Determining the Efficacy of Fit-Test Protocols Using N95 Filtering-Facepiece Respirators - Alternate Approaches

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ABSTRACT

A previous study has determined the ability of five fit-test methods (Bitrex™, saccharin, generated aerosol, PORTACOUNT® Plus corrected for filter penetration, and PORTACOUNT Plus/N95-COMPANION™) to screen out poorly fitting N95 filtering-facepiece respirator models. In that study, the results were compared to the 5th percentile of the simulated workplace protection factor (SWPF). No fit-test method met the new American National Standards Institute (ANSI) Z88.10 standard of no more than 50 percent for the alpha error (probability of rejecting an adequately fitting respirator; erroneous failure) and no more than 5 percent for the beta error (probability of accepting an inadequately fitting respirator; erroneous pass). The correlation between the PORTACOUNT Plus SWPF values and actual exposures is not 1.0, and their relationship can be better described by a quadratic equation based on available data. In this study, the original analysis was repeated using five alternate approaches to the 5th percentile as the reference test: (1) the unadjusted mean SWPF; (2) the bias-adjusted mean SWPF (i.e., the mean SWPF adjusted to account for possible bias in the fit-test instrument); (3) the bias-adjusted 5th percentile SWPF; (4) the unadjusted individual minimum SWPF; and (5) the bias-adjusted individual minimum SWPF. With these alternate references, the range of alpha errors for the Bitrex, saccharin, generated aerosol, PORTACOUNT Plus, and PORTACOUNT Plus/N95-COMPANION fit tests were 41 to 59 percent, 38 to 67 percent, 67 to 86 percent, 51 to 79 percent, and 38 to 87 percent, respectively. The corresponding beta errors were 6 to 25 percent, 9 to 16 percent, 0 to 3 percent, 2 to 6 percent, and 0 to 19 percent, respectively. Even with the alternate reference criteria for respirator performance, none of the fit-test methods met both error goals of the ANSI Z88.10 standard.

Keywords: fit-test, filtering-facepiece respirator, filter penetration, Simulated Workplace Protection Factor

INTRODUCTION

Previous National Institute for Occupational Safety and Health (NIOSH) studies have measured the accuracy of five fit-test methods for filtering-facepiece respirators (Coffey *et al.*, 1998b; Coffey *et al.*, 2002). Fit-test accuracy was judged by comparing the fit-test results to a reference criterion used to determine if a particular subject/respirator combination truly provided an adequate fit. As a reference criterion, the fit was classified as "adequate" if the 5th percentile simulated workplace protection factor (SWPF) was greater than 10, the commonly used assigned protection factor value for half-mask respirators. The distribution of SWPF values was measured in six trials with a TSI PORTACOUNT® Plus (TSI, Inc., St. Paul, MN) — a commercially available instrument which has been previously validated by demonstrating that its output correlated well with the wearers' exposure (Coffey *et al.*, 1998a).

The accuracy of the fit-test methods was determined by comparing the results of the fit-test to the 5th percentile SWPF for a panel of test subjects. From this comparison, the alpha (erroneous failure — probability of rejecting an adequately fitting respirator) and beta (erroneous pass — probability of accepting an inadequately fitting respirator) errors for each of the fit-test methods were computed. The alpha error was found to be 51% for the Bitrex™ method, 56% for the saccharin method, 84% for the generated aerosol method, 75% for the PORTACOUNT Plus method, and 57% for the N95-COMPANION method. The accuracy goal for the alpha error is generally considered to be ≤50% (ANSI, 2001). The beta error for the Bitrex method was 11%; saccharin method, 9%; generated aerosol method, 3%; PORTACOUNT Plus method, 4%; and the N95-COMPANION method, 9%. The generally accepted accuracy goal for the beta error is ≤ 5% (ANSI, 2001).

Although the 5th percentile SWPF was believed to be the appropriate choice as a reference criterion, other choices are possible. The current study was undertaken to determine how, or if, these other choices would change the general conclusions or results of previous fit-test accuracy studies. This paper presents the error rates of five fit-test methods using five alternate statistical approaches, as well as the 5th percentile SWPF approach (Coffey *et al.*, 2002). It has been demonstrated that PORTACOUNT Plus fit factors do not have a one-to-one correlation with a measure of actual exposure (Coffey *et al.*, 1998a). Three of the five alternative statistical approaches accounted for the apparent bias in PORTACOUNT Plus fit factors.

MATERIALS AND METHODS

This paper uses data collected in a previous study. A brief synopsis of that study is provided below. A more detailed account of the methods used in that study is available in a published paper (Coffey *et al.*, 2002).

Respirator Models

This study's resource and time constraints allowed 18 models of N95 filtering-facepiece respirators to be examined. The respirator models were randomly chosen from the over 165 models that were commercially available at the time the study began. Both foldable and cup-shaped respirators were used. Nine respirator manufacturers were represented among the 18 models studied.

Fit-Test Methods

The five fit-test methods evaluated included two qualitative (Bitrex [denatonium benzoate] and saccharin solutions) and three quantitative (generated aerosol, PORTACOUNT Plus condensation nuclei counter [CNC], and a modified CNC [N95-COMPANION]) testing methods. Of all currently available fit-test methods, these are the only five methods that can be adapted to fit-test N95 filtering-facepiece respirators.

Bitrex

The Bitrex test used the test subject's ability to taste a bitter solution to determine whether the respirator fit. Test subjects were given a taste-threshold screening test to ensure that he or she could detect the taste of Bitrex. After the screening test, test subjects left the laboratory, got a drink of water, and rinsed their lips and mouth. Immediately afterward, the subject returned to the laboratory and the Bitrex method was conducted (Allegro, 1997).

Saccharin

The saccharin test used the test subject's' ability to taste a sweet solution to determine whether the respirator fit. Test subjects were given a taste-threshold screening test to ensure that they could detect the taste of saccharin. After the screening test, subjects left the laboratory, got a drink of water, and rinsed their lips and mouth. Immediately afterward, the subjects returned to the laboratory and the saccharin method was conducted (3M, 1997).

Generated aerosol

The generated aerosol method used a spatially and temporally uniform concentration of approximately 16 milligrams per cubic meter corn oil aerosol in a laboratory chamber. The size of the aerosol is approximately 0.4 to 0.6 µm. The method of detection for the corn oil was a light-scattering photometer which could determine fit factors up to approximately 100,000. The generated aerosol method was chosen for inclusion in this study because it is a common in-facepiece sampling procedure used in the United States for evaluations of respirator fit using aerosols and it also has been used for some workplace protection factor studies (Coffey *et al.*, 1998a).

PORTACOUNT Plus

The PORTACOUNT Plus method used a TSI PORTACOUNT Plus Model 8020 and ambient aerosol to determine whether the respirator fit. The PORTACOUNT Plus is a quantitative fit-test instrument that uses ambient particles as the challenge agent and counts the number of particles outside and inside of the facepiece (TSI, 2001). The PORTACOUNT Plus was chosen because it is widely used for fit-testing, and because a previous study demonstrated that the fit factors (the reciprocal of face-seal leakage) obtained from this instrument during a simulated health-care workplace test have a high correlation with a wearer's actual exposure (Coffey *et al.*, 1998a).

N95-COMPANION

TSI has developed the N95-COMPANION accessory for the PORTACOUNT Plus for quantitatively fit-testing N95 respirators, specifically the filtering-facepiece type. The N95-COMPANION only allows a particle size range of 0.03 to 0.05 µm to be counted during a fit-test. Particles in this size range should be easily collected by N95 filter material. Therefore any particles that are counted should be due only to face-seal leakage. A fit factor is then calculated by comparing the number of particles present outside the mask to the number of particles present inside the mask (TSI, 1997).

Simulated Workplace Protection Factor Tests

In addition to the fit-test methods, SWPF tests were performed to determine the level of protection afforded the respirator wearer. The SWPF protocol entailed using a PORTACOUNT Plus while the wearer performed six basic simulated workplace movements. The PORTACOUNT Plus was chosen because its fit factors have been shown to have a high correlation (r^2 = 0.78) to a measure of a respirator wearer's exposure (Coffey *et al.*, 1998a). The results of six SWPF tests were used to calculate the 5th percentile SWPF. The respirators were doffed and re-donned between each test.

PORTACOUNT Plus Measurement Bias

A previous study has demonstrated that the overall fit factors obtained using a PORTACOUNT Plus do not correlate exactly with a measure of actual exposure (Coffey *et al.*, 1998a). In that study, subjects performed a PORTACOUNT Plus method while wearing a half-mask respirator. The subjects then entered a chamber containing 500 ppm of 1,1,2-trichloro-1,2,2-trifluoroethane (Freon® 113) and performed a thirty-minute simulated health care workplace test. After the simulated workplace test, the subjects provided an exhaled breath sample which was analyzed for Freon 113. The level of Freon 113 found in the exhaled breath was then converted into a total Freon 113 exposure dose (TFED), the total amount of Freon 113 the subject inhaled. The SWPFs based on the TFED were then plotted against the corresponding overall PORTACOUNT Plus fit factor. In the previous paper, the relationship was described by a linear equation: $y = 4.54 - 0.92*x$ (where y = the log of the TFED and x = the log of the PORTACOUNT Plus protection factor) (Coffey *et al.*, 1998a) to convert the TFED into SWPF based on TFED. The TFED values were divided into 15,000 ppm-min., the total exposure that would have occurred if the respirator did not provide any protection (500 ppm chamber concentration multiplied by the 30 minutes test duration). Figure 1 is a plot of the PORTACOUNT Plus fit factors versus TFED-based SWPF values.

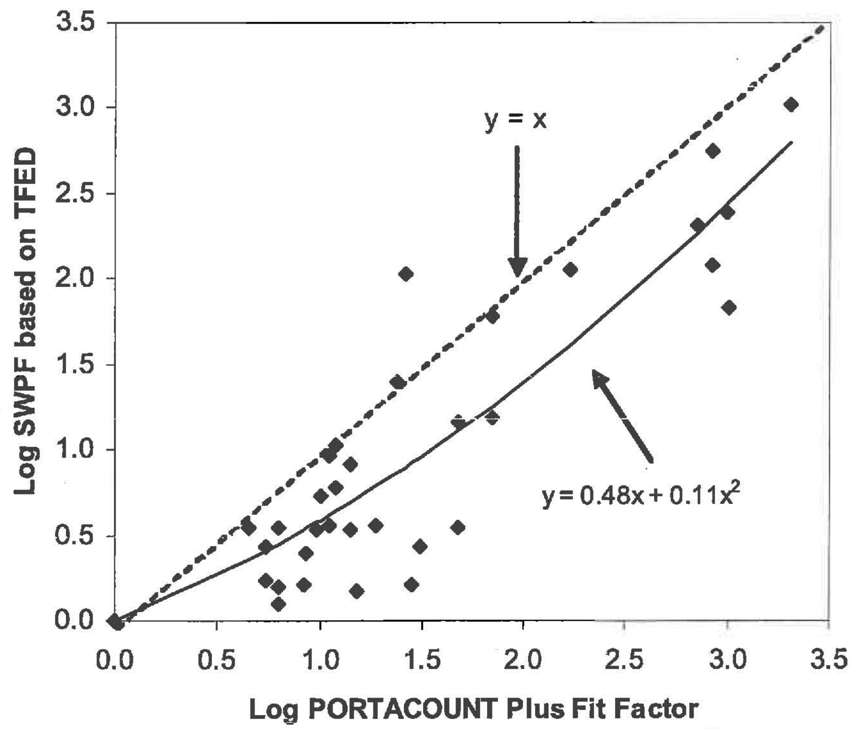

Figure 1. Plot of Log SWPF value based on total Freon exposure dose (TFED) versus Log PORTACOUNT Protection Factor (Data from study by Coffey *et al.*, 1998a).

In this study, a new equation was derived to more accurately fit the data. The new equation was: $y = 0.48*x + 0.11*x^2$ (where y = the log of the SWPF based on TFED and x = the log of the overall PORTACOUNT Plus fit factor), which has a coefficient of determination (r^2) value of 0.92 with a p-value of < 0.0001. The r^2 value is higher than the r^2 value for the best-fitting straight line. This equation was used to adjust the overall PORTACOUNT Plus fit factors to more accurately represent the actual level of protection received by the wearer.

Statistical Analysis

To determine if a fit-test adequately identified poor fits for N95 filtering-facepiece respirators, a statistical approach similar to that used in biomedical applications was used in this study (Brown and Hollander, 1997; Fleiss, 1981; Vecchio, 1966). Two statistics were calculated from a two-by-two contingency table (Table I). These statistics were the α (alpha) error and the β (beta) error.

Table I. Parameters of Two-by-Two Contingency Table

	Simulated Workplace Protection Factor Results	
Fit-Test Result	< 10	≥ 10
Pass	A (# of erroneous passes)	B (# of correct passes)
Fail	C (# of correct failures)	D (# of erroneous failures)

The α error is the fraction of subjects having a respirator which provides adequate protection but failed the fit-test (i.e., an erroneous inadequate protection conclusion). Using Table I, the α error was computed from the following formula: D/(D+B). The β error is the fraction of subjects having a respirator which provides inadequate protection but passed the fit-test (i.e., an erroneous adequate protection conclusion). Using Table I, the β error was calculated from the formula: A/(A+C). An adequately fitting respirator was defined as one which reduced the concentration inside the facepiece to at least 1/10th of that outside the respirator (i.e., a protection factor greater than or equal to 10), the traditional level of protection expected of half-facepiece respirators (ANSI, 1992). The α error is less significant than the β error in regard to worker health, which is why the American National Standards Institute (ANSI) goal for the α error (≤ 0.50) is so much greater than that for the β error (≤ 0.05). In the previous manuscript, the α and β errors were computed using the 5th percentile SWPF values unadjusted for the Freon test bias discussed above (Coffey *et al.*, 2002). The unadjusted 5th percentile SWPF was calculated from six SWPF values determined from six independent donnings of the respirator. If the 5th percentile was 10 or above, the fit of a particular respirator model on an individual test subject was classified as "adequate." This corresponds to considering the fit to be adequate when no more than 5% of the donnings resulted in a protection factor less than 10.

In the current analysis, the following five alternate statistical approaches to the unadjusted 5th percentile SWPF were used: (1) the unadjusted mean SWPF, (2) the bias-adjusted mean SWPF, (3) the bias-adjusted 5th percentile SWPF, (4) the unadjusted individual minimum SWPF, and (5) the bias-adjusted individual minimum SWPF.

The unadjusted mean SWPF is computed from:

$$\frac{1}{SWPF_{um}} = \left(\frac{1}{6}\right)\sum_{i=1}^{6} \frac{1}{SWPF_i}$$

where $SWPF_{um}$ = the unadjusted mean SWPF value and $SWPF_i$ = the overall SWPF value from each of the six donnings. The unadjusted mean SWPF is equivalent to computing the arithmetic mean of the total penetration of the respirator. It is a relevant parameter in that it relates to the average exposure of a worker who dons a respirator multiple times during the course of a work shift. When the respirator is donned several times under identical conditions, the worker's exposure is reduced by a factor of $SWPF_{um}$ from what it would have been if the respirator had not been worn. If the unadjusted mean SWPF of the six SWPF values was 10 or greater, the fit of the respirator was considered to be "adequate.

The bias-adjusted mean SWPF is computed in the same manner as the unadjusted mean except that the individual SWPF values were corrected for possible bias in the TSI PORTACOUNT Plus as discussed in the PORTACOUNT Plus Fit Factor Bias section. If the bias-adjusted mean SWPF value was greater than or equal to 10, the fit of the respirator was considered to be "adequate.

The bias-adjusted 5^{th} percentile SWPF is computed in the same manner as the unadjusted 5^{th} percentile SWPF except that the individual SWPF values are corrected for possible bias in the TSI PORTACOUNT Plus instrument. Again, the fit of a particular respirator model on an individual test subject was classified as "adequate" when the bias-adjusted 5^{th} percentile was 10 or greater.

Table II. Summary of Results Using Criteria for Defining Adequacy of Fit Based on Unadjusted and Bias-Adjusted Mean SWPF, by Fit-Test Method

Fit-Test Method	n	Statistical Approach	Passes		Failures		Error	
			Correct	Erroneous	Correct	Erroneous	α	β
Accuracy Goal	-	-	-	-	-	-	*. 50%*	*. 5%*
Bitrex	474[A]	Unadjusted	148	7	108	211	59%	6%
Bitrex	474[A]	Bias-adjusted	91	64	243	76	46%	21%
Saccharin	224[B]	Unadjusted	48	7	70	99	67%	9%
Saccharin	224[B]	Bias-adjusted	29	26	141	28	49%	16%
Generated Aerosol	250[C]	Unadjusted	30	0	38	182	86%	0%
Generated Aerosol	250[C]	Bias-adjusted	27	3	137	83	75%	2%
PORTACOUNT Plus	474[A]	Unadjusted	74	2	113	285	79%	2%
PORTACOUNT Plus	474[A]	Bias-adjusted	66	10	297	101	60%	3%
N95-COMPANION	474[A]	Unadjusted	132	5	110	227	63%	4%
N95-COMPANION	474[A]	Bias-adjusted	88	49	258	79	47%	16%

[A] 16 models of respirators tested on 25 subjects + one model of respirator tested on 50 subjects + one model tested on 24 subjects (one subject dropped from panel and not replaced).
[B] 8 models of respirators tested on 25 subjects + one model tested on 24 subjects (one subject dropped from panel and not replaced).
[C] 10 models of respirators tested on 25 subjects.

The approach using unadjusted individual minimum SWPF values relates to the minimum protection factor achieved by a worker who dons the respirator multiple times during the course of the work shift. The fit of the respirator was considered to be "adequate" if the minimum of the six SWPF values was 10 or greater.

The bias-adjusted individual minimum SWPF values were calculated the same as the unadjusted individual SWPF values except they were corrected for possible bias in the TSI PORTACOUNT Plus. The criterion used for the bias-adjusted individual minimum SWPF values was the same as the criterion for the unadjusted individual minimum SWPF values.

Table III. Summary of Results Using Criteria for Defining Adequacy of Fit Based on Unadjusted and Bias-Adjusted 5th Percentile SWPF, by Fit-Test Method

Fit-Test Method	n	Statistical Approach	Passes		Failures		Error	
			Correct	Erroneous	Correct	Erroneous	α	β
Accuracy Goal	-	-	-	-	-	-	*50%*	*5%*
Bitrex	474[A]	Unadjusted	134	21	177	142	51%	11%
Bitrex	474[A]	Bias-adjusted	64	91	274	45	41%	25%
Saccharin	224[B]	Unadjusted	44	11	112	57	56%	9%
Saccharin	224[B]	Bias-adjusted	21	34	156	13	38%	18%
Generated Aerosol	250[C]	Unadjusted	28	2	73	147	84%	3%
Generated Aerosol	250[C]	Bias-adjusted	25	5	170	50	67%	3%
PORTACOUNT Plus	474[A]	Unadjusted	69	7	191	207	75%	4%
PORTACOUNT Plus	474[A]	Bias-adjusted	53	23	342	56	51%	6%
N95-COMPANION	474[A]	Unadjusted	120	17	181	156	57%	9%
N95-COMPANION	474[A]	Bias-adjusted	68	69	296	41	38%	19%

[A] 16 models of respirators tested on 25 subjects + one model of respirator tested on 50 subjects + one model tested on 24 subjects (one subject dropped from panel and not replaced).
[B] 8 models of respirators tested on 25 subjects + one model tested on 24 subjects (one subject dropped from panel and not replaced).
[C] 10 models of respirators tested on 25 subjects.

RESULTS AND DISCUSSION

Tables II through IV contain the results for the two-by-two contingency tables using these alternate approaches. Table V is a summary of the α and β errors of all six approaches, for ease in comparing the efficacy of each fit-test method by alternate approach. Each fit-test result was categorized as either an erroneous pass, correct pass, correct failure, or erroneous failure. Of these categories, the erroneous passes — reflected in the β errors— are the most critical since an erroneous pass indicates that a person will be issued a poorly-fitting respirator, which could lead to a potentially higher exposure than would occur with a properly selected, fitted and donned respirator.

Table IV. Summary of Results Using Criteria for Defining Adequacy of Fit Based on Unadjusted and Bias-Adjusted Individual Minimum SWPF Values, by Fit-Test Method

Fit-Test Method	n	Statistical Approach	Passes		Failures		Error	
			Correct	Erroneous	Correct	Erroneous	α	β
Accuracy Goal	-	-	-	-	-	-	*≤50%*	*≤5%*
Bitrex	2844[A]	Unadjusted	878	52	687	1227	58%	7%
Bitrex	2844[A]	Bias-adjusted	551	379	1415	499	46%	21%
Saccharin	1344[B]	Unadjusted	287	43	462	552	66%	9%
Saccharin	1344[B]	Bias-adjusted	184	146	817	197	52%	15%
Generated Aerosol	1500[C]	Unadjusted	176	4	230	1090	86%	2%
Generated Aerosol	1500[C]	Bias-adjusted	164	16	815	505	75%	2%
PORTACOUNT Plus	2844[A]	Unadjusted	436	20	719	1669	79%	3%
PORTACOUNT Plus	2844[A]	Bias-adjusted	392	64	1730	658	63%	4%
N95-COMPANION	2844[A]	Unadjusted	280	0	739	1825	87%	0%
N95-COMPANION	2844[A]	Bias-adjusted	280	0	1794	770	73%	0%

[A] 16 models of respirators tested on 25 subjects + one model of respirator tested on 50 subjects + one model tested on 24 subjects (one subject dropped from panel and not replaced). Each subject performed 6 donnings per respirator model.
[B] 8 models of respirators tested on 25 subjects + one model tested on 24 subjects (one subject dropped from panel and not replaced). Each subject performed 6 donnings per respirator model.
[C] 10 models of respirators tested on 25 subjects. Each subject performed 6 donnings per respirator model.

Table II is the summary of the analysis using the unadjusted and bias-adjusted mean SWPF. With the unadjusted mean approach, the β errors ranged from 0 to 9 percent by fit-test method, with three methods (generated aerosol, PORTACOUNT Plus, and N95-COMPANION) meeting the ANSI goal of ≤ 5%. None of the fit-test methods met the ANSI goal for the α error (≤ 50%), with values ranging from 59 to 86 percent. The Bitrex method had the lowest α error at 59 percent, and the generated aerosol method had the highest α error at 86 percent. With the bias-adjusted mean approach, the β errors increased with all fit-test methods, ranging from 2 to 21 percent. Only two of the methods (generated aerosol and the PORTACOUNT Plus) met the ANSI goal. The α error ranged from 46 to 75 percent with the bias-adjusted mean approach. Three of the methods (Bitrex, saccharin and N95-COMPANION) met the ANSI goal of ≤ 50%. Tables III and IV show a similar pattern of results using other approaches for defining "adequate fit".

As shown in Table V, none of the alternative approaches met the ANSI goals for both α and β errors. The unadjusted individual value approach gave the highest α error for any fit-test method (87 percent with the N95-COMPANION method). The bias-adjusted 5th percentile approach provided the highest β error (25 percent with the Bitrex method), but also exhibited the lowest α error (38 percent with both the Bitrex and N95-COMPANION methods). The lowest β error for all fit-test methods was not provided by any single alternate approach. The unadjusted mean provided the lowest β errors for four of the tests — Bitrex, saccharin, generated aerosol, and PORTACOUNT Plus methods. The N95-COMPANION method had a β error of 0 percent with both the bias-adjusted and unadjusted individual values.

Table V. Alpha and Beta Error Percentage Results by Various Analytical Approaches for Defining Adequacy of Fit

Fit-Test Method	Unadjusted 5th percentile SWPF		Bias-adjusted 5th percentile SWPF		Unadjusted mean SWPF		Bias-adjusted mean SWPF		Unadjusted individual values		Bias-adjusted individual values	
	α [A]	β [B]	α [A]	β [B]	α [A]	β [B]	α [A]	β [B]	α [A]	β [B]	α [A]	β [B]
Bitrex	51	11	41	25	59	6	46	21	58	7	46	21
Saccharin	56	9	38	18	67	9	49	16	66	9	52	15
Generated aerosol	84	3	67	3	86	0	75	2	86	2	75	2
PORTACOUNT Plus	75	4	51	6	79	2	60	3	79	3	63	4
N95-COMPANION	57	9	38	19	63	4	47	16	87	0	73	0

[A] accuracy goal for alpha error (α) is ≤ 50 %
[B] accuracy goal for beta error (β) is ≤ 5%

Using all six approaches, α and β errors for each of the 18 individual respirator models were computed. The range of α and β errors, by method, is shown for each respirator in Table VI. The range of α and β errors obtained with the alternate approaches vary considerably by respirator model and by fit-test method. When the Bitrex method was used, four respirator models met the α goal regardless of the approach, while failing to meet the β goal with all approaches. No models consistently met the β goal. Using the PORTACOUNT Plus resulted in one model meeting the α and nine models meeting the β requirement with all approaches. With the N95-COMPANION there was one model that consistently met the α goal and a different model that consistently met the β goal. The generated aerosol method had one model that met the α requirement with all approaches and eight models that consistently met the β requirement. For the saccharin method, one model consistently met the α goal, and no models consistently met the β goal.

Table VI. Range of α and β Error Percentages of Individual Respirator Models Using Six Different Statistical Approaches for Defining Adequacy of Fit

Manufacturer and Model	Fit Test Method									
	Bitrex		Saccharin		Generated		PORTACOUNT		N95-COMPANION	
	α	β	α	β	α	β	α	β	α	β
All	41-59	6-25	38-67	9-18	67-86	0-3	51-79	2-6	38-87	0-19
Willson 1410N95	67-78	10-18	MNT [C]	MNT [C]	100[B]	0[B]	0-90	0-6	0-100	0-17
3M 1860	50-58	0-27	MNT [C]	MNT [C]	84-89	0[B]	50-66	0-2	28-83	0-45
Survivair 1930	33-50	15-26	MNT [C]	MNT [C]	79-100	0[B]	50-77	0-5	33-93	0-11
Moldex 2200N95	0-39	0-43	MNT [C]	MNT [C]	100[B]	0[B]	50-90	0[B]	25-96	0-24
Moldex 2207N95	60-100[A]	0-16	70-100	0-13	MNT [C]	MNT [C]	100[A B]	0[B]	50-100[A]	0-74
Moldex 2300N95	50-75	11-18	50-81	10-70	MNT [C]	MNT [C]	100[B]	0[B]	0-100	0-17
Moldex 2700N95	50-60	0-20	71-80	8-33	MNT [C]	MNT [C]	40-80	0-85	20-94	0-25
Gerson 2737	0-65	0-25	MNT [C]	MNT [C]	100[B]	0[B]	86-100	10-20	60-100	0-38
North 7175N95	19-54[A]	0-40	0-68[A]	3-28	100[A B]	0[B]	100[A B]	0[B]	81-100[A]	0-55
3M 8210	42-50	0-36	MNT [C]	MNT [C]	86-90	9-20	64-75	18-100	36-95	0-100
3M 8212	40-62	13-25	40-69	13-22	MNT [C]	MNT [C]	50-80	0-57	56-67	0-20
3M 8512	33-70	0-10	33-70	12-20	MNT [C]	MNT [C]	33-70	0-10	33-82	0-10
U. S. Safety ADN95	0-75[A]	2-12	0-83[A]	2-60	MNT [C]	MNT [C]	100[A B]	0[B]	100[A B]	0-6
Willson N9510F	16-52	0-31	17-52	0-32	MNT [C]	MNT [C]	33-65	0-21	33-81	0-50
Willson N9520F	18-47	7-13	25-47	8-46	MNT [C]	MNT [C]	66-76	0-7	42-91	0-13
Aearo Safety Pleats	62-76	8-20	MNT [C]	MNT [C]	71-82	7-13	57-85	0[B]	79-100	0-13
MSA Affinity Plus	50-66	0-25	MNT [C]	MNT [C]	100[B]	0[B]	100[B]	0[B]	95-100	0[B]
MSA Affinity Ultra	48-52	88-100[A]	MNT [C]	MNT [C]	2-22	100[A B]	24-26	87-100	9-13	0-100[A]

[A] For at least one approach the indicated value could not be computed due to all subjects having SWPF less than 10.
[B] All approaches resulted in indicated value.
[C] MNT = model not tested with method.

Limitations of Study

As previously discussed, the first limitation of the study is that there may be potential inaccuracy in the fit factors obtained with the PORTACOUNT Plus. It is important to note that this study only included N95 filtering-facepiece respirators. The results of this study may not be applicable to other types and classes of respiratory protection. Another limitation of this study is that the fit-test panel is not representative of all respirator wearers.

The limited number of individuals on the test panel also influenced the results. For example, the MSA Affinity Ultra had a β error of 100% using the bias-adjusted mean SWPF approach with the Bitrex fit-test method (Table VI). This was because only one test subject had a bias-adjusted mean SWPF of less than 10, and that same subject passed the Bitrex fit-test. If that person had failed the Bitrex fit-test, the β error would have been reduced to zero. If the fit-test panel were expanded to include a greater number of individuals, a more accurate β error estimate would be obtained.

In addition, the exercises performed in this study were a six-exercise regimen and may not be representative of work activities under actual workplace environments. The performance results of the individual respirator models are relative to each other and cannot be viewed as the actual protection a wearer would receive in the workplace.

At the beginning of this study, NIOSH policy recommended against the use of saccharin for fit-testing, due to its potential carcinogenicity. Approximately halfway through the study, NIOSH revised its policy to accept the use of the saccharin fit-test method (NIOSH, 1999). When NIOSH changed its policy, limited resources available for this study led to a decision to drop the generated aerosol method in favor of including the saccharin method because saccharin is widely used for fit-testing in workplaces. Thus, not all models were tested with all five fit-test methods.

CONCLUSIONS

Previous studies, using the unadjusted 5th percentile SWPF, have derived very high α and β errors for the common fit-test methods, especially the qualitative methods. This study was undertaken to determine if alternate analytical approaches would result in lower α and β errors. Although some of these alternate approaches improved the α and β error ranges overall, none of the alternate approaches enabled any fit-test method to meet the ANSI criteria for screening out poorly fitting respirators. Therefore using the unadjusted 5th percentile, as has been done in previous studies, is probably as good an approach as any we evaluated to determine the performance of a respirator. More research is needed to determine why none of the current fit-test methods meet the established ANSI goals for both α and β errors.

DISCLAIMER

Mention of company, commercial product, or trade names does not constitute endorsement by the Centers for Disease Control and Prevention and/or West Virginia University.

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