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Quantitative Fit-Testing of N95 Respirators: Part II—Results, Effect of Filter Penetration, Fit-Test, and Pass/Fail Criteria on Respirator Performance

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Abstract

This is the second of two articles dealing with quantitative fit-testing of N95 respirators (one of the new classes of particulate respirators) certified by the National Institute for Occupational Safety and Health in the United States. This portion of the study had three purposes to: 1) quantitatively fit-test twenty-one N95 respirators to evaluate the laboratory performance of these N95 respirators; 2) determine if their laboratory performance could be improved when the first donning was used as a surrogate fit-test to screen out poor fitting respirators; and 3) investigate the effect of face-seal leakage, pass/fail criteria, and the use of subsequent donnings as the surrogate fit-test on respirator performance. Each respirator was tested on a panel of 25 subjects with varying face sizes. Four total penetration tests were conducted for each subject/respirator combination resulting in a total of 100 measurements for each respirator. The 95th percentile for total penetrations of all the respirators combined was 33% which is more than three times the maximum allowable value of 10%. Further investigation revealed that the total inward leakage was mainly attributable to face-seal leakage, not filter penetration. When the first donning was used as a surrogate fit-test to separate the subjects into two groups (one passing the fit-test and the other failing the fit-test), significant differences in total penetration and face-seal leakage were found between the two groups (p -value = 0.0003). The results show that the level of protection provided by an N95 respirator is greatly enhanced when fit-testing is performed to screen out poor fits. This study also demonstrated that the pass/fail criterion of 1% is necessary to ensure that the respirator will reduce the in-facepiece concentration of workplace contaminants to 10% or less of the ambient concentration. In addition, it was found that the total penetration or face-seal leakage did not differ among the four different donnings. The subjects in this study were able to obtain consistent fits each time the respirator was donned. Thus, fit-testing protocols for N95 respirators may not have to include different donnings.

Introduction

This is the second of two articles describing the quantitative fit-testing of N95 respirators, one of the nine classes of respirators which are certified in accordance with Title 42, Code of Federal Regulations, Part 84 (Zhuang *et al.*, 1999; CFR, 1996). Of these new types of particulate respirators, the N95 respirators are the least resistant to degradation, the least efficient in aerosol removal, and the most commonly used.

As described in Part I, a new clamp was developed for use with the PortaCount Plus™ (TSI, Inc., Minneapolis, MN) for measuring filter penetration of microscopic particles in air (ambient aerosols) through N95 filtering facepiece respirators, the magnitude of this penetration was determined, four different filter penetration methods were compared, and the effect of testing position on ambient aerosol filter penetration was determined (Zhuang *et al.*, 1999). One-sided t-tests showed that filter penetration measured with the PortaCount Plus™ and a clamp was significantly greater than 0.03% ($\alpha = 0.05$). In addition, ambient aerosol filter penetration was found to be affected by the placement of the clamp on the respirator. It was also found that the NaCl test provided filter penetrations that were significantly higher than those measured with the PortaCount Plus™ and lab CNC ($\alpha = 0.05$).

Using these results, a quantitative fit-test method was developed to use the PortaCount Plus™ with the clamp to measure filter penetration and to fit-test N95 respirators. This method measures the total penetration and then filter penetration for each respirator after being worn by a subject. The filter penetration was then subtracted from the total penetration to give only the face-seal leakage. This portion of the study was designed to: 1) quantitatively fit-test twenty-one N95 respirators using the new method to evaluate their laboratory performance; 2) determine if the laboratory performance of these respirators could be improved when the first donning was used as a surrogate fit-test to screen out poor face fits; and 3) investigate the effect of face-seal leakage, pass/fail criteria, and using different donnings as the surrogate fit-test on the performance of these N95 respirators.

Each respirator was worn by a panel of 25 subjects with various face sizes. The number of particles was counted outside (C_o) and inside (C_i)

the respirator. A fit factor, defined as C_o/C_i , was determined for each respirator/subject combination (NIOSH, 1987). A fit factor is a measure of face-seal leakage only. N95 filter media has significant leakage when challenged with an ambient aerosol (Zhuang *et al.*, 1999). Therefore, the "fit factors" obtained in this second part of the study were not true fit factors but rather a measure of the total penetration (face-seal leakage and filter penetration) of the ambient aerosol. Each person donned each respirator four separate times resulting in 100 total penetration measurements for each respirator. Penetration of the ambient aerosol through these N95 respirators was measured right after the fourth total penetration test. Then face-seal leakage could be estimated by subtracting this filter penetration from the total penetration of the ambient aerosol through the respirator. The geometric mean, geometric standard deviation, and 95th percentile of these 100 total penetrations were then calculated to characterize the performance of each respirator when it was given to wearers without a fit-test being performed. The same parameters were determined for filter penetration and face-seal leakage.

Since all regulations dealing with the wearing of respirators require a fit-test before a respirator is allowed to be used in the workplace, a fit-test was simulated using the first of the four donnings performed by each subject (OSHA, 1998). The face-seal leakage of the first donning was compared to the American National Standards Institute Z88.2 and Occupational Safety and Health Administration pass/fail criterion of 1% face-seal leakage, which is equivalent to a fit factor of 100 (ANSI, 1992; Federal Register, 1998). The data from subjects who did not meet this criterion were separated from the data from subjects who met the criterion and the two groups were compared. This provided an indication of the performance of the respirator when properly fitted. The N95-COMPANION™ is available from TSI as an accessory to test N95 respirators with their PortaCount Plus™. The N95-COMPANION™ removes the aerosol size range that is most penetrating to the respirator filter. The PortaCount Plus™ can then count only the very small aerosol that does not significantly penetrate the filter. Thus, when using the N95-COMPANION™, filter penetration is not a concern. The N95-COMPANION™ fit test method was not used in this study.

Methods and Materials

Subjects

A total of 31 subjects (16 women and 15 men) participated in this study. Subjects who smoked were requested to refrain from smoking for at least one hour prior to the start of testing. From this panel of 31 subjects, 25 (13 women and 12 men) were chosen for each respirator based on face size. Therefore, each subject did not wear every respirator. Twelve subjects tested every respirator. The subjects had face lengths ranging from 93.5 to 133.5 mm and lip lengths of 34.5 to 61.5 mm (Hack *et al.*, 1974). Only the manufacturer's instructions on donning and checking the seal of the respirator were provided to each subject on how to wear a particular respirator. Each of the 31 subjects was an experienced respirator wearer and had participated in both qualitative and quantitative fit-testing prior to this study. The test subjects were instructed to refrain from smoking for at least one hour prior to the start of the test.

Respirators

For this study, twenty-one N95 respirators (20 filtering facepiece and one elastomeric) certified by the National Institute for Occupational Safety and Health (NIOSH) were tested. The models and number of sizes available for each respirator, style, and type are given in alphabetical order in Table 1. These filtering facepiece respirators are representative of those available at the beginning of the study. The one elastomeric facepiece respirator (Air Ace) was selected because it did not undergo a qualitative fit-test as part of the certification process. All of the respirators were probed approximately half way between the nose and mouth using the TSI Fit-test Probe Kit (P/N 8025-N95, St. Paul, MN) to allow sampling inside the respirator.

These models do not necessarily represent the models now available: some are no longer manufactured and marketed in the version tested since they have either been modified by the manufacturers or replaced by other versions. Also, many additional models are now available.

Measurement of Total Penetration

A TSI PortaCount Plus Model 8020™ (TSI Inc., St. Paul, MN), a quantitative fit-test instrument that utilizes a miniature condensation nuclei counter to count the number of particles in an ambient aerosol,

was used to measure the total penetration through the N95 respirators. The PortaCount Plus™ was chosen because it is widely used for fit-testing. In addition, it has been demonstrated, in a previous study, that the fit factors (the reciprocal of face-seal leakage) obtained from this instrument during a simulated healthcare workplace test have a high correlation with a wearer's actual exposure (Coffey *et al.*, 1998). Since it has been shown in the previous article that an ambient aerosol can have significant penetration through N95 filter media, the factors reported by the PortaCount Plus™ were not fit factors (a measure of the face-seal leakage only) but were measures of the total penetration (i.e., face-seal leakage and filter penetration combined). Therefore, the total penetrations were measured in the same manner as respirator performance is in the workplace (i.e., assessing the amount of a contaminant inside the facepiece without regard to whether it is filter penetration or face-seal leakage). The factors reported by the PortaCount Plus™ were converted into total penetration by dividing them into 100. To determine how well N95 respirators performed when worn without first being fit-tested, a series of four total penetration tests was conducted on each respirator using panel of twenty-five-subjects.

The respirators which were available in multiple sizes did not come with instructions on how to choose appropriately. Therefore, to provide the best performing respirator for each subject, each size for a particular respirator model was donned according to the manufacturer's instructions without assistance from the test operator and tested with the PortaCount Plus™ with the subject breathing normally for 80 seconds. The size having the lowest total penetration was then used for the series of four total penetration tests.

After sizing (if required), the subject donned and performed a user seal check on the respirator in accordance with the manufacturer's instructions. After the user seal check was completed and the subject felt an adequate fit had been obtained, the total penetration testing began. The subject performed the following exercises for approximately 80 seconds each: (1) normal breathing, (2) deep breathing, (3) moving the head side to side, (4) moving the head up and down, (5) reading the rainbow passage out loud, and (6) normal breathing. An overall total penetration value was obtained from all six exercises. After completing the first test, the subject removed the respirator and returned it to the

Table 1. List of respirators tested.

Company	Model [†]	Number of sizes	Style
3M (St. Paul, MN)	1860	1	Cup
3M	8210	1	Cup
Air Ace Oy (Jyvaskyla, Finland)	9100 with 300 filter*	1	NA
AlphaProtech (North Salt Lake, UT)	MAS695	1	Folding
Better Breathing, Inc. (Lawrence, MA)	RX-2	1	Cup
Gerson (Middleboro, MA)	1730	1	Cup
Gerson	2735	1	Cup
Moldex (Culver City, CA)	2001(S), 2002(M/L)	2	Cup
Moldex	2300N95	1	Cup
Mine Safety Appliances (MSA) (Pittsburgh, PA)	Affinity N95	1	Cup
MSA	Affinity Pro (S/M/L)	3	Cup
Racal Health and Safety, Inc. (Frederick, MD)	Delta (XS/S/M/L)	4	Folding
Racal	Racal (XS/S/M/L)	4	Folding
San Huei United Company, Ltd. (Taipei, Taiwan, Republic of China)	SH3810	1	Cup
Survivair, Inc. (Santa Ana, CA)	1930	1	Folding
Tecnol Inc. (Fort Worth, TX)	PFR95-174(S) PFR95-170(R)	2	Folding
Tecnol	PFR95-114 (S) PFR95-110 (R)	2	Folding
Uvex Safety, inc. (Smithfield, RI)	Pro-Tech-N95A S/M/L	3	Cup
Uvex	Pro-Tech-N95 (S/M/L)	3	Cup
Willson Safety (Reading, PA)	N9501 (S/M/L)	3	Cup
Willson	N9510 (S/M/L)	3	Cup

[†] XS = extra small, S = small, M = medium, L = large, and R = regular.

* Elastomeric half-mask with replaceable N95 filter.

test operator. The test operator then returned the respirator to its original configuration prior to donning it (e.g., loosening head straps, flattening nosepiece, etc.). The subject donned and performed a user seal check on the same respirator again according to the manufacturer's instructions. Then a second test, identical to the first, was conducted. This procedure was repeated two additional times for a total of four total penetration tests for each subject/respirator combination.

The 100 total penetration values were then used to characterize the performance of each respirator model without fit-testing (the subject wearing the respirator without regard to whether or not a satisfactory fit was obtained). The geometric mean (GM) and the geometric standard deviation (GSD) of the 100 total penetration values were first calculated. Then a 95th percentile was calculated using the GM and GSD values in a formula as $GM \cdot GSD^{1.645}$ (Lenhart and Campbell, 1984).

Measurement of Filter Penetration

Immediately after the fourth total penetration test, the PortaCount Plus™ was used with the newly developed filter penetration test clamp to measure filter penetration (Zhuang *et al.*, 1999). To do this, the respirator/filter was placed in the NIOSH filter penetration test clamp and the handle secured with a spring. The PortaCount Plus™ was then connected to the NIOSH filter penetration test clamp and run in the count mode for two minutes to clear any particles inside the respirator. The PortaCount Plus™ was placed in the fit-test mode and filter penetration testing started. After the first time period (approximately 80 seconds), the test was stopped. The "fit factor" of the filter calculated by dividing the ambient particle concentration (upstream of the filter) by the particle concentration downstream of the filter displayed on the PortaCount Plus™ was recorded and the filter penetration was later calculated.

Effect of Fit-testing on Performance of N95 Respirators

To estimate the performance of N95 respirators when fit-testing is conducted prior to use, the first of the four total penetration values was used as a surrogate fit-test. Face-seal leakage was calculated by subtracting out the filter penetration from the first total penetration value. All subjects having a first donning face-seal leakage greater than 1 percent were considered to have failed the fit-test and were separated from the subjects passing the fit-test (ANSI, 1992; Federal Register, 1998). The total penetrations for donnings 2, 3, and 4 were used to calculate the GM, GSD, and 95th percentile of total penetration and face-seal leakage for these two groups of subjects by respirator model. Typically, the 95th percentile of total penetration is used to indicate overall respirator performance rather than the geometric mean. Only five of the respirators had a 95th percentile value at or below 10%. The results for each group of subjects represent the performance of the respirator when properly fitted and the performance of the respirators when poorly fitted. The performance of these two groups was compared to determine the effect of fit-testing on respirator performance.

Effect of Pass/Fail Criterion on Respirator Performance

To evaluate the effect of the pass/fail criterion on respirator performance, two more criteria (face-seal leakage of 2 percent and 10 percent) were used instead of 1 percent face-seal leakage. The 2 percent

criterion was selected because it is twice the value currently required as the pass/fail criteria (ANSI, 1992; OSHA, 1998). The 10 percent criterion was chosen because it is equal to the expected level of protection provided by half-mask negative-pressure respirators in the workplace (NIOSH, 1987; ANSI, 1992). For each of the two new criteria, the respirator performance was determined using the method described above for the 1 percent criterion.

Effect of Different Donnings on Respirator Performance

In this study, four total penetrations were measured for each respirator/subject. To determine the effect of different donnings on respirator performance, the second through the fourth donnings were also used as a surrogate fit-test. Face-seal leakage was also determined for these donnings by subtracting the filter penetration from the total penetration (face-seal leakage plus filter penetration). Subjects having a donning face-seal leakage greater than 1 percent were considered to have failed the fit-test and were separated from subjects passing the fit-test. The total penetrations for the other three donnings were used to calculate a new 95th percentile of the total penetration for the respirator models for the two subject groups.

Statistical Design and Analyses

The hypothesis formulated in this study was that fit-testing significantly increases the laboratory performance of each N95 filtering-facepiece respirator. The response variable was total penetration and the independent variables were fit-test outcome (pass or fail) and subject. The total penetrations for each N95 respirator model were analyzed using a mixed effect, analysis of variance model (two fit-test outcomes \times 25 subjects) and nesting subjects within fit-test outcome to determine if fit-testing significantly effects total penetration. The number of subjects passing the fit-test for a respirator may not be the same as the number of subjects failing the fit-test. However, the two groups have a total of 25 subjects each with three total penetration tests. The effect of fit-test outcome is treated as fixed and the effect of subject is considered as random. One assumption in the statistical analysis was that differences among subjects were due to differences in face fit. A t-test was used to detect differences between mean total penetrations for subjects who passed the fit-test and for those who failed the fit-test. A significance level of 5 percent was used in all tests. All analyses were performed on log-transformed data.

Results and Discussion

Performance of N95 Respirators Based on Total Penetration

The total penetration results for each of the 21 respirators are summarized in Table 2. It should be noted that the respirator models in Table 2 are ordered by increasing total penetration. The geometric mean for each of the respirators was below 10%, the expected level of protection, with an overall geometric mean of 2.8% (NIOSH 1987). In addition, the 95th percentile for total penetration of all the respirators was 33% which is more than three times the amount of total penetration (10%) normally expected of half-masks.

The observation of five models having a 95th percentile of total penetration less than 10% should not be taken to mean that these models need not be fit-tested. First, the number of subjects in this study is too small to justify such a conclusion. Second, the laboratory test movements may not completely represent movements in actual workplace conditions. Third, continued product modifications by respirator manufacturers may affect the fitting characteristics of specific models. Finally, passing a fit-test ensures that the wearers can properly put on the respirator and greatly enhances the protection provided by the respirator will be discussed later in the face-seal leakage section.

Filter Penetration

It was initially assumed that filter penetration would be constant during the day because the ambient particle distribution would be stable during an eight-hour testing period and the consistency of the filter media for respirators/filters of the same brand of respirators would not vary greatly since only one lot per model was tested. Therefore, only a limited number of respirators were tested for filter penetration at the start of the study. For example, if six subjects wore a particular respirator model during a single day, only three were tested for filter penetration: the first respirator worn, one worn around midday, and the last one worn. The average filter penetration for these three respirators was then used in the conversion of total penetration to face seal leakage.

However, as the study progressed, it became evident that the assumption regarding filter penetration may have been in error. It became evident that there was large variation in the filter penetration

measurements, between respirators of the same model. So, at the midpoint of the study, filter penetration began to be measured on every respirator/filter that was fit-tested. Each individual respirator/filter's ambient aerosol penetration was then used to convert its total penetration into face seal leakage.

The wide variation in ambient aerosol penetration of N95 respirators is seen in Table 2. The filter penetration of the 21 respirators tested ranged from 0.003% to 1.08% with a geometric mean of 0.16% and a geometric standard deviation (GSD) of 4.2. A GSD of 2 or above represents a relatively large variation (NIOSH, 1977). This large variation was caused by respirators in the same lot not being uniform and thereby having different efficiencies. In addition, even though an effort was made to measure filter penetration at the same exact location on each respirator or filter, it may have varied enough to affect the filter penetration (Zhuang *et al.*, 1999). Finally, some variation in filter penetration may have been attributable to the changing of ambient particle size distribution through the course of the day which could have influenced the penetration.

Face-seal Leakage

The face-seal leakage results for each of the 21 respirators are summarized in Table 2. The geometric mean of the face-seal leakage for each of the respirators was below 10% with an overall geometric mean of 2.4%. Only those five respirators having 95th percentiles of total penetration less than 10% had 95th percentiles of face-seal leakage less than 10%. As expected, the variation in face-seal leakage is larger than that in total penetration resulting in a slightly higher 95th percentile.

The value of n is not equal to 100 for three of the respirators under the face-seal leakage column. This is due to the fact that in these eleven instances (less than 0.5% of all 2100 observations) the filter penetration was greater than the total penetration, resulting in a negative value for face-seal leakage. This could have been caused, in the case of respirator 3, by using the average filter penetration for a particular day. (The filter penetration of the five respirators not tested for filter penetration could have been more efficient than the ones that were tested resulting in the total penetration being less than the filter penetration.) For the other two models of respirators, the total penetration could have been caused by the

Table 2. Summary of total penetration, filter penetration, and face-seal leakage for all subjects by respirator model.

Respirator model	Total penetration				Filter penetration			Face-seal leakage			
	n	GM	GSD	95th	n	GM	GSD	n	GM	GSD	95th
1	100	1.0%	2.9	5.9 %	11	0.04%	2.2	100	1.0 %	3.1	6.1 %
2	100	1.6 %	2.2	6.1 %	25	0.12 %	2.8	100	1.4 %	2.5	6.1 %
3	100	0.3 %	6.3	6.6 %	14	0.03 %	2.6	95	0.2 %	9.4	8.9 %
4	100	1.7 %	2.4	7.0 %	25	0.21 %	1.7	100	1.3 %	2.9	7.5 %
5	100	2.4 %	2.4	9.8 %	15	0.17 %	3.6	100	2.0 %	2.6	9.9 %
6	100	1.3 %	3.7	10.7 %	25	0.04 %	3.1	100	1.2 %	3.8	10.7 %
7	100	2.7 %	2.5	11.7 %	25	0.40%	1.8	100	2.1 %	2.9	11.6%
8	100	2.4 %	2.8	13.4 %	11	0.29 %	2.4	100	1.9 %	3.4	13.9 %
9	100	5.9 %	2.0	17.8 %	13	0.18 %	3.1	100	5.6 %	2.0	17.8%
10	100	1.2 %	5.4	18.4 %	25	0.10%	2.3	100	0.8 %	7.5	20.9%
11	100	4.2 %	2.5	18.8 %	25	0.79 %	1.5	97	3.1 %	3.0	19.7%
12	100	2.8 %	3.5	21.4 %	14	0.23 %	1.9	100	2.1 %	4.8	28.2%
13	100	3.3 %	3.4	24.5 %	12	0.26 %	2.2	100	2.9 %	3.8	26.0%
14	100	8.2 %	2.0	26.0 %	25	0.16 %	1.6	100	8.0 %	2.1	26.2%
15	100	7.9 %	2.3	30.9 %	25	0.27 %	1.9	100	7.5 %	2.4	32.1%
16	100	4.6 %	3.3	32.5 %	25	0.26%	1.4	100	4.0 %	3.7	35.1%
17	100	7.8 %	2.4	33.2 %	25	1.08 %	2.6	97	5.5 %	3.2	36.8%
18	100	6.5 %	3.1	40.8 %	11	0.28 %	2.6	100	5.7 %	3.7	48.0%
19	100	1.1 %	10.0	50.1 %	15	0.03 %	4.6	100	0.9 %	12.9	59.1%
20	100	9.6 %	3.1	60.9 %	25	0.17 %	1.9	100	9.0%	3.3	65.1%
21	100	4.3 %	6.3	87.7%	12	0.003 %	4.5	100	4.2%	6.4	88.7%
All	2100	2.8%	4.5	33.0%	403	0.16%	4.2	2089	2.4%	5.3	36.4%

Notes: GM = Geometric Mean, GSD = Geometric Standard Deviation, and 95th = 95th Percentile.

respirators having very good fits (i.e., having very small amounts of face-seal leakage) so that filter penetration would comprise total penetration exclusively. Then, just the instrument variation in taking the total and filter penetration measurements could have caused the filter penetration to be greater than the total penetration. Filter penetration is usually small. Thus, the face-seal leakage associated with those observations is believed to be small as well. Exclusion of these data points would produce more conservative estimates of the respirator performance.

Effect of Face-seal Leakage on Respirator Performance

The data in Table 2 also show that the 95th percentiles of the total penetrations for each of the respirators are similar in value to the corresponding

95th percentiles of face-seal leakage. This indicates that the largest component, by far, of total penetration for each of the 21 respirators was face-seal leakage. This is also substantiated by the different geometric means. The GM for total penetration ranged from 0.3% observed with respirator model three to 9.6% with respirator model 20. Overall, the GM for total penetration was determined to be 2.8%. The geometric means for filter penetration ranged from 0.003% to 1.08% with an overall GM for filter penetration of 0.16%, which was dramatically smaller than the overall GM for total penetration (2.8%). On the other hand, the overall GM for face-seal leakage was 2.4% which was about the same as the GM for overall total penetration.

The finding that total penetration was mainly attributed to face-seal leakage is also illustrated in Fig. 1, which presents a scatter plot of individual

Table 3. Summary of total penetration for subjects passing and failing the fit-test for pass/fail criteria of 1% face-seal leakage by respirator model.

Respirator model	Total penetration for subjects passing fit-test				Total penetration for subjects failing fit-test			
	n	GM	GSD	95th	n	GM	GSD	95th
1	42	0.6%	2.5	2.7%	33	2.3%	2.5	10.2%
2	27	0.9%	1.5	1.8%	48	2.2%	2.3	8.7%
3	60	0.2%	4.0	1.7%	15	4.4%	4.2	46.5%
4	24	0.8%	1.6	1.8%	51	2.3%	2.3	8.9%
5	15	1.0%	1.6	2.2%	60	3.0%	2.4	12.7%
6	45	0.7%	2.8	3.7%	30	3.4%	2.9	19.7%
7	24	1.1%	1.6	2.5%	51	4.1%	2.1	14.2%
8	27	1.2%	2.1	3.9%	48	3.6%	2.6	17.7%
9	0	—	—	—	75	6.0%	2.0	17.9%
10	48	0.4%	1.9	1.3%	27	6.0%	5.8	99.0%
11	9	1.2%	1.7	2.8%	66	4.6%	2.4	19.1%
12	24	0.9%	2.6	4.1%	51	5.1%	2.7	25.4%
13	18	1.4%	2.3	5.4%	57	4.6%	3.4	34.8%
14	0	—	—	—	75	7.9%	2.0	25.4%
15	0	—	—	—	75	7.6%	2.4	31.8%
16	9	1.7%	1.7	4.1%	66	5.3%	3.4	39.3%
17	9	3.5%	2.5	16.2%	66	8.9%	2.2	33.8%
18	9	0.9%	1.9	2.6%	66	8.7%	2.5	39.5%
19	33	0.1%	3.2	1.0%	42	5.9%	4.6	71.8%
20	3	1.4%	1.2	2.0%	72	10.5%	2.9	59.8%
21	12	0.3%	2.2	1.0%	63	6.2%	5.4	99.0%
All	438	0.6%	3.3	4.0%	1137	5.2%	3.1	33.2%

Notes: GM = Geometric Mean, GSD = Geometric Standard Deviation, and 95th = 95th Percentile..

As expected, the level of performance for passing the fit-test was much higher than those who failed the fit-test. For those subjects failing the fit-test, the 95th percentile ranged from 8.7% to 99% as compared to 1.0% to 16.2% for those passing the surrogate fit-test. The average 95th percentile was 33.2% as compared to only 4.0% for those passing the fit-test. Interestingly, this value is almost identical to the average 95th percentile for total penetration for all test subjects without fit-testing.

The analysis of variance using a mixed model with subjects nested within outcome (pass or fail) for respirator model one is summarized in Table 4. Fit-test outcome significantly affected the total penetration for respirator model one (p-value = 0.0003). The

overall GM for total penetration for subjects passing the fit-test with model one was significantly smaller (0.6%) than that for subjects failing the fit-test (2.3%). The statistical analysis was performed on each of the remaining respirator models and the same findings were observed with every respirator model. A plot of residuals versus the fitted values did not reveal any obvious model inadequacies.

Tables 2 and 3 show conclusively the value of fit-testing. Fit-testing greatly increases the level of performance for N95 filtering-facepiece respirators by screening out poorly fitting respirators and helps to ensure that the respirator provides the highest protection possible.

Table 4. Analysis of variance for respirator one using a linear mixed model nesting subjects within outcome (pass or fail).

Source of variation	Degrees of freedom	Mean square	Expected mean square	F-ratio	P-value
Outcome (O)	1	6.515	$\sigma^2 + 3\sigma^2_{\beta} + 36.96\sum\tau_i^2$	17.7	0.0003
Subject (within O)	23	0.368	$\sigma^2 + 3\sigma^2_{\beta}$	5.7	0.0001
Errors	50	0.065	σ^2		
Total	74				

Notes: τ_i is the effect of the i^{th} level of outcome, $i = 1$ to 2.

σ^2_{β} is the variance for random effect of subjects within each outcome.

σ^2 is the variance for random error.

Effect of Pass/fail Criterion on Respirator Performance

In order to investigate the necessity of using 1% face-seal leakage (fit factor of 100) as the pass/fail criteria, the data were re-analyzed using 2% and 10% face-seal leakages (fit factors of 50 and 10, respectively). Table 5 is the summary of this re-analysis. When 2% leakage was used, the level of performance was decreased, i.e., 95th percentile for total penetration for subjects passing the test was increased to 6.7% as compared to 4.0% using a 1% criterion.

When the criterion was raised to 10%, the performance of the respirators was reduced even more drastically. The 95th percentile for total penetration for subject passing the test was 18.0%, more than twofold decrease in protection from the 2% criterion and over a fourfold decrease from the 1% criterion. These data suggest that a 1% criterion is necessary to ensure that half-mask respirators provide a level of protection greater than 10 in the workplace.

Effect of Different Donnings on Respirator Performance

In order to ensure that using the first donning as the surrogate fit-test did not bias the level of protec-

tion provided by the respirator, the other three donnings (2 to 4) were also used as the surrogate fit-test and the data re-analyzed. As can be seen in Table 6, the geometric means and 95th percentiles of total penetration did not appear to be different regardless of which donning was used as the surrogate fit-test. Therefore, it can be concluded that the level of performance was repeatable between donnings.

To investigate whether different donnings need to be included as part of the fit-testing protocol for N95 respirators, how indicative the results of any one donning were for the other three donnings (the ability of any one donning to forecast the results of the other donnings) was examined. The frequencies of respirator/subject combinations having zero, one, two, three, and four of all four donnings passing the fit-test were calculated. Of the 525 respirator/subject combinations tested, 306 (58%) had no donnings passing the surrogate fit-test, 48 (9%) had one donning, 37 (7%) had two donnings, 47 (9%) had three donnings, and 87 (17%) had all four donnings passing the fit-test. These results indicate that about 75% of the time, the result of any donning correctly predicts the actual results for the other three donnings.

Conclusions

Without fit-testing, the performance of the N95 respirators based on the 95th percentile of total penetration for all the respirators was determined to be 33%, which is more than three times the maximum allowable value of 10%. The total penetration was found to consist mainly of face-seal leakage. The

performance of N95 respirators is significantly increased when fit-testing is employed to screen out poor fitting respirators (those having face-seal leakage greater than 1%). Three of the brands tested did not have any subject passing the first donning surrogate fit-test (i.e., all of the subjects had a face

Table 5. Summary of total penetration for all subjects who passed the fit-test for pass/fail criteria of 2% and 10% face-seal leakages by respirator model.

Pass/Fail criteria	Subjects	Total penetration			
		n	GM	GSD	95th
1%	Passed	438	0.6%	3.3	4.0%
	Failed	1137	5.2%	3.1	33.2%
2%	Passed	687	0.9%	3.4	6.7%
	Failed	888	7.0%	2.7	36.0%
10%	Passed	1269	1.9%	3.9	18.0%
	Failed	306	14.6%	2.3	56.9%

Notes: GM = Geometric Mean, GSD = Geometric Standard Deviation, and 95th = 95th Percentile.

Table 6. Summary of total penetration for subjects passing and failing the fit-test for pass/fail criteria of 1% face-seal leakage when donnings 1, 2, 3, and 4 were used as the surrogate fit-test.

Donning	Subjects	Total penetration			
		n	GM	GSD	95th
1	Passed	438	0.6%	3.3	4.0%
	Failed	1137	5.2%	3.1	33.2%
2	Passed	453	0.6%	3.1	4.0%
	Failed	1122	5.2%	3.1	33.5%
3	Passed	456	0.6%	3.3	4.2%
	Failed	1119	5.2%	3.0	31.6%
4	Passed	486	0.7%	3.3	4.5%
	Failed	1089	5.6%	2.9	32.9%

Notes: GM = Geometric Mean, GSD = Geometric Standard Deviation, and 95th = 95th Percentile.

seal leakage greater than 1% when wearing these respirators). Thus, this study indicates fit-testing needs to be a component of a respiratory protection program and each employee must satisfactorily pass a fit-test before being allowed to wear a respirator in the work environment.

The study also demonstrated that the pass/fail criterion of 1% is necessary to ensure that the respirator will reduce the in-facepiece concentration of workplace contaminants to 10% or less of the ambient concentration. In this study, each subject had four different donnings of the same respirator. It was also found that the total penetration did not

differ among the four donnings (Table 6). Thus, fit-testing protocols for N95 respirators may not have to include different donnings.

In addition, the results of this study suggest two areas of further study. The first area would be determining the value of qualitative fit-testing to ensure that N95 respirators provide the expected level of protection. The second area would be to investigate whether the individuals who failed the surrogate fit-test can be trained and fitted in a manner so that they pass the fit-test and achieve an adequate level of performance.

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