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Comparison of Two Newly Developed Methods for Fit Testing N95 Respirators

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Abstract

The only 30 CFR 11 filters which could be used in quantitative fit testing were high-efficiency particulate aerosol (HEPA) filters. These were the only filters which did not have significant penetration of the aerosols used in quantitative fit tests. However, the new National Institute for Occupational Safety and Health (NIOSH) respirator certification regulations (42 CFR Part 84) require all particulate respirators to be tested with an aerosol in the most penetrating size range and to have a minimum filter efficiency of 95%. As a result of the improved filter performance assured by these new regulations, a question has arisen regarding whether N95 respirators (one of the new classes of particulate respirators) could be quantitatively fit tested. In response, NIOSH and TSI Incorporated researchers developed a method for fit testing N95 filtering-facepiece respirators using the PortaCount Plus™ with a filter ratio test clamp to measure filter penetration. Meanwhile, TSI also developed a new accessory (the N95-COMPANION™ for the PortaCount Plus™) to fit test N95 respirators. The purpose of this study was to determine how well the fit factors from these two methods correlate. The facepiece fit of each respirator model was measured on a panel of 25 subjects with varying face sizes. A "standard" PortaCount Plus™ test was conducted for each subject/respirator combination. However, since N95 filter media can have significant penetration of ambient particles, the "standard" PortaCount Plus™ fit test measured total penetration (i.e., filter penetration and face seal leakage) and not just face seal leakage. Filter penetration was measured on each respirator using the PortaCount Plus™ with the clamp, and an adjusted fit factor computed. Immediately after the "standard" PortaCount Plus™ test, a fit test for each subject/respirator combination was conducted using the N95-COMPANION™ in conjunction with the PortaCount Plus™ without the respirator being redonned. Log-transformed Companion fit factors and log-transformed adjusted fit factors were strongly correlated (R^2 ranged from 0.66 to 0.92 depending on the regression models). The slope of the regression equation for one respirator model was significantly different from the slopes for the other four respirator models. The authors concluded that both methods provided comparable fit factors for each respirator/subject combination. Future studies should characterize the ambient particle size distribution inside the N95 filtering-facepiece respirators.

Introduction

Previously, some types of filtering-facepiece respirators (i.e., dust/mist and dust/fume/mist respirators) certified in accordance with the provisions of Title 30, Code of Federal Regulations (CFR), Part 11 had filter efficiencies less than 99.97% (Chen *et al.*, 1992). Therefore, they could not be quantitatively fit tested due to the large amount of aerosol penetrating the filter. A quantitative fit test that could be used with these types of respirators used a large size corn oil aerosol (geometric count mean aerodynamic diameter of 2.5 µm and geometric standard deviation of 1.1) as the challenge agent and a single-particle optical particle counter to measure the test agent (Iverson *et al.*, 1992). A monodispersed aerosol with aerodynamic mean size of 2.5 µm was chosen because the particles are large enough that they do not significantly penetrate dust/mist and dust/fume/mist filters, yet are small enough to penetrate face seal leaks (Danisch *et al.*, 1992). However, this quantitative fit test has never been widely used to test filtering facepiece respirators. Therefore, dust/mist and dust/fume/mist filtering-facepiece respirators were usually fit tested using the saccharin and Bitrex™ qualitative fit test methods (Bollinger and Schutz, 1987; Mullins *et al.*, 1995; Marsh, 1984). The saccharin and Bitrex qualitative fit test methods are identical except for the challenge agent.

In July 1995, the National Institute for Occupational Safety and Health (NIOSH) promulgated new certification regulations under Title 42, Code of Federal Regulations, Part 84 (42 CFR 84) (CFR, 1996). Under these new regulations, all particulate respirators are tested with an aerosol in the most penetrating range and are required to have a minimum efficiency of 95%. The new 42 CFR 84 regulation provides nine classes of filters (three levels of filter efficiency, each with three categories of resistance to filter efficiency degradation). The three levels of filter efficiency are 95, 99, and 99.97%. The three categories of resistance to filter efficiency degradation are labeled N, R, and P (NIOSH, 1996). A filter marked N95 would mean an N-series filter that is at least 95% efficient when tested against sodium chloride in accordance with the provisions of 42 CFR 84 (CFR, 1996). N95 respirators are commonly used in the healthcare industry.

As a result of the new regulations, NIOSH has received many inquiries about the face-fitting characteristics of the new N95 respirators, especially the filtering facepieces. These inquiries raised the issue of whether N95 respirators could be quantitatively fit tested (i.e., is N95 filter media at least 99.97% efficient against ambient aerosols). To answer this question, the possibility of using the TSI Model 8020 PortaCount Plus™ Quantitative Respirator Fit Tester (TSI Inc., St. Paul, MN) for fit testing N95 respirators, especially the filtering-facepiece type, was investigated (Zhuang *et al.*, 1999). The PortaCount Plus™ was chosen for that study because it has been demonstrated that the fit factors provided by the PortaCount Plus™ correlate moderately well with an actual measure of inhalation exposure (Coffey *et al.*, 1998a and 1998b). The PortaCount Plus™ is widely used for fit testing and it counts the number of particles in the ambient air outside, C_{out}, and inside of the respirator facepiece, C_{in}, with a miniature condensation nuclei counter to determine a quantitative fit factor, a quantitative measure of the fit of a particular respirator facepiece to a particular individual. A fit factor is defined under the conditions of quantitative fit testing as the ratio of C_{out}/C_{in} (AIHARPC, 1985). Presently, the PortaCount Plus™ is used only with class-100 respirators (which have negligible filter penetration) to ensure any particles detected in the facepiece are due to face seal leakage. Since fit factors should only account for face seal leakage and not filter penetration, it is necessary to develop a procedure to measure the filtration penetration of the various N95 respirators. In order for the N95 respirators to be tested with the PortaCount Plus™ quantitative fit test method, the filter penetration of the ambient aerosol must be measured so that only face seal leakage can be determined (Zhuang *et al.*, 1999). Since the Occupational Safety and Health Administration (OSHA) regulations and NIOSH and ANSI recommendations dealing with the wearing of respirators require that a person be fit tested before being allowed to wear a respirator in the workplace, a field method to fit test N95 respirators has been developed (Zhuang *et al.*, 1999; Coffey *et al.*, 1999a; ANSI, 1992; Federal Register, 1998; Bollinger and Schutz, 1987).

The new field method consisted of first obtaining a performance factor (i.e., the reciprocal of total penetration which is the sum of face seal leakage and filter penetration) using only the PortaCount Plus™. After the performance factor was measured, the filter ratio (i.e., the reciprocal of filter penetration) for each respirator was determined using the PortaCount Plus™ with the filter ratio test clamp (Fig. 1). The performance factor and filter ratio were then converted to total penetration and filter penetration percentages. The filter penetration was subtracted from the total penetration resulting in just the

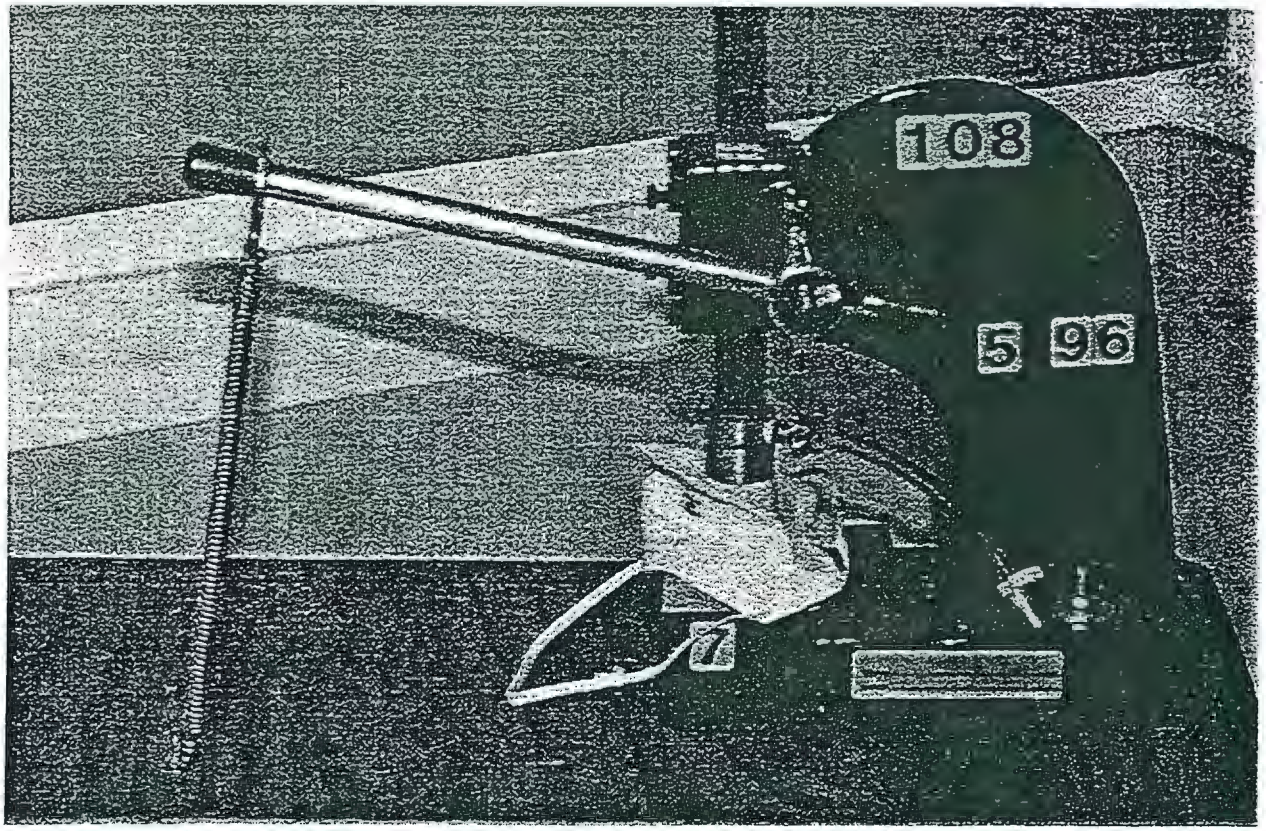

Figure 1. Side view of filter ratio test clamp with a N95 respirator.

leakage of the ambient particles through the respirator face seal. The assumption was made that the ambient aerosol was constant during each test.

While NIOSH was investigating the use of the clamp method, TSI developed a new accessory (N95-COMPANION™ for the PortaCount Plus™) to fit test N95 respirators. This new accessory is an aerosol pre-conditioner that selects particles in a specific size range (0.03 to 0.05 μm) and passes them on to the PortaCount Plus™. Particles that are not in the target size range are discarded. With the N95-COMPANION™ connected, the PortaCount Plus™ counts only particles that are in this size range for effective quantitative fit testing of N95 as well as R95 and P95 respirators. By using the N95-COMPANION™ to restrict the size range of the particles counted by the PortaCount Plus™, particles in the size range that can penetrate through the respirator filter and be counted incorrectly as face seal leakage are eliminated. This article details a study to compare these two newly developed methods for fit testing N95 filtering-facepiece respirators.

Methods and Materials

Subjects

A panel of 25 subjects (13 women and 12 men) was chosen for each respirator test sequence based on face size and availability from a total of 30 subjects. Therefore, each subject did not wear every respirator. The order of presentation of respirators to each subject was randomized. The subjects had face lengths ranging from 93.5 to 133.5 mm and lip lengths of 34.5 to 61.5 mm. The composition of each panel based on face size is shown in Fig. 2. Each subject received the manufacturer's instructions for donning the respirator. Each of the 30 subjects had previous experience wearing respirators and had participated in both qualitative and quantitative fit testing prior to this study.

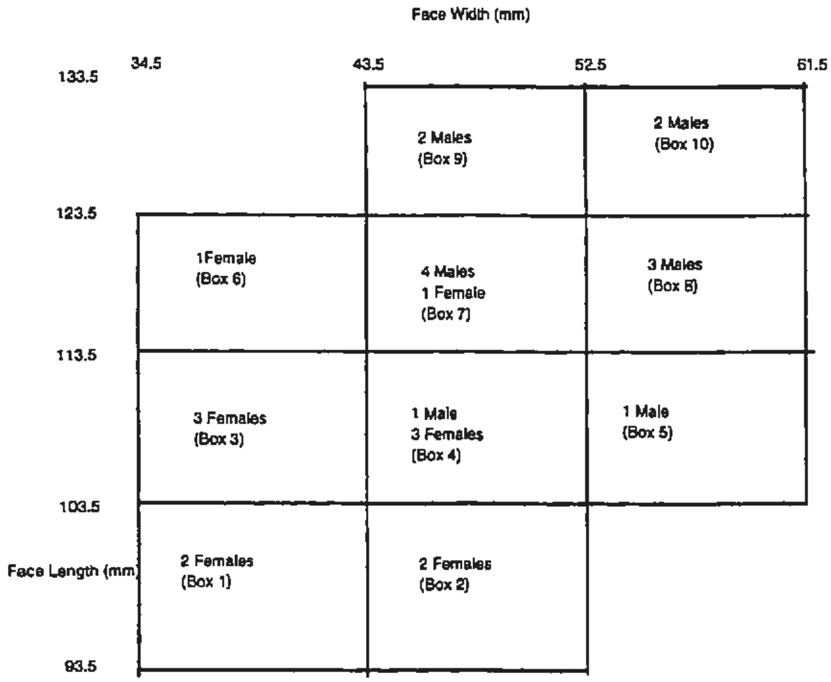

Figure 2. Distribution of 25-subject panel based on facial size.

Respirators

For this study, five NIOSH-certified filtering-facepiece N95 respirators were randomly selected and are listed in alphabetical order: Moldex Model 2300N95 (Moldex/Metric, Inc., Culver City, CA), MSA Model Affinity Pro (Mine Safety Appliances Company, Pittsburgh, PA), Tecnol Model PFR95-114/PFR95-110 (Tecnol Inc., Fort Worth, TX), and Willson Models N9501 and 9510 (Willson Safety, Reading, PA). Moldex respirators came in only one size and Tecnol respirators are manufactured in two sizes (small and regular). The remaining three respirator models were available in three sizes (small, medium, and large). Tecnol respirators are of the folding style and the rest of the models were cup style. These N95 filtering facepiece respirators were representative of those available during the first year after 42 CFR 84 was promulgated. All of the respirators were probed half way between the nose and mouth using the TSI Fit Test Probe Kit (P/N 8025-N95, St. Paul, MN) to allow sampling inside the respirator. The inlet of the probe was flush with the inside surface of the respirator. The TSI probe had the same geometry as the probes validated in a previous study (Coffey *et al.*, 1998b).

Fit Testing N95 Respirators with the PortaCount Plus™ and a Clamp

In this study, a TSI PortaCount Plus™ Model 8020 (TSI Inc., St. Paul, MN) was used to conduct fit testing of the N95 respirators in a laboratory setting. The PortaCount Plus™ is a quantitative fit test instrument that uses ambient particles as the challenge agent and counts the number of particles outside and inside of the facepiece. Fit factor is a measure of face seal leakage only. However, it has been demonstrated that ambient particles can have significant penetration (greater than 0.03%) through N95 filter media (Zhuang *et al.*, 1999). The fit factors reported by the PortaCount Plus™, therefore, were not "true" fit factors (a measure of the face seal leakage only) but were performance factors (a measure of face seal leakage and filter penetration) (Zhuang *et al.*, 1999). Thus, filter penetration needed to be measured in order to convert performance factors to fit factors.

A clamp (Fig. 1), developed by NIOSH in conjunction with TSI, was next used with the PortaCount Plus™ to measure the filter ratio (i.e., the reciprocal of filter penetration) of a respirator.

The clamp was designed to seal a small area of the filtering facepiece so that the air drawn with the PortaCount Plus™ flowed only through this area. The sealed area was determined in such a way that the flow rate per unit area through the sealed area is the same as that of a person breathing at rest through the entire respirator (Coffey *et al.*, 1999b). The filter penetration of ambient aerosols through this sealed area can then be used to approximate the penetration through the entire respirator. A filter ratio was obtained using the PortaCount Plus™ in the fit test mode with the clamp. The filter ratio was calculated by dividing the ambient particle concentration (upstream of the filter) by the particle concentration downstream of the filter.

The filter ratio and performance factors were converted to percentages by dividing them into 100. The filter penetration percentage was then subtracted from the total penetration percentage to obtain face seal leakage. The face seal leakage was then divided into 100 to get the "true" fit factor, subsequently called adjusted fit factor.

Fit Testing N95 Respirators with the N95-COMPANION™

A new accessory, the N95-COMPANION™ (TSI Inc., St. Paul, MN) for the PortaCount Plus™, has recently been developed for quantitatively fit testing N95 respirators, specifically the filtering-facepiece type. The N95-Companion contains an electrostatic particle classifier. The particle classifier takes advantage of electrostatic charges that exist on ambient particles to strip out a predetermined particle size range of interest (0.03 to 0.05 μm), from the broad range of sizes present in ambient air. The design of the N95-COMPANION™ assumes that the penetration in this size range through N95 filter media is insignificant so that any particles counted are due to face seal leaks and not filter penetration. These particles leave the N95-COMPANION™ and are transported via flexible tubing to the PortaCount Plus™ for counting. The PortaCount Plus™ then compares the number of particles outside the mask to the number inside the mask. This ratio of particles counted is the fit factor. In this configuration, the fit factor is obtained directly from the PortaCount Plus™ (TSI, 1997).

Data Collection Procedures

Each subject was given the respirator manufacturer's donning instructions. The respirators which were available in multiple sizes did not come with instructions on how to choose the appropriate size. Therefore, in order to provide the best performing respirator for each subject, all sizes were initially probed and donned per the manufacturer's instructions without assistance from the test operator and tested with the PortaCount Plus™ while the subject was breathing normally for 80 seconds. The size having the lowest performance factor (the value obtained directly from the PortaCount Plus™) was then used for the actual total penetration measurement.

After sizing (if needed), the subject donned the probed respirator in accordance with the manufacturer's instructions. After the respirator was donned, the total penetration testing began. The subject performed the following exercises for approximately 80 seconds each: (1) normal breathing, (2) deep breathing, (3) moving their head side to side, (4) moving their head up and down, (5) reading the rainbow passage out loud, and (6) normal breathing (CFR, 1996). An overall performance factor was obtained from all six exercises.

Right after the total penetration test and without re-donning or adjusting the respirator, a fit test was conducted using the N95-COMPANION™ in conjunction with PortaCount Plus™. Thus, the fit tests using N95-COMPANION™ were conducted on each of the five respirators using a 25-subject panel (Fig. 2). The subjects performed the same exercises for the N95-COMPANION™ fit test as for the total penetration test. An overall fit factor from all six exercises was obtained.

After the fit test using the N95-COMPANION™ the PortaCount Plus™ was then used with the newly developed clamp (see Fig. 1) to measure filter penetration. The respirator was first placed in the clamp and the handle secured with a spring. The PortaCount Plus™ was next connected to the clamp 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 filter penetration testing commenced. After 80 seconds, the PortaCount Plus™ displayed a "fit" factor and the test was stopped. The "fit" factor displayed on the PortaCount Plus™ was actually the filter ratio which was calculated by dividing the ambient particle concentration (upstream of the filter) by the particle concentration downstream of the filter.

The resulting filter ratio and performance factors were then converted to percentages by dividing them into 100. The percentage derived from the performance factor is referred as the total penetration. Filter penetration is the percentage derived from the filter ratio. Percent face seal leakage was then calculated by subtracting the filter penetration from total penetration. The percent total penetration and face seal leakage values were then used to calculate the 5th percentiles of the adjusted fit factor for each respirator model. The 5th percentile was calculated using the geometric mean (GM) and the geometric standard deviation (GSD) as $GM^*GSD^{1.645}$ (Lenhart and Campbell, 1984).

Statistical Analyses

The first hypothesis formulated in this study was that fit factors obtained with the PortaCount Plus™ and N95 Companion (subsequently called Companion fit factors) were significantly correlated with the fit factors measured with the PortaCount Plus™ and a clamp (subsequently called adjusted fit factors). The response variable was Companion fit factor and the independent one was the adjusted fit factor. To test this hypothesis, a correlation analysis was performed to evaluate the correlation between the Companion fit factor and the adjusted fit factor. The following simple regression model was used to correlate the two variables:

$$Y_i = \alpha + \beta X_i + e_i \quad (1)$$

where Y = log-transformed Companion fit factors
α = regression coefficient, i.e., the intercept
β = regression coefficient, i.e., the slope
X = log-transformed adjusted fit factors

This simple regression model implies that each respirator model has the same regression line, with the same intercept and slope. The second hypothesis to be tested was that the slope of the regression line was equal to one.

The third hypothesis was that the intercepts and slopes of the regression lines for each respirator were the same. To find out if each respirator model has its own regression line, with different intercepts and slopes for the different respirator models, a first-order multiple regression model with interactions was used to correlate Companion fit factor and two independent variables (adjusted fit factor and respirator model) as follows:

$$Y_i = \alpha_1 + \beta_1 X_{1i} + \alpha_2 X_2 + \beta_2 X_{1i} X_2 + \alpha_3 X_3 + \beta_3 X_{1i} X_3 + \alpha_4 X_4 + \beta_4 X_{1i} X_4 + \alpha_5 X_5 + \beta_5 X_{1i} X_5 + G_i \quad (2)$$

where

Y_i = log-transformed Companion fit factors (i=1–n)
α_j = regression coefficients, i.e., intercepts (j=1–5)
β_j = regression coefficients, i.e., slopes (j=1–5)
X_{1i} = log-transformed adjusted fit factors (i=1-n)
X_2 = indicator variable ($X_2 = 1$ if respirator model 2; $X_2 = 0$ otherwise)
X_3 = indicator variable ($X_3 = 1$ if respirator model 3; $X_3 = 0$ otherwise)
X_4 = indicator variable ($X_4 = 1$ if respirator model 4; $X_4 = 0$ otherwise)
X_5 = indicator variable ($X_5 = 1$ if respirator model 5; $X_5 = 0$ otherwise)

The advantage of this first-order multiple regression model is that it allows simultaneously testing of intercepts and slopes for the different respirator models.

Correlation analysis was performed by using the Statistical Analysis System (SAS®) software (SAS Institute Inc., Cary, NC). The SAS General Linear Models procedure was used to obtain all parameters on the correlation between Companion fit factors and adjusted fit factors. In addition, the Companion fit factors and adjusted fit factors were also analyzed using analysis of variance approach (two fit test methods × five respirator models) to determine if there is significant difference between the two fit test methods.

Results and Discussion

The total penetration, filter penetration, and face seal leakage obtained using the PortaCount Plus™ with the filter ratio test clamp are summarized by respirator model in Table 1. A total of 121 pairs of tests were conducted. Data for two pairs of tests (respirator/subject combinations) were excluded from the analysis because the Companion fit factors were less than one which may have resulted from instrument variation or a change in the ambient particle concentration between the start and finish of the test. Another two pairs were removed from the analysis because filter penetrations were larger than total penetrations. Filter penetration is usually small, thus the face seal leak associated with these two

Table 1. Summary of total penetration, filter penetration, and face seal leakage by respirator model using PortaCount Plus™ with a filter ratio test clamp.

Respirator	Total penetration			Filter penetration			Face seal leakage		
Model	n	GM	GSD	n	GM	GSD	n	GM	GSD
1	25	0.9%	5.7	25	0.1%	2.3	25	0.5%	8.9
2	24	7.2%	2.3	24	1.0%	2.4	24	5.3%	3.0
3	21	4.0%	2.4	21	0.8%	1.6	21	2.8%	3.2
4	24	4.0%	3.4	24	0.3%	1.4	24	3.4%	4.1
5	23	8.6%	2.8	23	0.2%	1.7	23	8.1%	2.9
All	117	3.8%	4.2	117	0.3%	2.9	117	2.9%	5.6

Notes: GM = Geometric Mean, GSD = Geometric Standard Deviation, and n=Number of Respirators.

observations is believed to be small as well. Exclusion of these data points would produce more conservative estimates of the respirator performance. One possible explanation for the filter penetration being larger than the total penetration is that there is a large variation of the filter media in the respirator (Huang *et al.*, 1998). If a large variation existed, the filter penetration through the clamp area may not be representative of the penetration through the whole filter. This method could be improved by measuring the ambient aerosol penetration through the filtering-facepiece respirator as worn on the subject. This could be accomplished by either mounting the respirator on a headform or a fixture. A vacuum pump could be then attached and the equivalent minute volume of a sedentary breathing rate (approximately 10 liters per minute) could be drawn through the respirator. The PortaCount Plus™ would then sample isokinetically from this flow.

The geometric mean (GM) for total penetration of each respirator model ranged from 0.9% to 8.6%. The GM of total penetrations for all the respirators combined was 3.8%. The GM for filter penetration ranged from 0.1% observed with respirator model one to 1.0% with respirator model two. Overall, the GM for filter penetration was determined to be 0.3%, which was smaller than the overall GM total penetration (3.8%). On the other hand, the overall GM for face seal leakage was 2.9% (ranged from 0.5% to 8.1%). Therefore, the total penetration was mainly attributable to face seal leakage. This finding can also be illustrated in Fig. 3, which presents a scatter plot of individual filter penetration, face seal leak, and adjusted fit factor against total penetration for all observations (regardless of respirator models, nature of tests, and subjects). As shown in Figure 3, most of the individual face seal leaks fall on line AB where face seal leak is equal to total penetration. Face seal leakage of almost 100% was observed. On the other hand, filter penetrations fall between 1% and 0.04% as total penetration ranges from 0.1% to near 100%. These observations support the reliability of the fit test method and validity of the adjusted fit factors.

The Companion and adjusted fit factors are summarized by respirator model in Table 2. Both methods gave the same order of respirator models with the largest to the smallest GM fit factors. The results of analysis of variance indicated that the GM of the Companion fit factor (49) was not significantly different from the GM of the adjusted fit factor (35). The GM for the Companion fit factor for each respirator model was not significantly different from the GM for the adjusted fit factor for the corresponding model.

The correlation analysis found that log-transformed Companion fit factor (Y) and log-transformed adjusted fit factor (X) are strongly correlated ($R^2 = 0.66$) and the linear regression model (Equation 3) is significant at the 1% significance level ($p = < 0.0001$). The intercept (0.0088) is not statistically different from zero, but the slope (1.0909) of the regression equation is significantly different from zero. A similar T-test showed that the slope was not significantly different from one. These results indicated that the fit factors for each respirator/subject combination obtained with these two methods were comparable.

$$Y = 0.0088 + 1.0909\,X \qquad (3)$$

Since the intercept for Equation 3 is not significantly different from zero, a modified simple regression model (i.e., $Y = \beta X$ and the intercept is set to be zero) was used to correlate the fit factors obtained

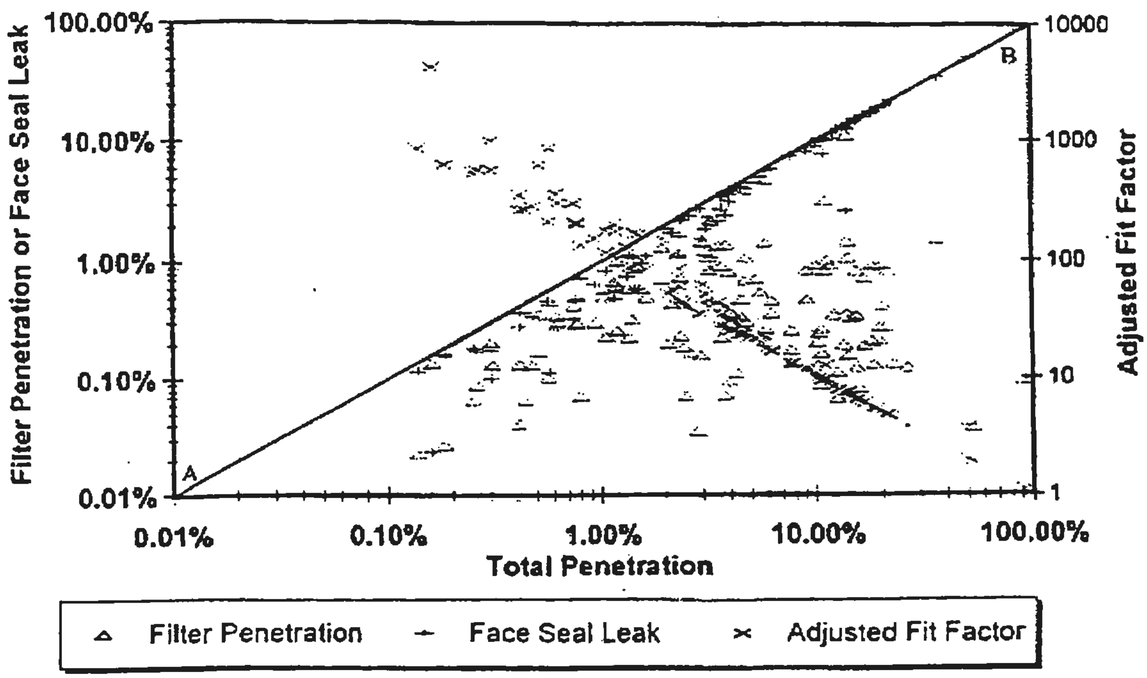

Figure 3. Scatter plot of filter penetration, face seal leak, and adjusted fit factor against total penetration.

Table 2. Summary of adjusted fit factors and Companion fit factors by respirator model.

Respirator model	Adjusted fit factors				Companion fit factors			
	n	GM	GSD	5th	n	GM	GSD	5th
1	25	186	8.9	5	25	301	17.6	3
2	24	19	3.0	3	24	38	7.9	1
3	21	36	3.2	5	21	49	4.8	4
4	24	30	4.1	3	24	40	7.7	1
5	23	12	2.9	2	23	11	4.2	1
All	117	35	5.6	2	117	49	10.1	1

Notes: GM = Geometric Mean, GSD = Geometric Standard Deviation, and 5^{th} = 5^{th} Percentile.

with the two methods. This modified regression model was believed to fit the data better than Equation 3. The R^2 for the modified simple model is now 0.91 and the resulting equation is expressed as Equation 4. The slope was found to be significantly greater than one from a T-test. However, this difference was small because on average, the log-transformed Companion fit factor was about 10% higher than the log-transformed adjusted fit factor as implied by the equation.

$$Y = 1.0955\,X \tag{4}$$

When the first-order multiple regression model was used, fit factors for the two methods were also found to be significantly correlated with an R^2 of 0.70 and the regression model is significant at the 1% significance level ($p = < 0.0001$). The regression equation based on log- transformed data is expressed as Equation 5.

$$Y = 0.3642 + 0.9313\,X_1 - 1.0074\,X_2 + 0.8074\,X_1 X_2 - 0.2626\,X_3 + 0.0876\,X_1 X_3 - 0.5594\,X_4 + 0.2865\,X_1 X_4 - 0.3029\,X_5 - 0.0180\,X_1 X_5 \tag{5}$$

The slope ($\beta_1 = 0.9313$) is significantly different from zero. The regression coefficients ($\alpha_2 = -1.0074$ and $\beta_2 = 0.8074$) are statistically different from zero as well indicating that the intercept and slope for regression line for respirator two are significantly different from those for respirator one. The rest of regression coefficients are not significantly different from zero indicating that the intercepts and slopes for regression lines for the corresponding respirators are not significantly different from those for respirator one. These results are also illustrated in Fig. 4, which plots the observed Companion fit factors and predicted Companion fit factors using Equation 5 against the adjusted fit factors for each respirator model.

Since the majority of the parameters (7 of 10) for Equation 5 are not significantly different from zero, another correlation analysis was performed on all data without those terms (i.e., all respirators except respirator two were set to have the same slope and zero intercept). The results showed that for this modified model, the intercept for respirator two (α_2) was not significantly different from zero. Thus, another correlation analysis (using a regression model with only two parameters, β_1 and β_2) was performed on all data again. The R^2 for this model is now 0.92 and the resulting equation is expressed as Equation 6.

$$Y = 1.0662\,X_1 + 0.2277\,X_1 X_2 \tag{6}$$

Both slopes ($\beta_1 = 1.0662$ and $\beta_2 = 0.2277$) are statistically different from zero indicating that the slope for regression line for respirator two is significantly different from the one for the other four respirators. The sign for β_2 is positive indicating that the slope for the regression line for respirator two is significantly greater than the slope for the regression line for the other respirator models. Therefore, hypothesis three is rejected. Equation 6 can be interpreted in practical term as that on average, the log-transformed Companion fit factor was about 7% higher than the log-transformed adjusted fit factor for four of the five respirator models. For respirator model two, the log-transformed COMPANION fit factor was about 30% higher than the log-transformed adjusted fit factor. This difference may not only be attributable to quantitative fit test methods but also respirator models, test subjects, and other unknown factors. Table 3 is a summary of the R^2 values and the slopes for different regression equations.

The newly developed fit test method to obtain adjusted fit factors is now only appropriate for research purposes. However, the technique could easily become commercially available. The availability of such a fit test system or similar fit test systems could simplify fit testing and would be a welcome option to many, especially those who already have the basic hardware for quantitative fit testing. The TSI N95-COMPANION™ is now commercially available.

Conclusions

This study found that log-transformed Companion fit factors and log-transformed adjusted fit factors were strongly correlated (R^2 ranged from 0.66 to 0.92 depending on the regression models). The slope of the regression equation for one respirator model was significantly different from the slopes for the other four respirator models. The authors concluded that both methods provided comparable fit factors for each respirator/subject combination. Future studies should investigate further refinements in the "adjusted" fit factor method to eliminate the anomalies associated with measuring filter penetration only over a small portion of the filtering-facepiece.

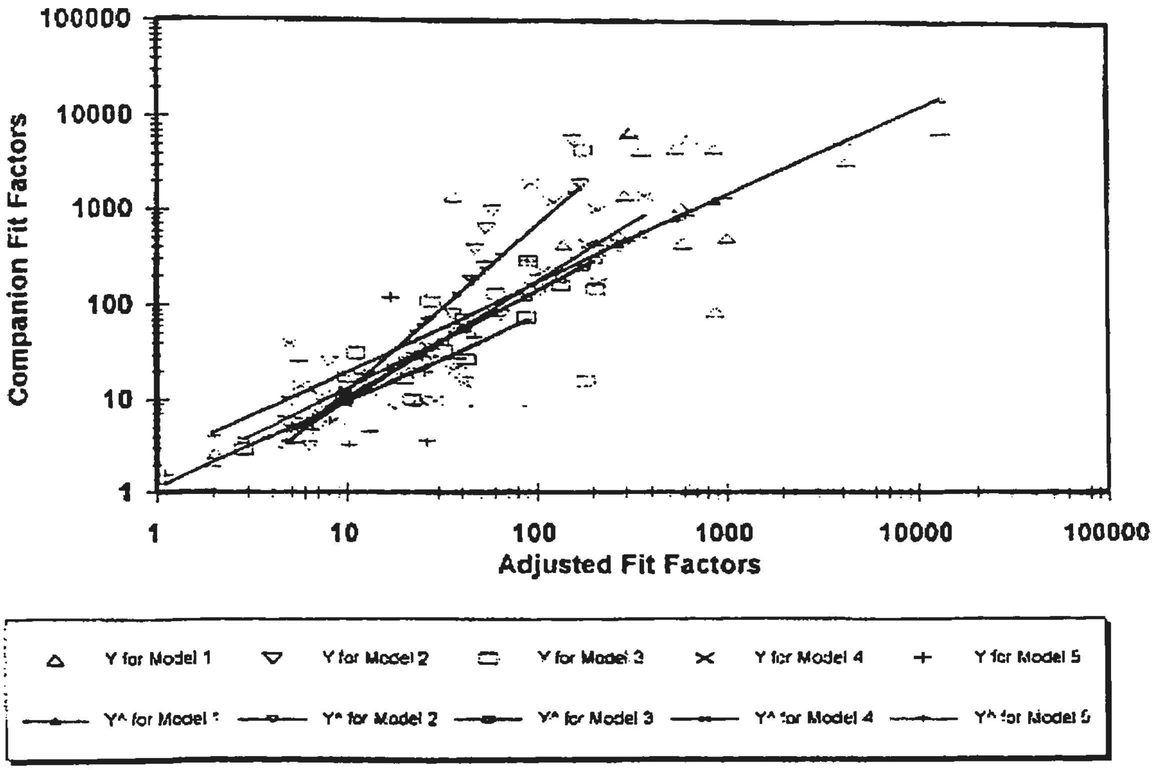

Figure 4. Plot of the observed companion fit factors (Y) and predicted companion fit factors (Y^) using Equation 5 against the adjusted fit factors for each respirator model.

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