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Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators

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Four performance measures were used to evaluate the fitting characteristics of 18 models of N95 filtering-facepiece respirators: (1) the 5th percentile simulated workplace protection factor (SWPF) value, (2) the shift average SWPF value, (3) the h-value, and (4) the assignment error. The effect of fit-testing on the level of protection provided by the respirators was also evaluated. The respirators were tested on a panel of 25 subjects with various face sizes. Simulated workplace protection factor values, determined from six total penetration (face-seal leakage plus filter penetration) tests with re-donning between each test, were used to indicate respirator performance. Five fit-tests were used: Bitrex™, saccharin, generated aerosol corrected for filter penetration, PortaCount® Plus corrected for filter penetration, and the PortaCount Plus with the N95-Companion™ accessory. Without fit-testing, the 5th percentile SWPF for all models combined was 2.9 with individual model values ranging from 1.3 to 48.0. Passing a fit-test generally resulted in an increase in protection. In addition, the h-value of each respirator was computed. The h-value has been determined to be the population fraction of individuals who will obtain an adequate level of protection (i.e., SWPF ≥10, which is the expected level of protection for half-facepiece respirators) when a respirator is selected and donned (including a user seal check) in accordance with the manufacturer's instructions without fit-testing. The h-value for all models combined was 0.74 (i.e., 74% of all donnings resulted in an adequate level of protection), with individual model h-values ranging from 0.31 to 0.99. Only three models had h-values above 0.95. Higher SWPF values were achieved by excluding SWPF values determined for test subject/respirator combinations that failed a fit-test. The improvement was greatest for respirator models with lower h-values. Using the concepts of shift average and assignment error to measure respirator performance yielded similar results. The highest level of protection was provided by passing a fit-test with a respirator having good fitting characteristics.

Keywords filtering-facepiece, fit-test, respirator, simulated workplace protection factor

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INTRODUCTION

In 1995, the National Institute for Occupational Safety and Health (NIOSH) promulgated new certification regulations for particulate respirators.(1) Soon after the introduction of N95 filtering-facepiece respirators into the marketplace, NIOSH and the Occupational Safety and Health Administration (OSHA) received many inquiries regarding the face-fitting characteristics of these respirators. In response, NIOSH has conducted two studies of N95 respirators. The first study evaluated 21 models of filtering-facepiece respirators purchased in 1996.(2,3) The current study evaluated the protection level of 18 respirator models purchased in late 1998. There are currently over 165 certified models of N95 filtering-facepiece respirators.

The first study of N95 filtering-facepiece respirators conducted by NIOSH was intended to determine: (1) the simulated workplace performance of N95 filtering-facepiece respirators; (2) if the simulated workplace performance of these respirators improved when a quantitative fit-test was used to eliminate wearers with poorly fitting respirators; and (3) the effect of various pass/fail criteria for a quantitative fit-test on the performance of these respirators.(2,3)

To answer these questions, the previous study determined the total penetration (the combination of filter penetration and face-seal leakage) of 21 models, each tested on a panel of 25 subjects. Four total penetration tests were performed on each subject/respirator combination and these 100 measurements were used to calculate a 95th percentile total penetration value for each respirator (i.e., 95 percent of wearers of that respirator can expect to have a total penetration value below the 95th percentile total penetration value). The first total penetration test was then used as a surrogate fit-test by subtracting the filter penetration to determine face-seal leakage. Those subjects having face-seal leakage greater than a given criterion were removed from the data set. The remaining subjects were then used to determine a new 95th percentile total penetration value to indicate expected performance of the respirator when used by individuals who pass a fit-test.

The study found that the level of performance among the N95 respirators tested varied greatly. Without fit-testing, the 95th percentile total penetration values for each respirator ranged from 6 to 88%. The 95th percentile total penetration value for all the respirator models combined was 33%, which exceeds by more than three times the level of performance (i.e., 10% penetration) normally expected of a half-facepiece respirator.[(4–6)] Five respirator models had a 95th percentile total penetration value $\leq$10%.

When the surrogate fit-test was applied to the data, the 95th percentile total penetration values for individual respirator models improved, ranging from 1 to 16%. The 95th percentile total penetration value for all the respirators combined was only 4%, which is less than one-eighth of the value (33%) without fit-testing. However, only 4 of the 21 models successfully fit more than 50% of the test subjects when a pass/fail criterion of 1% face-seal leakage was used.

The fitting characteristics of these 21 models were evaluated using a parameter called the h-value, which is the fraction of the population who will obtain an adequate fit when a respirator is selected and donned (including a user seal check) in accordance with the manufacturer's instructions prior to a fit-test being performed.[(7)] An adequate fit is one that results in a protection factor being greater than or equal to the commonly accepted assigned protection factor (APF). Assuming the APF for filtering, half-facepiece N95 respirators to be 10, the resulting h-values for individual respirator models ranged from 0.44 to 0.99, with a median value of 0.83. Only four of the models had an h-value $\leq$0.95, a value used by Hyatt[(8)] in establishing his APF values. That is, only four models provided protection factors $\leq$10 in at least 95 out of 100 donnings.

Campbell et al.[(9)] used a mathematical formula to estimate the respirator assignment error for each of the 21 models. The respirator assignment error is the percentage of respirator wearers erroneously assigned a poorly-fitting respirator despite passing a fit-test. The formula predicted respirator assignment errors ranging from 0 to 20%, depending upon the h-value of the particular respirator and the type of fit-test used.

The current study was carried out to assess the level of protection provided by 18 models of N95 filtering-facepiece respirators and the effect of fit-testing on the level of protection. Four different means were used to measure the level of protection: (1) the 5th percentile simulated workplace protection factor (SWPF) value, (2) the shift average SWPF, (3) the h-value, and (4) the assignment error.

MATERIALS AND METHODS

Respirator Models

The study's resource and time constraints allowed only 18 models of N95 filtering-facepiece respirators to be tested. The respirator models were randomly selected for this study from the over 165 commercially available at the time the study began in 1998. The models tested in this study may not necessarily represent the models currently available. Some models may no longer be manufactured and marketed in the version tested since they may have been either modified by the manufacturer or replaced by newer versions.

Fit-Testing and Simulated Workplace Testing

Thirty-three people (18 females and 15 males) participated in this study. From this group, a panel of only 25 subjects with various face sizes (based on the Los Alamos panel) tested each respirator.[(10)] The Los Alamos researchers investigated 21 facial dimensions to determine their applicability for assessing the facepiece-to-face seal. For half-facepiece respirators, face length and lip length (mouth width) were selected as the key dimensions for the selection of face sizes for testing half-facepiece respirators. The subjects in the current study had face lengths ranging from 93.5 mm to 133.5 mm and lip lengths of 34.5 mm to 61.5 mm. The performance of the respirators was determined using a SWPF test. The SWPF test determined the total penetration of six tests using the PortaCount® Plus (TSI, Inc., St. Paul, Minn.) with re-donning between each test.

The fit-tests used were: Bitrex™ (Allegro Industries, Paramount, Calif.); PortaCount Plus corrected for filter penetration; the PortaCount Plus with the N95-Companion™ accessory (which is designed to count only particles resulting from face-seal leakage); and either saccharin or generated aerosol corrected for filter penetration. Each panel member was assigned a separate respirator for each model tested. The two methods corrected for filter penetration are not currently used by the general public as they are not in the OSHA regulations.[(7)] They were included in this study to determine the feasibility and practicality of using the same hardware for fit-testing filtering-facepiece respirators as is used for other respirator types. The fit-test methods and the SWPF test are described in detail elsewhere.[(11)]

When the study began, NIOSH did not recommend the use of the saccharin fit-test due to its potential carcinogenicity. Halfway through the study NIOSH revised its policy regarding the saccharin fit-test method for use in qualitative fit-testing to be consistent with the OSHA regulations.[(12)] Due to resource limitations all 18 respirator models could not be tested with all five fit-test methods after the policy was changed. Since the saccharin fit-test method is the most commonly used qualitative fit-test method, it was decided to include it and drop the seldom used generated aerosol fit-test method. The modified generated aerosol, Bitrex, Companion, and PortaCount Plus methods were used with the models tested before the change in NIOSH policy. The saccharin, Bitrex, Companion, and PortaCount Plus methods were used with the models tested after the change in NIOSH policy.

Data Analysis

Fit-Test Passing Rate

The fit-test passing rate (i.e., the number of subjects passing each fit-test method divided by the total number of subjects performing that fit-test) was also computed for each model. The fit-test passing rate assists employers in selecting filtering-facepiece respirators that would likely fit the greatest percentage of their employees. This would result in time and financial savings by reducing the number of repeat fit-tests required and the number of respirators needing to be stocked. The level of protection (performance) provided by the various models of filtering-facepiece respirators were evaluated and rank-ordered in four ways.

Techniques for Measuring Respirator Performance

5th Percentile SWPF Values

The first technique to determine filtering-facepiece respirator performance was to investigate the distribution of the 5th percentile SWPF values. From the 150 overall SWPF values determined for each respirator model from each of the 25 subjects donning the respirator six times, the 5th percentile SWPF for each model was calculated, using the geometric mean (GM) and the geometric standard deviation (GSD), as $GM/GSD^{1.645}$.[13] These 5th percentile SWPF values were calculated without regard to the results of the fit-tests. The subjects were then divided into two groups for each fit-test method: those who passed that fit-test and those who failed it. Passing the qualitative fit-tests meant the subject did not taste the fit-test agent. Passing the quantitative tests meant that a subject had a fit factor $\geq$100 with a particular respirator model. The 5th percentile SWPF values were then separately calculated for subjects passing a fit-test and for subjects failing that fit-test.

Shift Average SWPF

The second method of determining respirator performance was the shift average SWPF, which corresponds to the protection factor averaged over the several donnings typical of a workday. It was computed by converting each of the six SWPF values for each subject/respirator combination into total penetration values (1/SWPF) and computing the average penetration and the shift average SWPF (1/average penetration). This resulted in 25 shift average values for each respirator model. The 5th percentile, geometric mean, and geometric standard deviation of those 25 values were calculated for each model.

h-Values

The third manner of assessing respirator performance was to compute the h-value for all the models combined as well as for each individual model. For this study, a respirator was considered to provide an adequate fit when its SWPF was greater than a specified target protection factor value. The h-value is the number of SWPF values greater than or equal to the target protection value divided by the total number of SWPF values. The three target protection values used were 10, 5, and 3. Ten was selected because it is the APF usually assigned to half-facepiece respirators.[4–6] Five was selected because that was the APF previously recommended by NIOSH for a single-use dust respirator if it was not quantitatively fit-tested.[4] Three was selected to determine how the poorer-performing models of filtering-facepiece respirators performed when compared to a lower performance standard.

Assignment Error

The fourth procedure for determining respirator performance was to compute the assignment error. A respirator assignment error is the percentage of respirator users who, even though they pass a fit-test, would mistakenly be assigned a poorly-fitting respirator. An assignment error was estimated using the formula (Equation 1) developed by Campbell et al. to account for the fact that an individual will have more than one chance to pass a fit-test. The assignment error was estimated for the case where only two fit-tests are allowed.[9]

$$A_e = N_{b,p}/(N_{b,p} + N_{g,p}) \quad \textbf{(1)}$$

where A_e = the fraction of the population of qualified respirator wearers with an inherently poor respirator fit who have mistakenly passed a fit-test and are assigned that respirator to wear in the workplace; $N_{b,p}$ = the total number of respirator wearers with an inherently bad fit who have qualified for respirator use by mistakenly passing either one of the two fit-test tries; and $N_{g,p}$ = the total number of respirator wearers with an inherently good fit who have qualified for respirator use by appropriately passing either one of the two fit-test tries.

RESULTS

5th Percentile SWPF Values

Table I is a summary of the 5th percentile SWPF values without fit-testing for all subjects and for those passing and failing each of the five fit-test methods for all 18 models combined (labeled as "All 18 Models" in Tables I through V) as well as for each individual model. Without fit-testing, the 5th percentile SWPF values ranged from 1.3 (i.e., virtually no protection) to 48.

Of the three models that had a 5th percentile SWPF $\geq$10 without fit-testing, the lowest was 13.7, approximately twice that of the next best-fitting respirator. For each respirator model, the 5th percentile SWPF value varied by fit-test method. The Companion method provided the highest 5th percentile SWPF value for 11 of the 12 respirator models having subjects passing this fit-test. The exception was the 3M 8212, for which the PortaCount Plus provided the highest 5th percentile SWPF value. The 3M 8212 had the lowest 5th percentile SWPF value compared to the other 11 respirators.

Shift Average SWPF

Table II contains the 5th percentile SWPF values based on the shift average method for the 18 models. The results are

TABLE I. Summary of 5th Percentile SWPF Values Without and with Fit-Testing by Fit-Test Method

Model	Without Fit-Testing	Bitrex Pass	Bitrex Fail	Saccharin Pass	Saccharin Fail	Companion Pass	Companion Fail	PortaCount Plus Pass	PortaCount Plus Fail	Generated Aerosol Pass	Generated Aerosol Fail
MSA Affinity Ultra	56.9	30.6	48.0	TNP[A]	TNP[A]	122.1	48.0	43.8	67.2	43.7	74.7
3M 8110S/8210	22.0	33.5	16.6	TNP[A]	TNP[A]	90.4	16.6	13.5	18.0	28.4	15.6
3M 1860/1860S	17.0	26.1	13.7	TNP[A]	TNP[A]	86.9	13.7	37.3	10.0	33.5	12.5
Moldex 2200N95/2201N95	11.4	11.4	6.1	TNP[A]	TNP[A]	105.2	6.1	32.2	5.8	NP[B]	6.1
MSA Affinity Plus	8.4	14.8	5.2	TNP[A]	TNP[A]	100.4	5.2	NP[B]	5.2	NP[B]	5.2
3M 8512	8.2	10.9	4.1	4.1	3.6	100.3	4.1	24.3	3.3	TNP[A]	TNP[A]
North 7175N95	8.0	12.3	7.2	5.6	4.7	10.1	6.7	NP[B]	7.3	NP[B]	7.2
Gerson 2737	7.7	9.0	4.9	TNP[A]	TNP[A]	NP[B]	4.9	6.7	4.8	NP[B]	2.0
Willson N9510F	7.2	13.8	5.6	5.6	4.4	85.1	5.6	13.6	4.3	TNP[A]	TNP[A]
Willson 1410N95	7.0	6.2	4.4	TNP[A]	TNP[A]	NP[B]	4.5	14.9	4.5	NP[B]	4.5
Aearo Safety Pleats	6.9	6.7	4.4	TNP[A]	TNP[A]	119.7	4.4	37.9	3.9	11.8	3.9
Moldex 2300N95/2301N95	5.5	4.8	2.3	2.3	2.1	NP[B]	2.3	NP[B]	2.3	TNP[A]	TNP[A]
Moldex 2700N95/2701N95	5.4	19.0	1.9	1.9	1.6	95.9	1.9	18.7	1.7	TNP[A]	TNP[A]
Moldex 2207N95	5.3	13.4	2.1	2.1	1.9	NP[B]	2.1	NP[B]	2.1	TNP[A]	TNP[A]
Willson N9520F	5.3	12.8	2.7	2.7	1.7	86.1	2.7	21.9	2.1	TNP[A]	TNP[A]
Survivair 1930	5.2	15.5	2.4	TNP[A]	TNP[A]	96.7	2.4	33.7	2.0	NP[B]	2.4
3M 8212	3.9	4.4	1.3	1.3	1.1	2.2	1.3	10.7	1.0	TNP[A]	TNP[A]
U.S. Safety ADN95	3.6	6.8	2.0	2.0	2.0	NP[B]	2.0	NP[B]	2.0	TNP[A]	TNP[A]
All 18 Models	2.9	7.4	2.1	6.9	1.9	74.5	2.3	14.6	2.7	21.6	4.7

[A]Test not performed using this model.
[B]No subjects passed the fit-test with this model.

similar to the 5th percentile SWPF values without fit-testing. The same three models that had 5th percentile SWPF values ≥10 also had shift average SWPF values ≥10. As with the 5th percentile SWPF values, the lowest of these three values was over 1.5 times greater than that of the next best-fitting respirator.

h-Values

Table III summarizes the h-value results. Hyatt[8] stated that a respirator, without fit-testing, should provide at least 95% of its wearers with a protection factor at least equal to or greater than its class APF. Fit-testing is important to identify that small percentage of individuals with an inadequate fit. Using the traditional APF of 10 for a half-facepiece respirator, only three of the models met Hyatt's criteria. These are the same three models that provided adequate protection without fit-testing in Table I. Lowering the target APF to 5 resulted in only two additional models meeting the criteria. Further lowering of the target APF to 3 resulted in 11 of the 18 models having h-values ≥0.95. In addition, a target APF of 3 resulted in all the models combined h-value being equal to 0.95.

Assignment Error

Assignment errors for each model are summarized in Table IV. Giving each wearer two trials to pass the fit-test, before requiring another model be used, resulted in assignment errors of 0.3% to 38.5% using the Bitrex method. The other four methods gave similar results.

Fit-Test Passing Rate

Table V is a summary of the fit-test passing rates for the five fit-test methods. There is a wide variation between models in the percentage of people passing the various fit-test methods. The MSA Affinity Ultra (Mine Safety Appliances Company, Pittsburgh, Pa.) had the largest percentage of subjects passing each fit-test method. It is interesting to note that with some models, the passing rate varied greatly depending upon the method. For example, the North 7175N95 (North Safety Products, Cranston, RI) had a passing rate of 0.55 with the Bitrex

TABLE II. 5th Percentile Shift Average SWPF by Respirator Model

Model	5th Percentile Shift Average
MSA Affinity Ultra	50.1
3M 8110S/8210	16.4
3M 1860/1860S	13.3
North 7175N95	7.6
Moldex 2200N95/2201N95	6.1
Willson N9510F	5.7
MSA Affinity Plus	5.2
Gerson 2737	5.0
Willson 1410N95	4.6
Aearo Safety Pleats	4.2
3M 8512	4.1
Willson N9520F	2.6
Survivair 1930	2.4
Moldex 2300N95/2301N95	2.3
Moldex 2207N95	2.1
U.S. Safety ADN95	2.1
Moldex 2700N95/2701N95	2.0
3M 8212	1.5
All 18 Models	3.0

method but no subjects passed with either the generated aerosol method or the PortaCount Plus method.

Comparison of Respirator Performance

To determine if the 5th percentile SWPFs without fit-testing were significantly different a Duncan's multiple range test was conducted. Duncan's multiple range test is used with an analysis of variance to determine whether (1) all of the means differ; (2) one of the means (e.g., m_A) differs from the others; or (3) there are groups of means that are the same but differ from other groups that are also the same. All of the 5th percentile SWPFs for each respirator model were converted to 95th percentile total penetration values by taking their reciprocals (i.e., 1/SWPF). The Duncan's multiple range test was conducted on the total penetration values. Table VI shows the Duncan's multiple range test results using a significance level (α) of 0.05. The results show that there were five groups of respirator models (as indicated by the different letters) whose 95th percentile total penetration values are significantly different from the other groups. The level of performance as measured in this study for any respirator model in a given group is not significantly different from the other models in the group.

TABLE III. Summary of h-values by Target Protection Factor

		Target Protection Factor					
		10		5		3	
Model	Total Donnings	Donnings $\geq$ APF	h-value	Donnings $\geq$ APF	h-value	Donnings $\geq$ APF	h-value
MSA Affinity Ultra	150	148	0.99	150	1.00	150	1.00
3M 1860/1860S	150	143	0.95	149	0.99	149	0.99
3M 8110S/8210	150	143	0.95	150	1.00	150	1.00
Moldex 2200N95/2201N95	150	126	0.84	142	0.95	148	0.99
Willson N9510F	150	126	0.84	139	0.93	149	0.99
North 7175N95	150	129	0.86	146	0.97	150	1.00
MSA Affinity Plus	150	123	0.82	135	0.90	148	0.99
Aearo Safety Pleats	150	120	0.80	135	0.90	144	0.96
Gerson 2737	150	116	0.77	135	0.90	150	1.00
Willson 1410N95	150	110	0.73	139	0.93	149	0.99
3M 8512	150	110	0.73	139	0.93	146	0.97
Survivair 1930	150	108	0.72	117	0.78	139	0.89
Willson N9520F	150	103	0.69	124	0.83	138	0.92
Moldex 2300N95/2301N95	150	92	0.61	108	0.72	132	0.88
3M 8212	150	85	0.57	104	0.69	123	0.82
Moldex 2700N95/2701N95	150	84	0.56	107	0.71	129	0.86
Moldex 2207N95	150	75	0.50	104	0.69	131	0.87
U.S. Safety ADN95	144[A]	44	0.31	89	0.61	122	0.85
All 18 Models	2694	1985	0.74	2312	0.86	2542	0.95

[A]One subject was not able to test this respirator and could not be replaced before end of the study.

TABLE IV. Summary of Assignment Errors in Percent by Fit-Test Method Using a Target Protection Factor of 10

Model	Fit-Test Method				
	Bitrex	Saccharin	Companion	PortaCount Plus	Generated Aerosol
MSA Affinity Ultra	0.3	0.3	0.3	0.2	0.2
3M 1860/1860S	1.5	1.3	1.3	0.9	1.1
3M 8110S/8210	1.5	1.3	1.3	0.9	1.1
North 7175N95	4.4	3.9	4.0	2.8	3.2
Moldex 2200N95/2201N95	5.1	4.6	4.6	3.3	3.7
Willson N9510F	5.1	4.6	4.6	3.3	3.7
MSA Affinity Plus	5.8	5.2	5.3	3.8	4.2
Aearo Safety Pleats	6.6	5.9	6.0	4.3	4.8
Gerson 2737	7.7	7.0	7.1	5.1	5.7
Willson 1410N95	9.4	8.5	8.6	6.2	6.9
3M 8512	9.4	8.5	8.6	6.2	6.9
Survivair 1930	9.9	8.9	9.0	6.5	7.2
Willson N9520F	11.2	10.1	10.3	7.5	8.3
Moldex 2300N95/2301N95	15.2	13.8	14.0	10.3	11.4
3M 8212	17.5	15.9	16.1	11.9	13.2
Moldex 2700N95/2701N95	18.1	16.4	16.7	12.3	13.6
Moldex 2207N95	21.9	20.0	20.3	15.2	16.7
U.S. Safety ADN95	38.5	35.8	36.2	28.5	30.9
All 18 Models	8.9	8.1	8.2	5.9	6.6

TABLE V. Summary of Fit-Test Passing Rates by Fit-Test Method

Model[A]	Total Number of Fit-Tests[B]	Bitrex		Saccharin		Companion		PortaCount Plus		Generated Aerosol	
		Passes	Rate	Passes	Rate	Passes	Rate	Passes	Rate	Passes	Rate
MSA Affinity Ultra	25	13	0.52	TNP[C]	TNP[C]	22	0.88	19	0.76	20	0.80
3M 8110S/8210	25	12	0.48	TNP[C]	TNP[C]	13	0.52	7	0.28	3	0.13
3M 1860/1860S	25	10	0.40	TNP[C]	TNP[C]	15	0.60	8	0.32	3	0.13
North 7175N95	25	11	0.55	7	0.28	5	0.20	0	0.00	0	0.00
Moldex 2200N95/2201N95	25	13	0.52	TNP[C]	TNP[C]	8	0.32	2	0.08	0	0.00
Willson N9510F	25	11	0.44	11	0.44	11	0.44	8	0.32	TNP[C]	TNP[C]
MSA Affinity Plus	25	7	0.28	TNP[C]	TNP[C]	0	0.00	0	0.00	0	0.00
Gerson 2737	25	7	0.28	TNP[C]	TNP[C]	9	0.36	3	0.12	0	0.00
Willson 1410N95	25	5	0.20	TNP[C]	TNP[C]	5	0.20	2	0.08	0	0.00
Aearo Safety Pleats	25	6	0.24	TNP[C]	TNP[C]	2	0.08	3	0.12	4	0.16
3M 8512	25	6	0.24	7	0.28	6	0.24	6	0.24	TNP[C]	TNP[C]
Moldex 2300N95/2301N95	25	5	0.20	4	0.16	11	0.44	0	0.00	TNP[C]	TNP[C]
Willson N9520F	25	10	0.40	10	0.40	7	0.28	4	0.16	TNP[C]	TNP[C]
Survivair 1930	25	9	0.36	TNP[C]	TNP[C]	6	0.24	4	0.16	0	0.00
Moldex 2207N95	25	4	0.16	3	0.12	6	0.24	0	0.00	TNP[C]	TNP[C]
U.S. Safety ADN95[D]	24	3	0.13	0	0.00	5	0.21	0	0.00	TNP[C]	TNP[C]
Moldex 2700N95/2701N95	25	6	0.24	4	0.16	5	0.20	4	0.16	TNP[C]	TNP[C]
3M 8212	25	8	0.32	7	0.28	6	0.24	6	0.24	TNP[C]	TNP[C]
All 18 Models	449	155	0.33	55	0.25	146	0.31	76	0.16	30	0.12

[A] Models listed in order of performance without fit-testing.
[B] Total number of tests conducted for each type of fit-test.
[C] Test not performed using this model.
[D] One subject was not able to test this respirator and could not be replaced before the end of the study.

TABLE VI. Statistical Comparison of Model 95th Percentile Total Penetration Values

Model	5th Percentile SWPF	95th Percentile Total Penetration	Duncan Grouping[A]
MSA Affinity Ultra	56.9	0.01758	A
3M 8110S/8210	22.0	0.04539	A,B
3M 1860/1860S	17.0	0.05884	A,B
Moldex 2200N95/2201N95	11.4	0.08739	A,B,C
MSA Affinity Plus	8.4	0.11919	B,C
3M 8512	8.2	0.12252	B,C,D
North 7175N95	8.0	0.12530	B,C,D
Gerson 2737	7.7	0.13069	B,C,D
Willson N9510F	7.2	0.13911	B,C,D
Willson 1410N95	7.0	0.14293	B,C,D
Aearo Safety Pleats	6.9	0.14487	B,C,D
Moldex 2300N95/2301N95	5.5	0.18112	C,D,E
Moldex 2700N95/2701N95	5.4	0.18641	C,D,E
Moldex 2207N95	5.3	0.18802	C,D,E
Willson N9520F	5.3	0.18996	D,E
Survivair 1930	5.2	0.19190	D,E
3M 8212	3.9	0.25870	E
U.S. Safety ADN95	3.6	0.27743	E

[A]95th Percentile total penetration values with the same letter are not significantly different.

DISCUSSION

Effect of Fit-Testing on Respirator Performance

Three respirator models met the expected level of protection without fit-testing. This is similar to the results of the previous study of N95 respirator performance, in which 4 of 21 models met the expected level of protection without fit-testing.[2,3] Table I demonstrates the value of fit-testing. It shows poor-performing respirators as determined by 5th percentile SWPF values generally have higher levels of protection among those passing a fit-test. The exceptions were the MSA Affinity Ultra with the Bitrex, PortaCount Plus, and generated aerosol methods and the 3M 8110S/8210 with the PortaCount Plus method. These exceptions are likely a manifestation of fit-testing error.[10]

The "all 18 models" combined results in Table I indicate that passing a qualitative fit-test does not necessarily guarantee the wearer an adequately fitting respirator. For subjects passing the saccharin fit-test with the tested respirator models, the 5th percentile SWPF value for "all 18 models" combined was only 6.9. For subjects passing the Bitrex fit-test with the tested respirator models, the 5th percentile SWPF value for "all 18 models" combined was only 8.7 when it should have been $\geq$10.[5,7] Passing a qualitative fit-test did result in an increase in protection (5th percentile SWPF value was 1.9 for those failing the saccharin fit-test and 2.1 for those failing the Bitrex fit-test). The low 5th percentile SWPF values for subjects passing the qualitative fit-tests are due to fit-test beta error. That error may be related to the effect reported by McKay[14] in which subjects who should have detected the taste of saccharin failed to do so.

In addition, when the individual models are considered, none of the tested models provided adequate protection (i.e., a 5th percentile SWPF value $\geq$10) after passing the saccharin fit-test. The individual 5th percentile SWPF values ranged from 1.3 to 5.6. The better-performing respirators were tested before the NIOSH policy change to recommend the use of saccharin as a qualitative fit-test agent, so they were not used with the saccharin fit-test method. The saccharin results may apply only to the poorly performing respirators.

As with the saccharin fit-test method, the "all 18 models" combined results indicated that passing the Bitrex fit-test method did not result in adequate protection (5th percentile SWPF value = 7.4). When the results of individual models are considered, passing the Bitrex fit-test method resulted in 12 of the 18 models providing adequate protection (as assessed by SWPF $\geq$10). The 12 respirator models with any subjects passing a Companion fit-test method provided adequate protection, but no subjects were able to pass the Companion fit-test method with six of the models. Passing the PortaCount Plus fit-test resulted in 12 of 13 models providing adequate protection (i.e., 5th percentile SWPF value $\geq$10).

No subjects were able to pass the PortaCount Plus fit-test with the remaining five models. The generated aerosol fit-test had the greatest proportion of models (6 of 10) with no subjects passing. The remaining four models all had 5th percentile SWPF values $\geq$10. With the three models having 5th percentile SWPF values $\geq$10 without fit-testing, subjects failing a fit-test also received adequate protection (i.e., 5th percentile SWPF value $\geq$10). A possible explanation is that these models had high alpha errors.[10] High alpha errors could result in subjects erroneously failing a particular fit-test with a higher level of protection than those subjects correctly passing the fit-test.

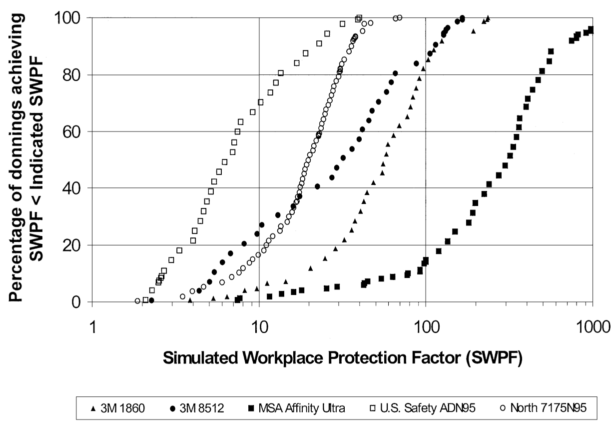

FIGURE 1. Distribution of simulated workplace protection factors without fit-testing for 5 representative respirator models using 25 subjects per respirator model and 6 simulated workplace protection factor tests per subject/respirator model combination

Figure 1 is a graphic presentation of the wide differences in protection provided by the different models without fit-testing. It indicates that one model clearly provided the highest protection without fit-testing—the MSA Affinity Ultra (with the right-most distribution of SWPF values). One of the two other models, which provided about the same level of protection that was higher than the rest of the respirators but not as high as the best performing model, is shown. At least 95% of the SWPF values for these three models were ≥10. The remaining 15 respirators provided substantially lower levels of protection. In approximately 15% to 70% of donnings, these respirators failed to provide adequate protection (i.e., their SWPF values were less than 10), without fit-testing.

Figure 2 is a graph of the three cumulative distributions of SWPF values for the Bitrex fit-test for all 18 respirator models combined. It demonstrates the considerable increase in protection resulting from passing the Bitrex fit-test. Every simulated workplace test (6 for each respirator and subject combination) is paired with the result of its corresponding fit-test. Ignoring the results of fit-testing, inadequate protection (i.e., SWPF < 10) was provided approximately 30% of the time. Passing the Bitrex fit-test reduced this percentage to approximately 5%, a substantial decrease. The other fit-test methods provided similar results.

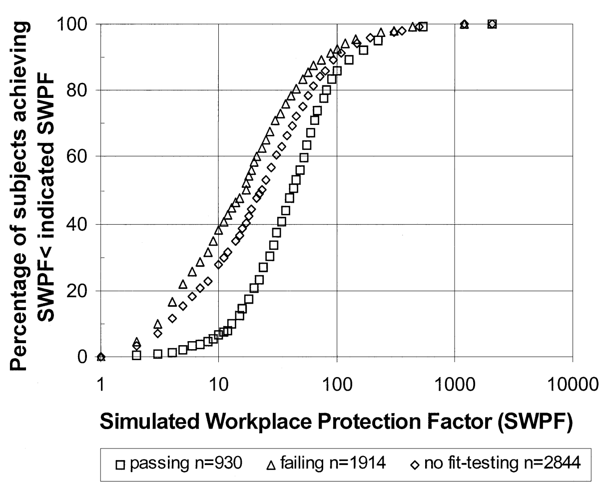

FIGURE 2. Cumulative distributions of simulated workplace protection factors for subjects with no fit-testing and those passing and failing the Bitrex fit-test

Figure 3 demonstrates that the level of protection is increased to a greater degree after passing a fit-test with a poorly performing respirator (i.e., one that does not provide the expected level of protection even after fit-testing) as compared with a well-performing one. This finding is consistent with previous findings that fit-testing is an important component of a respiratory protection program.(15) It should be noted that fit-testing is just one factor in determining the level of protection provided by a respirator. Respirators should be inherently designed to provide an adequate fit to the wearer. Even with an adequately performing respirator, a complete respiratory protection program must be in place for a respirator to achieve protection equal to the APF of its class.(7)

Figure 4 compares the distributions of the SWPF values for the three best-performing models with no fit-testing and the three poorest-performing models with fit-testing. Approximately 15% of the subjects, passing a Bitrex fit-test with the three poorest-performing models, had a SWPF < 10, while only 5% of those wearing the three best-performing models had a SWPF < 10, even without the benefit of a fit-test. This finding indicates why it is important for respirator manufacturers to produce well-performing respirators. By providing a respirator with both a high fit-test passing rate and a high level of protection, an employer may reduce the fraction of employees requiring another model.

STUDY DESIGN AND LIMITATIONS

Several differences should be noted between the current study and the previous NIOSH study that evaluated performance of N95 filtering-facepiece respirators.(2,3) The previous study used only four donnings during the SWPF testing, whereas six donnings were used for the SWPF values in the current study. Adding the two additional donnings should increase the accuracy of the 5th percentile SWPF results. Another difference is that the first study used a surrogate fit-test while this study used several actual fit-tests. Another difference is that the previous study used only a portion of the respirator to assess filter penetration for the surrogate fit-test, whereas, in the current study, the modified PortaCount Plus and generated aerosol methods utilized the complete respirator. The amount of filter penetration may vary spatially over the entire filter. Using only a portion of the respirator could have affected the results of the previous study by either overestimating or underestimating the amount of filter penetration.

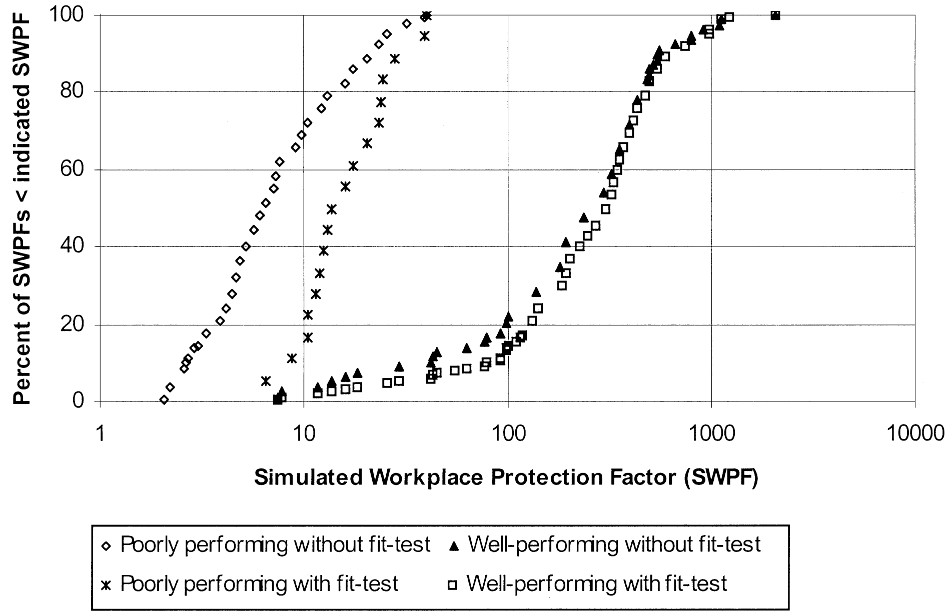

FIGURE 3. Effect of fit-testing protection provided by two respirators with differing fitting characteristics

This study had several limitations. It has been shown the fit factors provided by the PortaCount Plus may overestimate the exposure of a respirator wearer under actual working conditions.[16] The second limitation was the subject panel. Los Alamos determined that a panel of 25 with face lengths ranging from 94 to 133 mm and lip lengths ranging from 35 to 61 mm would represent a majority (almost 95%) of the working population in the United States.[10] These ranges were ascertained from the surveys of male and female personnel in the United States Air Force since the male data compared favorably to the measurements of 200 males selected from all available men working at Los Alamos who had been fitted with a respirator.[10]

The 25-member Los Alamos panel was used in this study because currently it is the best representation of the United States working population and has been used in other studies and in the development and certification of respirators. Recent NIOSH research has shown that the Los Alamos panel needs to be revised to better reflect the face sizes of current respirator wearers in regards to age and race.[17] The sample size of only 25 subjects based on the Los Alamos research may not be large enough to produce results that would be directly

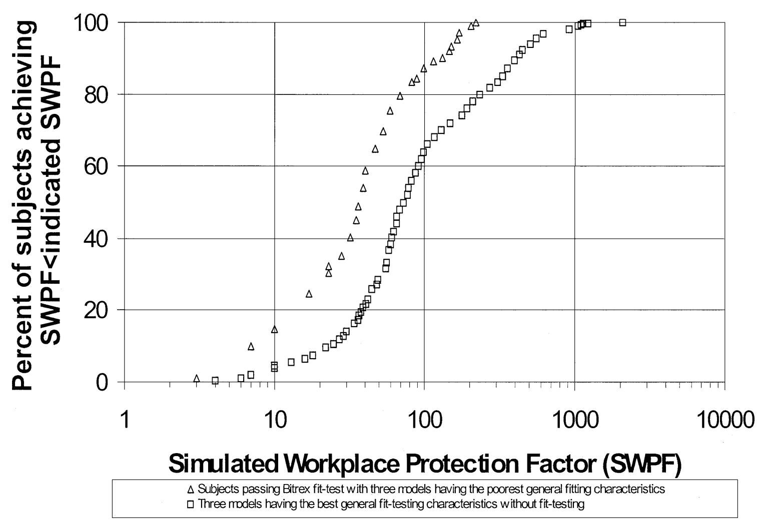

FIGURE 4. Comparison of simulated workplace protection factor distributions for the three best- and the three poorest-fitting respirators

applicable to actual respirator use. It is likely that the subjects who participated in this study may not be representative of all respirator wearers.

Another limitation is that the SWPF exercise regime used in this study consisted of six exercises that may not be representative of work activities in actual work environments. Therefore, the results obtained in this study provide the relative performance of each respirator model compared to the others under the given study conditions only. The performance data cannot be viewed as the protection that will be received in all workplace applications. The estimation of the level of protection provided to an individual can be altered by a number of factors: significant weight changes, dental changes (e.g., changes to dentures), and changes to the face in the sealing area of the respirator (e.g., scarring, facial surgery, swelling, and tumors).[18]

Only 18 randomly selected filtering-facepiece respirator models from a total of more than 165 were tested in this study. The models not tested may include ones that would have tested better or worse than any or all of these tested. In addition, respirator manufacturers are continually evaluating and re-designing their products while keeping the same model number. The respirator models tested in this study may not be representative of models currently on the market. The "all 18 models" combined results may not be representative of all N95 filtering-facepiece respirators now being manufactured.

CONCLUSIONS

Four different analytical methods (5th percentile SWPF value, shift average SWPF, h-value, and assignment error), used to measure the performance of N95 filtering-facepiece respirators, provided approximately the same basic relative ranking for the 18 respirator models tested. The findings of this study demonstrate that, with the current state of fit-testing, it may be of more benefit to the user to wear a respirator model with good-fitting characteristics without fit-testing than to wear a respirator model with poor-fitting characteristics after passing a fit-test.

The findings also demonstrate that fit-testing is an important element of a respiratory protection program. Passing a fit-test enhances a worker's probability of wearing a respirator that provides an adequate level of protection in the workplace. The performance of poor-fitting respirator models is improved to a greater extent with fit-testing than respirator models with generally good-fitting characteristics. The highest level of protection is provided by passing a fit-test with a respirator model that has good-fitting characteristics.

The current respirator certification regulations do not contain testing of the type described in this study, though incorporating such testing would have substantial potential value.[1] If methods can be validated and widely accepted by the respirator manufacturing industry, it would be helpful to have similar standardized performance evaluations for all available models. This would allow program directors to make more informed decisions about which models to provide workers and to encourage manufacturers to improve upon the performance of respirators shown to be relatively poor performers.

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