Nanoparticle Penetration through NIOSH-approved N95 Filtering-facepiece Respirators

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ABSTRACT

The aim of this study was to compare NaCl particle penetration through five NIOSH-approved N95 filtering-facepiece respirator models using two test methods. Data from a polydisperse aerosol challenge similar to the NIOSH respirator certification test was compared to data collected using monodisperse aerosols ranging from 20 nm to 400 nm. The average initial penetration levels from the polydisperse aerosol tests ranged from 0.61% to 1.24% for the five respirator models tested. Monodisperse aerosol penetrations behaved according to single fiber filtration theory. The most penetrating particle size was found to be near 40 nm. Average penetration of 40 nm particles was found to exceed 5% for two respirator models, but was not statistically significant compared to the 5% criteria for class "95" respirators used by NIOSH with the certification test. The rank ordering of the filtration performances of the five respirator models was consistent between the two test methods.

Keywords: Nanoparticle, Respirator, Monodisperse aerosol, Polydisperse aerosol, Particle penetration

INTRODUCTION

Occupational exposure to engineered nanoparticles has generated a number of human health concerns (NIOSH, 2006). Nanoparticles have been defined as particles having a diameter between 1 and 100 nm. NIOSH certifies the performance of respiratory protection devices that can be used for protecting workers against particulates, including those in the nanoparticle range. NIOSH published a process for selecting the appropriate respiratory protection to assist users and respiratory protection program administrators (NIOSH, 2004). Among the available choices for protection against particulate hazards, disposable N95 filtering-facepiece respirators are commonly used because of their relatively low cost and availability. N-series respirators are used against solid and water-based non-oil particles.

Electret filter media used in the N-series respirators capture particles efficiently by a combination of electrostatic, diffusion, interception, impaction and other mechanisms with a relatively reduced level of breathing resistance. According to single fiber filtration theory, there exists an intermediate particle size region, where none of the filtration mechanisms are dominant (Hinds, 1999). Particles in this size range are termed the most penetrating particle size (MPPS) and have the maximum penetration through the filter. In the development of the current test used in NIOSH certification, the MPPS was thought to occur in the range of 100-400 nm for most fibrous filters (Stevens & Moyer, 1989). However, the MPPS can vary under different conditions and is dependent on several factors including, filter type (mechanical, electret, etc.), filter media characteristics (fiber size, packing density, charge, etc.), and experimental conditions (flow rates and particle charge) (Lee & Liu, 1980; Lee & Liu, 1982; Martin & Moyer, 2000).

Several studies have reported the filtration efficiencies of N95 respirators and filter media previously (Qian et al. 1998; Willeke and Qian, 1998; Moyer & Bergman, 2000; Martin & Moyer, 2000; Lee et al. 2005; Kim et al. 2007). Qian et al. (1998) measured the filtration efficiencies of different types of respirators against NaCl (100 nm and above) and biological particles. Their results showed that N95 respirators met the NIOSH allowed 5% level penetration. Similar penetration levels for N95 respirators were obtained in other studies (Lee et al. 2005; Richardson et al. 2006). Studies by Richardson et al. (2006) showed less than 5% penetration of MS2 virus, *Bacillus globigii* bacteria and NaCl particles in the range of 20 to 2900 nm for N95 filtering-facepiece respirators at 85 L/min flow rate. Even at the MPPS (~50-100 nm), penetration levels for monodisperse particles did not exceed 5% for any of the respirators tested.

However, a recent study reported that penetration of 30 - 70 nm NaCl particles (in the MPPS range) through NIOSH-approved commercial N95 respirators could exceed 5% at 85 L/min flow rate (Balazy, et al. 2006a). In that study, one of the two tested models of N95 respirators showed higher than 5% penetration following a manikin-based protocol. Similar data was collected in a companion study by the same group, showing higher than 5% penetration of MS2 virus particles (~50 nm size based on electrical mobility) through one N95 respirator model at 85 L/min flow rate (Balazy et al. 2006b). Their observation that the MPPS for current N95 respirators is closer to the 50 nm range rather than somewhere between 100 nm - 400 nm as previously thought has been observed by others (Martin & Moyer, 2000; Richardson et al. 2006). However, data showing that penetration levels can exceed 5% at the MPPS for at least one respirator model warranted further investigation, even though the correlation between 50 nm monodisperse particle penetration and actual protection in the workplace is lacking.

In the final rule making notice, NIOSH described the rationale and details of the test method used to certify filter performance (Federal Register, 1995). The NIOSH certification test is based upon the assumption of "worst-case" conditions for assessing filtration performance. The test uses a charge neutralized polydisperse aerosol challenge with a count median diameter (CMD) of 0.075 ± 0.02 µm (75 ± 20 nm) and a geometric standard deviation of less than 1.86. This challenge size range was selected such that the filter performance at other aerosol size ranges will be higher than that certified by NIOSH. The maximum penetration level that is accepted for any class "95" respirator is <5 % (i.e., at least 95% efficient). The test flow rate of 85 L/min is higher than medium work flow and represents a very high work rate not sustainable by most individuals (Janssen, 2003). However, this flow rate does provide a rigorous ("worst-case") challenge for assessing filtration performance. Higher flow rates cause the MPPS to shift towards smaller particle sizes and increase particle penetration (Stevens and Moyer, 1989).

In this study, penetration of NaCl particles through five models of commercially available N95 respirators was measured using two test methods: a monodisperse aerosol test method similar to that used by Balazy, et al. (2006a) and a polydisperse aerosol test method similar to that used by NIOSH for certification. These data provide an explanation for the apparent discrepancies between the data described in the literature and demonstrate the appropriateness of the current NIOSH particulate respirator certification test for ensuring predictable filtration performance against nanoparticles.

MATERIALS AND METHODS

Filtering-facepiece respirators

Five models of NIOSH-certified N95 filtering-facepiece respirators from five different manufacturers were used in this study. The manufacturers were randomly selected from the NIOSH certified equipment list. A single respirator model was selected from each manufacturer and purchased commercially. Samples of each respirator model were removed from the packaging (i.e., no preconditioning) and challenged with either monodisperse or polydisperse NaCl aerosol at 85 L/min flow rate at room temperature. Initial percentage penetration was measured in all cases as described below. After each completed test, each respirator sample was discarded.

Polydisperse aerosol test method

The polydisperse aerosol test method used in this study was implemented using the TSI 8130 automated filter tester. The TSI 8130 uses the same charge neutralized polydisperse NaCl challenge as NIOSH uses for certification testing (Federal Register, 1995; NIOSH, 2005). The TSI 8130 employs a photometer to measure the flux of light scattering from aerosol particles. The flux of scattered light is proportional to particle $(\text{diameter})^6$ or $(\text{mass})^2$, when the diameter is smaller than the wavelength of coincident light (Johnson and Smith, 1998).

To measure particle penetration, a Plexiglas box (20 cm x 20 cm x 10 cm) was used to mount each respirator (Figure 1). The Plexiglas box has replaceable top and bottom plates (20 cm x 20 cm x 0.5 cm) with a circular hole (25 cm^2) in the center. A respirator was placed on the bottom plate with its concave side facing the hole and its periphery was sealed with melted wax. The bottom plate was placed in the Plexiglas box, so that the respirator was located inside the box. The Plexiglas box containing the respirator was placed in between the two filter chucks of the TSI 8130 and aligned to keep the top and bottom plate holes facing the downstream and upstream filter chucks, respectively. Experiments were carried out under airtight conditions by closing the filter chucks.

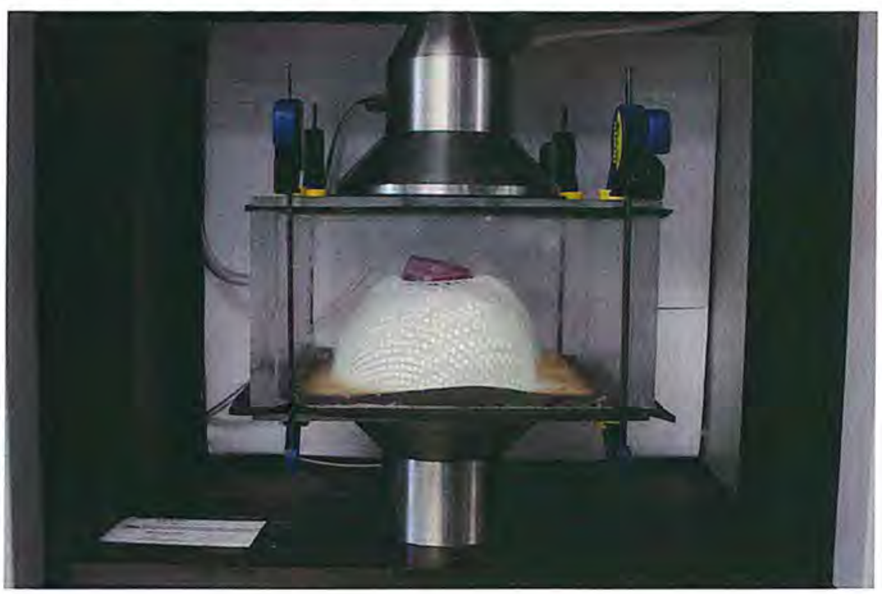

Figure 1: Respirator test box placed in between the upstream and downstream filter chucks of the TSI 3160.

Ten respirators from each of the five manufacturers were challenged with polydisperse NaCl particles. The test procedure used in this study is nearly identical to the one used for NIOSH certification with a few exceptions. Initial penetration levels were measured for 1 min of loading, instead of carrying out the entire NIOSH 42 CFR 84 test protocol (Federal Register, 1995; NIOSH, 2005). The NIOSH certification protocol also involves loading 200 mg of challenge aerosol to the respirator and preconditioning of the respirator samples at 85 ± 5% relative humidity and 38 ± 2.5 °C for 25 ± 1 hour before testing. These steps were not included in the polydisperse aerosol test protocol used in this study to be consistent with the monodisperse aerosol testing described below.

Monodisperse NaCl aerosol test method

A different set of N95 filtering-facepiece respirators from the same models that were employed for the polydisperse aerosol experiments were tested against monodisperse NaCl particles using a TSI 3160 Fractional Efficiency Tester (TSI 3160). A scanning mobility particle sizer (SMPS) spectrometer in the TSI 3160 classifies particles based on electrical mobility. The TSI 3160 was programmed for measuring the percentage initial penetration of different size monodisperse particles in the range of 20-400 nm at 85 L/min flow rate. The percentage of particle penetration was measured by counting the number of particles that penetrate through the respirator instead of measuring the flux of light scattering in the case of polydisperse aerosol. Initial particle penetration through each respirator was measured using the same Plexiglas box that was employed for experiments with the TSI 8130. The Plexiglas box was mounted so that the concave side of the respirator was facing the downstream airflow during the tests. In the first set of experiments, five respirators from each manufacturer were tested for penetration at different size monodisperse NaCl particles. Some respirators from two of the five manufacturers showed higher than 5% penetration at the most penetrating particle size range. Five additional respirators from both of these manufacturers were tested for particle penetration. For those two manufacturers, the data from all 10 samples were pooled for analysis.

Data Analysis

The penetration levels for each respirator model were measured using the TSI 8130 or TSI 3160 and statistical analysis of the percentage penetration data was done using the SigmaStat computer program. The average and 95% confidence interval penetration level were calculated for each model. The particle penetration data of the polydisperse aerosol and 40, 100, 200 and 300 nm monodisperse aerosols from the TSI 3160 were compared using analysis of variance (ANOVA) test. Monodisperse aerosol sizes were selected to represent the MPPS (40 nm), a particle size (300 nm) with a penetration level similar to that obtained for the polydisperse aerosols with the TSI 8130 and two other intermediate sizes (100 nm and 200 nm). Comparisons were done by Dunnett's method in cases where normality test passed. When normality test failed, Kruskal-Wallis ANOVA on Ranks was used to compare data by Dunn's method. Statistical *t*-tests were used to compare the average penetration values from both test methods with the 5% penetration level for class "95" respirators used with the NIOSH certification test.

RESULTS

For the monodisperse NaCl aerosol, initial penetrations levels of eleven different size particles in the range of 20 to 400 nm were measured using a TSI 3160. A typical monodisperse NaCl particle penetration curve for an individual N95 respirator is shown in Figure 2. Penetration levels increased with increasing particle size from 20 nm, reached a maximum at 40 nm, and then, slowly decreased up to 400 nm size. Figure 3 shows the penetration levels for N95 respirators from the five manufacturers. All five manufacturers N95 respirators showed a trend in particle penetration similar to the typical particle penetrations shown in Figure 2. Respirators from manufacturers 2 and 3 showed the highest penetration levels, while respirators from manufacturers 4 and 5 had the least penetration levels. The MPPS was in the 40 nm range for all five manufacturers respirators tested.

Polydisperse NaCl aerosol particle penetrations were carried out using the TSI 8130 and initial penetration levels for 1 min were measured. The average and 95% confidence intervals for the percentage penetration levels are shown in Figure 4. Polydisperse aerosol particle penetration levels (Poly) were less than 5% for all five models as expected for NIOSH-approved respirators. Respirator models 4 and 5 showed slightly lower penetration levels compared to the other models. The average particle penetration levels ranged from 0.61% to 1.24%.

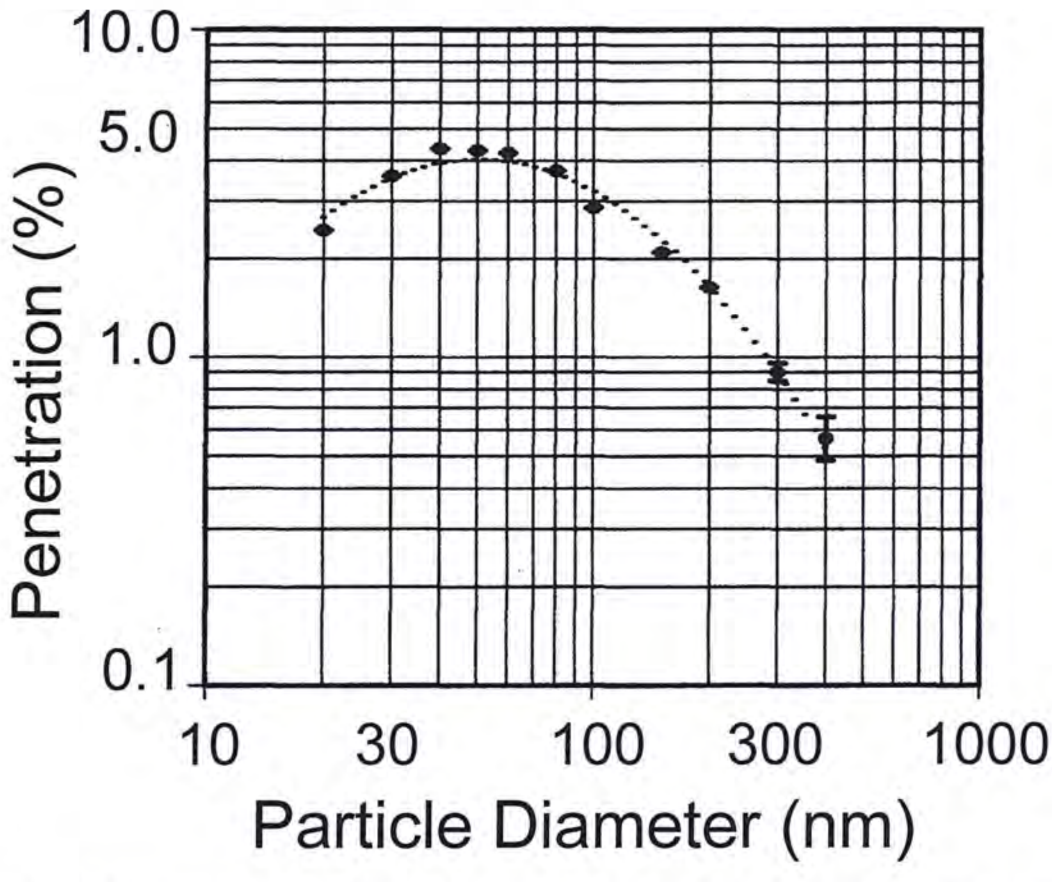

Figure 2: A typical monodisperse NaCl particle penetration curve for a single N95 filtering-facepiece respirator.

Figure 4 also shows the average and 95% confidence intervals for the percentage penetration levels measured using the monodisperse aerosol particles of 40, 100, 200, and 300 nm sizes. All five respirator models showed higher penetration levels of monodisperse 40 nm particles compared to other size particles. The 95% confidence intervals indicated some variation in the penetration values from respirator to respirator, even within the same model. The average penetration level at the MPPS varied widely between manufacturers (1.4% to 5.2%). Two of the five respirator models had average penetration levels slightly higher than 5%. However, the average penetration levels for these two N95 models were not significantly ($p<0.05$) different compared to 5%, the maximum allowable penetration level for NIOSH certification of class "95" respirators according to the 42 CFR 84 test.

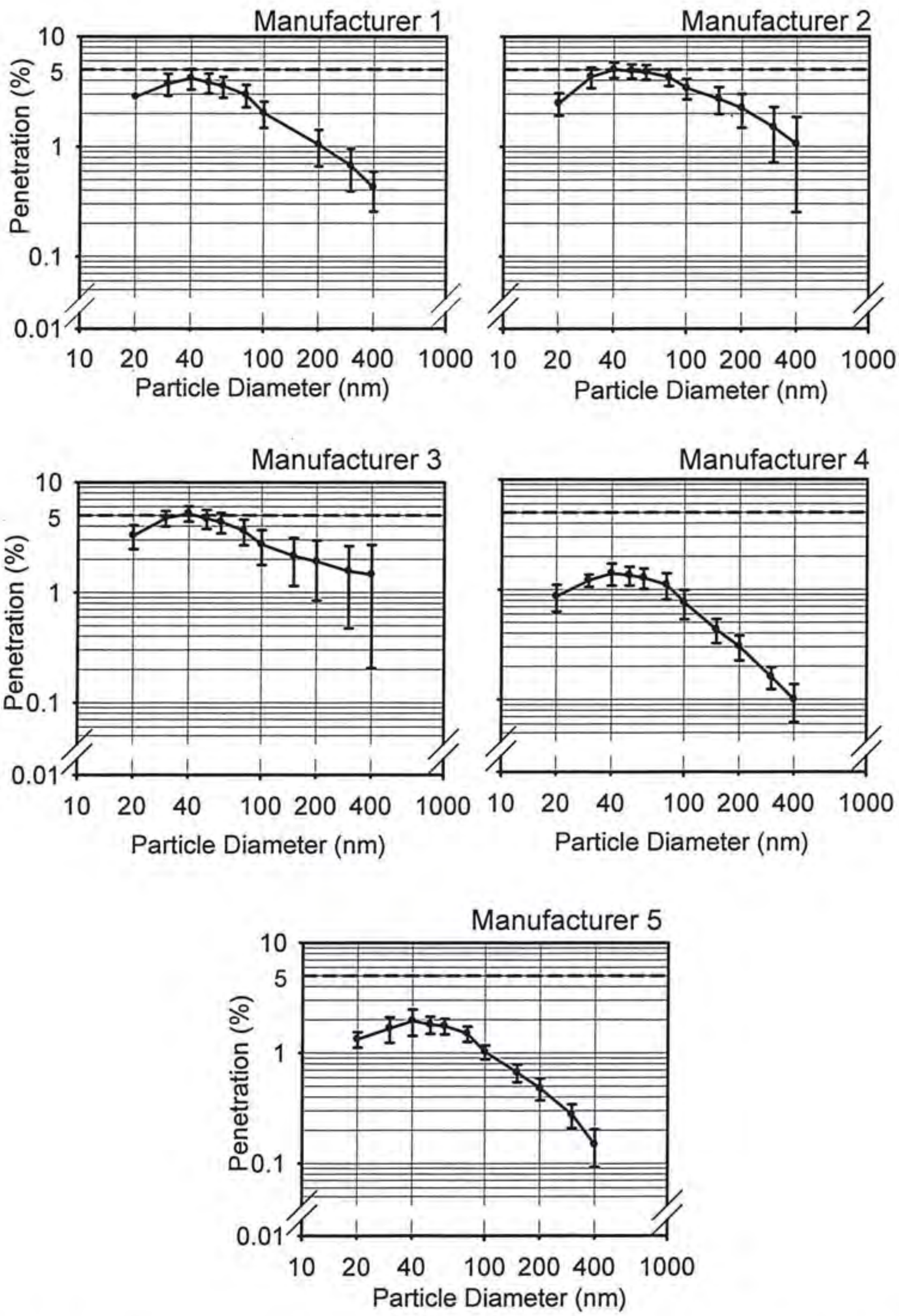

Figure 3: Monodisperse NaCl aerosol penetration curves for the five respirator models tested. The error bars represent 95% confidence intervals.

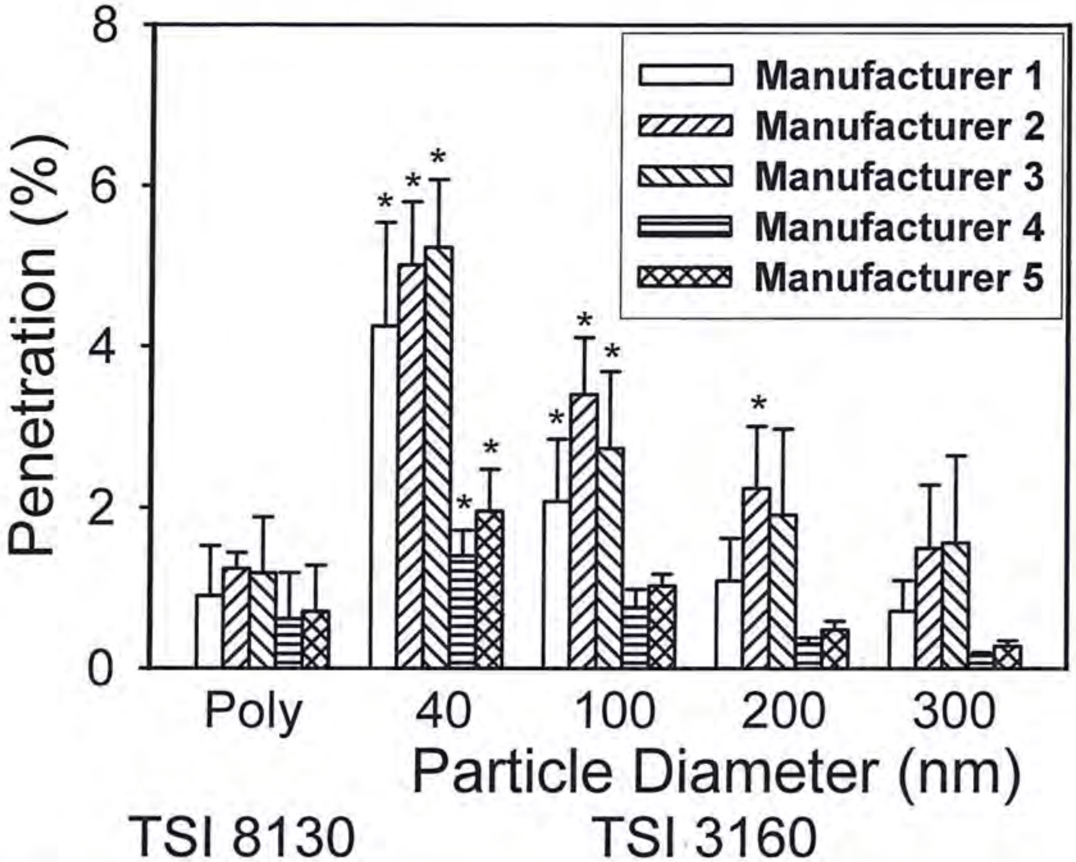

Figure 4: Comparison of the average NaCl particle penetration levels of polydisperse (Poly, using the TSI 8130) and monodisperse (40, 100, 200 and 300 nm, using the TSI 3160) aerosols. *Significantly ($p<0.05$) different from the penetration level of polydisperse aerosol particles (n=5 or more).

The polydisperse aerosol penetrations measured using the TSI 8130 were compared with the results of four different diameter size (40, 100, 200 and 300 nm) monodisperse aerosol penetrations. The penetration levels between polydisperse and 40 nm monodisperse particles were significantly ($p<0.05$) different for all five respirator models. Significant ($p<0.05$) differences between polydisperse and monodisperse aerosols of 100 and 200 nm for four and one respirator models, respectively, were also observed (Figure 4). The average penetration levels of polydisperse aerosol were not significantly different from the penetration levels of 300 nm size monodisperse particles for all five respirator models tested.

Figure 5 shows the rank ordering of penetrations of polydisperse and monodisperse (40 nm and 300 nm size) aerosol particles for the five models. As shown in Figure 4, the products (i.e., manufacturers 4 and 5) with the smallest average penetration using the polydisperse aerosol test also had the smallest average penetration of the monodisperse particles. Likewise, the products (i.e., manufacturers 2 and 3) that had the largest average penetration in the polydisperse aerosol test also had the largest average penetration of monodisperse particles among the five respirator models tested. The correlation coefficients (r) between the average penetrations of the polydisperse aerosols and average penetrations of monodisperse particles of 40, 100, 200 and 300 nm were 0.945, 0.979, 0.996 and 0.994, respectively.

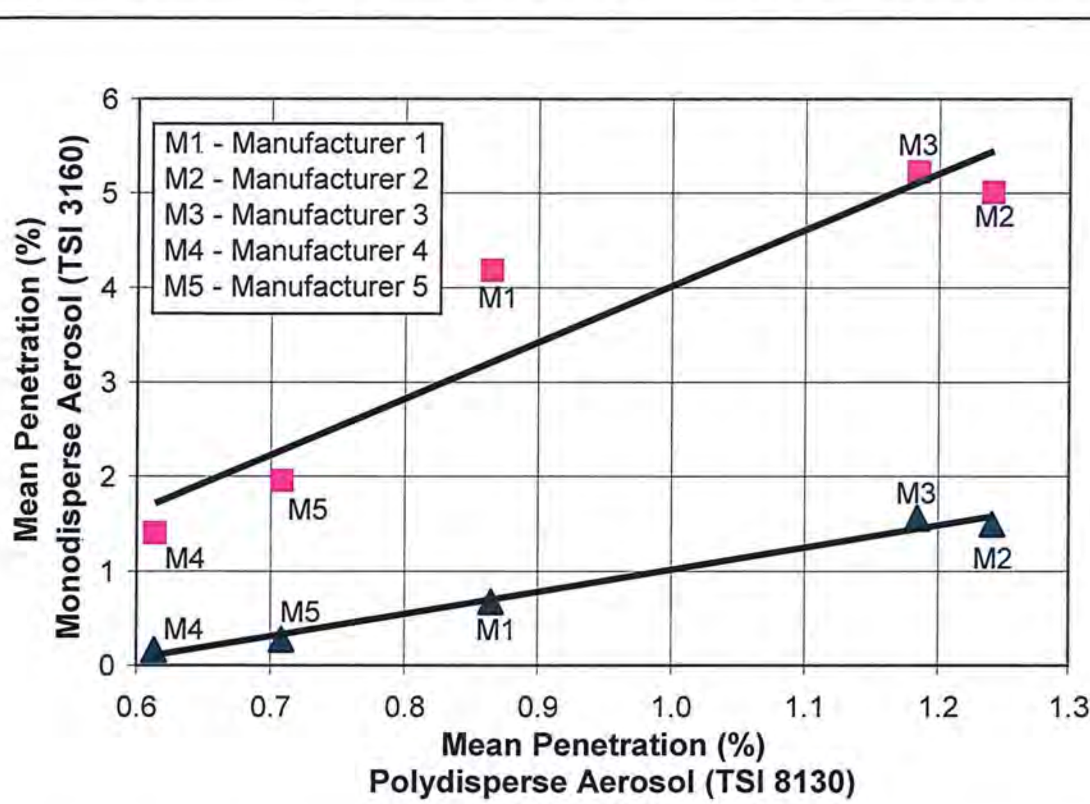

Figure 5: Correlation of polydisperse and 40 nm monodisperse aerosol penetrations (squares) and polydisperse and 300 nm monodisperse aerosol penetrations (triangles) for the five respirator models tested.

DISCUSSION

Monodisperse aerosol penetrations showed that the MPPS was in the 40 nm range for all the respirator models tested. The MPPS of filters has been shown to depend on several factors including particle charge, filter fiber charge and aerosol flow rate (Lee & Liu, 1980; Lee & Liu, 1982; Martin & Moyer, 2000). For this reason, the MPPS observed in this study were compared to similar recent studies, which investigated monodisperse particle penetrations at 85 L/min flow rate (Richardson, 2006; Balazy et al. 2006a). The MPPS observed in this study agreed with the MPPS reported in the previous studies. Richardson et al. (2006) measured the penetrations of monodisperse NaCl particles using the TSI 3160 and observed that the MPPS was 50 nm. In their study, limited numbers of monodisperse particle sizes (20, 50, 100 nm and larger size particles) were employed. On the other hand, Balazy et al. (2006a) used more than 20 different monodisperse NaCl particle sizes between 20 and 100 nm range for penetration measurements with a Wide-Range Particle Spectrometer 1000 XP (MSP Corp.) using a manikin model. Their study clearly showed that the MPPS was 50 nm, which is slightly higher than the MPPS observed in our study. The reasons for the difference in the MPPS between these two studies are unclear. In our studies, two of the five respirator models had average penetration levels slightly higher than 5%, which partially agree with previous reports on inert and biological particles (Balazy et al. 2006a, 2006b). However, the average penetration levels found in this study were not statistically significant ($p<0.05$) compared to 5%, the maximum allowable penetration level for NIOSH certification of class "95" respirators according to the 42 CFR 84 test.

Average particle penetration levels ranging from 1.4% to 5.2% and 0.61% to 1.24% were observed with monodisperse 40 nm particles and polydisperse aerosols, respectively. The differences observed between monodisperse and polydisperse aerosol results may be explained by examining the particle penetration measurement methodologies. The TSI 3160 employs an electrostatic classifier, which separates by electrical mobility various size monodisperse particles for respirator testing. Particle concentrations upstream and downstream of a respirator are measured by two condensation particle counters (CPCs, TSI 3760A). In addition, the upstream CPC employs a dilution bridge to provide optimum numbers of particles for counting. The CPCs count the actual number of particles (Martin and Moyer, 2000). On the other hand, the TSI 8130 uses polydisperse NaCl particles with a count median diameter (CMD) of 0.075 ± 0.02 μm and a geometric standard deviation of less than 1.86 (Federal Register 1995; NIOSH, 2005). The TSI 8130 employs a forward light scattering photometer to measure the flux of light scattering from particles. The scattering light flux is proportional to the particle $(\text{diameter})^6$ or $(\text{mass})^2$, when particle diameter is lower than the wavelength of coincident light (Johnson and Smith, 1998). The observation that penetration levels for monodisperse particles measured using a particle counter exceeds that of the polydisperse aerosol test using a photometric detector has been noted previously (Martin and Moyer, 2000) and agrees with data presented here. Thus, the penetration results for monodisperse particles obtained by the TSI 3160 are based on particle number and the polydisperse aerosol tests with the TSI 8130 test results are based on the flux of particle light scattered and cannot be directly compared.

However, the two test methods employed in our study do agree on the relative rank ordering of the filtration performance of the five different respirator models. N95 respirators from the manufacturers that had the smallest and largest penetration levels for the polydisperse aerosol test also had the smallest and largest, respectively, penetration levels with the monodisperse aerosol test at each particle size tested. The consistent rank-ordering of filtration performance between the two test methods and, in particular, the consistency of the rankings for the monodisperse test at different particle sizes can be rationalized by examining the filtration "curves" shown in Figure 3. The changes in filtration penetration levels between the MPPS and 300 nm follow a smooth curve that can be fitted to a linear model. Similarly, the region between 20 nm and the MPPS can also be fitted to a linear model. Both general trends can be seen for all five respirator models tested. Similar filtration performance vs. particle size curves have been found by others (Richardson et al. 2006; Balazy et al. 2006a; Balazy et al. 2006b). Both the monodisperse and polydisperse aerosol test methods measure the same particle interaction with filter media as described by single fiber filtration theory. Thus, polydisperse aerosol testing with the TSI 8130 similar to the NIOSH certification test provides a useful method for ranking the expected filtration performance of the N95 respirators against 40-300 nm monodisperse particles.

To put these results into perspective it is important to consider that the Occupational Safety and Health Administration (OSHA) has set the assigned protection factor (APF) for disposable filtering-facepiece respirators and elastomeric half facepiece respirators at 10, regardless of the particulate filter classification (Federal Register, 2006). The APF is defined as the minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of trained and properly fitted subjects when used in a complete respiratory program. The APF values take into account a variety of factors including the inward leakage caused by filter penetration and leakage through the face/seal interface region. An APF of 10 implies that the respirator wearer is expected to have no more than one tenth of the ambient aerosol particles in the breathing zone. The particle penetration levels seen in this laboratory data collected under "worst-case" conditions (e.g., high flow rates, charge neutralized monodisperse aerosols, etc.) constitutes less than half of that possible exposure. In most workplace settings, the particle size ranges observed tend to involve larger particles and thus workplace protection factors are typically dominated by the leakage around the face seal and not by filter penetration. The data presented in this paper suggests that NIOSH certified respirators should provide expected levels of protection (consistent with their APF) when used in the context of a complete respiratory protection program including proper selection and fit testing. However, in the unlikely scenario that the workplace exposure consists of a large percentage of particles in the MPPS, the employer should take this information into account during the respirator selection process, perhaps by choosing a respirator with higher levels of filtration performance (APF would stay the same) as suggested by OSHA (Federal Register, 2006) or a respirator with a higher APF than a half facepiece respirator, such as a full facepiece respirator (increasing the APF from 10 to 50).

CONCLUSIONS

For the five NIOSH certified respirator models used in this study, the average initial particle penetration levels measured with polydisperse aerosols using the TSI 8130 ranged from 0.61% to 1.24%. Monodisperse aerosol penetration behaved as expected by single fiber filtration theory. The MPPS was found to be in the 40 nm range. The mean penetration level of 40 nm particles for the five models ranged from 1.4% to 5.2% and exceeded 5% for two respirator models, which is the maximum penetration level allowed by NIOSH for certification using the 42 CFR 84 test. However, the average penetration levels for each of the five products were not statistically larger than 5%. The polydisperse aerosol test provided a consistent rank-ordering of the filtration performance seen with the 40-300 nm monodisperse particles.

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Disclaimer

Mention of commercial product or trade name does not constitute endorsement by the National Institute for Occupational Safety and Health. The findings and conclusions of this report are those of the author(s) and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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