Ann. Occup. Hyg., Vol. 52, No. 3, pp. 177–185, 2008

doi:10.1093/annhyg/men005

Respiratory Performance Offered by N95 Respirators and Surgical Masks: Human Subject Evaluation with NaCl Aerosol Representing Bacterial and Viral Particle Size Range

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Received 16 March 2007; in final form 21 December 2007; published online 7 March 2008

Objectives: This study aimed at determining the protection factors (PFs) provided by N95 filtering facepiece respirators and surgical masks against particles representing bacterial and viral size ranges (aerodynamic size: 0.04–1.3 μm).

Methods: The protection levels of N95 filtering facepiece respirators (four models) and surgical masks (three models) were investigated while they were donned by 12 subjects performing the OSHA (US Occupational Safety and Health Administration) fit-testing exercises in a test chamber.

Results: About 29% of N95 respirators and ~100% of surgical masks had PFs <10, which is the assigned PF designated for this type of respirator by the OSHA. On average, the PFs of N95 respirators were 8–12 times greater than those of surgical masks. The minimum PFs were observed in the size range of 0.04–0.2 μm. No significant difference in PF results was found between N95 respirators with and without an exhalation valve.

Conclusions: The study indicates that N95 filtering facepiece respirators may not achieve the expected protection level against bacteria and viruses. An exhalation valve on the N95 respirator does not affect the respiratory protection; it appears to be an appropriate alternative to reduce the breathing resistance.

Keywords: bacteria; exhalation valve; protection factor; respirator; virus

NOTE: WUHAN-CoV is showing particle size range at 0.06 - 0.12 μm - which is at the smallest range of the scale in this study, and greatly increases concern of this specific pathogens ability to penetrate the N95.

INTRODUCTION

Since the outbreaks of SARS (severe acute respiratory syndrome) occurred in Asia and spread over ~30 countries (WHO, 2003a), viruses have gained additional attention worldwide. SARS is caused by a coronavirus, which has been found in patients' body fluids and respiratory secretions such as feces, saliva and sneezing and coughing droplets from nose and mouth (Nassiri, 2003; Wang *et al.*, 2004). Avian influenza, another emerging viral disease spreading among birds, also threatens human health since the H5N1 subtype has caused a number of human deaths by crossing from poultry to humans (WHO, 2006a). Among other measures, prevention of the above-mentioned emerging diseases requires the development and implementation of efficient respiratory protection techniques. There is also an increasing interest in respiratory protection against bioterrorism agents, e.g. *Bacillus anthracis* bacteria.

The Center for Disease Control and Prevention (CDC) has issued several interim guidelines that include protection of health-care workers and flight crew members against coronaviruses (CDC, 2003), infection control precautions against airborne influenza A (H5N1) transmitted from bird-to-person or person-to-person (CDC, 2004) and protection of workers against *B. anthracis* in mail-handling facilities (CDC, 2001). The World Health Organization has also published recommendations related to the use of respirators within health-care settings by

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health-care workers exposed to persons suspected of having SARS (WHO, 2003) or avian influenza (WHO, 2005). All guidelines and recommendations suggest the use of a fit-tested respirator, at least as protective as a National Institute of Occupational Safety and Health (NIOSH)-approved N95 filtering facepiece respirator. Surgical masks, however, are indicated as an alternative when N95 respirators are not available.

All filtering facepiece respirators that are certified by NIOSH (1995) satisfy the CDC recommendations for respiratory protection against coronavirus and H5N1 virus and *B. anthracis* bacteria. The number 95 in this designation means that the filtration efficiency of the respirator is at least 95% at the most penetrating particle size range (presently defined as a mass median aerodynamic size of 0.3 μm) at a flow rate of 85 l min^{-1} simulating the respiratory rate at heavy workload (International Commission on Radiological Protection, 1994). The letter 'N' means that this type of respirator is not resistant to oil (NIOSH, 1995). The NIOSH respirator certification test is performed using aerosol with a mass median diameter of 0.3 μm. For comparison, the physical size of an SARS-causing coronavirus is about 0.08–0.14 μm (Ksiazek *et al.*, 2003) and that of an H5N1 virus, which causes Avian influenza, is 0.08–0.12 μm (Mandell *et al.*, 1995). The average physical size of *B. anthracis* is about 0.81–0.86 μm in diameter and 1.26–1.67 μm in length (Carrera *et al.*, 2007). The size of infective airborne viral particles is not well known and the aerosol transmission of viral diseases is currently debated in the literature (Roy and Milton, 2004; Tellier, 2006). A recent study provides evidence on the infectivity of single airborne virions as it showed that aerosol transmission of influenza virus was improved under low relative humidity (20%) (Lowen *et al.*, 2007). This was associated with two possible factors: small size of airborne viral particles due to quick evaporation of water and the stability of airborne infectious virions at low humidity (Lowen *et al.*, 2007).

We have recently studied the filtration efficiency of N95 respirator filters and surgical masks using inert NaCl particles (Balazy *et al.*, 2006a) and MS2 viruses (Balazy *et al.*, 2006b) as a challenge aerosol. While we confirmed that the highest particle penetration for mechanical filters, utilized in surgical masks, occurs when a count median diameter of particles is ~0.3 μm, the most penetrating particle size was found to be about 0.03–0.07 μm for precharged fiber filters, which are widely used for N95 respirators. When testing at an inhalation flow rate of 85 l min^{-1}, the penetration of MS2 virions (0.01–0.08 μm) through the N95 respirator filter exceeded 5%. For surgical masks, the penetration was much higher and varied from 20.5 to 84.5%. In these studies, the respirators were sealed on a manikin face to account only for particles penetrating through the respirator filter material. However, airborne particles can also enter the respirator cavity through face-seal leaks and be subsequently inhaled into human respiratory systems.

In some previous investigations, artificial leaks were created on a manikin face to examine the effect of leak shape, leak size and leak location on the particle penetration through face-seal leaks in the size range of about 0.1–5 μm (Chen and Willeke, 1992; Lee *et al.*, 2005a). At the same time, it is still unknown whether these artificial leaks represent real human face-seal leaks.

Face-seal leaks, i.e. respirator fit on the subjects' face, are routinely assessed by using the qualitative or quantitative fit tests [US Occupational Safety and Health Administration (OSHA) 29 CFR 1910. 134] (Department of Labor, Occupational Safety and Health Administration, 1998). Among the quantitative fit-testing tools, a TSI PortaCount Plus with N95-Companion is commonly used to quantify the fit of N95 filtering facepiece respirators. However, the fit factor (FF) obtained through fit testing may not adequately predict the true respiratory protection when the worker is performing his/her actual work activities. As true workplace protection factors (WPFs) (during actual work activities) are often difficult to measure, simulated workplace protection factors (SWPFs) are used as an alternative to estimate the respiratory protection level. The SWPFs are determined in a laboratory using test exercises designed to simulate work activities. The SWPF, in contrast to the FF, takes into account both filter penetration and face-seal leakage as well as the leakage through the exhalation valve. The SWPF has been used in several recent studies for characterizing respirator performance (e.g. Coffey *et al.*, 2004; Zhuang *et al.*, 2005; Coffey *et al.*, 2006; Lawrence *et al.*, 2006; Duling *et al.*, 2007). The aerosol measurements in these studies were conducted using a TSI PortaCount Plus Model 8020, which is not a size-selective device and cannot distinguish particles in the bacterial and viral size range. As a result, there is a lack of information on the respiratory protection at discrete particle sizes, especially those representing the size of airborne bacterial and viral contaminants.

Due to the difficulty in accessing the WPF data in the workplace and very few studies investigating the correlation between FFs, WPFs and SWPFs, NIOSH has proposed the use of a total inward leakage (TIL) test for assessing respirator performance as part of the certification process for a respirator (NIOSH, 2004). The TIL test is meant to assess the protective level achieved by a respirator when contributions of all leakage paths are considered. However, the TIL testing performed under laboratory conditions is not expected to reflect actual field personal protective equipment performance or to replace individual fit testing as mandated by the OSHA. The testing is only

intended to quantify the ability of respirators to fit individuals under laboratory conditions. Thus, in this study, we adopted the TIL concept and conducted the TIL tests particle size selectively using our newly developed personal sampling system to investigate the performance of respirator devices against particles in the bacterial and viral size range.

In our recent paper, we described a new personal sampling system that was developed to determine the protection provided by respirators against airborne dust and microorganisms in the size range of 0.7–10 μm (Lee *et al.*, 2004). This sampling system, based on measurements of concentrations inside and outside respirators worn by human subjects, has been validated through both laboratory (Lee *et al.*, 2005a) and field testing (Lee *et al.*, 2005b). In the present study, we modified the system to cover particles of aerodynamic size, d_a, from 0.0414 to 1.2625 μm, representing the size of bacteria and viruses. This study was carried out with human subjects and intended (i) to estimate how much protection can be provided by N95 filtering facepiece respirators and surgical masks against bacteria and viruses and (ii) to investigate whether exhalation valves affect the protection levels provided by N95 filtering facepiece respirators.

METHODS

Study design

The particle concentrations outside and inside the N95 respirator were measured using our newly developed personal sampling system (Lee *et al.*, 2004), which was modified by connecting it to an Electrical Low Pressure Impactor (ELPI 3935 series, Dekati Ltd, Tampere, Finland). This instrument size-selectively measures the number concentration of particles in an aerodynamic size, ranging from d_a = 0.029 to 10.18 μm, in 12 channels. For the current study, we utilized the eight lowest channels with geometric mean (GM) diameters of 0.0414, 0.078, 0.1304, 0.2047, 0.3155, 0.4993, 0.7935 and 1.2625 μm, which represent the size of most airborne viruses and bacteria. The sampling system was donned by a human subject wearing either a N95 facepiece respirator or a surgical mask. The experiments were conducted in a walk-in indoor test chamber (Choe *et al.*, 2000). The laboratory test environment is described in detail in Lee *et al.* (2005a). Four different models of N95 filtering facepiece respirators and three different models of surgical masks were employed for the testing.

Modification of the personal sampling system

The original personal sampling system had two sampling lines for measurement of airborne dust and microorganisms inside and outside the N95 filtering facepiece respirator (Lee *et al.*, 2004). Each sampling line consisted of a sampling probe, sampling tubing, a sampling chamber, an optical particle counter (0.7–10 μm), a 25-mm cassette with a 1-μm polycarbonate filter membrane and a pump. We modified the system so that it could be used to measure particles in the size range of 0.04–1.3 μm by replacing the two optical particle counters with an ELPI, as presented in Fig. 1. Since only one ELPI instrument was available, the sampling configuration was rebuilt to allow the measurement device to serve both lines. A four-way connector was built up to split the ELPI flow of 30 l min^{-1}into three equal parts. One part offered a sampling flow of 10 l min^{-1}. This flow came either from the ambient sampling line or from the in-facepiece sampling line. The two other parts offered dilution air. These two parts were later merged into one line and filtered by a HEPA (high-efficiency particulate air) filter. These two initially separate air lines for dilution air allowed the sampling flow to be maintained accurately and steadily at 10 l min^{-1}. One airflow valve and one thermal mass flow meter (Model 4043, TSI Inc., St Paul, MN, USA) were connected before the HEPA filter to adjust and monitor the dilution airflow (which had a total of 20 l min^{-1}). The sampling flow of 10 l min^{-1} was adjusted by modifying the dilution flow and calibrated by using a DryCal DC-Lite Calibrator (Bios International Corporation, Butler, NJ, USA). Immediately at the upstream of a four-way connector there was a three-way airflow controller acting as a switch between the ambient sampling line and the in-facepiece sampling line. A Nafion dryer (PD-50T-12MP, Perma Pure LLC, Toms River, NJ, USA) was installed between the four-way connector and the ELPI inlet to remove the water content from the sampling line.

Selection of the N95 filtering facepiece respirators and surgical masks

Two N95 filtering facepiece respirators were selected in this study based on the expected protection levels: high (N95 Respirator A) and medium (N95 Respirator B). The selection was based on the available data on the fitting characteristics of 18 commercially available N95 filtering facepiece respirators (Coffey *et al.*, 2004). In addition, we investigated the effect of the exhalation valve on the protection factors (PFs) because the protection levels might decrease due to leaks from the exhalation valve. Therefore, we included two more N95 filtering facepiece respirators, which are otherwise similar except for an exhalation valve: one does not have it (N95 Respirator C), while the other one does (N95 Respirator D).

Three models of surgical masks were also tested. As there was no information available on the performance of surgical masks at the time of these experiments, a three-step protocol was utilized to select representative surgical masks from commercially available models. First, nine models of surgical

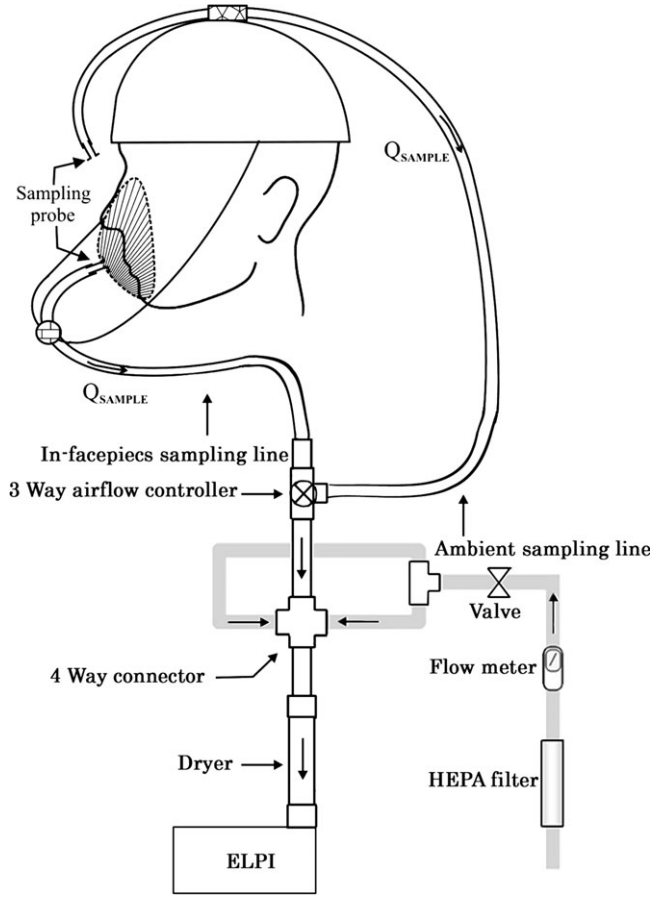

Fig. 1. Schematic presentation of the modified personal sampling system.

masks were chosen based on respirator type (cup or pleat) and strap type (ear loops or tie on). Second, these surgical masks were divided into three groups (high, medium and low protection) based on the standard quantitative fit-testing results. Third, three models of surgical masks were chosen by randomly selecting one model from each group. Fit testing was conducted using a PortaCount Plus with an N95-Companion (TSI Inc.). A human subject performed the OSHA fit-testing exercise protocol during the test (Department of Labor, Occupational Safety and Health Administration, 1998). Each model of the surgical masks was tested in three replicates, and each replicate was performed with an identical, unused respirator. The prescreening fit testing was conducted using one human subject.

Experimental protocols

In this study, the number concentrations of NaCl particles (challenge aerosol) were size-selectively measured using the ELPI, so that the protection levels provided by N95 filtering facepiece respirators and surgical masks were determined when human subjects donned the tested respirators and 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 (Department of Labor, Occupational Safety and Health Administration, 1998). Earlier studies have shown that the protection levels determined using the set of exercises included in the OSHA protocol highly correlated with the actual exposures from a simulated health-care workplace study (Coffey *et al.*, 1999; Lawrence *et al.*, 2006). Twelve subjects were recruited from students and staff members of the University of Cincinnati, Cincinnati, OH, USA, without regard to any particular facial size distribution. The range for the face length was 10–13.7 cm and the range for the lip length was 4.8–7 cm. Each exercise was performed for 2 min and the particle concentrations inside the respirator were averaged over the second minute. The concentration inside the respirator (c_{in}) for the entire test was averaged over all the exercises, excluding the grimace maneuver. The particle concentrations outside the respirator (c_{out}) were measured at the beginning, middle and end of the test. The average of these concentrations was used

as the concentration outside the respirator for each test. The PF was calculated by dividing the particle concentrations outside the respirator (c_{out}) by those inside the respirator (c_{in}):

$$PF = \frac{c_{out}}{c_{in}}. \quad (1)$$

To investigate the effect of the exhalation valve on the protection provided by N95 filtering facepiece respirators, 12 subjects were first tested with respirators that did not have exhalation valves. Based on the results, three subjects (with high, medium and low protection levels) were chosen to perform the test with an equivalent respirator that had an exhalation valve.

Each respirator model was examined in three replicates for each of the 12 subjects, and each replicate was conducted with an identical and unused respirator. Thus, there were 36 tests per respirator model for the N95 Respirators A, B and C and Surgical masks A, B and C (examined similarly as the N95 respirators) and 9 tests for N95 Respirator D.

The particle losses in the sampling line have been addressed in our previous study (Lee *et al.*, 2004). We found a difference in the penetration efficiencies of particles between the two sampling lines due to slightly different configurations. Therefore, all PFs presented in this paper were corrected by a ratio of concentrations measured in the two sampling lines when no respirator was attached in the system. These ratios varied from 0.93 to 1, depending on the particle size.

Data analysis

The data analysis was performed using an analysis of variance (ANOVA) model provided by the Statistical Analysis System version 8.0 (SAS Institute Inc., Cary, NC, USA). *P*-values of <0.05 were considered significant. The difference in mean FFs among nine surgical masks was examined by the ANOVA followed by a pairwise comparison using the Tukey's studentized range test. This statistical method was also used to examine the difference in the PFs among different particle sizes. A *t*-test was performed to investigate the difference in PFs between N95 filtering facepiece respirators with and without exhalation valves.

RESULTS

N95 respirators

Figure 2 presents the PFs for four models of N95 filtering facepiece respirators against particles in the size range of approximately 0.04–1.3 μm. The GM of the PFs calculated for the four N95 facepiece respirators over the eight particle size ranges was 21.5 (4 models × 8 size classes × 12 subjects × 3 repeats = 1152 data points). The lowest protection provided by N95 filtering facepiece respirators occurred approximately between d_a = 0.08 and 0.2 μm.

The assigned protection factor (APF) of 10 for N95 filtering facepiece respirators (Department of

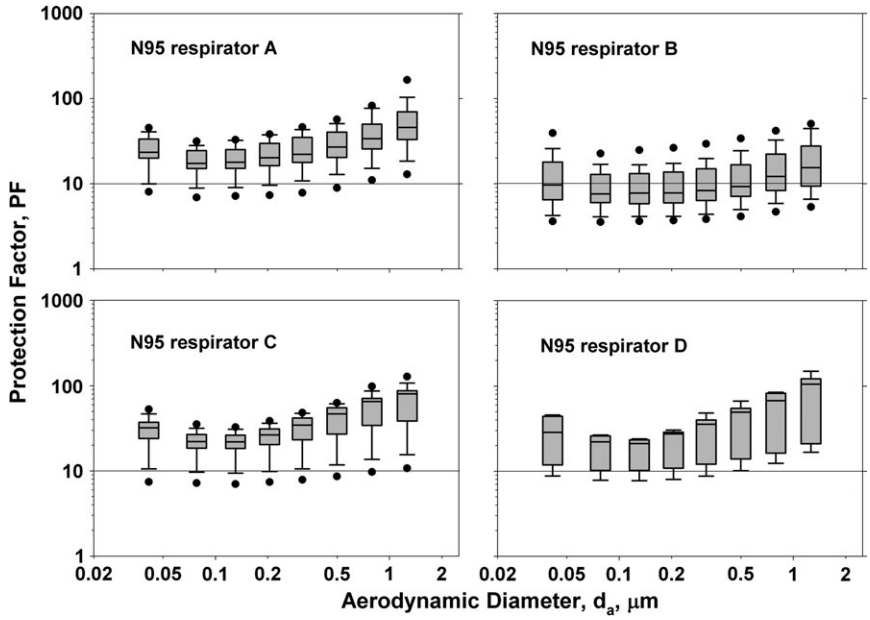

Fig. 2. PF values against particles representing bacterial and viral size range for four models of N95 filtering facepiece respirators: A, B, C and D. The tests were performed when the N95 respirators were donned on human subjects. Total observations are 36 (12 subjects × 3 replicates) for Models A, B and C and 9 (3 subjects × 3 replicates) for Model D. The boxplots show the following: dots (from bottom) represent 5th and 95th percentiles; horizontal lines (from bottom) represent 10th, 25th, 50th, 75th, and 90th percentiles.

Labor, Occupational Safety and Health Administration, 2006) is shown in Fig. 2 by a horizontal line. The APF-value represents the level of protection that a properly functioning respirator is expected to provide to adequately fitted and trained users in the workplace. Among the 36 tested N95 respirators of Types A, B and C and among 9 tested N95 respirators of Type D, PFs <10 were found for 13.9, 63.9, 11.1 and 22.2% of the respirators, respectively. The respective percentages for PFs <5 were 0, 16.7, 0 and 0%.

The effect of the exhalation valve on the PFs provided by N95 filtering facepiece respirators can be further observed from the data presented in Fig. 3 for Respirator C (without a valve) and Respirator D (equipped with a valve). The PFs appeared to have a good agreement for all tested particle sizes. A *t*-test showed no significant difference in the PFs between N95 filtering facepiece respirators with and without the exhalation valve for 0.04- to 1.3-μm particles ($P > 0.05$).

Surgical masks

The overall FFs measured for nine models of surgical masks are presented in Fig. 4. Based on these results, the nine surgical masks were divided into three classes, representing different levels of protection as tested by the ANOVA: high (Surgical masks 1, 2, 3 and 4), medium (Surgical masks 5, 6 and 7) and low (Surgical masks 8 and 9). Three surgical

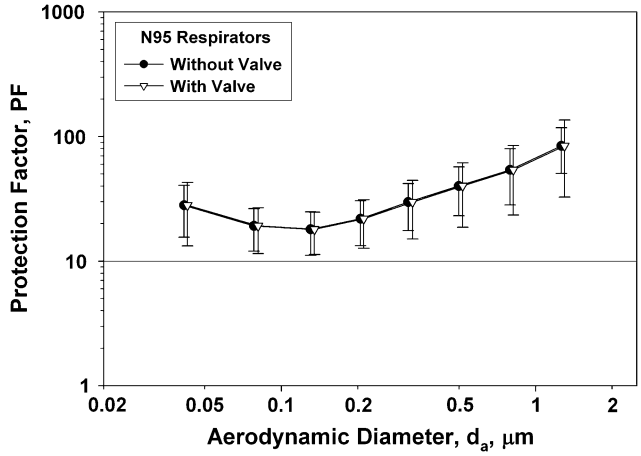

Fig. 3. The comparison of PFs against particles in bacterial and viral size ranges between respirators without (N95 Respirator C) and with (N95 Respirator D) exhalation valves. The tests were performed when the N95 respirators were donned on human subjects. Each data point represents an average and standard deviation of 36 observations for N95 Respirator C and 9 observations for N95 Respirator D.

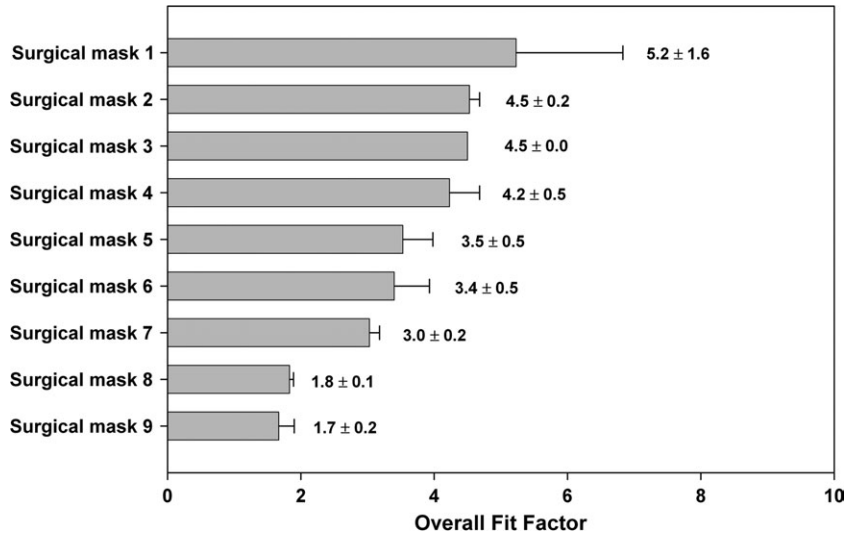

Fig. 4. Overall FFs measured for nine models of surgical masks with the PortaCount (with N95-Companion). The mask was donned on a human subject. Each bar represents an average and standard deviation of three replicate measurements performed by one human subject. Each replicate was done with the same type of unused surgical mask.

mask models were chosen by randomly drawing one model from each class. As a result, Surgical masks 1, 5 and 8 were selected; they are labeled A, B and C, respectively, in the following text and figures.

The PFs for these three models of surgical masks are shown in Fig. 5. The overall GM of PFs was 2.4 (3 models × 8 size classes × 12 subjects × 3 repeats = 864 data points). The minimum PFs were found to be approximately between d_a = 0.04 and 0.32 μm for Surgical masks A and B and in a somewhat wider range for Surgical mask C. With respect to the geometric mean of PFs, the PF provided by surgical masks was nine times lower than that provided by N95 respirators.

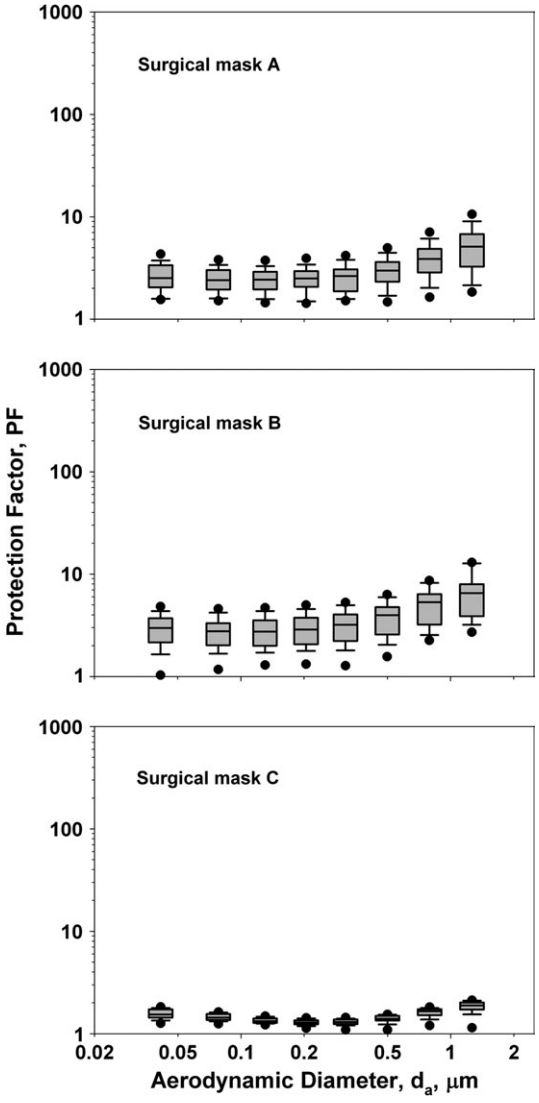

Fig. 5. PF values against particles representing bacterial and viral size range for three models of surgical masks: A, B and C. The boxplots show the same as in Fig. 1. The tests were performed when the surgical masks were donned on human subjects. Total observations are 36 (12 subjects × 3 replicates).

DISCUSSION

Current guidelines issued by the CDC and the WHO recommend the use of N95 or higher level protection respirators against airborne transmission of bacteria and viruses. When N95 filtering facepiece respirators are not available, surgical masks are suggested as an alternative. No previous investigations have utilized human subjects to investigate the protection level provided by N95 filtering facepiece respirators and surgical masks against particles representing bacterial and viral size ranges. In most of the published field studies, total mass concentrations were determined outside and inside the respirator to investigate respiratory protection against particles regardless of particle size. This study provides data on the protection provided by the N95 filtering facepiece respirators and surgical masks as a function of particle size in the size range of d_a = 0.0414–1.2625 μm.

If one graphs the PF provided by N95 respirators versus particle size, the result appears to be an upside-down bell-shaped curve. This supports the results of several previous laboratory studies (Holton and Willeke, 1992; Chen *et al.*, 1990; Chen and Willeke, 1992; Balazy *et al.*, 2006a) as well as our recent field study in agricultural environments (Lee *et al.*, 2005b), which have shown that the size of particles affects their penetration through filter materials and face-seal leaks. The data obtained in the present study by count-based measurement show that particles approximately between 0.08 and 0.2 μm in aerodynamic diameter are more likely to penetrate into most of the tested N95 respirators. The respective size was 0.04–0.2 μm for surgical masks. Strikingly, the physical size of SARS-causing coronavirus is approximately 0.08–0.14 μm, and the physical size of influenza virus is 0.08–0.12 μm, i.e. the size ranges of these viruses fall into the most penetrating particle size range.

The percentage of the respirators that had PFs >5 for all tested particle sizes was ~100% for most of the tested N95 filtering facepiece respirators, except for N95 Respirator B (83.3%). However, the corresponding percentages for PFs >10 were 86.1% for N95 Respirator A, 36.1% for N95 Respirator B, 88.9% for N95 Respirator C and 77.8% for N95 Respirator D (71% when the data for all the tested N95 respirators were combined). Similarly, Coffey *et al.* (2004) have shown that the PF was <10 for ~26% of 18 N95 respirators tested by using 25 human subjects and <5 for ~14% of the respirators. In addition, Duling *et al.* (2007) presented that ~14% of PFs for N95 filtering facepiece respirators were found to be <10, while ~5% were observed to be <5. We have previously shown that assigning APF = 10 for N95 filtering facepiece respirators may not be justified for protection against fungal spores and bacteria (Lee *et al.*, 2005b). This was

explained by the small size of these particles: the current APF values are mostly based on studies that measured particle mass. Larger particles, which comprise most of the mass, were found to be less penetrative than particles representing the size of fungal spores and bacteria. As the present study was conducted using the particle size-selective TIL test under well-controlled laboratory conditions, the results may not be representative enough to reflect true protection levels in the field. However, the laboratory-generated PF results are expected to be more conservative and greater than the field PF results due to lower workload and narrower range of head movements performed in the test. Consequently, the results of the present study indirectly implicate that the APF of 10 may also overestimate the protection that N95 filtering facepiece respirators provide against viral particles.

After accounting for the individual differences, the average PF offered by N95 filtering facepiece respirators against particles in the tested size range was about 8–12 times greater than that provided by surgical masks. This result is similar to that obtained by Lawrence *et al.* (2006) who found, using a nonsize-selective device (TSI PortaCount Plus), that the protection provided by N95 filtering facepiece respirators is about seven times greater than that of surgical masks. Zhuang *et al.* (2005) evaluated the protection levels of 18 N95 filtering facepiece respirators and found that the GM of the PFs was ∼25, which is somewhat greater than GM = 21.4 obtained in the present study. The PFs of surgical masks varied widely in our tests, depending on the model and particle size: from 1.3 to 6.5.

The exhalation valve on N95 filtering facepiece respirators is designed to ease the wearer's breathing when the wearer has difficulty exhaling through the respirator due to filter resistance. Our results show that the N95 filtering facepiece respirator with an exhalation valve will not lose its ability to protect wearers from the exposure to airborne particles in the bacterial and viral size range. Aerosol penetration through the exhalation valve was also investigated for half-facepiece negative-pressure respirators by Brosseau (1998), who found that the penetration values were about 0.03–0.04%, indicating no valve failure. N95 filtering facepiece respirators with valves appear to be a good alternative when wearers feel uncomfortable wearing an N95 filtering facepiece respirator without a valve. It should be noted, however, that the valve may allow the spread of any infectious agents that are carried by the respirator wearer.

CONCLUSIONS

Most of the tested N95 respirators and surgical masks in this study were observed to perform at their worst against particles approximately between 0.04 and 0.2 μm, which includes the sizes of coronavirus and influenza virus. The tested N95 respirators provided about 8–12 times better protection than the surgical masks. However, ∼29% of the tested N95 respirators had PFs <10, indicating that the newly assigned OSHA PF of 10 may overestimate the actual protection offered by N95 respirators against bacteria and viruses. N95 filtering facepiece respirators with valves have about equal protection to those without valves against bacterial and viral particles and appear to be useful for reducing breathing resistance.

FUNDING

The National Institute for Occupational Safety and Health (R01 OH0408501); Pilot Project Research Training Program of the University of Cincinnati Education and Research Center (T42/CCT510420).

Acknowledgements—The authors thank students and staff members who volunteered to be human subjects in this study

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