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Effect of Fit Testing on the Protection Offered by N95 Filtering Facepiece Respirators Against Fine Particles in a Laboratory Setting

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Objectives: This study investigated particle-size-selective protection factors (PFs) of four models of N95 filtering facepiece respirators (FFRs) that passed and failed fit testing. Particle size ranges were representative of individual viruses and bacteria (aerodynamic diameter d_a = 0.04–1.3 μm).

Methods: Standard respirator fit testing was followed by particle-size-selective measurement of PFs while subjects wore N95 FFRs in a test chamber. PF values obtained for all subjects were then compared to those obtained for the subjects who passed the fit testing.

Results: Overall fit test passing rate for all four models of FFRs was 67%. Of these, 29% had PFs <10 (the Occupational Safety and Health Administration Assigned Protection Factor designated for this type of respirator). When only subjects that passed fit testing were included, PFs improved with 9% having values <10. On average, the PFs were 1.4 times (29.5/21.5) higher when only data for those who passed fit testing were included. The minimum PFs were consistently observed in the particle size range of 0.08–0.2 μm.

Conclusions: Overall PFs increased when subjects passed fit testing. The results support the value of fit testing but also show for the first time that PFs are dependent on particle size regardless of fit testing status.

Keywords: bioaerosols; fine particles; fit test; nanoparticles; N95; protection factor; respiratory protection

INTRODUCTION

There is increased interest in the performance of respirators against fine particles such as nanoparticles (natural and engineered) and bioaerosol particles (e.g. viruses and bacteria). Although the effect of particle size on the performance of respirators has been studied in the laboratory using manikins (Hinds and Kraske, 1987; Chen and Willeke, 1990; Chen *et al.*, 1990; Weber *et al.*, 1993; Lee *et al.*, 2005b; Cho *et al.*, 2010), only a few studies have been conducted with human subjects (Holton *et al.*, 1987; Lee *et al.*, 2008; Grinshpun *et al.*, 2009). Even fewer have featured particle-size-selective measurements with human subjects in the field, i.e. determined size-selective workplace protection factors (WPFs). Lee *et al.* (2005a) investigated the effect of particle size on WPFs by simultaneously measuring the concentration and size distribution of particles inside and outside of a filtering facepiece respirator (FFR). The authors demonstrated that WPFs decreased with decreasing particle size within the size range of 0.8–10 μm.

More recently, Lee *et al.* (2008) modified the equipment used in the above-quoted field study to size selectively count smaller particles, down to 0.04 μm in aerodynamic diameter. In the latter investigation, sodium chloride particles representative of

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size ranges of individual viruses and bacteria (aerodynamic diameter: 0.04–1.3 μm) were counted inside and outside N95 FFRs and surgical masks worn in a laboratory setting. The ratio of the number of particles outside to the number of particles inside was referred to as a 'protection factor' (PF). The generic term 'protection factor' was used to distinguish between other specific types of PFs that are strictly defined, e.g. assigned protection factor (APF), simulated workplace protection factor (SWPF), and WPF.

The subjects in the study of Lee *et al.* (2008) were quantitatively fit tested prior to laboratory determination of PFs. The majority, but not all, of subject–respirator combinations passed fit testing (fit factor >100). At the same time, poor fitting subject–respirator combinations were not removed from analyses because the overall study design also included evaluation of surgical masks, which are not routinely fit tested prior to use. This is why the term PF was used rather than SWPF. About 29% of all tested respirators had PFs <10 [this threshold is numerically equal to the APF designated by the US Occupational Safety and Health Administration (OSHA) for negative pressure air purifying half mask respirators]. The lowest PFs for the FFRs used in this study were obtained for particles ranging from 0.08 to 0.2 μm (Lee *et al.*, 2008). PFs would of course vary with the type of respirator selected, fitting characteristics, and other factors. The OSHA APF of 10 only applies when respirators are used in conjunction with a respiratory protection program that meets all the requirements of the OSHA respiratory protection standard, including fit testing. However, existing data on the association between PFs and corresponding fit testing results are contradictory (Dixon and Nelson, 1984; Myers *et al.*, 1984; Gaboury *et al.*, 1993; Zhuang *et al.*, 1996; Duling *et al.*, 2007).

Because the paper of Lee *et al.* (2008) appears to be the only one to report particle-size-selective PFs for fine particles in human subjects, it is of special interest to examine how passing a fit test affects the subsequent PFs. Herein, we report additional analyses for a subset of the data which includes only subject–respirator combinations that passed fit testing with four different models of N95 FFRs. Results are then compared to the previous analysis that included all subject–respirator combinations (i.e. those which passed and failed fit testing).

MATERIALS AND METHODS

Materials and methods have been described in detail before (Lee *et al.*, 2008). In brief, four models (A, B, C, and D) of N95 FFRs were investigated. Respirator models A, B, and C were tested with 12 human subjects. Respirator D was tested with only three subjects because it was essentially the same as Respirator C, except it had an exhalation valve. Each subject was trained to wear the tested respirator using the manufacturer's instruction followed by guidance from a trainer. The subject was then fit tested. During the fit testing, subjects performed the OSHA fit testing exercises: normal breathing, deep breathing, turning head side to side, moving head up and down, talking, grimace, bending over, and returning to normal breathing (US Department of Labor, 1998). Particle number concentration was measured inside and outside the respirator using a PortaCount® Plus with an N95-Companion (TSI Inc., St. Paul, MN, USA). The overall fit factor is calculated as follows:

$$\mathrm{FF} = \frac{\text{Number of excercises}}{\frac{1}{\mathrm{ff}_1} + \frac{1}{\mathrm{ff}_2} + \frac{1}{\mathrm{ff}_3} + \frac{1}{\mathrm{ff}_4} + \frac{1}{\mathrm{ff}_5} + \frac{1}{\mathrm{ff}_6} + \frac{1}{\mathrm{ff}_7} + \frac{1}{\mathrm{ff}_8}},$$

where ff_1, ff_2, ff_3, etc. are the fit factors for Exercises 1, 2, 3, etc [grimace (Exercise 6) is excluded].

In order to have sufficient and stable aerosol concentrations, fit testing and PF evaluation for N95 FFRs were conducted in a walk-in laboratory test chamber filled with sodium chloride aerosols as the challenge agent. Sodium chloride solution (NaCl, 1%, w/v) was continuously aerosolized in the chamber by a six-hole Collison nebulizer (BGI Inc., Waltham, MA, USA) at a flow rate of 12 l min^{-1}. Dry air was mixed with NaCl aerosol at a flow rate of 40 l min^{-1}. As laboratory-generated particles may carry high electrical charges, the entire airflow of 52 l min^{-1} was directed through a 10-mCi 85Kr charge equilibrator (Model 3054; TSI, Inc.) to achieve the Boltzmann charge equilibrium. An air circulation fan located at the outlet of the aerosol generation system distributed the aerosolized particles within the chamber. The concentration of NaCl in the test chamber ranged from 3.3×10^6 to 4.0×10^7 particles l^{-1} for particles in the size range of 0.04–1.26 μm. The corresponding aerosol concentrations inside the respirator varied by subject and respirator model and were above 1.2×10^5 particles l^{-1}.

Subjects performed exercises similar to those used during fit testing. An electrical low-pressure impactor (ELPI 3935 series; Dekati Ltd., Tampere, Finland) was used to size selectively count particles inside and outside the respirator. The eight lowest channels with geometric mean diameters of 0.0414, 0.078, 0.1304, 0.2047, 0.3155, 0.4993, 0.7935, and 1.2625 μm were utilized to represent the size of most single viruses and bacteria. The most penetrating particle sizes of filters used in presently

available N95 FFRs fall into the size range represented by the above channels. This process was repeated twice more with an identical unused respirator for a total of three replicates. Fit testing was only performed prior to the first test.

The data analysis was conducted using Statistical Analysis System (SAS) version 8.0 (SAS Institute Inc., Cary, NC, USA) software. PFs were log-transformed before analyses and P-values <0.05 were considered significant. The difference in the PFs among different particle sizes was examined with the analysis of variance (ANOVA) followed by a pair-wise comparison using the Tukey's studentized range test.

In order to demonstrate the potential effect of respiratory deposition of particles and respirator dead space, the data obtained for Respirator A were also corrected for these factors as described previously (Hinds and Bellin 1993; Lee *et al.*, 2005a). In brief, the particle concentration measured inside the respirator was corrected by taking into account respirator dead space volume, tidal volume, and fractional deposition of particles in the respiratory tract.

RESULTS

All subjects passed fit testing with Respirator A (100% pass rate), 11 of 12 subjects (92%) passed fit testing with Respirator C, and 2 of 3 subjects (67%) passed with Respirator D. In contrast, only 1 of 12 subjects (8%) passed fit testing with Respirator B. The overall passing rate for fit testing of all four model N95 FFRs was 67%.

Figure 1 presents the size-selective PFs for subject–respirator combinations that passed fit testing. The difference in the PFs among different particle sizes was statistically significant (ANOVA: $P < 0.001$) for all respirators except for Respirator B. The pair-wise comparison for Respirators A, C, and D showed that the PFs in the particle size range of $d_a = 0.08$–0.2 μm were consistently lower than those in the range of 0.8–1.3 μm (the two largest particle sizes included in the analysis). Thus, the lowest respirator performance provided by N95 respirators occurred approximately between 0.08 and 0.2 μm. The earlier reported findings on the effect of particle size obtained by analyzing the entire data set (passed and failed fit testing) (Lee *et al.*, 2008) remain essentially unchanged. The effect of particle size for Respirator B was significant when all subjects were included (Lee *et al.*, 2008) but lost statistical significance after subjects that did not pass fit testing were excluded. The small number of data points ($n = 3$) is the most likely reason for the lack of significance.

The geometric mean (GM) of the PFs calculated over the entire tested particle size range for the subset of data that passed fit testing was 24.0 for Respirator A, 21.8 for Respirator B, 34.9 for Respirator C, 41.7 for Respirator D, and 29.5 for all four models combined. The respective GMs for the data set that included all subject–respirator combinations regardless of fit testing results were 24.0, 10.3, 32.5, 27.3, and 21.5 (Lee *et al.*, 2008). Thus, on average, the PFs were 1.4 times (29.5/21.5) higher when only data for those who passed fit testing were included in the analysis. The GM of the PFs calculated for Respirator C (without exhalation valve) was 45.2 when the two subjects who passed the fit testing with Respirator D (with exhalation valve; PF = 41.7) were included, and the difference between Respirators C and D was not statistically significant (paired t-test: $P > 0.05$).

Tables 1 and 2 show the percentage of subject–respirator combinations which had PFs below 5, 10, 25, and 50 for the particle sizes tested. Twenty-nine percent of the subject–respirator combinations had PFs <10 when all subjects were included (Table 1). When only subjects who passed fit testing were analyzed, the 'below 10' fraction decreased to 9% (Table 2). The most drastic difference between the two data sets was observed for Respirator B, which had the highest fit testing failing rate (92% of 36 subject–respirator combinations failed). In both cases, all the respirator–subject combinations had at least one particle size for which the PF was <50. Except for the largest particles ($d_a = 1.3$ μm), the particle size-selective data showed that $>95\%$ of the data points were <100, which is the pass–fail criteria for the quantitative fit testing (Fig. 1).

Figure 2 shows the effect of respiratory deposition and respirator dead space on PFs using Respirator A as an example. For all particles sizes, the PFs decreased after correcting the sample inside the respirator for lung deposition and respirator dead space.

DISCUSSION

Fit testing is required by the OSHA, but not all workplaces are in compliance (US Department of Labor, Bureau of Labor Statistics, 2003). Members of the general public who wear respirators are also not normally fit tested prior to use. Furthermore, a National Institute of Occupational Safety and Health survey found that ~43% of employers did not comply with the OSHA annual fit testing requirement (Doney *et al.*, 2005).

An important finding of this study is that the PFs increased when subjects who did not pass fit testing

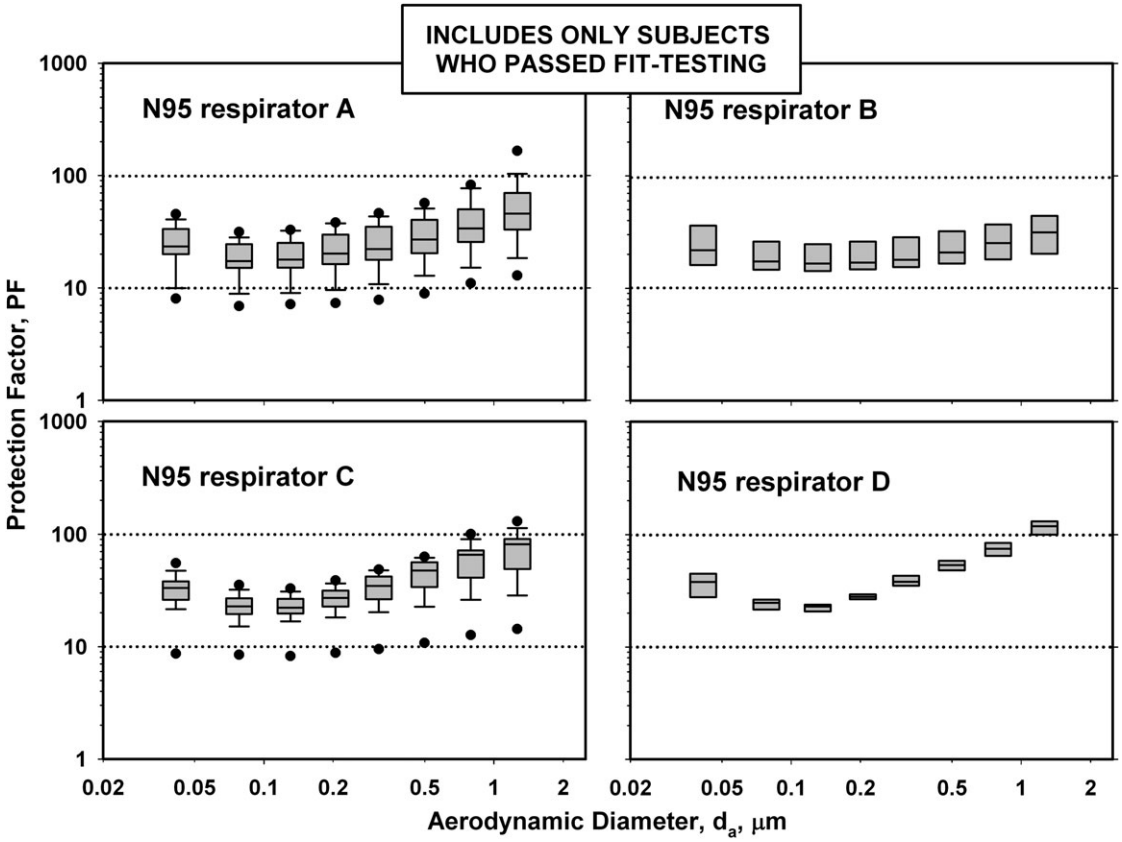

Fig. 1. PF values against particles representing bacterial and viral size ranges for four models of N95 FFRs: A, B, C, and D. The tests were performed when the N95 respirators were donned on human subjects. Data include only subject–respirator combinations that passed quantitative fit testing (data for all subjects are published in Lee *et al.*, 2008). Number of observations are as follows: 36 for Model A, 3 for Model B, 33 for Model C, and 6 for Model D. The box plots show the following: dots (from bottom) represent 5% and 95% percentiles; horizontal lines (from bottom) represent 10, 25, 50, 75, and 90% percentiles (some percentile values could not be calculated for Respirators B and D due to small number of data points). The dotted horizontal lines illustrate PF = 10 which is the OSHA APF for FFRs and PF = 100 which is the criterion for passing quantitative fit testing.

were excluded from the analysis. While the overall improvement in PF may appear small in this study, it is highly dependent upon the fitting characteristics of the respirators selected for study. Only 8% of subjects passed the fit testing with Respirator B, which may be due to the design of this respirator. If we had intentionally selected a greater number of respirators with poor fitting characteristics, we expect that the overall improvement in PF between respirators that passed and failed fit testing would have been higher.

Several previous studies have failed to show correlation between fit factors and WPFs (e.g. Dixon and Nelson, 1984; Myers *et al.*, 1984; Gaboury *et al.*, 1993; Zhuang *et al.*, 1996). In contrast, Zhuang *et al.* (2003) demonstrated a mixed correlation between fit factors and PFs when studying performance of two respirator models worn by 15 burners and welders at a steel foundry (correlation coefficients 0.71 and 0.32). In the quoted study, the PF was assessed by measuring the mass concentration of iron inside and outside the respirator. Correlations coefficient was 0.71 when all subjects were included in the analysis but decreased to 0.32 when subjects who failed the fit testing were excluded. Recently, Duling *et al.* (2007) measured SWPFs of half-facepiece respiratory protection devices using a PortaCount® Plus. They found that when all subjects (n = 25) were included, regardless of passing a fit test, 14% had SWPFs <10. When only subjects who passed quantitative fit testing using a PortaCount® Plus with an N95-Companion were included, none showed SWPFs <10. It is noted that even though in the latter case all subjects had a fit factor of at least

Table 1. Percentage of data points below certain PF (all data included)[a]

PF	Percentage of respirators below the PF				
	Respirator A (n = 36)	Respirator B (n = 36)	Respirator C (n = 36)	Respirator D (n = 9)	All respirators (n = 117)
5	0	16.7	0	0	5.1
10	13.9	63.9	11.1	22.2	29.0
25	77.8	97.2	63.9	66.7	78.6
50	100	100	100	100	100

[a]The data show the percentage of subject–respirator combinations that had at least one size-selective data point below certain PF within the entire particle size range studied (data from Lee *et al.*, 2008).

Table 2. Percentage of data points below certain PF[a] (includes only those subject–respirator combinations that passed fit testing)

PF	Percentage of respirators below the PF				
	Respirator A (n = 36)	Respirator B (n = 3)	Respirator C (n = 33)	Respirator D (n = 6)	All respirators (n = 78)
5	0	0	0	0	0
10	13.9	0	6.1	0	9.0
25	77.8	66.7	60.6	50.0	67.9
50	100	100	100	100	100

[a]The data show the percentage of subject–respirator combinations that had at least one size-selective data point below certain PF within the entire particle size range studied.

100, the fifth percentile of SWPFs was 20.5, i.e. 5% of the data points of SWPFs were <20.5 (Duling *et al.*, 2007). Similarly, we observed PFs <100 even for subjects who passed fit testing (fit factor > 100). This is intriguing given that the same exercises were used during fit testing and during studies of PFs and may be explained by the differences in particle charge and size measured with the different instruments. PortaCount® Plus with an N95-Companion measures only negatively charged particles at a nominal particle size of 55 nm (deAzevedo, 2010), whereas the ELPI and PortaCount® Plus (without the N95-Companion) measure all particles and include a wider particle size range. Although different methods (size and non-size-selective measurement) were used to investigate PF results in our study and Duling's study, both led to similar findings. To our knowledge, the associations between fit factor and size-selective PFs in the workplace have not been established for any type of respirator.

The novelty of our measurement method is that it counts particles of different specific sizes inside and outside of respirators worn by human subjects. The additional analysis offered in this paper suggests that particle size differences in PFs persisted even when subjects not passing a fit test were excluded. Exception was the PF of Respirator B, for which the effect of particle size lost statistical significance after subjects who did not pass fit testing were excluded. This may be due to small number of data points as only one subject passed the fit testing with Respirator B. The significance of this in the workplace is unknown, as it would depend on the size of aerosol present and the importance of exposure to individual particles versus exposure by other metrics such as mass. The particles in this study included those expected to be in the most penetrating particle size for the respirator filters involved and therefore might be considered 'worst case' for the filter penetration.

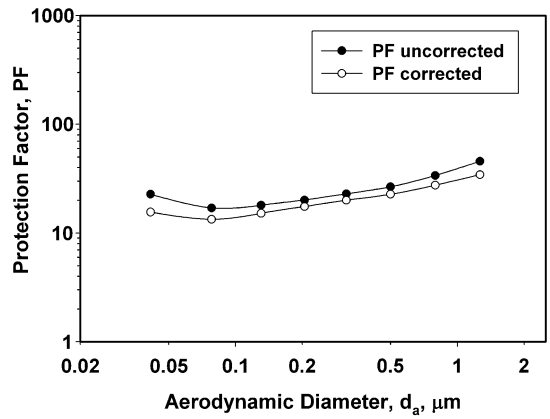

Fig. 2. Differences in PF data before and after correcting for respiratory deposition of particles and respirator dead space for Respirator A.

Our data show that the tested size range may also include the most penetrating particle size for the total inward leakage. Thus, in workplace environments containing particles that are smaller or larger than this most penetrating particle size, the PFs would be expected to be higher.

These findings support the results of previous laboratory studies conducted with fixed leaks and medium to high flow rates that showed the particle-size dependency of total inward leakage (penetration both through filter and through fixed leaks) (Hinds and Kraske, 1987; Holton *et al.*, 1987; Myers *et al.*, 1991; Chen and Willeke, 1992; Weber *et al.*, 1993). Similar findings were reported in a study of measuring WPFs with human subjects without induced fixed leaks (Lee *et al.*, 2005a). In addition, a recent laboratory-based investigation conducted with human subjects (Grinshpun *et al.*, 2009) confirms the particle size effect on PFs. However, at lower flow rates (5–12 l min^{-1} constant flow), total inward leakage was shown to be less dependent on particle size (Chen and Willeke, 1992; Jenum, 1995).

In human subjects, it is commonly assumed that the leak area is constantly changing during breathing and head/body movement, which limits the applicability of studies done with fixed leaks. Several papers (Myers *et al.*, 1996; Janssen *et al.*, 2007a,b) have qualitatively shown that large particles (5–20 μm) may enter the respirator during use, but the percent penetration of these larger particles was not quantitatively determined. In addition, several studies measuring WPFs have shown no correlation between WPFs and particle sizes Runge, 2006. These studies, however, were not designed to measure WPFs as a function of particle size but instead generated a few samples (e.g. using cascade impactors) to nominally characterize the (often wide) size distribution of aerosol particles in the workplace. Therefore, it is difficult to compare the results of the quoted reports to the present study.

At certain particle sizes, our measured laboratory-based PFs were lower than the WPFs for half-facepiece respirators reported by others (Nelson, 1995; US Department of Labor, Occupational Safety and Health Administration, 2006) and the OSHA APF of 10 for half-mask respirators. This may be a result of the respirators used in the various studies, the fitting characteristics of the respirators, the size distribution of particles in the ambient air, breathing rate of the wearer, method of measurement, training and motivation of the subject, and statistical treatment of the data. We will comment briefly on the method of measurement used in this study and the size distribution of biological aerosols.

The human subject may bias the inside particle count either higher or lower and change the size distribution. It is known that people generate particles of various sizes when breathing, speaking, coughing, etc. (Fairchild and Stampfer, 1987; Edwards *et al.*, 2007; Morawska *et al.*, 2009). However, based on these references, the number of particles generated by the subject would be expected to be minimal compared to the large numbers of particles in the chamber and—consequently—the number of particles entering the facepiece from either filter penetration or face seal leakage. Moreover, none of the subjects in this study were identified as smokers. Therefore, no measurements were made of background particle levels inside the respirator in order to subtract these particle counts from the inside samples. Conversely, as shown in the calculation with Respirator A, the inside sample may be biased low due to respiratory deposition. The size distribution inside the respirator may change due to the growth of particles in humid exhaled air. A dehumidifier was used to minimize this effect (Lee *et al.*, 2005b).

The sampling method may also bias the particle counts either higher or lower. To compensate for this, correction factors were applied for particle losses in the sampling lines. An in-facepiece sampling flow (10 l min^{-1}) was chosen to decrease the respirator purge time, to reduce potential sampling bias for non-homogenous distributions of the particle concentration inside the respirator, and to decrease the detection limit (Lee *et al.*, 2004). The latter is important for evaluating the respirator performance against aerosol hazards presented at low concentration levels. Johnston *et al.* (1992) noted that sampling rates of 1–2 l min^{-1} have been used in many workplace studies to avoid significant pressure changes inside facepieces. Our higher sampling rate may affect the particle penetration through both the filter media and the face seal leakage. In another study, we observed that increasing mean inspiratory flow from 16 l min^{-1} (during normal breathing) to 28 l min^{-1} (deep breathing) resulted in a small decrease in PF (<20%). The decrease was equal for all particle sizes between 0.04 and 1.3 μm (raw data from Grinshpun *et al.*, 2009). These data suggest that the particle size differences in PFs reported here would be unaffected, but inside particle counts may be slightly overestimated. Other factors may have contributed to the slightly increased penetration observed at the higher breathing rate. For example, the deep breathing maneuver may have had some influence on the face seal fit.

The current study reports data for the particle size range of 0.04–1.3 μm. As noted previously, this is

approximately the size range of individual viruses or bacteria, but these organisms may also be present in groups or carried on larger particles. There is much debate in the literature regarding the size of aerosolized particles that may cause viral infection (Roy and Milton, 2004; Tellier, 2006). Infection may also be caused by particles larger than those tested in this study (e.g. droplets). Blachere *et al.* (2009) and Lindsley *et al.* (2010) studied airborne influenza virus concentrations using size-selective samplers and found that ~50% of airborne influenza A-containing particles are in the size range <4 μm. They did not investigate the viability and infectivity of collected virions. Nevertheless, their data show for the first time the existence of airborne virus particles in the submicrometer size range.

CONCLUSIONS

The following can be concluded from the data set including all subjects as well as from the data set excluding subjects who did not pass fit testing: (i) minimum PFs were in the size range of 0.08–0.2 μm and (ii) some data points of PFs were <10. However, the fraction of data points that fell <10 decreased when subjects who failed fit testing were excluded. In addition, the average PFs increased by 1.4-fold after the subject–respirator combinations that failed fit testing were excluded. The findings support the value of fit testing.

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