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Validation of a Respirator Performance Model

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This article presents results of an experimental validation of a model for predicting the performance of half-mask respirators. The model predicts respirator performance for protection against aerosols. It uses as input the measured fit factor, an estimated work rate, the exposure particle size distribution, and known performance characteristics for the type and brand of filter used. The validation tests involved the measurement of respirator performance, using human subjects, under simulated use conditions with known fit, work rate, particle size distribution, and filter performance. Comparison is made between measured and predicted performance for two conditions each of fit, particle size, and work rate. Fit factors ranged from 5 to 231, test aerosol mass median aerodynamic diameters from 0.6 to 1.3 μm, and work rates from 0 to 50 W. Based on tests conducted here, the predictive model does a reasonable job of predicting penetration under simulated use conditions where fit factor, size distribution, work rate, and filter efficiency are known. It is able to account for 58 percent of variability in measured penetration under the conditions of these tests. The model adequately accounts for the effect of fit (as determined by quantitative fit test), work rate (breathing pattern), and particle size distribution, and shows no bias with the magnitude of these parameters. Given the intrinsic variability of respirator performance measurements, the model is useful for predicting the effect of these variables on respirator performance. HINDS, W.C.; RISI, D.; KUO, T.-L.: VALIDATION OF A RESPIRATOR PERFORMANCE MODEL. APPL. OCCUP. ENVIRON. HYG. 10(10):827–832; 1995.

There are many situations in the field of industrial hygiene for which it is desirable to estimate the actual exposure experienced by a respirator wearer, that is, the concentration or amount of contaminant he or she inhales. Examples of such situations include: (1) good industrial hygiene practice where it is always desirable to know the actual exposure experienced by each worker; (2) epidemiological studies where accurate exposure assessment is needed to establish associations between exposure and the occurrence of symptoms or disease; (3) liability protection; (4) industrial hygiene evaluation as a follow-up to observed occurrence of disease or symptoms; and (5) design and development of improved respirators by respirator manufacturers.

There are many difficulties in measuring or predicting a respirator wearer's actual exposure on the job. The penetration of particles into a respirator is a complex process involving two primary routes of entry: penetration through the filter(s) and facial seal leakage. Unlike gases and vapors, there is always some penetration of aerosol particles through the filters, and it is strongly dependent on particle size and the flow rate through respirator filters. Also, there is some size-dependent particle loss as particle-laden air traverses facial seal leaks, but this loss affects primarily particles greater than a few micrometers. The instantaneous inhalation flow rate controls the pressure difference between ambient pressure and that inside the mask (pressure drop), which in turn controls the leak flow rate for a given facial seal leak situation. This is further complicated by the fact that resistance versus flow rate is linear for filters but is nonlinear for typical leaks, so the proportion of leak flow to total flow changes as instantaneous flow rate changes during a breath.(1) As currently practiced, fit testing only measures facial seal leakage under a specific set of conditions, and consequently is an unreliable predictor of workplace exposure.(2) Additional problems in predicting actual exposures include the fact that the use filters may have different characteristics than the ones used for fit testing, work rate in use may be different from that for fit testing, and the exposure particle size distribution will likely be different from that used for fit testing.

A respirator performance model for aerosols described by Hinds and Bellin(3) takes into account the factors outlined above and predicts the overall performance of a respirator for known or measured environmental and use conditions. This allows one to estimate the concentration or mass of aerosol inhaled by a respirator wearer. Its use requires knowing the concentration and size distribution of the exposure aerosol, the approximate work rate of the wearer (to estimate tidal volume), and the facial seal leakage rate under conditions of use, which is estimated from quantitative fit test (QNFT) measurements. The model uses experimentally determined data for (1) filter performance for the specific brand and type of filter used (penetration versus particle size and flow rate, and resistance versus flow rate), and (2) leak flow rate and leak penetration versus pressure drop. These data are combined to form a database matrix of 98 penetration values [7 flow rates (2 to 150 L/min) and 14 particle sizes (0.14 to 11 μm)] for each type of filter and for facial seal leaks.

The model first calculates the proportion of total inward flow that passes through the filters and through the leaks for each of seven flow rates. Next it calculates the total penetration into the mask (filter penetration plus facial seal leakage) for each of the 7 flow rates and 14 particle sizes. These data are integrated over the instantaneous flow rate for one of six breathing cycles associated with six work rates [sedentary to 140 W (830 kg-m/min)] to get total penetration for each of the 14 particle sizes. Finally, these results are integrated over a lognormal exposure particle size distribution with a specified mass median aerodynamic diameter (MMAD) and geometric standard deviation (GSD) to get total penetration into the mask during inhalation. From these results various respirator protection factors are calculated and then corrected for the effect of respirator dead space on average inhalation concentration based on Hinds and Bellin.(4)

The model can only be used for a respirator with a filter type and brand whose performance has been experimentally evaluated. The model addresses only those factors affecting performance that can be quantified based on the exposure situation. Other factors affecting the performance of an air-purifying respirator not addressed by the model include a different fit during use than for fit testing, a change of fit during use, respirator removal during use, filter loading during use, wearing a respirator with a dirty valve, fit change due to perspiration, a change in exposure size distribution or wearer work rate from that assumed, and mask movement when working in certain positions.

Objectives

This model has proved to be a useful tool for analyzing the performance and limitations of air-purifying respirators for protection against aerosols. Its utility has been demonstrated by showing the relative effect a change in particle size, work rate, or filter type has on respirator performance.(5) Despite the care that went into the experimental measurements and model development, confidence in the model would be enhanced by demonstrating that it correctly predicts protection factors under different use conditions and correctly shows the effect of particle size, fit, and work rate on the protection provided. This requires that the model be validated with human subjects wearing respirators under simulated or actual work conditions. Thus, the primary objective of the work presented here is to make an objective measurement of how well the model can predict actual exposure concentrations (inside the mask) for a person wearing a respirator. A secondary objective is to evaluate what effect, if any, particle size, fit, and work rate have on the accuracy of the model predictions. Measurements of respirator performance under use conditions are intrinsically highly variable measurements and the analysis and confidence limits show the extent to which the model can explain some of this variability.

Experimental

To validate the model, experimental measurements of respirator performance were made with a mannequin and with human subjects. In each case the model was used to predict the respirator performance based on environmental and use conditions.

A test aerosol of oleic acid containing sodium fluorescein dye was used for all tests. It was produced by a constant output atomizer (model 3076; TSI, Inc., St. Paul, Minnesota). Liquid feed was accomplished by a syringe pump operating at 0.34 ml/min. The concentration of oleic acid in an ethanol and water solution and the generator operating pressure (10 and 4 psi, respectively) were set to give two size distributions: a MMAD of 0.65 μm with a GSD of 2.33; and a MMAD of 1.42 μm with a GSD of 2.12. The alcohol and water were allowed to evaporate after aerosol generation by mixing the aerosol stream with 50 L/min of dry air. The aerosol passed through an aerosol neutralizer (model 3054; TSI, Inc.) to remove any static charge.

A fiberglass mannequin with a facial shape in the overlapping region for males and females was modified so that all the inhaled air passed through a 90-mm sample filter after entering the mouth. The respirator, a dual-cartridge half-mask, was glued to the mannequin's face with hot-melt adhesive and sealed with silicone caulking compound. Facial seal leaks were simulated by installing one to five 3.7-mm ID tubes at the facial seal. Leak tightness was verified by blocking off filter cartridges and facial seal leaks and measuring the inward flow rate when the interior of the respirator was maintained at 1″H_2O below ambient. At 1″H_2O the maximum leakage allowed was 36 ml/min. A leak of this size would cause less than 0.02 percent penetration for a respirator with dusts, fumes, and mists (DFM) cartridges at 85 L/min.

Different fit conditions were established by opening from one to five leak paths. In each case, fit was determined in two ways: (1) by blocking the filters and measuring inward air flow rate at a pressure drop associated with average inhalation flow rate, and (2) with a Portacount fit testing apparatus (TSI, Inc.) with the respirator fitted with high efficiency dusts, fumes, mists, asbestos, and radionuclides (DFMR) filters. The former is a direct measurement of leakage flow rate; the latter is a conventional measurement of fit factor. In general, the Portacount indicated a better fit than the air flow measurement method. As explained below, this error was minimized in subsequent tests with human subjects by extending the sample inlet as close as possible to the mouth without touching it. This is consistent with recommendations given in Reference 6. The Portacount also showed more variability but it was used for all analyses because it was the only method available for the human subjects and is a standard method that can be applied to all experiments.

The first set of measurements used DFM filters and six constant air flow rates through the respirator: 2, 5, 10, 20, 50, and 100 L/min. A test aerosol concentration of 25 mg/m^3 was established in a bench top exposure chamber described previously.(7) Glass fiber filter samples of the test aerosol were taken from inside and outside the respirator. The inside sample flow rate was 100 percent of the respirator flow rate as described above and the outside sample flow rate was 2.0 L/min, a condition that meets Davies'(8) criteria for still air sampling. Fractional sample losses due to the volatility of oleic acid (vapor pressure $= 6 \times 10^{-6}$ mmHg at 20°C) were assumed to be the same for inside and outside filter samples.

Filter samples were extracted with gentle agitation for 30 minutes in 0.2 *M* boric acid buffer (pH 9). Extraction efficiency was greater than 90 percent over the range of concentrations encountered in this study. Fluorescence was measured with a Perkin-Elmer model 650 fluorometer (Norwalk, Connecticut) at 515 nm with illumination at 494 nm and a 4-mm slit width. Fluorescence measurements were corrected for nonlinearity at high concentrations by a calibration curve.

The same mannequin setup, but with a different inside sampler arrangement, was used for model validation with a cyclical flow produced by a breathing machine instead of the steady flow described above. The atmosphere inside the mask was sampled with a through-mask fitting described by Liu *et al.*(9) at 2 L/min. The breathing machine, a cam-driven piston type, operated at breathing cycles associated with work rates of

0 and 70 W (0 and 415 kg-m/min). Both the inside and outside samplers sampled only during inhalation.

Human Subjects

The primary validation tests were experimental measurements with human subjects. Subjects were paid volunteers and graduate students. Sixteen subjects were tested, 7 males and 9 females. All subjects passed a medical screening examination before testing and signed a consent form.

Each subject participated in two 3-hour sessions, each conducted on a separate day. Each subject wore a dual-cartridge half-mask respirator fitted with DFM cartridges (assigned protection factor = 10). Each session used a different aerosol size distribution. For each 3-hour session four tests were run, two work rates for each of two fit conditions. Work rates were 0 and 50 W. Fit conditions were loose (median fit factor 37) and snug (median fit factor 68) as measured by the Portacount instrument with the modified through-mask fitting. The fit condition and work rate for the initial test on a given day were randomized.

All human subject tests were conducted using a nylon tent exposure chamber, model 223 manufactured by Dynatech Nevada Inc. (Carson City, Nevada) for QNFT. The tent measured 1.2 by 1.2 m at the base and was 2.3 m high. It had a nylon door on one side and windows on the other three sides. Test aerosol entered through a flow distributor at the top and exited at the bottom. The air flow circulating fan for a Dynatech Nevada model 264 QNFT apparatus was used to circulate the test aerosol through the tent at approximately 140 L/min. Because approximately 60 L/min of test aerosol was added to the input stream, an identical amount was removed from the exit stream to prevent overinflation of the tent. The tent was modified with ports to allow vacuum and pressure sensor lines to penetrate the tent. Sample flow rates and inhalation-only sampling were controlled external to the tent.

Before and after each test a quantitative fit test was conducted using the Portacount quantitative fit tester. The subject stood outside the exposure tent. Filters were carefully replaced with high efficiency filters and a 30 second per exercise sequence was followed. The arithmetic average of two fit tests, one before and one after each validation test, was used to characterize the fit during the test and as an input to the model.

Experimental measurements of respirator performance were made for subjects working at two work rates, 0 and 50 W. A Monark exercise bicycle ergonometer model 815E (Performance USA, Dallas, Texas) was placed inside the exposure tent. The power output scale was calibrated following the manufacturer's instructions. For all tests the subject sat on the bicycle seat, not pedaling for the 0-W work rate condition, and pedaling at 60 rpm against a preset resistance for the 50-W work rate condition.

The particle size distribution of the test aerosol was measured with an eight-stage cascade impactor (model 218; Sierra Instruments, Carmel Valley, California) located inside the exposure tent for each set of four runs at a given aerosol size distribution. A composite sample was taken by sampling for 5 minutes during each run. Concentration in the exposure tent was monitored continuously with a photometer (RAM-1; MIE, Inc., Billerica, Massachusetts) located outside the tent. A reading was recorded every minute to provide a record of tent concentration during each validation test.

Respirator performance was evaluated by taking simultaneous samples inside and outside the respirator at approximately 10 L/min. Both samples were taken only during the inhalation portion of the breathing cycle. A second fitting on the respirator was connected to a Photohelic pressure switch (Dwyer Instruments, Inc., Michigan City, Indiana) mounted outside the exposure tent. The switch with appropriate circuitry and solenoid valves was set to start sampling when the negative pressure in the mask reached 0.005 "H_2O below ambient and to stop sampling when the pressure in the mask returned to -0.095 "H_2O (-0.135 "H_2O when pedaling). The sample shut-off pressure was more negative than the sample start pressure, because the additional 10 L/min of sample air created a negative pressure even when the subject had ceased inhaling. Samples were collected on 25-mm diameter glass fiber filters. Filters were extracted and analyzed by fluorometry as described above.

The inside sample probe was a modified version of that described by Liu *et al.*[9] It used the same inlet geometry, but spacers were used to extend the probe as close to the mouth as possible to conform with recommendations given in Reference 6. Preliminary tests with the mannequin and a mask with facial seal leaks showed that this arrangement with the Portacount gave the closest agreement to direct measurement of fit based on leakage flow rate. The outside sample was taken with a 25-mm open-face filter holder. This setup met Davies'[8] criteria for still air sampling for particles up to 10 μm.

Model

Some modifications to the model were made to accommodate the special conditions of the experimental measurements. As explained in the experimental section, the two work rates used were 0 and 50 W. The breathing conditions for 50 W were estimated by linear interpolation between data for work rates of 35 and 70 W (208 and 415 kg-m/min).[10]

During the experiments inside (and outside) concentrations were sampled at approximately 10 L/min only during inhalation. This means an extra 10 L/min entered the respirator, through the respirator filters and facial seal leaks, during each inhalation. Consequently an extra 10 L/min was added in the model to each of the 16 instantaneous flow rates that characterize the inhalation breath profile. This permits the model to reflect the actual respirator operating conditions used during the test.

Dead space correction was included for the particular conditions used in the experiments. Dead space volume of 270 ml was measured for this type of half-mask.[4] Average breathing volumes for the two work rates were determined from Silverman *et al.*[10] The dead space correction factor corrects the model estimate of average inhaled concentration for the effect of residual exhaled air (with lower aerosol concentration due to lung deposition) in the mask during the sampling period. Correction factors were calculated using the stepwise procedure described in Reference 4. Explicit polynomial equations were determined for the specific conditions of the two work rates used. Correction factors ranged from 0.94 to 1.21 with a median value of 1.03. Correction factors can be slightly less than one for certain conditions, low fractional deposition and

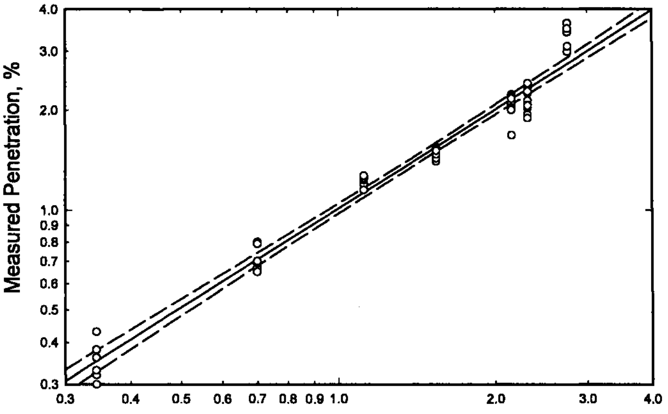

FIGURE 1. Measured penetration versus model-predicted penetration for steady flow conditions with mannequin.

poor-fitting respirators, due to the assumption of streaming leak flow used in the correction factor calculations.[4]

Results

Mannequin

A log–log graph of measured penetration versus model-predicted penetration for the steady flow tests with the mannequin is shown in Figure 1. The six steady flow rates range from 2 to 100 L/min. The measured and model results are well correlated with correlation coefficient $r = 0.98$ ($p < 0.001$). A Mann–Whitney rank sum test indicated that there is no statistically significant difference between measured penetration and model-predicted penetration ($p = 0.531$). The vertical spread of values shown in Figure 1 indicates the range of measurement error.

Figure 2 shows mannequin results for cyclical breathing with four leak conditions, fit factors ranging from 43 to >5000. The two breathing cycles used correspond to work rates of 0 and 70 W (0 and 415 kg-m/min). Measured penetration values are arithmetic averages of three replications. The trend of model-predicted penetration and measured penetration agree reasonably well, with a correlation coefficient of 0.88 ($p = 0.004$). A *t*-test indicated that there was no statistically significant difference between measured penetration and model-predicted penetration. The increased variability compared with Figure 1 reflects multiple leak locations with variable sampling errors and inhalation-only sampling conditions.

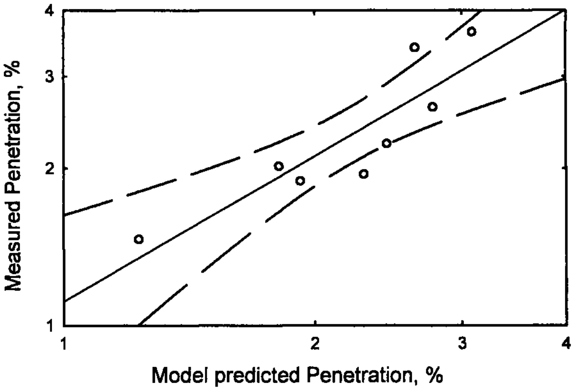

FIGURE 2. Measured penetration versus model-predicted penetration for machine breathing with mannequin.

TABLE 1. Mean and Standard Deviation for Measured and Model-Predicted Penetration for Human Subject Validation Tests

	Work Rate = 0 W		Work Rate = 50 W	
MMAD	Measured	Predicted	Measured	Predicted
0.65 μm	3.41 (1.67)	4.32 (1.83)	4.55 (2.00)	4.40 (1.29)
1.42 μm	2.21 (1.45)	2.65 (2.27)	2.82 (1.56)	2.36 (1.33)

Human Subjects

Sixteen human subjects completed the full set of eight tests, two fit conditions (loose and snug), two work rates (0 and 50 W), and two particle size distributions (MMAD 0.65 and 1.42 μm). Measured fit factors ranged from 5 to 231. Higher fit factors were avoided because of limitations on analytical sensitivity. This gave a total of 128 measurements over a wide range of conditions with which to evaluate the model. After the first eight subjects were tested, a potential biasing effect was discovered that caused an increase in facial seal leakage for some subjects during testing relative to leakage measured during fit testing. The tachometer on the bicycle ergometer was located on the handlebars. During exercise the subject had to monitor the tachometer constantly by leaning forward and looking down. In this position the weight of the mask and the tubes, especially for loose fits, is believed to have increased leakage during the validation tests compared with standing upright when the fit tests were conducted. For the second group of eight subjects very loose fits were avoided and careful monitoring for this situation reduced this bias. Thus, only the second group of eight subjects, 64 measurements, represents unbiased results and was used in the analysis below.

Table 1 gives the mean and standard deviation of the measured and model-predicted penetration for each of the four combinations of work rate and particle size. Penetration is used instead of protection factor throughout the analysis because of the potential calculation bias described by Brown.[11] Protection factor is the reciprocal of fractional penetration.

Figure 3 compares measured and model-predicted penetration for the 64 data points on a log–log graph. The Pearson product moment correlation coefficient for measured and model-predicted penetration was 0.76 ($p < 0.001$). A correlation coefficient of 0.76 means that 58 percent of the observed variation in penetration can be attributed to the model and the rest is due to the random nature of respirator performance and its measurement. The regression line, its 95 percent confidence interval, and the 95 percent confidence interval for the population are shown in Figure 3. The latter gives the range for which one can be 95 percent confident that the measured (or true) penetration will lie within (approximately −56 to +129 percent of the regression line) for a given model-predicted penetration.

A Spearman rank order correlation between the ratio, model-predicted penetration to measured penetration, and fit factor

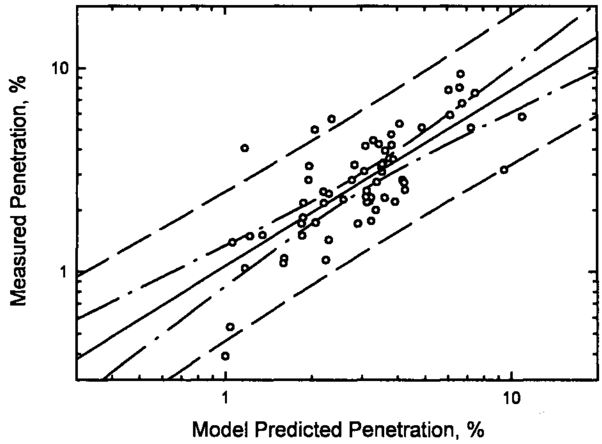

FIGURE 3. Measured penetration versus model-predicted penetration for human subjects.

gave a correlation coefficient that did not exceed ± 0.10, indicating that the ability of the model to predict penetration is not influenced by the magnitude of the value for fit factor. Similar correlations between this ratio and the value of particle size distribution (MMAD) and work rate also gave correlation coefficients of <0.1, indicating that the ability of the model to predict penetration is not influenced by the magnitude of the value for MMAD or work rate.

A check of the correlation between the ratio (predicted to measured penetration) to measured penetration gave a correlation coefficient of $r = -0.43$ ($p < 0.001$), indicating a slight tendency for the model to underpredict penetration for very poorly fitting respirators, especially for penetration greater than 10 percent (protection factor < 10). This is probably due to a relationship between leak flow rate and pressure drop for very large facial seal leaks that differs from that for the average leak condition used in the model.(1,3)

A check of the relationship between $(\text{fit factor})^{-1}$ and measured penetration gave a Spearman rank order correlation coefficient $r = 0.41$ ($p < 0.005$), indicating a weak relationship between $(\text{fit factor})^{-1}$ and actual penetration (or protection factor). This is consistent with previous work that found that fit factor is not a good predictor of workplace protection factor.(2) Brown(11) and Hinds and Bellin(3) discuss the limitation of the use of fit factors for estimating protection factors. The use of the fit factor combined with the predictive model evaluated here significantly increases one's ability to predict protection compared with using the fit factor alone ($r = 0.76$ versus $r = 0.41$ for the conditions of these tests).

A *t*-test was conducted to compare log-measured to log-predicted penetration. The null hypothesis is that the two means are equal. Results indicate that we cannot reject the null hypothesis and that there is no statistically significant difference between the measured and model-predicted penetration ($p = 0.49$).

Similar tests comparing the mean of the ratio of ln(model-predicted penetration) to ln(measured penetration) for the two size distributions used indicated that there is no significant difference between the means ($p = 0.44$). The same result was obtained for the two levels of fit and for the two work rates ($p = 0.86$ in both cases). Thus, we conclude that there is no statistically significant difference in the model's ability to predict respirator performance at the different values of size distribution, fit, and work rate used.

Discussion

Fluorescence for the outside samples was much greater than that for the inside samples; consequently, outside samples were diluted to a suitable concentration range. Any remaining nonlinearity was corrected with a calibration curve. After this correction the remaining systematic errors are estimated to be <5 percent for extraction, dilution, and measurement.

The aerosol size distributions, as measured by the cascade impactor, showed significant variability (MMADs ranged from -26 to $+50\%$ of the mean) for aerosols produced under the same conditions. The measured size distributions were used as model inputs to calculate the predicted performance results given here. A supplemental exercise was conducted to determine what effect, if any, these differences would have on the validation if they represented measurement error rather than differences in size distribution. The model was run for all subjects using only the average size distribution for the large- and small-sized aerosols. The mean difference between the two approaches was 0.5 percent, indicating that whether or not measurement error occurred it would have little effect on the validation.

Sampling bias error, due to flow rate error or sampler location within the tent, is believed to be less than ± 5 percent based on mannequin studies.

A systematic error could have been introduced by the inhalation-only sampling system. Although both samplers sampled at the same time, there was a slight delay in starting sampling after inhalation started. The model assumed that the full sample flow started the instant inhalation started. This delay would cause the measurement to be conducted during a period with a slightly greater average inhalation flow rate than the model calculation. This effect is unlikely to cause an error of more than a few percent in the model-predicted penetration.

The fit test measurement in itself can be biased and show significant variability. Myers *et al.*(12) and Crutchfield *et al.*(13) discuss variability and measurement errors for aerosol QNFT methods, and daRoza *et al.*(14) and Oestenstad and Graffeo(15) for the CNC (Portacount) QNFT method. Based on our mannequin studies, we think the Portacount, using the extended inlet sampler, may be biased to overpredict the true fit factor by up to 30 percent for our setup. The authors cited above found much larger differences between Portacount, negative pressure, and aerosol QNFT methods, with Portacount measurements of fit factor 2 to 20 times greater than the other methods. These errors are large compared with the differences between measured and predicted penetration found here.

It should be noted that these validation tests were conducted under carefully controlled conditions that are unlikely to be duplicated in actual use situations. The predictive model used filter performance data for the actual filter pair used in the test. This eliminated a source of variability, namely, the variability in filter performance associated with different filters of the same type and manufacturer. Thus, the correlation results presented here reflect model performance under favorable conditions of input data accuracy and precision.

The variability of model-predicted penetration can be put in perspective by noting the results of a study of intrasubject variability for laboratory measurement of respirator performance.(16) This study found a median GSD for fit factors for repeated donning of a half-mask respirator by an individual to be 2.5. This suggests that 95 percent of fit factors for a particular mask and face combination will be within a factor of six of the median fit factor. Part of this variability is probably due to sampling bias caused by the streaming effect described by Myers *et al.*(12) The portion of the variability of our measurements not explained by the predictive model is small compared with this reported intrasubject variability. As stated in the introduction, variability of fit with repeated wearings is one aspect of respirator performance variability that is not addressed by the predictive model.

Conclusions

Based on tests conducted here, the predictive model does a reasonable job of predicting respirator penetration under simulated use conditions where fit factor, particle size distribution, work rate, and filter efficiency are known. It is able to account for 58 percent of variability in measured penetration under the conditions of these tests: fit factors from 5 to 231, MMAD from 0.6 to 1.3 μm, and work rates from 0 to 50 W. The model adequately accounts for the effect of QNFT-determined fit factor, work rate (breathing pattern), and particle size distribution, and shows no bias with the magnitude of these parameters. Given the intrinsic variability of respirator performance measurements, the model is useful for predicting the effect on respirator performance of the variables it can model.

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