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Quantitative Fit-Testing of N95 Respirators: Part I—Method Development

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Abstract

This is the first of two articles dealing with quantitative fit-testing of N95 filtering- facepiece respirators (a new class of particulate respirators in the United States). The purpose of this study was to develop a protocol for using the TSI, Inc. PortaCount Plus™ to quantitatively fit test N95 respirators. The development of the protocol consisted of four parts: 1) designing a clamp so that the PortaCount Plus™ could be used to measure the penetration of ambient aerosol through N95 filters; 2) determining the magnitude of the ambient aerosol penetration; 3) comparing different filter penetration methods, i.e., the PortaCount Plus™, a laboratory condensation nuclei counter (lab CNC), and the sodium chloride (NaCl) filter efficiency level test; and 4) determining the effect of testing position on ambient aerosol filter penetration. Ambient aerosol filter penetration was measured with the PortaCount Plus™ and clamps designed in such a way that a small area of the filter was sealed so that the filter penetration of ambient aerosol through this sealed area was measured and used to estimate the penetration through the respirator when a wearer breathes. One-sided t-tests showed that filter penetration measured with the PortaCount Plus™ and a clamp was significantly greater than 0.03% ($\alpha = 0.05$). To investigate the effect of filter penetration testing position, ambient aerosol filter penetration was measured with a clamp at 10 testing positions on five different respirators of the same model. Ambient aerosol filter penetration was found to be affected by the placement of the clamp on the respirator. It was also found that the NaCl test provided filter penetrations that were significantly higher than those measured with the PortaCount Plus™ and lab CNC ($\alpha = 0.05$). To fit test N95 respirators using ambient aerosol, the filter penetration needed to be subtracted from the total inward leakage to obtain face-seal leakage. Finally, a protocol was developed to fit test N95 respirators, use the PortaCount Plus™ and the clamp to measure filter penetration, and adjust the measured fit factor for filter penetration. Part II gives the results of quantitatively fit-testing 21 N95 respirators using this protocol.

Introduction

Recently, new classes of particulate respirator filters have become available in the United States. Since these new filters have higher filtration efficiencies than previous filters, the purpose of this study was to determine if respirators utilizing these new filters could be fit tested using a commercially-available quantitative fit-test. In the United States, fit-testing is used to assess the fit of the respirator during the initial selection process and at intervals of one year (FR, 1998).

In most quantitative fit-tests performed in the United States, an instrument is used to measure the concentration of a challenge aerosol (e.g., oil mist or ambient aerosols, the microscopic particles in air) in the facepiece (C_{in}) and outside the respirator (C_{out}). Then, a fit factor (which is a quantitative measure of the fit of a particular respirator to a particular individual and is defined under the conditions of a quantitative fit-test as the ratio C_{out}/C_{in}) can be calculated (AIHARPC, 1985). In order for a person to wear a particular respirator, a minimum fit factor of 100 must be obtained (ANSI, 1992; NIOSH, 1987; FR, 1998).

The quantitative fit-test instrument used in this study was the TSI PortaCount Plus™ Model 8020 (TSI Inc., St. Paul, MN). This instrument was chosen because it is used to conduct a large number of fit-tests in the United States and it has been demonstrated, in a previous study, that the fit factors (the reciprocal of face-seal leakage) obtained from this instrument during a simulated healthcare workplace test have a high correlation with a wearer's actual exposure (Coffey *et al.*, 1998). The PortaCount Plus™ does not need a chamber and measures ambient aerosols inside and outside the respirator to determine the fit factor. A miniature condensation nuclei counter (CNC) is used to detect the aerosols. The PortaCount Plus™ can determine fit factors in excess of 10,000 (TSI, 1993).

In this study, N95 filtering-facepiece respirators were used because N95 filters are the least efficient of the filters now available. There are nine classes of filters (three classes of filter efficiency, each with three categories of resistance to filter efficiency degradation) in use in the United States. The three classes of filter efficiency are 95%, 99%, and 99.97%. These efficiencies are determined by a filter efficiency level test which uses a high flow rate and neutralized aerosols in the most penetrating size range. The three categories of resistance to filter degradation are labeled N, R, and P, with the N category filters the least resistant to degradation by oil aerosols and P category filters the most resistant (NIOSH, 1996). Therefore, a filter marked N95 is a N-category filter that is at least 95% efficient.

In order to investigate the suitability of using the PortaCount Plus™ as a quantitative fit- test method for N95 respirators, several areas were researched. The first was to design a clamp so that the PortaCount Plus™ could be used to measure the penetration of ambient aerosol through N95 filters. Because a fit-test measures only face-seal leakage, it was necessary to determine if filter penetration was a significant component of the penetration measured during a fit-test of a N95 respirator. If the filter penetration was found to be significant, face-seal leakage could be calculated by subtracting the filter penetration from the measured penetration (face-seal leakage plus filter penetration). The second area was to compare three different methods of determining filter penetration: the PortaCount Plus™ with the clamp, a laboratory condensation nuclei counter (lab CNC) using ambient aerosols, and the sodium chloride filter efficiency level test for N-category filters (NaCl test). This comparison was made to experimentally investigate if the NaCl filter efficiency level test results can be used as the filter penetration during a fit-test. The third area was to determine the effect of testing position on ambient aerosol filter penetration since it has been reported that N95 filters have spatial variability, i.e., the penetration is not constant through every part of the filter (Huang *et al.*, 1998). Then, a protocol for using the PortaCount Plus™ for quantitative fit-testing of N95 respirators and adjusting the resulting fit factors for filter penetration was developed. [Part II presents the quantitative fit-test results of 21 N95 respirators using the developed protocol.]

Methods and Materials

Respirators

Seventeen models of N95 filtering-facepiece respirators from 11 different manufacturers (Table 1) were used in this study. Various manufacturer-model combinations of these 11 manufacturers and 17 models of respirators were used in different portions of the study. The 17 models were selected randomly from those available in the United States at the start of the study.

Clamp Design

It was advantageous to measure the penetration of ambient aerosol through the N95 filtering-facepiece respirators during conditions most closely

Table 1. List of respirators tested.

Manufacturer	Model	Respirator style
3M Company (St. Paul, MN)	1860	Cup
3M Company	8210	Cup
AlphaProTech (Salt Lake City, UT)	MAS 695	Folding
Better Breathing, Inc. (Lawrence, MA)	RX-2	Cup
Gerson Safety and Health (Middleboro, MA)	1730	Cup
Gerson Safety and Health	2735	Cup
Moldex/Metric, Inc. (Culver City, CA)	2001/2002	Cup
Moldex/Metric, Inc.	2300N95	Cup
Mine Safety Appliances Company (MSA) (Pittsburgh, PA)	Affinity N95	Cup
MSA	Affinity Pro	Cup
San Huei United Company, Ltd. (Taipei, Taiwan, Republic of China)	SH3810	Cup
Survivair, Inc. (Santa Ana, CA)	1930	Folding
Tecnol, Inc. (Fort Worth, TX)	PFR95	Folding
Tecnol, Inc.	46737	Folding
Uvex Safety, Inc. (Smithfield, RI)	Pro-Tech-N95	Cup
Willson Safety (Reading, PA)	9501	Cup
Willson Safety	9510	Cup

resembling those encountered while a person is performing a fit-test. According to Silverman's data, a person at rest has 10.3 L/min average minute volume and a peak inspiratory flow rate of 40 L/min at standard temperature and pressure (STP; Silverman *et al.*, 1952). Since the exercises performed during a fit-test (i.e., normal breathing, deep breathing, moving the head side to side, moving the head up and down, and reading out loud) are not strenuous, it was assumed that the average minute volume and peak inspiratory flow rate for a person conducting a fit-test would be similar to an individual at rest. Therefore, it was decided to use the Silverman values to approximate the fit-test flow rates through a respirator.

In order to obtain the equivalent of the Silverman flow rates with the low flow rate of the PortaCount Plus^{TM} (0.7 L/min at STP), the ambient aerosol filter penetration had to be determined only through a small part of the filtering-facepiece (TSI, 1993). In consultation with TSI, a prototype (NIOSH) clamp (Fig. 1 and 2) was designed to seal a small area of the filtering-facepiece so that the air drawn with the PortaCount Plus^{TM} flowed only through this area. The size of the sealed area was determined in such a way that the flow rate per unit area of the sealed area approximates the average flow rate through the entire respirator while being worn during a fit-test. The filter penetration of ambient aerosol through the sealed area was then used to approximate the penetration through the entire respirator. The area which needed to be sealed was determined in the following manner. During inspiration, the flow is not steady but approximately sinusoidal (Silverman *et al.*, 1952). Since the filter penetration is a function of the flow rate, a volume weighted average of the flow is appropriate for selecting a single flow. It can be shown that the volume weighted average flow is $(p/4) \times$ peak flow rate. Therefore, a representative flow through the filtering-facepiece respirator during a fit-test is 31.4 L/min (40 L/min $\times$ p/4).

The filter area of several of the N95 filtering-facepiece respirators was measured and estimated to be 194 cm^2. Therefore, the filter area over which the filter penetration was measured with the

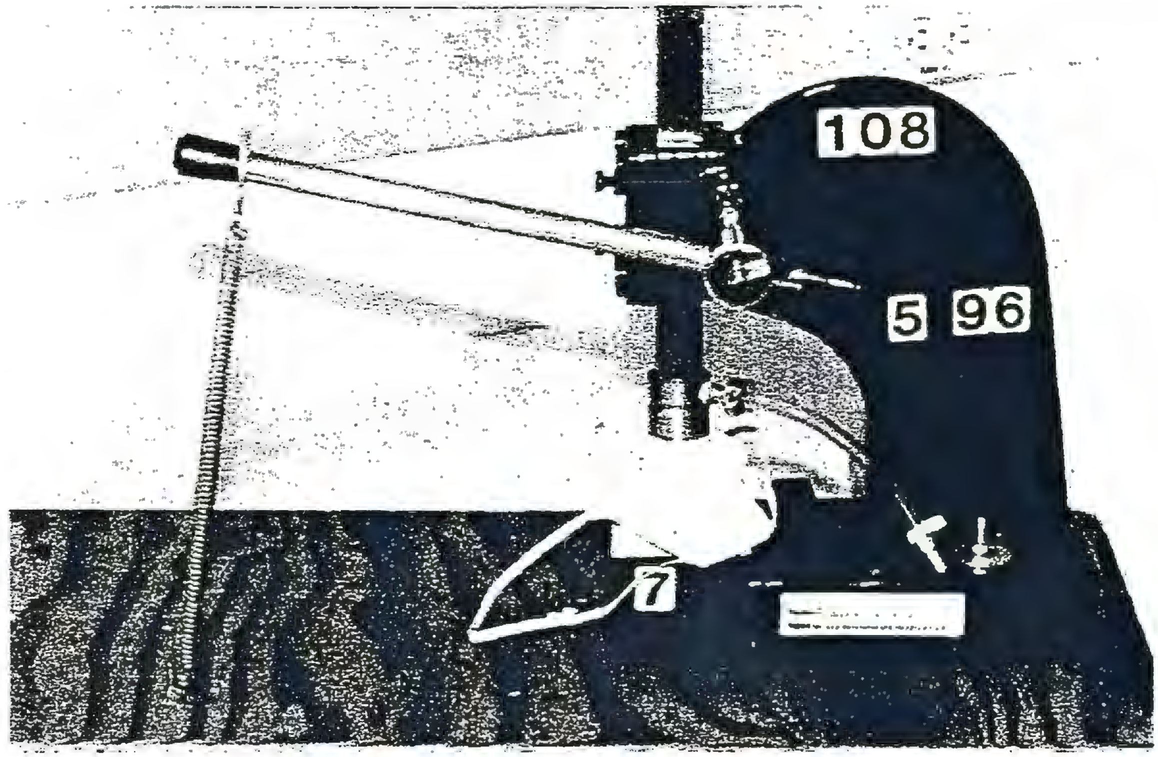

Figure 1. Side view of the NIOSH filter penetration test clamp with an N95 respirator.

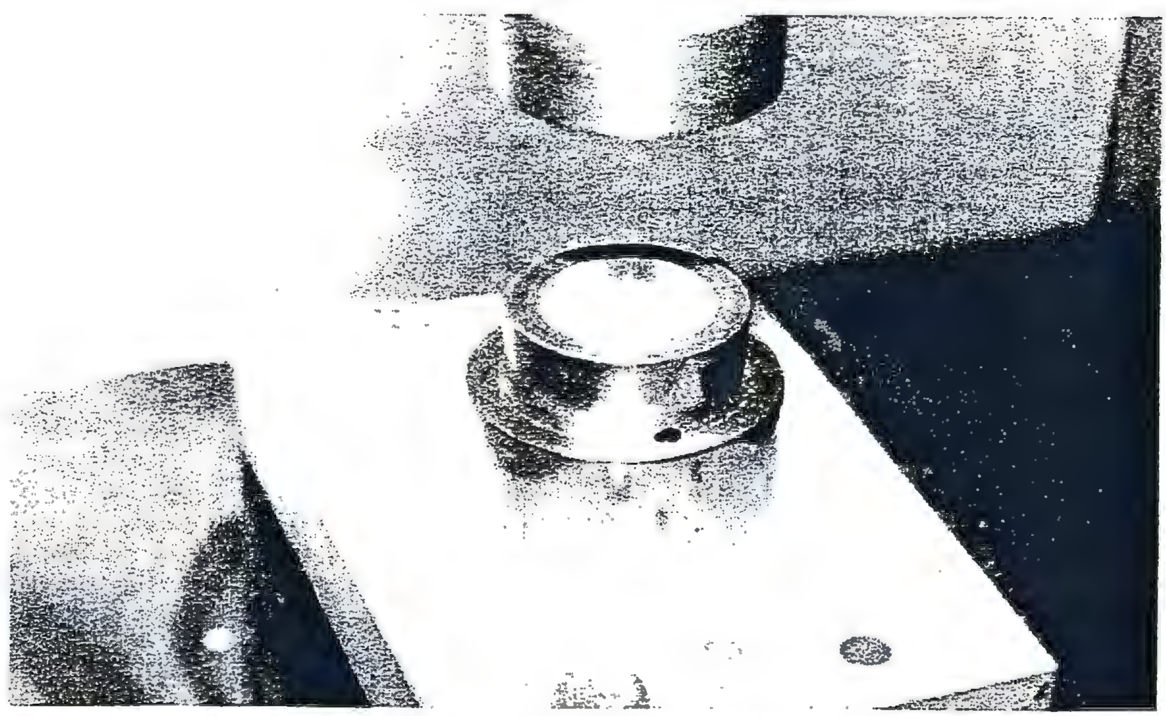

Figure 2. Close-up view of the sealing area of the NIOSH filter penetration test clamp.

PortaCount Plus™ was set at 4.32 cm^2 (0.7 L/min/ 31.4 L/min × 194 cm^2). With a circular area, the sealing area of the clamp had a diameter of 2.34 cm.

Due to the size and weight of the NIOSH clamp, TSI, Inc. developed small, lighter clamps (T-100, T-150, and T-200) to be used with the PortaCount Plus for testing penetration of ambient aerosol through N95 respirators (Fig. 3). Two additional prototype clamps were made by TSI, Inc. The T-150 and T-200 clamps were identical in design to the T-100 except for the filter area which would be sealed. The T-150 clamp had a sealing area 50% larger than the T-100 clamps, whereas the T-200 clamp had a sealing 100% larger. The filter penetration test area of the T-100 clamp is the same as the NIOSH clamp. However, the two clamps use different mechanisms to ensure that the filter media is held tightly in the sealing area. The tension exerted by the NIOSH clamp is adjustable allowing different thicknesses of filter media while the tension exerted by the T-100 clamp is not adjustable. In addition, the sealing flanges of the clamps differ. The T-100 is wider; the NIOSH clamp has a small ridge on the flange to help seal the filter.

For ambient aerosol filter penetration (the reciprocal of the value displayed by the PortaCount Plus™ during filter testing), the respirator was placed either in the NIOSH clamp and the handle secured with the spring (Fig. 1) or in a TSI clamp (Fig. 3). The PortaCount Plus™ was then connected to the clamp through the tubing (approximately 1.5 m) supplied by TSI to do fit-testing. The PortaCount Plus™ was run in the count mode for two minutes to clear any particles present inside the respirator due to mounting. The PortaCount Plus™ was then placed in the fit- test mode and filter penetration testing commenced. After the PortaCount Plus™ determined the "fit factor" for the first time period, the fit-test was stopped. The filter penetration was then calculated from the "fit factor" displayed on the PortaCount Plus™. Twenty-five respirators randomly selected from the same lot, to eliminate lot-to-lot variability from 11 different models of respirators, were tested. Ambient aerosol filter penetration was measured in approximately the same location on the respirator and the performance of all four clamps was compared.

Comparison of Filter Penetration Testing Methods

Three different filter penetration test methods were compared using the five respirators from seven different models. The ambient conditions during this phase of testing were a temperature of 23 ± 2.5°C and a relative humidity of 50 ± 5 percent. The first method used the TSI PortaCount Plus™ to determine the ambient aerosol penetration. The respirator/filter was placed in the NIOSH clamp and filter penetration calculated in the same manner as previously described. The "fit factor" displayed on the PortaCount Plus™ was recorded as filter penetration, which was calculated by dividing the ambient particle concentration (upstream of the filter) by the particle concentration downstream of the filter and taking the reciprocal.

Since the PortaCount Plus™ uses a miniature CNC which may not be suitable for measuring ambient aerosol filter penetration, it was necessary to compare it to a lab CNC method which used a TSI Model 3020™ condensation nuclei counter (TSI Inc., St. Paul, MN) to determine the ambient aerosol filter penetration. The respirator/filter was placed in the T-100 clamp and secured (Fig. 3). The T-100 clamp was utilized because of its smaller size and weight which made it more suitable for use with Model 3020™. The flow rate through Model 3020™ was 0.3 L/min at STP. First, the number of particles present in the same room environment as the PortaCount Plus™ testing was determined by taking three measurements, each lasting 10 seconds. Then, the respirator in the T-100 clamp was connected to the Model 3020™ through a 5-cm long piece of tubing. The filter penetration was measured by taking three 10-second measurements of the number of particles in the downstream side of the filter. The recorded filter penetration of each respirator equaled the average of the three ambient measurements downstream of the filter divided by the average of the three measurements upstream of the filter. A laser aerosol spectrometer (LAS-X, Particle Measuring Systems, Inc., Boulder, CO) was used to determine the ambient aerosol particle size distribution during the PortaCount Plus™ and Model 3020™ tests.

The third filter penetration test method was the NaCl test. In this test, a TSI Model 8110™ filter tester with a light scattering photometer (TSI Inc., St. Paul, MN) was used to generate a sodium chloride (NaCl) aerosol and measure penetration. The respirators, sealed to a flat plate, were tested at a flow rate of 85 ± 4 L/min at STP (CFR 42, 1996). The NaCl aerosol was neutralized to the Boltzman equilibrium state at a temperature of 25 ± 5°C and relative humidity of 30 ± 10 percent. The NaCl aerosol had a count median diameter of 0.07 μm and

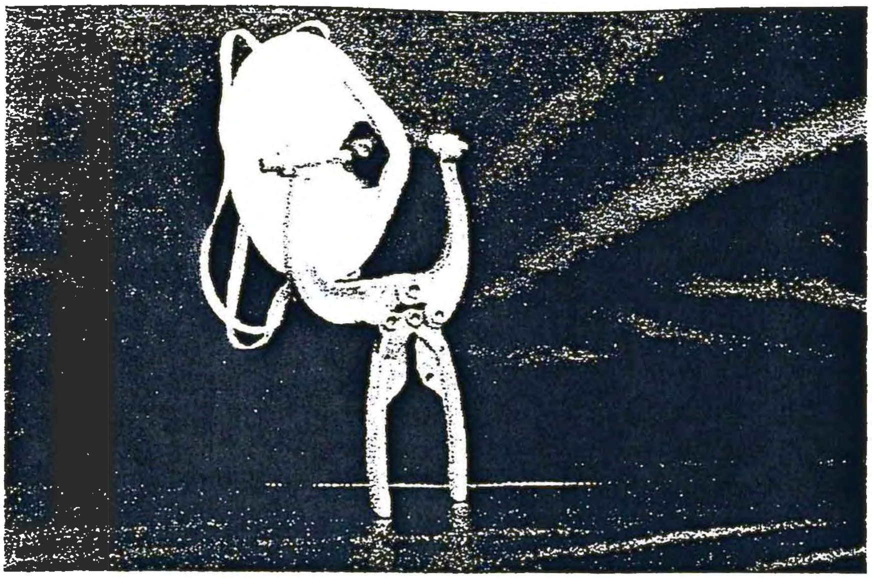

Figure 3. View of respirator in the T-100 clamp for filter penetration testing.

a geometric standard deviation of 1.66. The particle size distribution was determined with a TSI Model 3932™ Differential Mobility Particle Sizer (TSI Inc., St. Paul, MN). The concentration of the NaCl aerosol was approximately 15 mg/m^3. The test lasted two minutes with a penetration measurement taken each minute.

Effect of Testing Position on Ambient Aerosol Penetration

It has been demonstrated that N95 filter media can have spatial variations in aerosol penetration in excess of 100% as compared to the average aerosol penetration for the entire respirator, especially with particles approximately 0.1 µm in diameter (Huang *et al.*, 1998). This spatial variability was investigated in relation to the ambient aerosol filter penetration tests performed during this study. This consisted of performing ambient aerosol filter penetration testing at 10 positions on five respirators of the same randomly selected N95 respirator model (Fig. 4). The filter penetrations were measured with the PortaCount Plus™ with the NIOSH clamp.

Statistical Analysis

The first hypothesis formulated in this study was that ambient aerosol filter penetration was not different among the four clamps using a multiple regression with two independent variables. The response variable was filter penetration and the independent variables were clamp and respirator model. Eleven models of N95 respirators were randomly selected and tested. The filter penetrations for these 11 respirator models measured with the PortaCount Plus™ and four clamps (NIOSH, T-100, T-150, and T-200) were analyzed using a mixed effect, analysis of variance (ANOVA) model (four clamps/11 model combinations each with 25 replications) to determine the effect of clamp designs on filter penetration. The Ryan-Einot-Gabriel-Welsh multiple range test was also used to detect differences between mean filter penetrations for the different clamps. A significance level of 5% was used in all tests.

The second hypothesis was that the filter penetration of ambient aerosol using the PortaCount Plus™ and the NIOSH clamp was less than or equal to 0.03% which is the maximum allowable filter penetration of a 100-series filter. A one-sided t-test was used for testing this hypothesis. Filter penetration of 0.03% or less would not contribute significantly to the aerosol detected inside the facepiece by the PortaCount Plus™ and the fit factors would not have to be adjusted or corrected for filter penetration. For example, the fit factor obtained with the PortaCount Plus™ corresponding to 1% face-seal leakage with no filter penetration is 100. If 1%

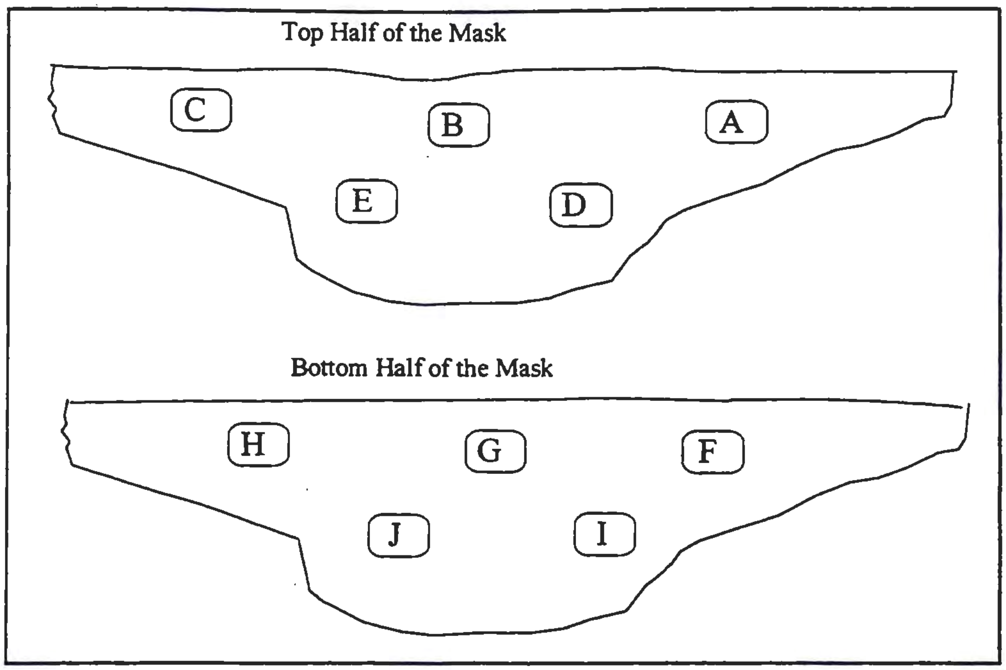

Figure 4. Illustration of the 10 filter-penetration-testing positions of a respirator.

leakage is measured and the filter penetration is 0.03%, the face-seal leakage is 0.97%. Face-seal leakage of 0.97% results in a fit factor of 103. These numbers can be considered equivalent.

The third hypothesis was that filter penetration through N95 filtering-facepiece respirators were the same for all three of the filter penetration test methods (PortaCount Plus™, lab CNC, and NaCl). The response variable was filter penetration which may be dependent on testing method and respirator model. The filter penetrations for five N95 respirators from seven models measured with all three methods were analyzed using a mixed-effect, ANOVA model (three testing methods/7 models each with 5 replications) to determine the effect of testing methods on filter penetration. Five respirators from each model were randomly selected from the same lot to eliminate lot-to-lot variability. Every respirator was tested with the three methods on the same day. The Ryan-Einot-Gabriel-Welsh multiple range test was used to detect differences between mean penetrations for each testing method.

The fourth hypothesis was the ambient aerosol filter penetration was not affected by testing position. The filter penetrations measured with the PortaCount Plus™ and NIOSH clamp were analyzed using a random effect ANOVA model which nested testing positions within respirators (10 testing positions/5 N95 respirators of the same model/3 replications) to determine if testing position significantly affects filter penetration. The Ryan-Einot-Gabriel-Welsh multiple range test was used to detect differences between mean filter penetration values for each testing position. The response variable was filter penetration and the independent variables were testing position and respirator. The analysis was performed using the General Linear Models Procedure in the Statistical Analysis System (SAS, 1996) computer software.

Results and Discussion

Clamp Evaluation

Table 2 summarizes the ambient aerosol filter penetration for the 11 models of filtering-facepiece respirators measured using the four different clamps (i.e., NIOSH, T-100, T-150, and T-200) and the PortaCount Plus™ by respirator model and clamp. The respirators in Table 2 are listed by increasing NIOSH clamp penetration. The ANOVA results showed significant differences in filter penetration among the different respirators as well as the four clamps. Thus, the first hypothesis was rejected,

Table 2. Summary of ambient aerosol filter penetrations by respirator model and clamp.

Respirator model	N	NIOSH		T-100		T-150		T-200	
		GM (%)	GSD	GM (%)	GSD	GM (%)	GSD	GM (%)	GSD
1	25	0.04^{A}	3.1	0.06^{A}	3.7	0.02^{B}	3.9	0.01^{C}	3.6
2	25	0.10^{B}	2.3	0.73^{A}	3.6	0.04^{C}	2.8	0.01^{D}	3.0
3	25	$0.12^{A,B}$	2.8	0.13^{A}	2.6	0.06^{B}	3.0	0.02^{C}	3.8
4	25	0.16^{A}	1.6	0.20^{A}	1.7	0.08^{B}	1.8	0.04^{C}	2.0
5	25	0.17^{B}	1.9	0.82^{A}	2.4	0.08^{C}	2.0	0.03^{D}	2.1
6	25	0.21^{A}	1.7	0.26^{A}	2.6	0.10^{B}	2.2	0.05^{C}	3.0
7	25	0.26^{B}	1.4	0.71^{A}	2.1	0.11^{C}	1.5	0.05^{D}	2.2
8	25	0.27^{A}	1.9	0.33^{A}	2.1	0.13^{B}	2.0	0.05^{C}	3.6
9	25	0.40^{A}	1.8	0.49^{A}	2.0	0.18^{B}	3.0	0.10^{C}	3.8
10	25	0.79^{B}	1.5	1.07^{A}	1.6	0.33^{C}	1.7	0.19^{D}	4.0
11	25	$1.08^{A,B}$	2.6	1.75^{A}	2.0	0.61^{B}	2.4	0.26^{C}	2.9
All	275	0.22^{B}	3.1	0.41^{A}	3.6	0.10^{C}	3.6	0.04^{D}	4.1

Notes:

1) GM = geometric mean; GSD = geometric standard deviation; statistical comparisons were made for each respirator model and all models, and means with the same superscript letter (A through D) are not significantly different among different clamps (p>0.05).
2) Both the NIOSH and T-100 clamps have the same sealed area. The sealed areas for T- 150 and T-200 are increased by 50% and 100% of the area for T-100, respectively.

i.e., filter penetration was different among the four clamps. Since the interaction between respirator and clamp was also statistically significant, ANOVA was also run by model. The Ryan-Einot-Gabriel-Welsh grouping of clamps for each model of N95 respirators is illustrated with superscript letters in Table 2. Means with the same superscript letter are not significantly different among different clamps (p>0.05). Plots of residuals versus the fitted values did not reveal any obvious model inadequacies.

Since the areas for the T-150 and T-200 clamps are larger than the NIOSH and T-100 clamps, the flow rates through the sealed filter area are decreased with these two clamps. Thus, filter penetrations for these two clamps are expected to decrease proportionally with the increase in the size of the sealed filter area. The data in Table 2 are consistent with this expectation. In seven of the 11 models of respirators (model 1, 3, 4, 6, 8, 9, 10, and 11), the mean filter penetrations were not significantly different for the NIOSH and T-100 clamps. For the T-150 and T-200 clamps the mean filter penetrations were significantly different from each other and both were significantly lower than the NIOSH and T-100 clamps. For the other four respirator models, significant differences were found between all four clamps. One possible explanation for the NIOSH and T-100 clamps being different on the three respirators is that the design of one of the clamps did not allow it to close properly on certain respirators which could affect the filter penetration values. This could have resulted in air being drawn around the clamp as well as through the sealed area. Both the mean filter penetrations for the NIOSH and T-100 clamps were always higher than both the T-150 and T-200 clamps except in two instances (Respirators 3 and 11). This could have been the result of these two respirators having high geometric standard deviations.

Magnitude of Ambient Aerosol Penetration

The one-sided t-test used to analyze the filter penetrations as measured with the NIOSH clamp showed they were significantly greater than 0.03% for every respirator model. Therefore, the second hypothesis, i.e., the filter penetration of ambient aerosol is not significant, was rejected. Therefore, if the PortaCount Plus™ is to be used to quantitatively fit-test N95 respirators, ambient aerosol filter penetration must be taken into account. Otherwise, respirators providing adequate fits would be erroneously rejected as not fitting properly. For example, if the PortaCount Plus™ measured 2% leakage (composed of 1.5% filter penetration and 0.5% face- seal leakage), it would display a fit factor of 50 and the respirator would be rejected. However, the respirator should not be rejected because when only face-seal leakage is considered, the fit factor becomes 200.

Comparison of Filter Penetration Test Methods

The filter penetration data are summarized for the seven models of filtering-facepiece respirators by filter penetration test method in Table 3. The geometric mean of the filter penetration for all of the respirators combined measured wa1.2% with the NaCl test, 0.05% with the lab CNC and 0.11% with the PortaCount Plus™. An ANOVA was conducted using these values and the results show that they are significantly different from one another at a significance level of 0.5%. Thus, the third hypothesis, i.e., filter penetration was the same for all three methods, was rejected. Filter penetration test method does have an effect on filter penetration.

The ANOVA results also show the significance of method-model interaction, therefore, the experimental data for all three methods were analyzed by each model. The Ryan-Einot-Gabriel-Welsh grouping of models of N95 respirators for each test method is illustrated with superscript letters in Table 3. The NaCl test was consistently found to be significantly different from the other two methods except for respirator E. For respirator E, no significant difference was found in penetration between the PortaCount Plus™ method and the NaCl test or the PortaCount Plus™ method and lab CNC method. For respirator models C, D, and G, a significant difference was found between the PortaCount Plus™ and the lab CNC methods.

Both the PortaCount Plus™ and NaCl tests were found to be sufficiently sensitive to discern the difference among filters. Significant differences in penetration among different models of N95 respirators were observed with each method. However, the magnitude of difference in penetration between respirator models with the NaCl test (as large as 3.00%) appeared to be larger than that with the PortaCount Plus™ (only up to 0.90%).

Possible reasons for the different filter penetrations determined for a filter by these three methods may be due to differences in aerosols, particle sizes, test flow rates, particle shape, temperature, humidity, and other factors like aerosol charge (Moyer, 1986; Brosseau *et al.*, 1989; Stevens and Moyer, 1989; Moyer and Stevens, 1989a; and Moyer and Stevens, 1989b). For example, both the lab CNC and the PortaCount Plus™ methods used ambient aerosol as the challenge agent, while the NaCl used a more mono-dispersed aerosol as the challenge agent. The laboratory aerosol aerodynamic particle size, measured by the LAS-X™ spectrometer, ranged from 0.09 µm to 0.65 µm and followed a normal distribution with a geometric count median diameter of 0.16 µm and a geometric standard deviation of 2.66 (Fig. 5). This is in contrast to the NaCl test particle size distribution with a count median diameter of 0.07 m and a geometric standard deviation of 1.66.

Therefore, the count median diameter of both the NaCl test and the ambient aerosol were in the size range of the most penetrating aerosol (Stevens and Moyer, 1989). However, the majority of particles in the ambient aerosol were outside of the most penetrating particle size range while most of the NaCl test particles were inside of it. This was probably a major cause of the different filtration penetrations for a respirator measured by these methods. Another major cause was the NaCl test uses a neutralized aerosol, whereas the ambient aerosol had not been neutralized. The NaCl test also uses a higher flow rate (85 L/min compared to 31.4 L/min). Therefore, the results in this study are in accordance with previous findings and the single fiber theory that high flow rate and small particle size both increase the particle penetration rate (Moyer, 1986; Brosseau *et al.*, 1989; Stevens and Moyer, 1989; Moyer and Stevens, 1989a; and Moyer and Stevens, 1989b). In addition, penetration through the entire facepiece was measured for the NaCl test as compared to penetration through a small sealed area with the PortaCount Plus™ and lab CNC methods. Using the entire filtering-facepiece eliminates any effects due to variations in the composition of the filter media.

Effect of Testing Position on Ambient Aerosol Penetration

Ambient aerosol filter penetrations were measured with the NIOSH clamp at 10 testing positions on 5 different respirators of the same model (Table 4). The ANOVA results showed that significant differences were found among the 10 testing positions (Table 5). Thus, filter penetration for N95 respirators was affected by testing position.

These differences among positions are probably due to the non-uniformity of respirator filter material

Table 3. Percent filter penetration for seven models of N95 respirators by filter penetration test method.

Respirator models	N	PortaCount		Lab CNC		NaCl	
		GM (%)	GSD	GM (%)	GSD	GM (%)	GSD
A	5	0.11^{B}	2.0	0.05^{B}	2.9	0.79^{A}	1.6
B	5	0.02^{B}	1.2	0.02^{B}	1.8	0.82^{A}	1.2
C	5	0.16^{B}	1.1	0.03^{C}	1.2	2.26^{A}	1.3
D	5	0.57^{B}	1.3	0.08^{C}	1.4	3.45^{A}	1.3
E	5	0.92$^{A, B}$	1.2	0.70^{B}	1.3	1.07^{A}	1.3
F	5	0.03^{B}	1.2	0.02^{B}	1.5	1.47^{A}	1.3
G	5	0.04^{B}	1.2	0.02^{C}	1.2	0.45^{A}	1.2
All	35	0.11^{B}	4.1	0.05^{C}	3.7	1.2^{A}	2.0

Notes:

1) GM = geometric mean; GSD = geometric standard deviation.
2) Ambient aerosol count median diameter ≈ 0.15 μm; GSD = 2.28.
3) Sodium chloride (NaCl) count median diameter ≈ 0.07 μm; GSD = 1.66.
4) Statistical comparisons were made for each respirator model and all models, and means with the same superscript letter (A through C) are not significantly different among different testing methods ($p>0.05$).

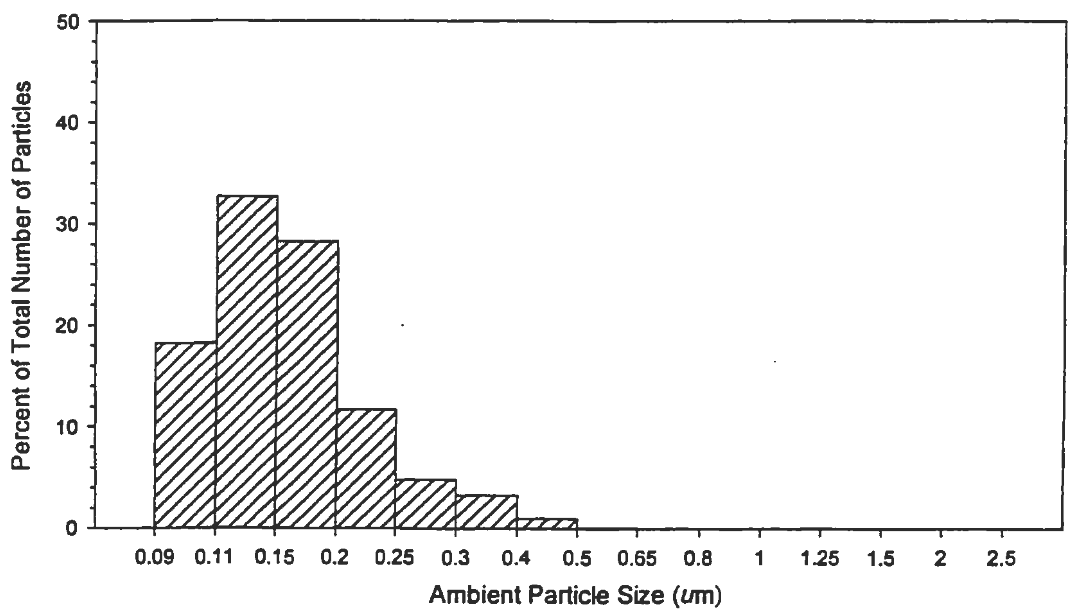

Figure 5. Typical ambient aerosol particle size distribution.

(Huang, 1998). The ambient aerosol concentration also affects the filter penetration testing results. Thus, it was important to estimate the variation for a future single measurement of ambient filter penetration for each respirator. This variation may include two components: random measurement error, variation among testing positions, and variation among respirators. For any single position on the same respirator, the random measurement error (s) is estimated to be 0.09% using the mean square data in Table 5. The standard deviation for the random effect of testing positions (s_b = 0.14%) is of the same magnitude as the random measurement error. The standard deviation for the random effect of

Table 4. Summary of ambient aerosol filter penetration measured with the NIOSH clamp at 10 positions on each of the five respirators from the same model by respirator and position.

Position	n	Respirator 1		Respirator 2		Respirator 3		Respirator 4		Respirator 5	
		Mean (%)	Standard deviation	Mean (%)	Standard deviation	Mean (%)	Standard deviation	Mean (%)	Standard deviation	Mean (%)	Standard deviation
A	3	0.61	0.01	0.66	0.12	0.67	0.02	0.93	0.15	0.57	0.07
B	3	0.44	0.05	0.68	0.06	1.04	0.08	0.74	0.12	0.67	0.06
C	3	0.58	0.09	0.32	0.01	0.96	0.04	1.08	0.08	0.83	0.16
D	3	0.38	0.08	0.43	0.06	0.65	0.00	0.53	0.02	0.54	0.13
E	3	0.41	0.02	0.38	0.04	0.65	0.06	0.77	0.13	0.55	0.17
F	3	0.52	0.13	0.45	0.06	0.88	0.09	0.77	0.21	0.49	0.08
G	3	0.42	0.06	0.37	0.03	0.57	0.04	0.62	0.07	0.84	0.15
H	3	0.54	0.13	0.67	0.08	0.80	0.04	0.92	0.24	0.65	0.09
I	3	0.39	0.06	0.49	0.08	0.95	0.03	0.64	0.06	0.42	0.10
J	3	0.46	0.03	0.30	0.05	0.58	0.03	0.56	0.07	0.39	0.04
All	30	0.48	0.10	0.47	0.15	0.78	0.17	0.75	0.20	0.60	0.18

Table 5. Analysis of variance for ambient aerosol filter penetration at different positions.

Sources of variation	Degrees of freedom	Mean square	Expected mean square	F-ratio	P-value
Respirator (R)	4	0.00006354	$\sigma^2 + 3\sigma_\beta^2 + 30\,\sigma_\tau^2$	9.4	0.0001
Position (within R)	45	0.00000678	$\sigma^2 + 3\sigma_\beta^2$	8.0	0.0001
Errors	100	0.00000085	σ^2		
Total	149				

Notes: σ_τ^2 is the variance for random effect of respirators.

σ_β^2 is the variance for random effect of positions within respirators.

σ^2 is the variance for random error.

respirators of the same model/lot (s_t) is estimated to be 0.14%. Thus, the variation associated with any single measurement of filter penetration is reasonable because the estimates of variance components are well below the fit-test pass/fail criterion of 1%.

Protocol for Quantitative Fit-testing N95 Respirators

Since filter penetration was found to be significant (i.e., greater than 0.03% and therefore, would affect the fit results), a means of correcting or adjusting the PortaCount Plus™ fit factors for filter penetration needed to be incorporated into the protocol for quantitatively fit-testing N95 respirators. One means of adjusting a PortaCount Plus™ fit factor is to use the filter penetration from the NaCl test. This testing could be performed by the respirator manufacturer or respirator certification agency and disseminated to the person performing the fit-test. The data could be printed on the label along with the filter class and other information and then subtracted from the measured total penetration by the person performing the fit-test. Using such data would eliminate individual filter penetration tests. However, using the results of the NaCl test would be unsuitable for adjusting the measured fit factor of a N95 filtering-facepiece respirator. As indicated previously, the NaCl test provided penetration values significantly higher than either ambient aerosol method (i.e., PortaCount Plus™ and lab CNC). Therefore, using the NaCl penetration test could lead to a high percentage of N95 respirators that would provide adequate protection in the workplace but that would fail the fit-test and be rejected. This would impose an unnecessary economic burden by causing more fit-tests and respirator purchases than necessary to protect workers. In addition, the NaCl test could result in a large number of negative adjusted fit factors because the penetration measured by the NaCl test is greater than the PortaCount Plus™ measured fit factor. This would cause confusion since negative fit factors are physically impossible.

Measured N95 respirator fit factors were adjusted using filter penetration evaluated with the NIOSH clamp and the PortaCount Plus™, since it would not be economically feasible for everyone wishing to quantitatively fit-test N95 respirators to purchase a lab CNC. In addition, since the filter penetration measured by the PortaCount Plus™ is generally higher than the lab CNC, it provides a more conservative value for the adjusted fit factor. This helps to protect the wearer by eliminating more of the respirators having a marginally adequate fit (i.e, those respirators having an adjusted fit factor close to 100).

The fit-testing protocol developed for the next portion of the study consisted of the following steps. A measured fit factor was obtained from the PortaCount Plus™ in the normal manner. The respirator was placed in the NIOSH clamp and the handle secured with the spring. The PortaCount Plus™ was then connected to the NIOSH clamp through the tubing (approximately 1.5 m) supplied by TSI and run in the count mode for two minutes to clear any particles present inside the respirator due to mounting. The PortaCount Plus™ was then placed in the fit-test mode and started to commence filter penetration testing. After the PortaCount Plus™ determined the "fit factor" for the first time period, the fit-test was stopped. The "fit factor" displayed on the PortaCount Plus™ was then recorded.

Then an adjusted fit factor was calculated using Equation 1 and compared to the established pass/fail criterion to determine if an N95 respirator fit a wearer or achieve an adequate level of fit. If the adjusted fit factor was greater than the established pass/fail criterion, the wearer achieved a satisfactory fit with the N95 respirator.

$$AFF = MFF * FFF / (FFF - MFF) \quad (1)$$

where AFF = adjusted fit factor;
MFF = measured fit factor; and
FFF = "fit factor" displayed by the PortaCount Plus™ during filter penetration testing.

An alternative approach to determine if an N95 respirator fits a wearer is to adjust the pass/fail criterion, which is equivalent to an adjusted fit factor of 100, using Equation 2. The American pass/fail criterion, to determine if a half-mask respirator provides an adequate fit and can be used in the workplace, is a minimum fit factor of 100 (ANSI, 1992; FR, 1998), although many employers use higher fit factor criteria. The measured fit factor is then compared with the adjusted pass/fail criterion to determine if an N95 respirator achieves an adequate level of fit. If the measured fit factor is greater than the adjusted pass/fail criterion, the N95 respirator fits the wearer.

$$APFC = 100 * FFF / (100 + FFF) \quad (2)$$

where APFC = adjusted pass/fail criterion; and
FFF = "fit factor" displayed by the PortaCount Plus™ during filter penetration testing.

For example, usin"fit factor" of 200 (0.5% penetration), displayed by the PortaCount Plus™ during filter penetration testing in Equation 2, results in an adjusted pass/fail criterion of 67. Then, the measured fit factor directly from the PortaCount Plus™ can be compared to this value to decide if the respirator provides an adequate fit. This approach can be applied to future studies to establish a new pass/fail criterion for N95 respirators instead of 100.

Conclusions

A protocol for fit-testing N95 respirators using the PortaCount Plus™ was developed. This protocol used the PortaCount Plus™ to measure ambient aerosol filter penetration through N95 respirators. A clamp was developed to make the flow rate through a small sealed portion of the filter equivalent to that through the whole respirator during a fit-test. Since this study found that filter penetration measured with the PortaCount Plus™ and NIOSH clamp was significantly greater than 0.03%, filter penetration needed to be accounted for and subtracted from the total inward leakage to obtain face-seal leakage. Ambient aerosol filter penetration was found to be affected by the placement of the clamp on the respirator. It was also found that the NaCl test provided filter penetrations that were significantly higher than those measured with the PortaCount Plus™ and lab CNC (a = 0.05).

Due to the differences among filters and the changing nature of the ambient aerosol, the fit-testing protocol measured filter penetration for each filter immediately after the fit-test. Finally, procedures were developed to adjust the fit factors of PortaCount Plus™ quantitative fit-tests for ambient aerosol filter penetration through the use of a simple equation (Equation 1) or the pass/fail criterion (Equation 2), so that fit-test operators can determine if an N95 respirator fits a wearer. The results of fit-testing 21 N95 respirators using this new protocol will be discussed in Part II - Results, Effect of Filter Penetration, Fit-Test, and Pass/Fail Criteria on Respirator Performance.

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