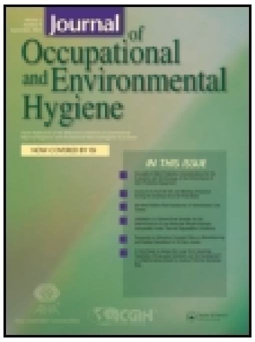

Journal of Occupational and Environmental Hygiene

ISSN: 1545-9624 (Print) 1545-9632 (Online) Journal homepage: https://www.tandfonline.com/loi/uoeh20

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Journal of Occupational and Environmental Hygiene, 6: 593–603
ISSN: 1545-9624 print / 1545-9632 online

DOI: 10.1080/15459620903120086

Performance of an N95 Filtering Facepiece Particulate Respirator and a Surgical Mask During Human Breathing: Two Pathways for Particle Penetration

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The protection level offered by filtering facepiece particulate respirators and face masks is defined by the percentage of ambient particles penetrating inside the protection device. There are two penetration pathways: (1) through the faceseal leakage, and the (2) filter medium. This study aimed at differentiating the contributions of these two pathways for particles in the size range of 0.03–1 μm under actual breathing conditions. One N95 filtering facepiece respirator and one surgical mask commonly used in health care environments were tested on 25 subjects (matching the latest National Institute for Occupational Safety and Health fit testing panel) as the subjects performed conventional fit test exercises. The respirator and the mask were also tested with breathing manikins that precisely mimicked the prerecorded breathing patterns of the tested subjects. The penetration data obtained in the human subject- and manikin-based tests were compared for different particle sizes and breathing patterns. Overall, 5250 particle size- and exercise-specific penetration values were determined. For each value, the faceseal leakage-to-filter ratio was calculated to quantify the relative contributions of the two penetration pathways. The number of particles penetrating through the faceseal leakage of the tested respirator/mask far exceeded the number of those penetrating through the filter medium. For the N95 respirator, the excess was (on average) by an order of magnitude and significantly increased with an increase in particle size ($p < 0.001$): ∼7-fold greater for 0.04 μm, ∼10-fold for 0.1 μm, and ∼20-fold for 1 μm. For the surgical mask, the faceseal leakage-to-filter ratio ranged from 4.8 to 5.8 and was not significantly affected by the particle size for the tested submicrometer fraction. Facial/body movement had a pronounced effect on the relative contribution of the two penetration pathways. Breathing intensity and facial dimensions showed some (although limited) influence. Because most of the penetrated particles entered through the faceseal, the priority in respirator/mask development should be shifted from improving the efficiency of the filter medium to establishing a better fit that would eliminate or minimize faceseal leakage.

Keywords aerosol, breathing, leakage, penetration, respirator, surgical mask

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INTRODUCTION

Filtering facepiece particulate respirators and facemasks are widely utilized for reducing inhalation exposure to airborne particles that may be associated with various health effects. In health care environments, NIOSH-certified N95 filtering facepiece respirators (N95 FFR) and surgical masks are considered basic nonpharmacological means of preventing or slowing transmission of numerous infectious diseases.

These respiratory protection devices (RPDs) are used by health care workers as well as patients and hospital visitors. In 2008, the Institute of Medicine reported that during an influenza pandemic, it may be necessary to protect more than 13 million health care workers (HCW) from illness or from infecting their families or patients.[(1)] The nonoccupational use of various RPD is expected to rise dramatically in the event of a disease outbreak or a bioterrorist attack. Although N95 FFRs are designed to protect a wearer from inhaling ambient aerosol particles, the main function of a surgical mask is to protect others from the aerosol expelled by its wearer. Nonetheless, applications of surgical masks in some health care settings have evolved over time, promoting their widespread use as RPDs (a subject of ongoing debate in the health care industry).[(2)]

Currently, NIOSH certifies respirators in accordance with Title 42 of the *Code of Federal Regulations*.[(3)] Their efficiency is evaluated by testing the filter media under constant airflow. However, measuring the particle penetration under constant flow may not accurately predict the filter efficiency under actual cyclic or pulsatile breathing conditions.[(4,5)]

In addition, the existing filter certification procedure evaluates filter efficiency but not faceseal leaks, which can be an important penetration pathway for aerosol particles. When N95 FFRs are required, the respirator wearer must pass a fit test before being used in the workplace. The fit test measures total aerosol penetration, i.e., occurring through the filter medium and through the faceseal leaks. No method clearly differentiates between the two pathways under actual breathing conditions. Chen and Willeke[6] and Chen et al.[7] investigated faceseal versus filter penetration for particles of 0.5–5 μm, but their experiments were performed with a breathing manikin under constant-flow conditions and artificially created faceseal leaks.

Unlike respirators, surgical masks are not subjected to NIOSH filter certification testing and are not required to be fit tested. In the United States, the Food and Drug Administration (FDA) oversees the sales and marketing of surgical masks, which are defined as medical devices. The FDA does not conduct testing to qualify the efficacy of surgical masks, rather, it recommends performance be demonstrated by the manufacturer. Filter efficiency testing is required; however, the test conditions are not as challenging as those by NIOSH for N95 FFR.

To our knowledge, little information is available in peer reviewed literature about the relative contribution of particle penetration through the surgical mask filter versus faceseal leakage. The latter is anticipated to be significant given that a surgical mask is not required to achieve a tight seal to the face.

The goal of this study was to differentiate the contributions of filter versus faceseal penetration under actual breathing conditions for an N95 FFR and surgical mask. Utilizing a novel Breathing Recording and Simulation System, we were able to identify the contribution of these two pathways under simulated use conditions. We also examined how particle size, facial/body movement, facial dimensions, and breathing intensity affect the relative contribution of the two penetration pathways in the size range of 0.03–1 μm, which was selected to represent the viral and bacterial particles that are of special concern in the health care industry.

MATERIALS AND METHODS

Test Protocol

Twenty-five subjects were selected with facial dimensions according to the recently proposed NIOSH fit test panel.[8] The test population comprised healthy adults between 19 and 49 years of age, including 15 males and 10 females; 11 Caucasians, 3 African Americans, 1 Hispanic American, and 10 Asians/Asian Americans. The subjects' faces ranged from 102.05 to 136.30 mm in length (L) and from 123.65 to 157.30 mm in width (W). All subjects completed an Occupational Safety and Health Administration (OSHA) respirator medical clearance questionnaire and were medically cleared by a physician prior to respirator use. University of Cincinnati IRB-approved informed consent was obtained from each subject.

For each subject wearing the RPD, the particle penetration was determined as a ratio of the aerosol concentration measured inside and outside the respirator/mask. Aerosol concentration was measured particle size selectively using an Electrical Low Pressure Impactor (ELPI; Dekati Ltd., Tampere, Finland) with an air diluter. Each subject performed a variety of head and breathing exercises[9] that were modified to include a longer, 2-min in-facepiece sampling time. This modified fit testing procedure allowed for determination of exercise-specific penetration values for the tested N95 respirator and surgical mask.

Figure 1A schematically presents the experimental setup for testing RPDs donned by a human subject. A similar setup was used previously by Lee et al.[10] for investigating total penetration of 0.03–1 μm particles into N95 FFRs and surgical masks. The testing was conducted in a room-size chamber (24.3 m^3). A solution of NaCl in ultrapure water was aerosolized with a 6-jet Collison nebulizer (BGI Inc., Waltham, Mass.). The freshly generated aerosol was diluted and dried with HEPA-filtered air, charge-equilibrated to a Boltzmann charge distribution using a Kr^{85} sealed source (model 3054; TSI Inc., Minneapolis, Minn.) and fed to the test chamber.

The particle concentrations—ambient and in-facepiece—were measured with the ELPI. A 3-way valve allowed sampling from ambient and in-facepiece lines. The airflow, Q_{sample}, through each sampling was 10 L min^{-1}. To establish the operational flow rate for the ELPI, HEPA-filtered dilution air (20 L min^{-1}) was provided and monitored using a flow control valve and mass flow meter (model 4043; TSI). Airflow calibration was conducted with a DryCal DC-Lite Calibrator (Bios International Corp., Butler, N.J.). A Nafion dryer (model PD-50T-12MP; PermaPure LLC, Toms River, N.J.) was installed in front of the ELPI inlet to prevent the water content generated by the subject's exhalation from entering the instrument. The "zeroing" procedure was performed before each exercise. The ELPI-recorded electrical current distribution was monitored to ensure that the particle bounce had no major effect on the instrument's performance.

Uniquely for this study, breathing patterns were recorded for every subject using a newly designed Breathing Recording and Simulation System (BRSS; Koken Ltd., Japan)[5,11] while the subject conducted the fit testing exercises. Based on the BRSS-recorded exercise-specific data, mean inspiratory flow rates (Q_{MIF}) were calculated. The BRSS was then used to reproduce the recorded breathing patterns on a manikin with the respirator/mask sealed to its face with glue (Figure 1B). The seal of the RPD to the manikin was evaluated with a bubble leak detector prior to the experiment to assure there were no leaks.

A 3-way pressure valve was installed upstream of the breathing simulator to prevent the challenge aerosol from returning to the sample lines during exhalation. A gas meter (model DC-5; Sinagawa Corp., Tokyo, Japan) was set at the end of the line to measure exhaled volume and subsequently determine flow rate. The utilization of the actual breathing patterns produced by the subjects wearing RPDs provides a more realistic flow

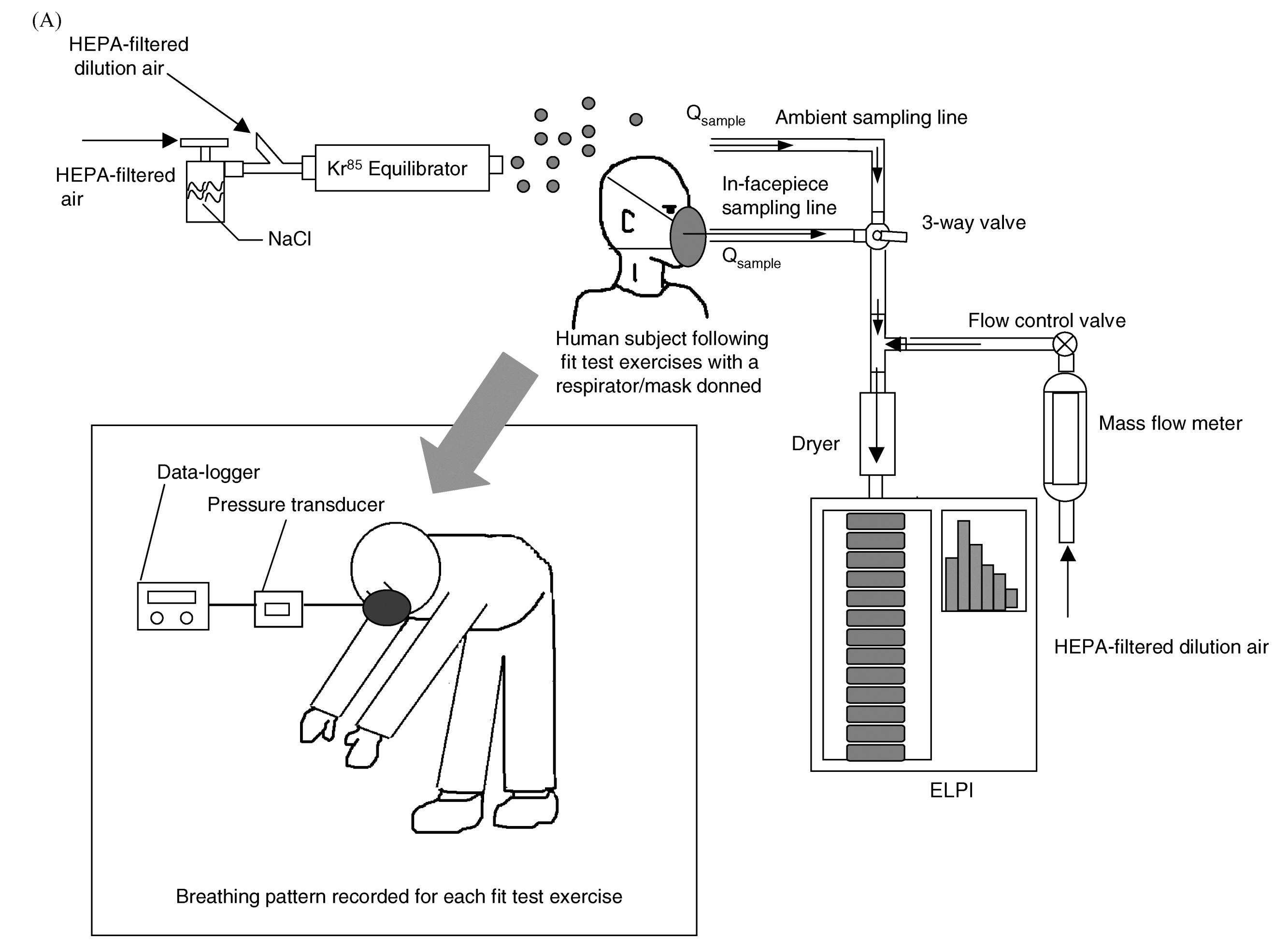

FIGURE 1. (A) Experimental setup for testing respirators/masks donned on a human subject; (B) Experimental setup for testing respirators/masks on a manikin equipped with the Breathing Recording and Simulation System. (*Continued*)

through the filter than a sinusoidal flow pattern employed in earlier studies.[4,5,12,13]

Equipped with an electronic control unit and a set of cylinders, the BRSS was capable of replicating specific airflow patterns identical to those of our study subjects. The high torque of the electromechanical cylinder (3.92 kN·m) ensured sufficient precision and flow even at the sizable pressure changes observed with the respirator/mask sealed to the manikin. With a stroke up to 25 cm, a frequency up to 0.5 Hz, and a total capacity of 6.0 L, the breathing simulator is capable of generating Q_{MIF} up to 360 L min^{-1}. The stroke distance can be adjusted with a resolution of 0.1 mm, thus allowing for very small changes in flow rate when human breathing is simulated.

Whereas the recorded breathing pattern for each subject was reproduced with the tested RPD sealed on the manikin, the aerosol concentrations inside and outside the RPD were measured with the ELPI. This allowed exercise-specific filter penetration values to be determined for the N95 respirator and surgical mask.

The human subject testing allowed determination of particle penetration through both the filter media and the faceseal leakage ($P_{filter+leakage}$), while filter penetration (P_{filter}) was obtained from the manikin tests with the respirator/mask perfectly sealed to the manikin's face (i.e., zero faceseal leakage). For each recorded breathing pattern, the subject-generated penetration values were compared with those obtained with the breathing manikin operating under the same (recorded and reproduced) pattern. This allowed calculating the "faceseal leakage-to-filter" (FLTF) ratio

$$\mathrm{FLTF} = \frac{\text{Particle flux through the faceseal leakage}}{\text{Particle flux through the filter medium}} \quad \textbf{(1)}$$

which quantifies the relative contribution of each of the two particle penetration pathways.

Of all exercises included in the OSHA standard fit testing procedure, five were applicable to manikin-subject comparisons. "Talking" could not be reproduced with the manikin, and the "normal breathing" exercise was performed only once

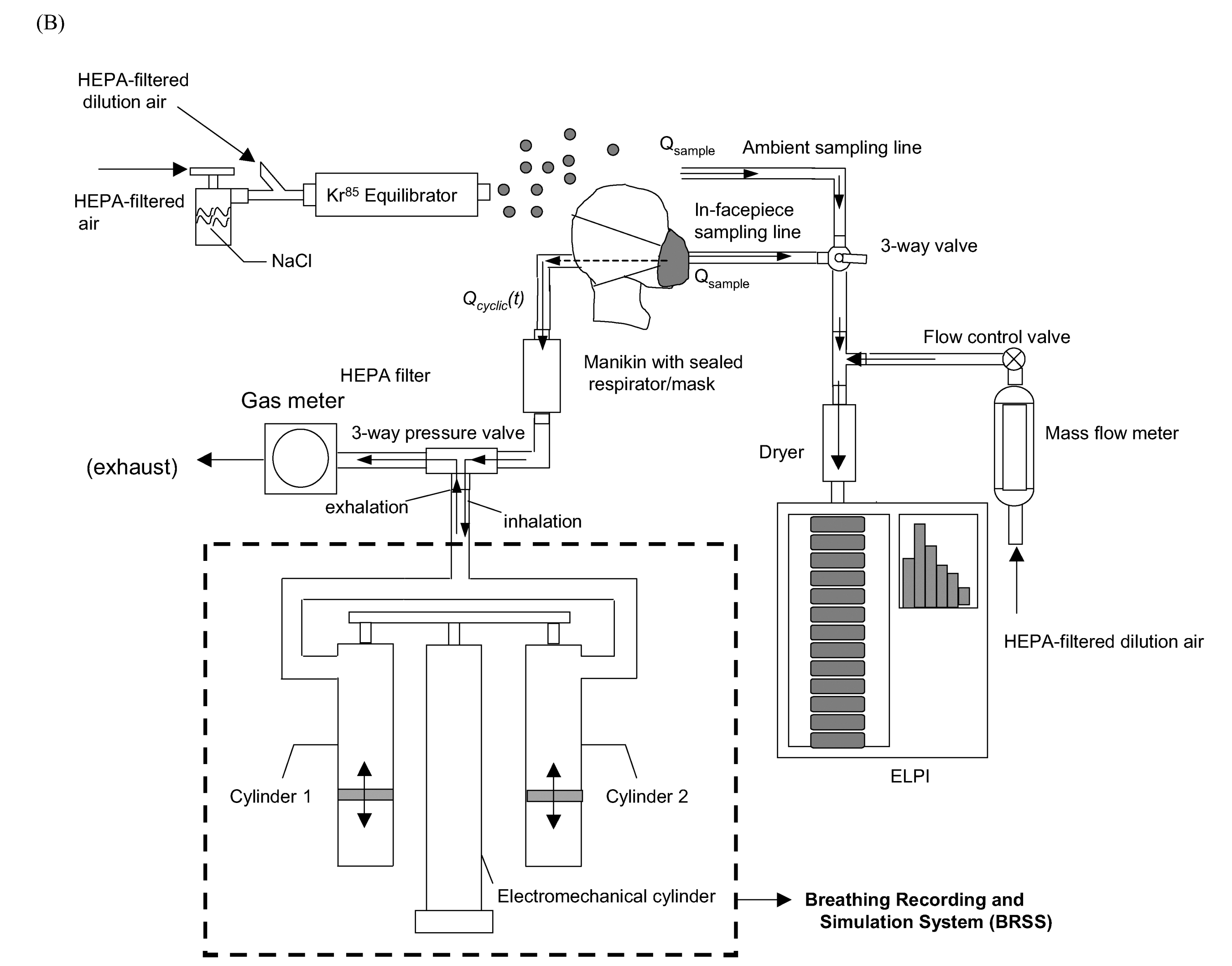

FIGURE 1. Continued.

because its repeat would not contribute any new information. Consequently, the overall penetration was determined using an "abbreviated" equation:

$$\overline{P}_{\text{abbreviated}} = \frac{1}{5} \times P_{\text{normal}} + P_{\text{deep}} + P_{\text{side-to-side}} + P_{\text{up \& down}} + P_{\text{bending}} \quad \textbf{(2)}$$

It derives from the full-format fit factor calculation procedure conventionally applied for determining the overall particle penetration based on the standard fit test:

$$\overline{P}_{\text{full}} = \frac{1}{7} \times P_{\text{normal}} + P_{\text{deep}} + P_{\text{side-to-side}} + P_{\text{up \& down}} + P_{\text{talking}} + P_{\text{bending}} + P_{\text{normal}} \quad \textbf{(3)}$$

Penetration values (exercise-specific and overall) were plotted against particle sizes ranging from approximately 0.03 to almost 1 μm, which covers the size range of most airborne viruses and bacteria, making it particularly relevant for health care environments. Because this study was focused on submicrometer particles, we recorded the first seven particle size fractions provided by the ELPI: 0.029–0.059 μm ($\overline{d}_p = 0.0414$ μm), 0.059–0.103 μm ($\overline{d}_p = 0.078$ μm), 0.103–0.165 μm ($\overline{d}_p = 0.1304$ μm), 0.165–0.254 μm ($\overline{d}_p = 0.2047$ μm), 0.254–0.392 μm ($\overline{d}_p = 0.3155$ μm), 0.392–0.636 μm ($\overline{d}_p = 0.4993$ μm), and 0.636–0.990 μm ($\overline{d}_p = 0.7935$ μm). The ambient concentration of supermicrometer particles generated in these experiments was very low, and the particle counts were not recorded beyond 1 μm.

Respirator and Surgical Mask

A 3-layer, cup-shaped, N95 filtering facepiece respirator and a 3-layer, flat surgical mask were selected for this study. These RPDs came from major manufacturers and are among the most commonly used models in the health care industry. Both devices were equipped with an adjustable nose clip. The RPDs were stored in a box at a normal room temperature and relative humidity. Every device was visually inspected before testing.

Data Analysis

The exercise-specific Q_{MIF} determined with the BRSS for each subject were integrated over 25 subjects, and the average Q_{MIF} value with the standard deviation was calculated for each of the five exercises selected for testing. Every penetration experiment (human subject and manikin) was conducted in three replicates, which resulted in the following matrix:

- types of data generated = 2 (human subject and manikin)
- subjects = 25
- exercises per test = 5
- replicates = 3
- recorded particle sizes = 7.

Thus, $2 \times 25 \times 5 \times 3 \times 7 = 5250$ particle size- and exercise-specific penetration values were determined. For each set of five exercises (abbreviated protocol), the overall penetration value was calculated (total of 1050 values). For each subject, the average and the standard deviation from three replicates were calculated. For each of the seven particle size fraction between $\overline{d}_p = 0.0414$ μm and $\overline{d}_p = 0.7935$ μm, the integrated penetration value was calculated over 25 subjects and 3 replicates (75 data points). The leakage-to-filter ratios were calculated for each particle size with a result presented as the average and the standard deviation calculated for the 75 data points representing 25 subjects and 3 replicates. This is further referred to as the panel-integrated FLTF ratio.

The data analysis was performed using SPSS version 11.0 and Microsoft Office Excel. The FLTF ratios obtained for different particle sizes were compared utilizing ANOVA followed by a pairwise comparison using the Tukey's method. This statistical approach was also used to test the difference in the FLTF ratio values among different exercises. Assuming "normal breathing" to be the fundamental/reference exercise most appropriate for comparison, a paired t-test was performed to examine the difference in Q_{MIF} obtained from the breathing patterns recorded during normal breathing and other exercises. Linear regression analysis was used to examine the relationship between the subject's facial characteristics and the FLTF ratio. Within- and between-subject variability in the FLTF ratios was investigated by a variance component analysis using PROC MIXED procedure in SAS version 8.0.

RESULTS AND DISCUSSION

Figure 2 presents the Q_{MIF} values averaged over 25 subjects for five different exercises. It was observed that "deep breathing" produced noticeably higher Q_{MIF} followed by "bending over." Prominent statistically significant differences were identified between normal and deep breathing ($p < 0.001$) and between "normal breathing" and "bending over" ($p < 0.001$). Once these two differences were identified, we specifically compared the Q_{MIF} produced by "deep breathing" versus "bending over" using a paired t-test and found that the difference was statistically significant ($p = 0.015$).

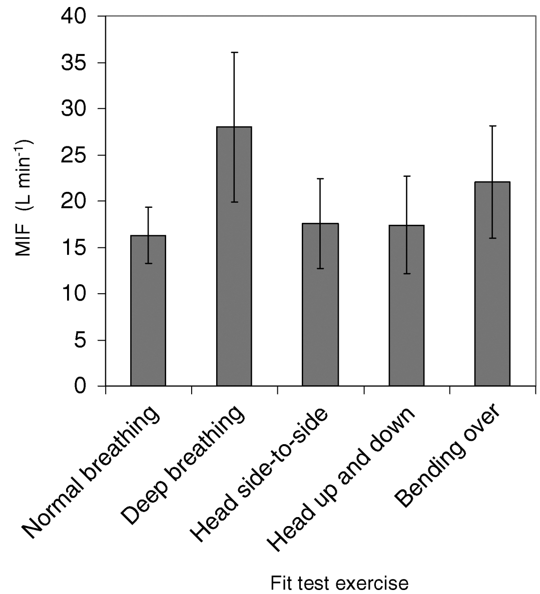

FIGURE 2. Mean inspiratory flow rates (Q_{MIF}) recorded with the Breathing Recording and Simulation System for each fit test exercise. Each bar represents the average value of MIF and the standard deviation integrated over 25 subjects of the NIOSH fit testing panel.

It is notable that the maximum recorded $Q_{MIF} = 43.2$ L min^{-1} was obtained with a subject performing the deep breathing exercise. This level is lower than expected for someone in a more strenuous work environment.

The differences in breathing patterns corresponding to different test exercises are visually presented in Figure 3 for the "most representative" subject—the one who exhibited the Q_{MIF} closest to the average values shown in Figure 2. During normal breathing, the breathing pattern shows an almost perfect periodic function of time with the inhalation and exhalation durations being about the same and the peak inspiratory flow rate value well approximated by an ideal sinusoidal function.

The other exercises exhibited more irregularity. Whereas exhibiting a longer inspiratory period, the "head side-to-side" and "head up and down" exercises produced approximately the same Q_{MIF} values as "normal breathing." "Deep breathing" was characterized by noticeable variability of the tidal inspiratory volume with the peak flow rates ranging from 35 to 57 L min^{-1} (an ideal sinusoidal pattern would produce a peak flow rate approximately 42 L min^{-1}). During the "bending over" exercise, the breathing pattern demonstrated the spikiest changes among all five exercises.

Figure 4 (top) demonstrates the overall particle penetration through the N95 respirator averaged over 25 subjects and 3 repeats. It presents separately the faceseal leakage component, which ranged from <3% ($\sim$1 μm particles) to 5% ($\sim$0.1 μm particles) and the filter medium component, which was below 1% for all the tested particle sizes. Although the total

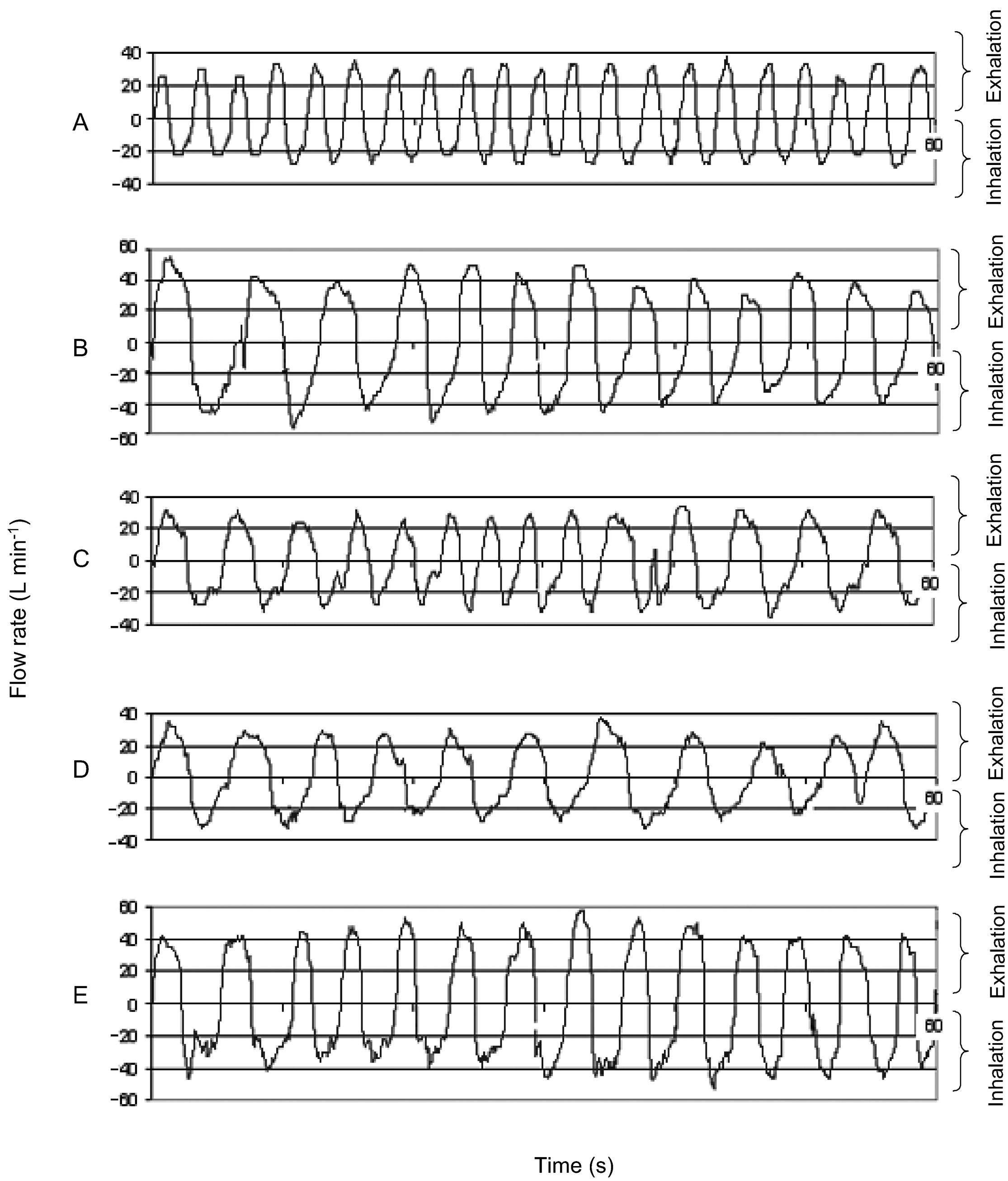

FIGURE 3. The exercise-specific breathing patterns recorded by the Breathing Recording and Simulation System from a selected subject exhibiting Q_{MIF} closest to the average values calculated for 25-subject panel: normal breathing (A), deep breathing (B), head side-to-side (C), head up and down (D), bending over (E).

(filter + leakage) penetration varied, its average value was between 2.5% and about 5.5%, which is greater than expected. This may be attributed to a relatively high airflow rate in the in-facepiece sampling line of the ELPI (10 L min^{-1}).

For both pathways, penetration generally decreased with increasing particle size (at least, beyond the ultrafine fraction); ANOVA revealed that this effect was statistically significant (both p-values are lower than 0.001). However, if determined specifically for smaller particles (up to 0.20 μm), the penetrations associated with the faceseal leakage showed no significant dependence on the particle size ($p = 0.43$).

Similar to our results, Chen et al.[7] concluded from their manikin-based experiments performed under constant flow conditions that the relative contribution of the faceseal leakage to the total penetration increases with increase in particle size. The above study was conducted with larger particles, 0.5–5 μm, and the finding was explained by the increased impaction losses in the faceseal leaks for larger particles.

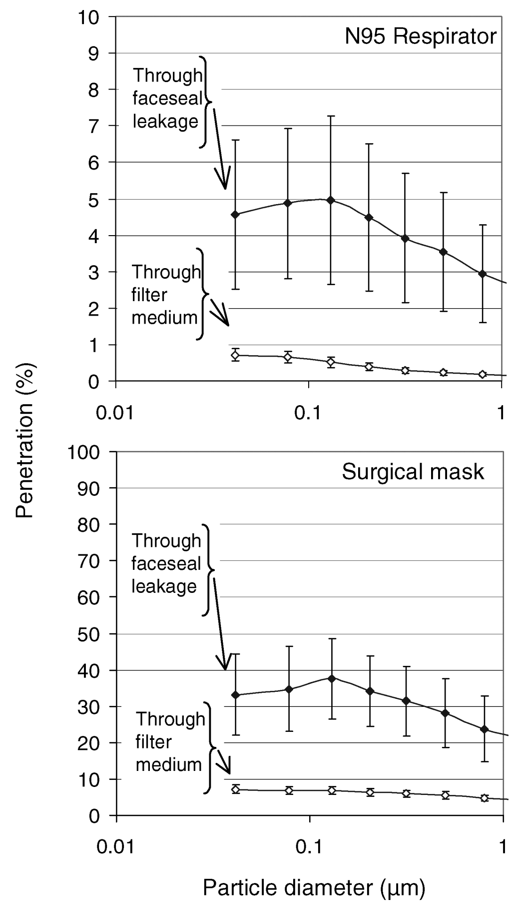

FIGURE 4. The panel-integrated particle penetration through the N95 facepiece respirator and the surgical mask as a function of particle size. Each point represents the average value and the standard deviation of 75 observations (25 subjects × 3 replicates).

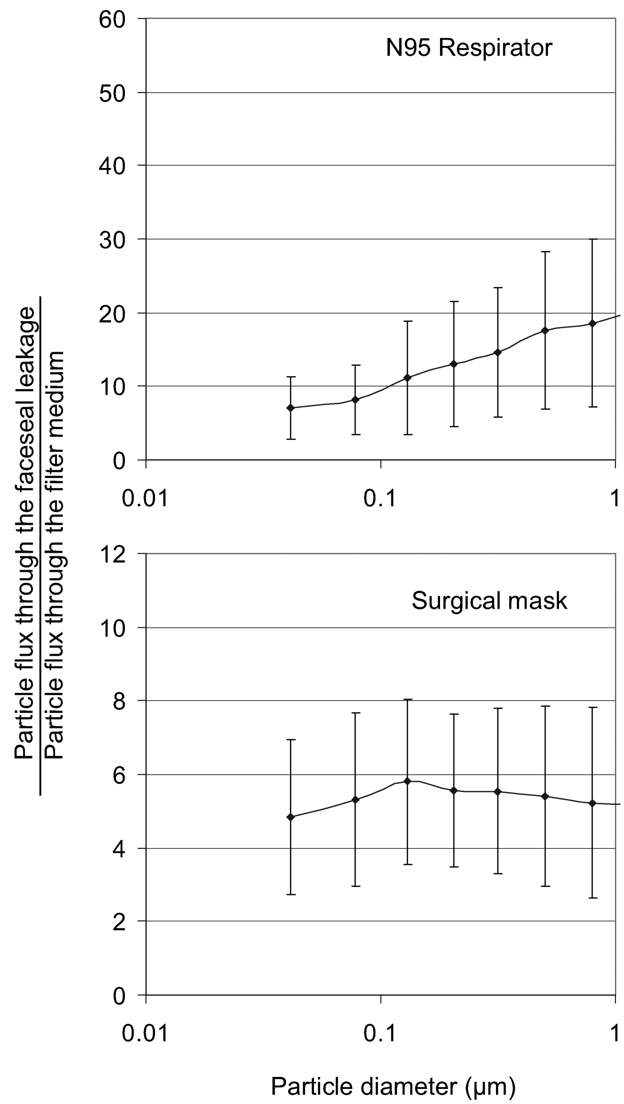

FIGURE 5. The panel-integrated FLTF ratio for the N95 facepiece respirator and the surgical mask. Each point represents the average value and the standard deviation of 75 observations (25 subjects × 3 replicates).

Figure 4 (bottom) presents similar trends observed for the surgical mask. Across the board, the penetration associated with each pathway was significantly affected by particle size ($p < 0.001$). At the same time, when calculated for the particle size fraction of up to 0.20 μm, the penetration associated with the faceseal leakage was not significantly influenced by the size of aerosol particles. This finding does not extend to the particle penetration through the mask's filter medium. Obviously, the penetration levels determined for the surgical mask were much higher as compared with those obtained for the N95 respirator. The results agree with the study by Lee et al.,[10] that showed 8–12 times higher total penetration for surgical masks compared with N95 FFRs.

The overall FLTF ratio is plotted against particle size in Figure 5. By comparing the subject- and manikin-generated penetration values obtained under the same breathing pattern (actual and simulated), we found that the particle flux through the faceseal leakage of the N95 respirator exceeded the flux through the filter medium by approximately an order of magnitude. On average, the difference was ~7-fold for 0.04-μm, ~10-fold for 0.1-μm, and ~20-fold for 1-μm particles. For example, the latter means that approximately 1 out of every 21 particles penetrated into the respirator came through the filter, whereas the other 20 came through the faceseal. The effect of the particle size on the overall FLTF ratio was statistically significant ($p < 0.001$).

For the surgical mask, the average overall FLTF ratio was in the range of 4.8 to 5.8. This means approximately one out of every six or seven particles that penetrate into the mask makes its way through the filter, whereas the other five or six go through the faceseal leak. The relative contribution of the two penetration pathways was not significantly affected by the particle size ($p = 0.31$). Because the filter efficiency of the surgical mask is not as particle size-dependent as the efficiency of the N95 filter medium, the FLTF ratio was relatively constant.

TABLE I. Coefficient of Determination, R^2, of a Simple Linear Regression Between Overall FLTF Ratio and Facial Characteristics

	R^2 Value at a Specific Particle Size		
Facial Characteristics	**0.05 μm**	**0.3 μm**	**1 μm**
	N95 Respirator		
Length (L)	0.0444	0.0437	0.0392
Width (W)	0.0054	0.0007	0.0013
L/W	0.0708	0.0579	0.0560
L×W	0.0072	0.0120	0.0160
	Surgical Mask		
Length (L)	0.0518	0.1311	0.1635*
Width (W)	0.0518	0.2677*	0.2359*
L/W	0.0176	0.0407	0.0560
L×W	0.1123	0.2773*	0.1879*

Notes: Each cell includes 25 data points, each representing an average of 3 test replicates done for a subject. Statistically significant associations ($p < 0.05$) are marked with an asterisk.

We also examined the influence of the subjects' facial characteristics on the relative contributions represented by the two tested penetration pathways. The overall FLTF ratios obtained for each subject (average of three replicates) were related to his/her face length (L) and width (W) as well as to L/W and L×W (the latter represents an estimate of overall facial area). The linear regression modeling was conducted for three particle sizes:

1. 0.05 μm, representing the most penetrating particle sizes (MPPS) in terms of number concentration for the filter media used in N95 filtering facepiece respirators;(14) also representing sizes of single airborne viruses.(15)
2. 0.3 μm, representing the MPPS for mechanical filtration; also adopted in the present NIOSH respirator certification protocol(3) as the mass median aerodynamic diameter of the challenge aerosol particles
3. 1 μm, the largest particle size tested and a representative size for most airborne bacterial particles.(15)

The associations were examined by calculating the coefficient of determination (R^2) for 12 combinations of facial characteristics and particle sizes (four × three). Table I lists the R^2-values for the N95 respirator and the surgical mask. No statistically significant association was found between the overall FLTF ratio and either dimensional or nondimensional facial characteristics for the N95 respirator. Similarly, the linear regression analysis performed with the surgical mask data failed to reveal significant associations in many cases.

However, in 5 out of 12 combinations, the FLTF ratio did show a very modest ($R^2 < 0.3$) but statistically significant negative association with the face width and with the face area (L × W) for 0.3 μm as well as with the face length, width, and the area for 1-μm particles. The analysis of experimental data suggests that the facial characteristics, especially the width and the area, are more likely to affect the FLTF ratio of the surgical mask if the particle size is greater than 0.3 μm.

TABLE II. Variability of FLTF Ratios Between Subjects (σ_B^2) and Within Subjects (σ_W^2)

Particle Size (μm)	σ_B^2	σ_W^2	$\sigma_B^2/(\sigma_B^2 + \sigma_W^2)$
	N95 Respirator		
0.05	9.92	4.71	0.70
0.3	45.73	22.92	0.67
1	66.81	29.21	0.70
	Surgical Mask		
0.05	2.98	0.66	0.82
0.3	2.79	0.98	0.74
1	4.21	1.22	0.78

We believe that the differences found for the N95 respirator and the surgical mask with respect to the influence of facial characteristics on the FLTF ratio reflects the difference in fit and adjustability of these RPDs to the wearer's facial features. This, in turn, leads to different size and shapes of faceseal leakage when the respirator or mask is being worn. The above difference is believed to be less pronounced for ultrafine particles because they are captured primarily by diffusional and electrical polarization forces, while it should be more pronounced for larger (0.3- and 1-μm) particles, as these are removed by several mechanisms including inertial deposition so that the shape of the leakage can make a more substantial difference.

Because the overall FLTF ratio was determined for each of the 25 subjects while conducting three replicate tests, we also calculated the within-subject and between-subject variability values. The calculations were conducted for the previously selected particle sizes: 0.05 μm, 0.3 μm, and 1 μm. Table II presents σ_B^2 (between-subject variability) and σ_W^2 (within-subject variability) as well as the intraclass correlation coefficient $\sigma_B^2/(\sigma_B^2 + \sigma_W^2)$ characterizing how much the variability between subjects (σ_B^2) contributed to the total variability ($\sigma_B^2 + \sigma_W^2$).

We found that about 70% of total variability in the FLTF ratio of the N95 respirator was associated with the subject characteristics (represented by σ_B^2), while only 30% occurred due to donning (represented by σ_W^2). For the surgical mask, the influence of the between-subject variability is even greater (close to 80%). Overall, both the within- and between-subject variability values were higher for the N95 respirator as compared with the surgical mask (Table II).

The effect of test exercises on the relative contribution of the two penetration pathways was also investigated. The head and breathing exercises used in this study are routinely used for fit testing and considered to represent movements that might commonly occur during actual respirator use. All five exercises examined in this study seem relevant to most workplace

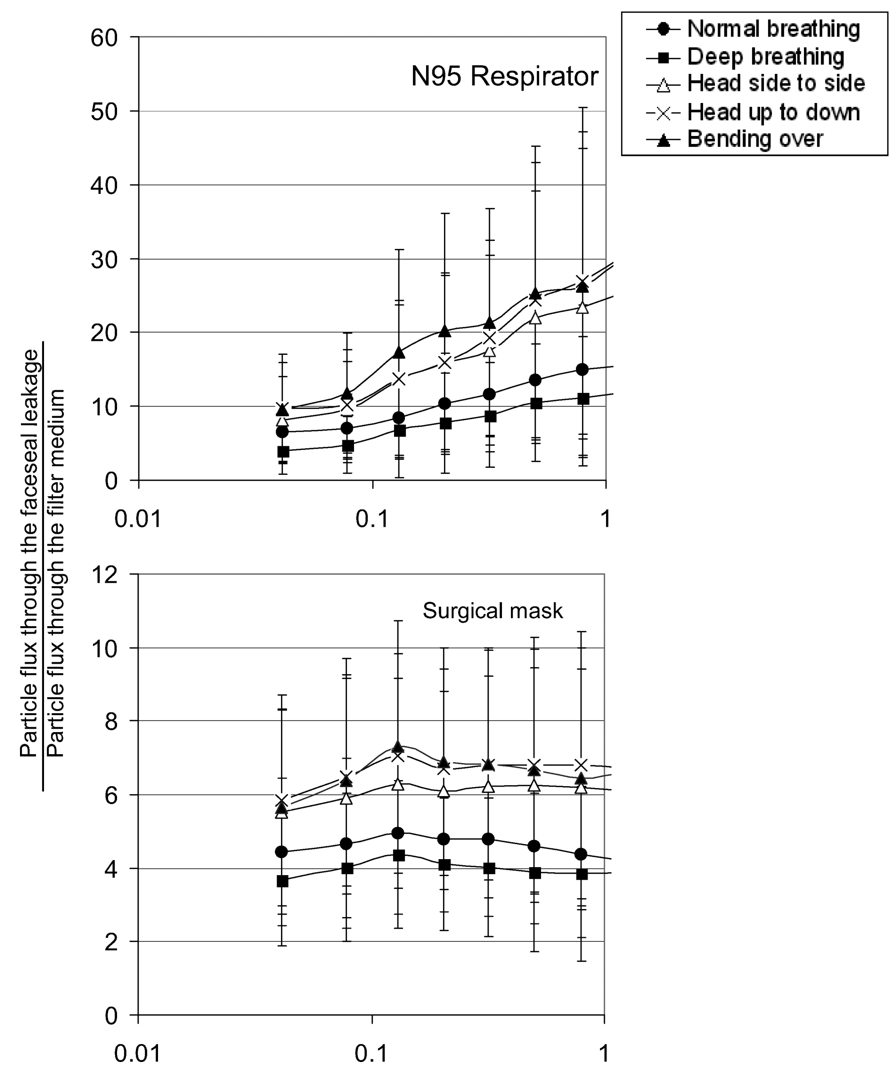

FIGURE 6. The exercise-specific, panel-integrated FLTF ratio for the N95 facepiece respirator and the surgical mask. Each point represents the average value and the standard deviation of 75 observations (25 subjects × 3 replicates).

environments, including health care settings. The "normal breathing" exercise is adequate for assessing the fundamental fit achieved when the respirator is donned; "deep breathing" simulates an increased work load with greater flows and pressures; moving exercises such as "head side-to-side," "head up and down," and "bending over" allow assessing the transient leakage associated with head and body movements.[16]

Figure 6 presents exercise-specific FLTF ratio as a function of the particle size. The analysis revealed that, for the N95, the ratio significantly increased as the particle size increased for each exercise ($p < 0.001$ for all five exercises). In contrast, for the surgical mask, the ratio was independent of the particle size (p-value ranges from 0.125 for "bending over" to 0.810 for "head side-to-side").

Regardless of particle size, movement exercises such as "head side-to-side," "head up and down," and "bending over" produced higher FLTF ratios than nonmovement ones (normal breathing and deep breathing). This is attributed to the fact that movement exercises have a detrimental effect on faceseal leakage.

In our study, the sequence for exercises was not randomized, so we were not able to evaluate the potential effect one exercise may have had on any subsequent maneuver. The data shown in Figure 6 were, however, analyzed to determine if the exercise-specific ratios determined for $d_p = \text{const}$ were statistically significant from one another. For the N95 respirator, FLTF ratios obtained during the two nonmoving test exercises (normal and deep breathing) were not significantly different for any of the particle sizes. Likewise, the difference in ratios observed in the three moving exercises had no statistical significance.

However, when comparing the moving and nonmoving test exercises ($2 \times 3 = 6$ pairs), we found pronounced statistically significant differences for almost all combinations with most p-values below 0.001. The only exception was "normal breathing" versus "head side-to-side" that appeared to exhibit no statistically significant difference at the lowest particle sizes

of 0.04 and 0.08 μm. Note that "head side-to-side" was the first moving exercise performed by a subject after the nonmoving ones. Note also that Lee et al.[17] found that N95 respirators with good fit could recover from faceseal breaks caused by the head and facial movements after their completion.

The statistical analysis of the data presented in Figure 6 for the surgical mask revealed the trends similar to those reported above for the N95 respirator, except for the dependence on particle size. The differences in FLTF ratios observed for moving versus nonmoving exercises were statistically significant and even more pronounced (lower p-values) than those obtained for N95 respirators. This is explainable, as the fit provided by a surgical mask is not as good as the one provided by a N95 facepiece respirator.

Our findings for "normal breathing" and "deep breathing" allow examining the role of the respiration flow rate. The average Q_{MIF} was 16.7 L min^{-1} during "normal breathing" and 27.8 L min^{-1} during "deep breathing." While the average FLTF ratios were consistently lower during "normal breathing" than during "deep breathing" for both the N95 and the surgical mask, this difference lacked statistical significance. This is in agreement with earlier results presented by Chen et al.[7] and Chen and Willeke,[6] who have shown that the fraction of particles penetrating through the faceseal decreases when the constant flow rate through the respirator increases from 5 to 95 L min^{-1}.

The type of exercise had more pronounced effect than respiratory flow rate on the fraction of particles penetrating through the face seal. Whereas the maximum Q_{MIF} produced by a subject in our study was only 43.2 L min^{-1}, in many real-life situations respiration flow rate can be higher under heavy work load, which may generally lead to lower contribution of the faceseal penetration, at least for larger particles.[7] However, higher flow rate is usually combined with activity comparable to moving exercises that in turn tend to increase faceseal leakage.

It is acknowledged that the study has an important limitation associated with a relatively high in-mask sampling flow rate. The latter was chosen because higher sampling flow rate decreases the respirator purge time and significantly reduces potential sampling bias for nonhomogenous distributions of the particle concentration inside the respirator.[18–20] The high flow rate also decreases the detection limit when measuring particles over a specific sampling period, which is important for evaluating the respirator performance against aerosol hazards presented at low concentration levels. On the other hand, ideally, the sampling flow rate should be kept well below of the total flow when conducting fit testing. The high sampling flow rate is expected to affect the particle penetration through both the filter media and the faceseal leakage.

SUMMARY AND PRACTICAL IMPLICATIONS

A novel experimental protocol was developed to quantitatively characterize the two pathways (faceseal versus filter) of penetration for aerosol particles into RPDs. The efficiencies offered by an N95 filtering facepiece respirator and a surgical mask commonly used in health care environments were determined for 25 subjects (matching the latest NIOSH fit testing panel) as the subjects performed a series of exercises. The respirator and the mask were also tested through experiments with breathing manikins that precisely mimicked the prerecorded breathing patterns of the tested subjects.

The penetration data obtained in these two types of tests were compared for different particles sizes and breathing patterns while conducting standard fit test exercises. The penetration levels determined for the surgical mask were much higher than those obtained for the N95 respirator. The number of particles penetrating through the facepiece seal far exceeded penetration through the filter medium for both RPDs tested. For the N95 respirator, the excess was, on average, by an order of magnitude and increased with an increase in particle size: ~7-fold greater for $d_p = 0.04$ μm, ~10-fold for 0.1 μm, and ~20-fold for 1 μm. For the surgical mask, the FLTF ratio ranged from 4.8 to 5.8 and was not significantly affected by the particle sizes used in this study.

The between- and within-subject variability in FLTF ratios for the N95 respirator suggested that about 70% of total variability was associated with the subject characteristics (between-subject variability), while only 30% occurred due to donning (within-subject variability). For the surgical mask, the influence of between-subject variability was even greater. The within-and between-subject variability values were not particle size dependent. The total variability values were higher for the N95 respirator compared with the surgical mask. This can be attributed to the fact that the N95 FFR's FLTF ratio is more sensitive to the facial/body movement than that of the surgical mask, which is a much more loose-fit device.

The subjects' facial characteristics in this study had limited influence on the relative contributions represented by the two, tested penetration pathways. The FLTF ratios obtained for different subjects wearing the N95 respirator (average of three replicates) showed no statistically significant association with any of the four parameters: (1) face length, (2) width, (3) length-to-width ratio, and (4) the face area. This suggests that the between-subject variability was associated primarily with differences in facial/body movement along with variations of the breathing pattern rather than facial dimensions. For the surgical mask, no significant association was observed with any of the above indicated four parameters for 0.05 μm particles, but similar linear regression analysis conducted for larger particles, such as 0.3 μm or 1 μm, suggest some associations with less than 30% of variance in the FLTF ratio attributed to the facial dimensions.

The exercise-specific faceseal FLTF ratios generally followed the same trends as the exercise-integrated ones: for the N95 respirator the ratios significantly increased as the particle size increased for each exercise, while for the surgical mask the ratio was independent of the particle size. Although we did not randomize exercise order, our data suggest that moving exercises such as "head side-to-side," "head up and down," and "bending over" produced higher FLTF ratios than

nonmoving ones. This is attributed, at least partially, to the fact that considerable facial or body movements have a detrimental effect on the faceseal, increasing the fraction of particles that penetrate through the facepiece seal as compared with those penetrating through the filter medium. These data support continuing the use of head movement exercises for routine respirator fit testing.

Exhibiting statistically significant dependence on the particle size, the exercise-specific ratios may or may not differ from each other. For instance, the ratios obtained with the N95 respirator during the two nonmoving test exercises (normal and deep breathing) were not significantly different for any of the particle sizes. Similarly, no statistically significant difference was observed among the three moving exercises.

However, when the FLTF ratios determined for the moving and nonmoving test exercises were compared, we found a strong statistically significant difference for almost all combinations. The above conclusions regarding the differences between the FLTF ratios obtained for different exercises generally extends to the surgical mask.

Based on the findings of this study, we concluded that the future efforts in designing new RPDs for health care environments should be increasingly focused on the peripheral design rather than on the further improvement of the filter media. The faceseal leakage was found to represent the main pathway for the submicrometer particles penetrating into the respirator/mask. Thus, we believe that the priority in product development should be given to establishing a better fit that would eliminate or minimize the faceseal leakage. The implementation of this recommendation should, of course, not undermine the effort to develop RPDs with appropriate comfort level, which requires maintaining relatively low pressure drop through the respirator/mask.

ACKNOWLEDGMENTS

This research was partially supported by Cardinal Health, Inc., McGraw Park, Illinois. Hiroki Haruta's effort was funded by Koken Ltd., Tokyo. The authors appreciate this support. The authors also extend their gratitude to Linda Levin and graduate students Ashutosh Mani and Umesh Singh of the University of Cincinnati for their assistance in conducting statistical analyses.

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