[15] A new invention by K. Willeke[16] (parts of which are reported and evaluated in this article) utilizes a dynamic pressure sensor which is directly connected to the respirator cavity. Figure 1 illustrates one possible method of use: a pressure transducer is attached to a modified filter cartridge and placed on the respirator. The other cartridge is modified to allow capping so that a negative pressure may be applied to the respirator cavity. Air leakage through an orifice of known size permits the fast determination of the respirator cavity volume. The signal from the pressure transducer is sent to an electronic readout device for instantaneous recording. By using this system, the pressure decay rate caused by respirator leakage is measured, resulting in an exact determination of the respirator leakage as further shown below.

This new dynamic pressure test, as described, does not meet the current Occupational Safety and Health Administration (OSHA) and American National Standards Institute (ANSI) standards because this paper does not take issue with the various test exercises. This paper has been written to show the advantages of the new over the conventional techniques in meeting the standards' objectives of determining the quality of respirator fit. Additional studies are warranted and will include the test exercises.

Experimental Design

The critical element of this test method is the pressure transducer. As shown in Figure 1, it is attached directly to the respirator. Its weight must be light so that its torque produced on the respirator does not affect the seal between the face and the respirator. The pressure transducer must have a fast response time. Finally, it must be able to operate in the low pressure range of 0 to 10 cm w.g. The pressure transducer used for this study weighed 28 g, had a response time of less than 10 msec and had an operating range of 0 to 25 cm w.g. A computer-based data acquisition system was used to collect the data.

Data obtained with this pressure sensing system prove the validity of the new method. In order to evaluate the method, experiments were designed to determine the effect of sensor and leak location, leak hole size and respirator cavity volume on the measured pressure decay. To achieve these goals, 3 respirators of different manufacture were used. Each respirator was sealed to the face of the wearer, and artificial leak holes were introduced at 3 locations on the periphery: at the top near the bridge of the nose, at midheight above the air intake on the right side of the face, and at the chin below the exhaust valve at the bottom of the respirator. The leak holes were of 4 different sizes, simulating a range of typical respirator leakages, as also used in the authors' previous studies.[14] The diameters of the 0.5-cm long leak holes, determined by drill bit size, are 0.046, 0.053, 0.071 and 0.081 cm.

The pressure transducer was attached to a fitting which was mounted to the respirator at the filter inlet. As will be shown later in this paper, the pressure test does not depend on having the same initial negative pressure differential between the interior and exterior of the respirator. In order to be able to conduct the pressure test repeatedly at about the same initial pressure, however, a small flexible diaphragm apparatus was constructed which expands the respirator cavity by a small amount, thus lowering the internal pressure. This apparatus was fitted to the other filter inlet of the respirator. The pressure transducer and the diaphragm could be interchanged from one side to the other of the respirator.

To test the effects of sensor and leak location, the respirator was sealed to the subject's face. First, petroleum jelly was applied to the face. Next, a protective skin barrier cream used on stomas and fistulas was applied to the respirator contact surface. The respirator then was secured to the subject's face and silicon weather sealant was applied to the interface between respirator and face. The seal thus was maintained during all tests as confirmed by pressure decay tests with all artificial holes closed. To determine the effect of respirator volume on the pressure decay, three different brands of respirators were used. To negate equipment effects, the order of testing was randomized.

No special test environment was required for the pressure decay test. All tests, therefore, were performed in an office or in an available laboratory space. After the respirator was sealed to the subject's face, all leak locations were capped, and a baseline test was performed, *i.e.*, the aerosol concentration inside the respirator was confirmed to be negligible during aerosol testing, and the pressure was confirmed to maintain a constant value with time during pressure testing. Next, the leak testing was initiated by inserting one of the four leak holes at one of the three leak locations in the predetermined, randomized order. The other two leak locations were capped. The pressure transducer was attached to a special cartridge assembly on one side of the respirator. After the subject took a deep breath, the diaphragm was attached to the other side of the respirator and was moved outward to decrease the internal pressure, thus initiating a pressure decay record caused by air leakage into the respirator. Next, the pressure transducer and diaphragm were reversed and the test was repeated. All leak hole and leak location combinations were tested. The baseline test was repeated midway and after testing with each respirator.

Method Evaluation

Figure 2 illustrates typical pressure decay curves obtained when testing 1 respirator. These were obtained by exerting a negative pressure of about 10 cm w.g. in the mask by means of the flexible diaphragm and recording the time change of pressure through leak holes of different sizes. For comparison purposes, the initial pressure, P_1, for each trace shown in Figure 2 is 6 cm w.g. at time $t_1 = 0$. As seen, the decay of pressure differential between the interior and exterior of the respirator is exponential with time. This can be seen more clearly in Figure 3 where the pressure is plotted on a logarithmic scale. The logarithmic pressure decay curves have constant slopes, *i.e.*:

$$P = e^{-Kt} \quad (1)$$

or

$$\ln(P_1/P_2) = K(t_2 - t_1) \quad (2)$$

Figures 2 and 3 also show that the time for a given pressure decay decreases with increasing leak hole size in a fixed

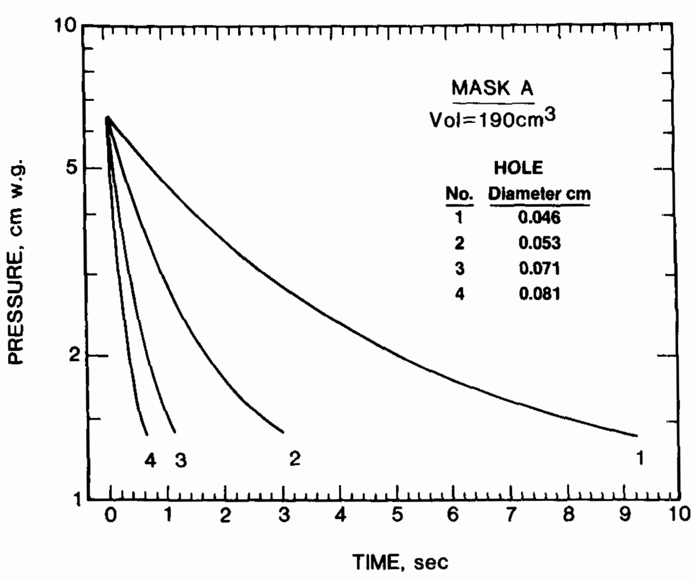

Figure 2—Typical pressure decay curves for a fixed, half-mask respirator cavity volume and different leak hole diameters.

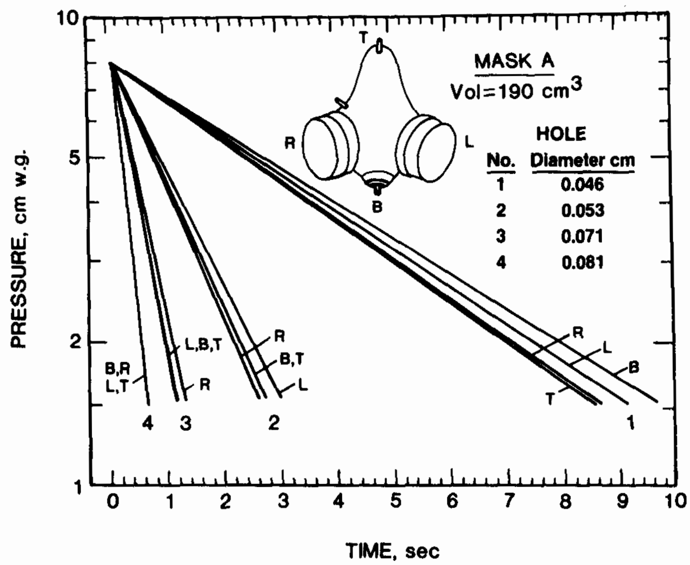

Figure 3—Logarithmic recording of pressure decay curves for different leak hole and sensor locations. T = top, B = bottom, R = right, L = left.

respirator volume. The slope of a pressure decay curve, K, thus is a measure of air leakage into the respirator cavity and has been defined[16] as

$$\text{WLS} = \text{Willeke leak slope} = K \quad (3)$$

Each fit of a respirator, therefore, has a unique WLS:

$$\text{WLS} = \frac{\ln(P_1/P_2)}{t_2 - t_1} \quad (4)$$

Figure 3 also illustrates the effect of leak and sensor location. Leak holes of all four sizes were inserted at the top, the bottom and at midheight above the air intake on the right side of the face. The curves indicated as T and B are the averages for pressure decays caused by leak holes at the top and bottom, respectively, with the pressure sensor located on either side of the face. For curve R, the sensor was located on the right side next to the leak hole. For curve L, the sensor was located on the left side while the leak hole remained on the right side. As seen, all the responses for a given leak hole have similar slopes. The pressure decay slopes for the largest leak hole are indistinguishable from each other. There is no order in the curves by leak or sensor location, indicating that the differences in slopes are within the range of measurement accuracy.

When the data for all leak locations in the respirator are averaged, Figure 4 results. As seen, the standard deviation, σ, decreases with increasing leak hole diameter. Each leak hole size has a unique band of pressure decays. While the data shown here clearly illustrate the new method, future testing on many subjects with several brands of respirators will define more precisely the intersubject variability.

To determine the effect of respirator cavity volume on pressure decay, three different brands of respirators with different cavity volumes were tested. Figure 5 illustrates the relationship between pressure decay and respirator cavity

TABLE I
Statistical Data Analysis

Parameter	p-value[A]
Hole location	0.99
Probe location	0.99
Respirator volume	0.016
Hole size	$<10^{-5}$

[A] By analysis of variance

volume for different leak hole diameters. The larger respirator cavity volume required a longer period of time to achieve the same pressure decay than the smaller respirator cavity volume. This trend is the same for all four leak hole sizes. One would expect such a behavior, since the volume of air entering through a fixed leak hole in a given time has to be related to the volume of space into which it flows. Preliminary tests have shown that there is enough of a pressure decay in full-face pieces to permit the use of this method for such respirators.

The presented graphical analysis is supported by a statistical analysis (see Table I). An analysis of variance was performed on the data. A p-value of 1.0 determined by such an analysis indicates no dependence of measured leak slope on the independent variable. As seen in Table I, hole location and probe location do not affect the measured leak slope. A p-value of less than 0.05 indicates that there is a dependence of the measured quantity on the independent variable. Table I shows that the respirator volume and the hole size do affect the measured leak slope (also shown in Figures 2–5).

Leak Rate Calculation

Determination of the WLS generally is sufficient to assess quantitatively and noninvasively in a few seconds the quality of fit for respirators having similar respirator cavity volumes. If one wishes to determine the leak rate exactly, the following needs to be considered.

Figure 5 shows that the pressure decay curve depends on the size of the leak hole diameter, D, and the volume of the respirator cavity, V. When the leak slopes of that figure are plotted as a function of respirator cavity volume, the WLS is found to decrease with increasing respirator volume for all four leak hole sizes tested, see Figure 6. Since the volume of air leaked through a hole depends on the hole diameter, the authors defined a new nondimensional parameter:

$$\text{LCR} = \text{leak to cavity ratio} = \frac{D^3}{V} \quad \textbf{(5)}$$

The leak slope can be expressed as a unique function of this parameter:

$$\text{WLS} = c_1\left(\frac{D^3}{V}\right)^{\alpha} = c_1(\text{LCR})^{\alpha} \quad \textbf{(6)}$$

Based on the authors' limited data, coefficient c_1 is 5.5×10^9/sec, and exponent α is 5/3, *i.e.,*

$$\text{WLS} = \frac{5.5 \times 10^9}{\text{sec}}(\text{LCR})^{5/3} \quad \textbf{(7)}$$

This equation is represented by the solid line in Figure 7. Future data are likely to refine the constants in this equation. The 4 lines in Figure 6 result from this same equation. The data for Hole 2 lie above the line, indicating a possible error in the measurement of the hole size, which was assumed to be equal to the indicated drill bit size. A 10% increase of the quoted leak hole diameter from 0.053 cm to 0.058 cm results in agreement between data and Equation 7 in Figures 6 and 7.

The diameter of the leak in a respirator or the equivalent diameter of several leaks thus may be determined from the

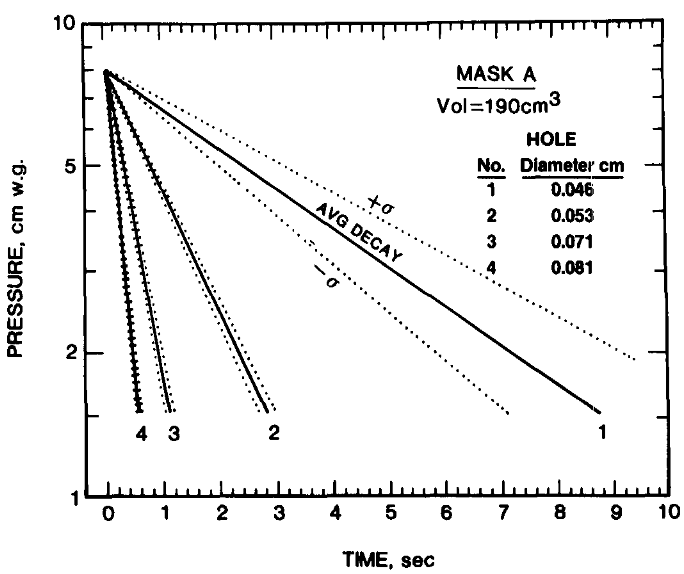

Figure 4—Statistical variation in pressure decay curves for measurements made with all leak hole and sensor locations on one respirator.

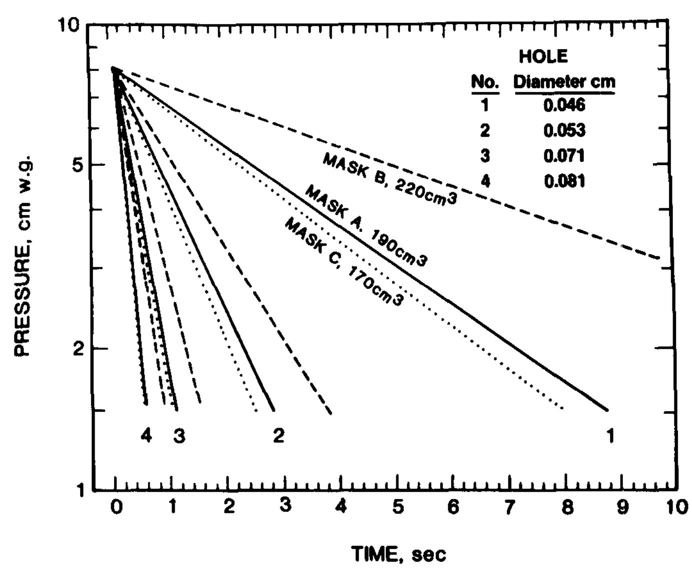

Figure 5—Average pressure decay for three different respirator cavity volumes and four different leak hole diameters. All leak and sensor locations were used in averaging.

respirator volume, V, and the measured leak slope, WLS,

$$D = 1.13 \times 10^{-2} V^{1/3} WLS^{1/5}, \text{cm} \tag{8}$$

where V is measured in cm^3 and WLS in 1/sec.

The leakage into the respirator is not dependent only on the size of the leak hole but, to some degree, on the leak shape as well, irrespective of how the leakage is measured. Future studies are needed to show the extent of this dependence for conventional and new methods.

The respirator cavity volume can be determined by the same pressure decay technique. An orifice of known size, larger than any leak hole size resulting in a permissible respirator fit, is connected to the respirator as shown in Figure 1. The pressure decay in the respirator cavity upon opening of the valve is compared to the pressure decays in airspaces of known volume into which air is leaked through a hole of the same size.[16] The respirator cavity thus is determined in about a second or less by the same pressure sensing system. Details of this technique will be discussed in a future publication.

Since the size of the leak now can be calculated from the pressure measurement, the flow rate through the leak can be determined. Any flow through a hole, however, depends on the pressure differential across the hole. Figure 8 shows the volumetric flow rates measured for the four leak holes used in these experiments. The selected pressure range corresponds to pressures measured inside respirators during wear. The general relationship between volumetric flow rate, Q, and pressure, P, for a given hole may be expressed as

$$Q = F P^{\beta} \tag{9}$$

where coefficient F and exponent β need to be determined.

At low flow rates through a small hole, the flow is laminar, resulting in a linear relationship between pressure and flow

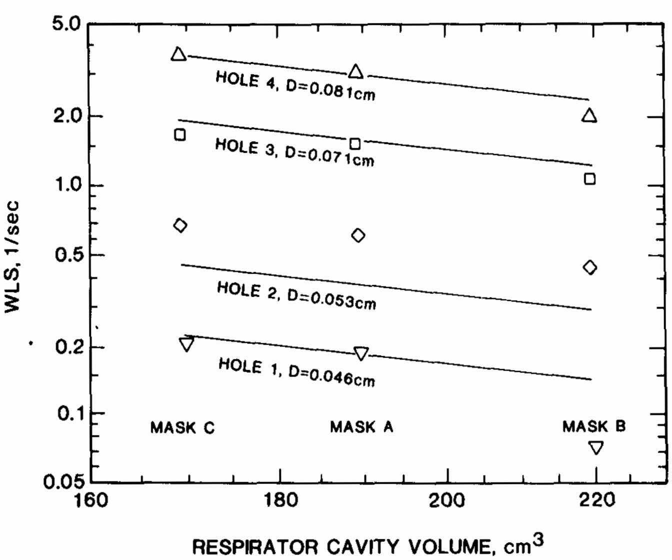

Figure 6—Effect of respirator cavity volume on the measured leak slope for fixed leak hole diameters. The solid lines represent calculations through Equations 6 and 7. WLS = Willeke leak slope.

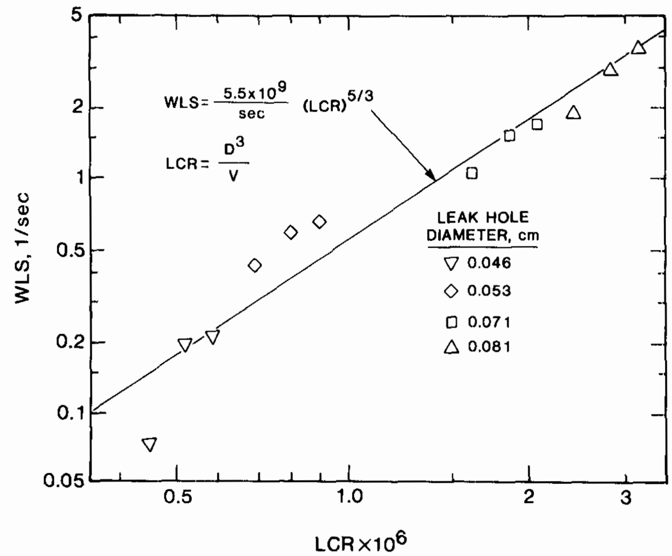

Figure 7—Unified representation of all pressure decay data by one equation. LCR = leak to cavity ratio, a new, nondimensional parameter relating the volume of air passed through a leak of diameter D to the respirator cavity volume, V.

rate, *i.e.*, $\beta = 1$. This can be seen in Figure 8 at low pressures of about $P < 0.1$ cm w.g. For large pressure differences, the air exiting from the hole mixes turbulently with the surrounding air, and the flow rate varies with the square root of pressure, *i.e.*, $\beta = 0.5$ in Equation 9. For pressures larger than about 8 cm w.g. in Figure 8, the flow rate curves approach a slope 0.5. For illustration purposes, the pressure range of 0.1 to 5 cm w.g. will be represented by an average slope of $\beta = 0.75$. Thus, respirator leaks resulting in acceptable respirator fits at respirator cavity pressures typical of normal wear are in the transition regime between laminar and turbulent flow.

Since the flow rate depends on the size of the hole, the diameter of the hole was cubed again and coefficient F was expressed as

$$F = c_2 D^3 \tag{10}$$

where c_2 is a constant. Based on the authors' limited data (shown in Figure 8) the volumetric airflow rate through the leak site, Q_{leak}, is

$$Q_{leak} = 4 \times 10^5 D^3 P^{3/4}, \text{cm}^3/\text{min} \tag{11}$$

where P is in cm w.g. and D in cm.

Since the WLS also is related to leak hole diameter, Equations 8 and 11 can be combined and result in an exact expression for air leakage rate

$$Q_{leak} = 0.057 V P^{3/4} WLS^{3/5}, \text{cm}^3/\text{min} \tag{12}$$

where V is in cm^3, WLS in sec^{-1} and P in cm w.g.

In order to assess the fit of the respirator, the leakage flow has to be related to the flow through the air purifying elements or the flow entering the respirator cavity through the air supply hose in an air-supplied respirator. This clean airflow, Q_{clean}, is shown in Figure 8 for two filter cartridges used in one of the half-mask respirators. As seen, the flow through the two filters is laminar, *i.e.*, $\beta = 1$ in Equation 9. From the authors' limited data the combined clean airflow for the two filters is

$$Q_{clean} = (20\,000 + 27\,000)P = 47\,000P,\ cm^3min \quad (13)$$

where P is in cm w.g.

The ratio of the two airflows has been defined[16] as the Willeke protection number, WPN,

$$WPN = \frac{Q_{clean}}{Q_{leak}} \quad (14)$$

For the filters used in these tests, and assuming a constant slope for the pressure-flow relationship through the leak, Equations 12 and 13 can be substituted in Equation 14:

$$WPN = 8.2 \times 10^4\ V^{-1}\ P^{1/4}\ WLS^{-3/5} \quad (15)$$

where V is in cm^3, WLS in sec^{-1}, and P is the average pressure during inhalation in cm w.g.

The inverse of the WPN is the amount of air leakage through the leak site. If the aerosol concentration outside the respirator is unmodified by passage through the leak site, the aerosol leakage is equal to the air leakage, and WPN equals the conventional fit factor. As shown in previous work by the authors,[12,14] however, the aerosol concentration is reduced in a particle-size dependent manner while the aerosol is drawn through the leak site. The aerosol leakage, thus, may be lower than the air leakage, and the conventional fit factor may be higher than the WPN.

The leak determination by pressure testing is not dependent on leak location, nor on probe location as observed in fit testing with aerosols.[13,14] The new method does not average the leakage flow during inhalation with the expired airflow after aerosol deposition in the respiratory system.[12] The more aerosols are deposited in the lung, the better is the indicated fit when the conventional aerosol method is used. If one wishes to know the amount and size distribution of aerosols that have entered the respirator cavity through the leak,[12,14] the efficiency of penetration through a leak can be determined exactly as a function of flow rate and particle size. Finally, one should realize that the WPN and, therefore, the respirator fit are dependent on the breathing pattern of the wearer. Figure 8 illustrates this clearly. The slope of the flow rate–pressure curves for the leak holes is unity for low pressures and tends towards half that value for higher pressures, while the slope for the air purifying elements used on the half-mask respirators remains constant at unity. Therefore, the ratio of the 2 flows reflecting the respirator fit varies with pressure, *i.e.*, the WPN increases as the work load of the respirator wearer increases, if the leak size remains constant. This also is apparent from Equation 15 which assumes an average constant exponent of 0.75 in the pressure–flow rate relationship. As the wearer works harder, the magnitude of the average pressure inside the respirator cavity increases, also increasing the WPN or fit factor. The percent leakage into the respirator decreases accordingly since relatively more clean air enters through the filters than ambient air enters through the leak holes as the work function increases. The slope of the flow rate versus pressure curve for some high efficiency filters may be somewhat less than unity at higher pressures, but the change in slope is less than for the leak flow.

The standard protocol for conventional fit testing requires a minimum test duration for several face and head movements, all of which are required to simulate working conditions that may break the seal. The test time can be satisfied by repeating the pressure test several times. The head and face movements of the standard protocol can be performed as well, as long as the wearer does not breathe while making the face seal "talk" movements. A break in seal instantly changes the pressure to a new level. The difference between initial and final pressure is an exact measure of the air penetration into the respirator cavity. Since the pressure adjustment upon leakage is instant, the new method is ideal for training workers in respirator wear.

Example

The following example illustrates this new method: a half-mask respirator is worn at an average negative pressure of 1 cm w.g. during inhalation. From the dynamic pressure test, the leak slope is found to be

$$WLS = 1.53/sec$$

For respirators of comparable size, this generally is sufficient to indicate the quality of fit. For an exact determination of the leakage, the following further analysis is made. The leak to cavity ratio (LCR) is calculated from the leak slope through Equation 7

$$LCR = 1.85 \times 10^{-6} = \frac{D^3}{V}$$

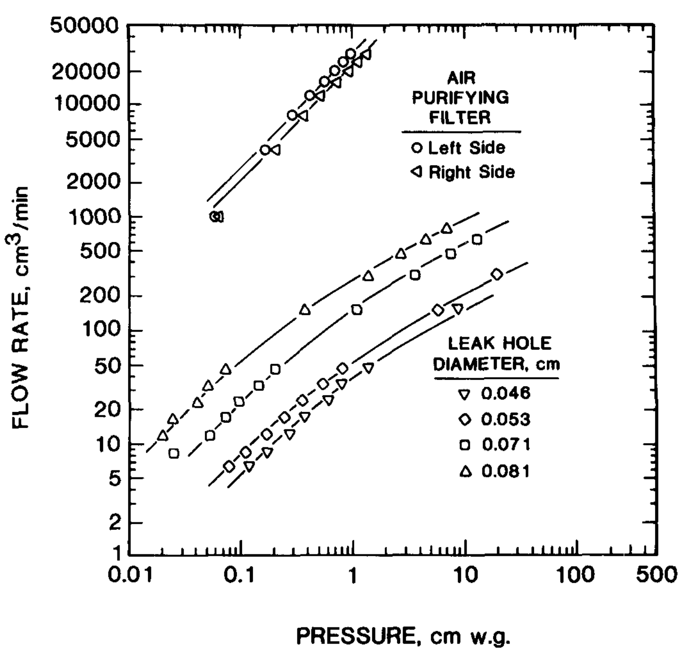

Figure 8—Pressure dependence of volumetric airflow rates through the air purifying filters and different diameter leak holes in a typical half-mask respirator. The indicated pressure range is typical of respirator use.

For a respirator cavity volume of 190 cm^3, determined by the same pressure technique, the leak hole diameter is calculated from the above or from Equation 8 to be 0.071 cm. This confirms the data point for D = 0.071 cm and V = 190 cm^3 in Figures 6 and 7. The volumetric airflow rate through the leak at P = 1 cm w.g., from Equation 11, is

$$Q_{leak} = 143\ cm^3/min$$

The measured leakage at about that pressure is approximately the same, as seen in Figure 8.

The combined clean airflow through the 2 filters is, from Equation 13 or Figure 8,

$$Q_{clean} = 47\,000\ cm^3/min$$

The ratio of the 2 flows determines the WPN

$$WPN = \frac{47\,000}{143} = 329$$

or the inverse of this

$$\text{Air leakage} = 0.3\%$$

Conclusions

This new method of dynamically recording the pressure decay in a sealed respirator while the wearer holds his or her breath has the following advantages.

1. The measured leak slope is a unique and sensitive function of air leakage into the respirator and, therefore, of respirator fit.
2. The method is less expensive than available quantitative fit testing methods. It does not require an aerosol generator nor an exposure booth or tent.
3. The test is fast, requiring only a few seconds to perform.
4. The method is noninvasive and can be used before and after exposure with the actual respirator worn. The wearer may exchange the filter cartridges with the special test cartridges while wearing the respirator itself.
5. The apparatus is lightweight and compact. The sensor can be built into the respirator.
6. The test can be performed anywhere.
7. The method determines the leakage into the respirator exactly, independent of aerosol deposition in the respiratory tract which has considerable intersubject variability.
8. The method is independent of leak and sensor location.
9. The same method can be used to determine the volume of the respirator cavity. This measurement takes about a second or less.
10. The method can be used on any type of respirator in which the airflow can be interrupted for a few seconds.

Additional studies are needed to evaluate further the effect of leak shape and variability between different test subjects and respirators and to investigate the addition of different fit test exercises.

Acknowledgment

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