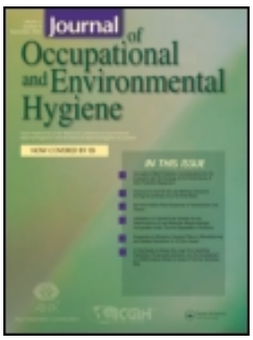

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Comparison of Performance of Three Different Types of Respiratory Protection Devices

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Respiratory protection is offered to American workers in a variety of ways to guard against potential inhalation hazards. Two of the most common ways are elastomeric N95 respirators and N95 filtering-facepiece respirators. Some in the health care industry feel that surgical masks provide an acceptable level of protection in certain situations against particular hazards. This study compared the performance of these types of respiratory protection during a simulated workplace test that measured both filter penetration and face-seal leakage. A panel of 25 test subjects with varying face sizes tested 15 models of elastomeric N95 respirators, 15 models of N95 filtering-facepiece respirators, and 6 models of surgical masks. Simulated workplace testing was conducted using a TSI PORTACOUNT Plus model 8020, and consisted of a series of seven exercises. Six simulated workplace tests were performed with redonning of the respirator/mask occurring between each test. The results of these tests produced a simulated workplace protection factor (SWPF). The geometric mean (GM) and the 5th percentile values of the SWPFs were computed by category of respiratory protection using the six overall SWPF values. The level of protection provided by each of the three respiratory protection types was compared. The GM and 5th percentile SWPF values without fit testing were used for the comparison, as surgical masks were not intended to be fit tested. The GM values were 36 for elastomeric N95 respirators, 21 for N95 filtering-facepiece respirators, and 3 for surgical masks. An analysis of variance demonstrated a statistically significant difference between all three. Elastomeric N95 respirators had the highest 5th percentile SWPF of 7. N95 filtering-facepiece respirators and surgical masks had 5th percentile SWPFs of 3 and 1, respectively. A Fisher Exact Test revealed that the 5th percentile SWPFs for all three types of respiratory protection were statistically different. In addition, both qualitative (Bitrex and saccharin) and quantitative (N95-Companion) fit testing were performed on the N95 filtering- and elastomeric-facepiece respirators. It was found that passing a fit test generally improves the protection afforded the wearer. Passing the Bitrex fit test resulted in 5th percentile SWPFs of 11.1 and 7.9 for elastomeric and filtering-facepiece respirators, respectively. After passing the saccharin tests, the elastomeric respirators provided a 5th percentile of 11.7, and the filtering-facepiece respirators provided a 5th percentile of 11.0. The 5th percentiles after passing the N95-Companion were 13.0 for the elastomeric respirators and 20.5 for the filtering-facepiece respirators. The data supports fit testing as an essential element of a complete respiratory protection program.

Keywords N95 respirators, respiratory protection, simulated workplace protection factor, surgical masks

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The findings and conclusions in this report are our own and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

INTRODUCTION

Respirators are worn by 3,300,000 American workers.[1] Of these workers, 3 million of them wear tight-fitting facepiece respirators that are required by the Occupational Safety and Health Administration (OSHA) to be fit tested. The health of these workers depends on the inherent fitting properties of each respirator model and on the accuracy of the fit-test method used to identify those individuals who do not achieve the good fit necessary for adequate protection. Because current fit-test methods are not error free, the errors inherent in fit-testing methods can result in individuals inappropriately being assigned poorly fitting respirators for use in hazardous environments.[2] The chance of an individual being assigned a poorly fitting respirator rises with increasing fit-testing error and falls with improvements in the face-fitting characteristics of the respirator.

Consequently, the most important and most variable attribute of any negative-pressure respirator is how well it seals to the face (i.e., the fitting characteristics of the respirator model). Here, the term "fitting characteristics" is used to refer to the ability of a particular respirator model to provide an adequate fit to a large percentage of the general population with its wide variety of face sizes and shapes. An adequate fit is one in which an individual consistently achieves a protection factor equal to or greater than the assigned protection factor (APF)

for the respirator class, for at least 95% of the donnings. For half-facepiece respirators, the APF is 10.[3–5]

The National Institute for Occupational Safety and Health (NIOSH) has demonstrated previously that N95 filtering-facepiece respirators have a wide range of fitting characteristics.[6,7] Elastomeric type half-facepieces have not been assessed since the mid-1980s in NIOSH-sponsored studies.[8,9] This study assesses the fitting characteristics of both N95 elastomeric half-facepiece and filtering-facepiece respirators.

Previous NIOSH studies on half-facepiece respirators have not included surgical masks, as they are not NIOSH-certified devices. Some in the health care industry consider N95 filtering-facepiece respirators to be cost prohibitive, including the cost of the respirator and the administrative costs, such as fit testing. They would like to be able to use surgical masks to protect workers under certain circumstances. There are no data that indicate a surgical mask will not provide the same level of protection as an N95 respirator. Six surgical masks were included in this study to compare their level of protection with that of N95 filtering-facepiece and elastomeric respirators.

The purposes of this study were to determine if the three types of respiratory protection devices provided the same level of protection, if the devices provided the expected level of protection, if the level of protection varied between the individual models within each type, and if passing a fit test improved the level of protection provided by an N95 respirator.

MATERIALS AND METHODS

Test Subjects

There were 37 people (20 females and 17 males) who participated in this study. The age of the panel members ranged from 19 years to 48 years. Panel members were selected to provide a variety of facial sizes without regard to any particular facial size distribution. The subjects' lip and face lengths were measured. Female subjects had lip lengths ranging from 43 to 55 mm and face lengths ranging from 104 to 124 mm. Male subjects had lip lengths from 44 to 59 mm and face lengths from 112 to 135 mm.

Respirator Models

We tested 15 models of N95 filtering-facepiece respirators, 15 models of N95 elastomeric half-facepiece respirators, and 6 surgical masks. The N95 respirator models used were selected randomly from those that were commercially available at the time of the study. The filtering-facepiece respirators selected had not been tested previously as part of a NIOSH research study, and they were of two different configurations (i.e., cup and folding). The surgical masks were selected to provide a variety of configurations (e.g., ear-loop, face shield, folding, cup-shaped, etc.). Only two surgical masks (the Medline Prohibit and the 3M 1818) were approved by the Food and Drug Administration (FDA). The Makrite 910 was approved by NIOSH as an N95 filtering-facepiece respirator and by the FDA as a surgical mask.

Some of the respiratory protective device models tested in this study may no longer be manufactured and marketed in the version tested in as much as manufacturers continually modify or replace respiratory protective devices with newer versions. Table I lists the respirator and surgical mask models tested.

Fit Testing and Simulated Workplace Testing

A panel of 25 subjects from the pool of 37 was selected to test each respiratory protective device. Respiratory protective devices available in multiple sizes did not have instructions describing how to choose an appropriate size. Test subjects were given a device based on their face and lip length measurements as recommended by the Los Alamos National Laboratory.[10]

The performance of the respiratory protective devices was determined by using a simulated workplace protection factor (SWPF) test (i.e., the concentration measured outside the respiratory protective device divided by the concentration inside the device). The SWPF test determined the total penetration (i.e., filter penetration and face-seal leakage) of six tests using the PORTACOUNT Plus (TSI, St. Paul, Minn.). This SWPF test is similar to the Program Concept for Total Inward Leakage Performance Requirements and Test Methods being proposed by NIOSH for incorporation into the certification program.

The fit-test methods used were: Bitrex Solution Aerosol Fit Test (Allegro Industries, Paramount, Calif.); TSI PORTACOUNT Plus with the N95-Companion accessory (which is designed to count only particles resulting from face-seal leakage); and Saccharin Solution Aerosol Fit Test (3M Co., St. Paul, Minn.). Each of the three fit-test methods was performed once with a specific subject/respiratory protective device combination. The subject wore the same respiratory protective device during each of the six SWPF tests and the three fit tests. Between each test of a particular respirator, the subject removed the respirator, gave it to the test operator, who returned the respirator to its original configuration (e.g., loosening head straps, straightening the nosepiece, etc.), and then the subject redonned it. Surgical masks were not fit-tested.

Because smokers exhale particles for at least 30 min after smoking a cigarette or cigar, all test subjects who were smokers refrained from smoking for at least 30 min before the tests. The PORTACOUNT Plus will detect exhaled particles and interpret them as being caused by face-seal leakage and, thus, produce erroneous results. All subjects abstained from eating, chewing gum, and drinking (except for plain water) for at least 15 min prior to testing. These restrictions ensured that the subjects would be able to detect the qualitative fit-testing agents at the lowest possible concentration. The order in which each subject tested the 36 respiratory protective devices was randomized to the greatest extent possible.

Fit-Test Methods

All fit testing was conducted in accordance with the protocols contained in the OSHA respiratory protection standard, including the number, type, and duration of the exercises as well as performing a user seal check in accordance with the

TABLE I. List of Respiratory Protective Devices

Company	Model Number	Device Type	Description
3M	8511	N95 filtering-facepiece	Cup
3M	8515	N95 filtering-facepiece	Cup
3M	9210	N95 filtering-facepiece	Flat/folding
3M	9211	N95 filtering-facepiece	Flat/folding
Alpha Pro Tech	MAS695	N95 filtering-facepiece	Flat/folding
Aswan	M-12	N95 filtering-facepiece	Flat/folding
Draeger	Piccola w/o valve	N95 filtering-facepiece	Flat/folding
Gerson	1730	N95 filtering-facepiece	Cup
Gerson	2747	N95 filtering-facepiece	Cup
Gerson	3945	N95 filtering-facepiece	Cup
Makrite	910	N95 filtering-facepiece	Flat/folding
Moldex	2600/2601	N95 filtering-facepiece	Cup
MSA	FR200 Affinity	N95 filtering-facepiece	Flat/folding
San M Package	TN01	N95 filtering-facepiece	Flat/folding
Survivair	1913	N95 filtering-facepiece	Flat/folding
3M	7000	N95 elastomeric	—
AO Safety	5 Star	N95 elastomeric	—
Lab Safety	11291	N95 elastomeric	Not applicable
Moldex	8000	N95 elastomeric	Not applicable
MSA	Comfo Classic	N95 elastomeric	Not applicable
MSA	Comfo Elite	N95 elastomeric	Not applicable
North	7700	N95 elastomeric	Not applicable
Pro-Tech	1490/1590	N95 elastomeric	Not applicable
Scott	66	N95 elastomeric	Not applicable
Sellstrom	2900	N95 elastomeric	Not applicable
Survivair	2000	N95 elastomeric	Not applicable
Survivair	7000	N95 elastomeric	Not applicable
Willson	1200	N95 elastomeric	Not applicable
Willson	6100	N95 elastomeric	Not applicable
Willson	6800	N95 elastomeric	Not applicable
3M	1818	Surgical mask	Flat/folding
3M	Aseptex 1800+	Surgical mask	Flat/folding
3M	Nexcare First Aid	Surgical mask	Flat/folding
Johnson & Johnson	Surgine 4238	Surgical mask	Flat/folding
Medline	Prohibit series	Surgical mask	Cup
Tecnol	48237	Surgical mask	Flat/folding

Note: Dashes indicate fit testing not done.

manufacturers' instructions. A summary of the fit-test methods is presented here; they are described in detail elsewhere.[11]

Bitrex (Denatonium Benzoate) Solution Aerosol Fit Test

The Bitrex test uses a person's ability to taste a bitter solution to determine whether a respirator fits properly. Each subject was given a taste-threshold screening test to ensure that he or she could taste Bitrex at the specified concentration. All subjects reported tasting the Bitrex during each screening test before 10 squeezes were applied. After the screening test, a subject left the laboratory, drank water, and rinsed his or her lips and mouth. The subject returned to the laboratory, donned the respirator, and the Bitrex fit test was conducted. If the person did not taste Bitrex, the test was considered a pass. If a subject tasted Bitrex at any time, the test was considered a failure.

Saccharin Solution Aerosol Fit Test

The saccharin test uses a person's ability to taste a sweet solution to determine whether a respirator fits properly. As with the Bitrex test, subjects were given a taste-threshold screening test to ensure that they could taste saccharin at the specified concentration. After the screening test, a subject left the laboratory, drank water, and rinsed his or her lips and mouth. The subject returned to the laboratory, donned the respirator, and the saccharin fit test was conducted. If the person did not taste saccharin, the test was considered a pass. If a subject tasted saccharin at any time, the test was considered a failure.

Ambient Aerosol Condensation Nuclei Counter Fit Test with the N95-Companion (Companion Method)

TSI developed the N95-Companion accessory to the PORTACOUNT Plus specifically for fit testing N95 filtering-facepiece respirators. The N95-Companion is an aerosol preconditioner that selects particles in a specific size range (approximately 0.03 to 0.06 μm, which are assumed not to penetrate the N95 filter media) and passes them on to the PORTACOUNT Plus. Particles that are not in this range are discarded. The PORTACOUNT Plus then compares the number of particles outside the mask to the number inside the mask in this size range. The ratio is a fit factor. In this configuration, the fit factor is obtained directly from the PORTACOUNT Plus. A TSI model 8026 Particle Generator was used to generate a sodium chloride aerosol to ensure that the ambient aerosol contained at least 100 particles/cc in the appropriate size range.

SWPF Testing

The SWPF test values were used to determine the level of protection provided without a fit test being performed and to compare the results of the fit tests. An SWPF is a measure of the protection received by an individual from a respirator; it considers both filter penetration and face-seal leakage. The SWPF testing in this study used the PORTACOUNT Plus to determine whether an acceptable level of protection was obtained. This SWPF test was selected because PORTACOUNT Plus fit factors have been demonstrated to have a high correlation (coefficient of determination [r^2] of 0.78) to a measurement of a wearer's actual exposure in a simulated health care workplace test. This r^2 value is comparable to the continuous high-flow deep-probe (CHD) method's r^2 value of 0.81, which was the highest in the previous study.[12] The CHD method was not used as the SWPF test as it requires a chamber, uses corn oil, and has a longer duration than an ambient aerosol test (30 min compared with 12 min). The SWPF values were computed in the same manner as the N95-Companion method fit factors. Individual exercise SWPF values were calculated by dividing the number of particles outside the facepiece by the number of particles counted inside. The harmonic mean of the individual exercise SWPF values from each test was computed and used as the SWPF value compared with the fit-test results.

Before starting an SWPF test, a subject donned the respirator and performed a user-seal check, per the respirator manufacturer's instructions. After the respirator was donned, SWPF testing began.

An SWPF test consisted of a test subject performing the following seven exercises for one minute each: (1) normal breathing, (2) deep breathing, (3) moving head side to side, (4) moving head up and down, (5) reading the rainbow passage out loud, (6) bending at the waist, and (7) normal breathing. This SWPF protocol was used because it is based on a fit-test protocol that provides fit factors that are highly correlated with a measure of actual exposure during a simulated health care workplace study.[12] An overall SWPF was obtained from the seven individual exercises using Equation 1.1.[11]

$$\text{Overall SWPF} = \frac{7}{\frac{1}{\text{SWPF}_1} + \frac{1}{\text{SWPF}_2} + \cdots + \frac{1}{\text{SWPF}_6} + \frac{1}{\text{SWPF}_7}}$$

where SWPF_x equals simulated workplace protection factor for a given exercise.

After completing the first test, a subject removed the respirator and gave it to the test operator. The test operator returned the respirator to its original configuration (e.g., loosening head straps, flattening the nosepiece). Then, the subject donned the same respirator and checked the user-seal again, per the manufacturer's instructions. A second test, identical to the first, was conducted. This procedure was repeated four additional times for a total of six SWPF tests for each subject and respirator combination.

Data Analysis

5th Percentile SWPF Values

The performance of the respiratory protective devices was measured by using the 5th percentile and geometric mean (GM) SWPF values. The 5th percentile SWPF was computed from the formula $\text{GM}/\text{GSD}^{1.645}$, where GSD equals the geometric standard deviation.[9] NIOSH has used this 5th percentile method for determining SWPF values for computing its recommended APF values based on workplace protection factor studies since 1987.[13]

From the 150 overall SWPF values, the GM and the 5th percentile SWPF values for each device were calculated, which will be referred to as "without fit testing." The subjects who wore either an N95 filtering-facepiece or elastomeric respirator were 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 N95-Companion quantitative test meant that a subject had a fit factor $\geq$100 with a particular respirator model. The GM and the 5th percentile SWPF values were then separately calculated for subjects passing a fit-test and for subjects failing that fit test.

A Duncan's Multiple Range test was used to compare the GM SWPF values for each of the respiratory protective device types and to compare the GMs for each model within a given type. The Duncan's Multiple Range test is intended to give groupings of means that are not significantly different between themselves. Other tests to compare the GM SWPF values were considered: Least Significant Difference (LSD) and Tukey's Honest Significant Difference (HSD). The LSD test tends to declare the most differences between means whereas the HSD test declares the least. The Duncan's Multiple Range test is between the LSD and the HSD tests, so it was selected. The Fisher Exact test was used to compare the 5th percentile SWPF values between and within each of the respiratory protective device types.

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) also was 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 results in both time and financial savings by reducing the number of repeat fit tests required as well as reducing the number of respirators that need to be stocked.

h-values

Another manner of assessing respirator performance was to compute the h-value for all the models combined as well as for each individual model. For the purposes of this study, the h-value is the number of SWPF values greater than the target protection value of 10 divided by the total number of SWPF values. A target value of 10 was selected because it is the APF usually assigned to half-facepiece respirators.[3–5]

RESULTS

Table II is a summary of the performance statistics (i.e., GM, GSD, and 5th percentile) for the three different types of respiratory protective devices as determined by the SWPF testing. Surgical masks, as a class, provided the lowest level of protection with a SWPF GM of 2.6 and a SWPF 5th percentile of 1.2. The class of elastomeric facepieces equipped with N95 filters provides the greatest level of protection with a GM and a 5th percentile of 35.5 and 7.3, respectively. None of the three respiratory protective devices as a group provided the expected level of protection for a half-facepiece respirator (i.e., all three classes had a 5th percentile <10).[3–5]

Table III provides the individual performance statistics for each of the six surgical mask models. The GMs ranged from a low of 1.6 to a high of 4.0, whereas the 5th percentiles ranged from 1.0 to 1.9. Table IV shows the GMs without fit testing for the individual N95 filtering-facepiece respirators ranged from 3.0 to 55.0, whereas the 5th percentiles ranged from 1.1 to 13.2. After fit testing, the 5th percentiles ranged from 2.8 to 39.2 using the Bitrex test, from 1.2 to 49.8 using the saccharin test, and from 12.6 to 35.9 for the Companion test.

TABLE II. Summary Statistics of the Three Respiratory Protective Devices

Respiratory Protective Device Type	GM	Duncan Grouping of the GM[A]	GSD	5th Percentile
N95 elastomeric facepiece	35.5	A	2.6	7.3
N95 filtering-facepiece	20.5	B	3.1	3.3
Surgical masks	2.6	C	1.6	1.2

[A] All means having the same Duncan Grouping letter are statistically the same.

TABLE III. Summary Statistics of the Surgical Masks

Model	GM	Duncan Grouping of the GM[A]	GSD	5th Percentile
All surgical masks combined	2.6	—	1.6	1.2
1818	4.0	A	1.6	1.9
Nexcare Surgical	3.2	B	1.4	1.9
Surgine 4238	3.2	B	1.5	1.6
48237	2.6	C	1.5	1.3
Aseptex 1800+	1.9	D	1.3	1.3
Prohibit	1.6	E	1.4	1.0

Note: Dash indicates fit testing not done.
[A] All means having the same Duncan Grouping letter are statistically the same.

Two models did not have any subjects passing the Bitrex fit test. No subjects passed the saccharin test with three models. With the Companion test, four models had no subjects passing the fit test. The worst performing filtering facepiece model was the MSA FR200 Affinity, with no subjects passing any of the three fit tests.

Table V presents the performance statistics for the 15 N95 elastomeric half-facepiece respirator models. Without fit testing, the GMs and 5th percentiles ranged from 22.2 to 161.1 and 3.8 to 25.3, respectively. Passing the Bitrex test produced 5th percentile ranges from 7.8 to 39.8. After passing the saccharin test, the 5th percentiles ranged from 7.1 to 50.0. The 5th percentiles for those subjects passing the Companion test ranged from 10.2 to 50.7.

Six filtering-facepiece respirator models did not have any subjects passing with at least one fit-test method. Five of the six models were of the folding design. All elastomeric models had at least one subject passing each fit test.

A Fisher Exact test was performed to determine if indeed the level of protection by respirators is different between the three fit tests. A Fisher Exact test conducted on the data from both types of respiratory protective devices combined demonstrated that there was no significant difference between the 5th percentiles after passing any of the three fit-test methods ($p = 0.1031$). Next, Fisher Exact tests were performed using the filtering-facepiece and elastomeric respirator data separately to determine if the level of protection differed between the three fit-test methods based on respirator type. These tests indicated that there was a significant difference between the levels of protection within the three fit-test methods ($p = 0.0073$) using filtering facepieces, but no difference using elastomeric facepieces ($p = 0.5870$). Using filtering facepiece respirators, no significant difference was found between the saccharin and Bitrex fit-test methods ($p = 0.2380$). A significant difference was found between the Bitrex and the Companion methods ($p = 0.0011$), with the level of protection after passing the Bitrex fit-test method being lower

TABLE IV. Summary SWPF Statistics for N95 Filtering-Facepiece Respirators by Fit-Test Method

Model	GM Without Fit Testing	Duncan Grouping of the GM[A]	GSD Without Fit Testing	5th Percentile Without Fit Testing	5th Percentile by Fit-Test Method					
					Bitrex		Saccharin		Companion	
					Pass	Fail	Pass	Fail	Pass	Fail
All filtering facepieces	20.4	—	3.1	3.3	7.9	3.0	11.0	3.0	20.5	2.7
9210	55.0	A	2.4	13.2	17.1	11.7	10.6	13.4	16.7	11.4
3945	43.7	B	2.2	11.8	37.6	10.5	39.7	9.6	24.8	6.5
8511	40.8	B,C	2.0	12.8	14.2	12.6	25.9	11.5	21.2	11.9
9211	37.9	B,C	2.9	6.7	39.2	6.2	26.3	5.8	34.6	5.3
8515	33.4	C,D	2.6	6.9	22.8	5.9	49.8	5.6	26.1	3.5
1913	29.0	D,E	1.9	9.9	21.6	9.5	19.3	9.7	30.9	8.7
1730	26.4	E	1.8	9.8	14.7	8.5	20.2	8.0	24.5	6.9
2600/2601	25.1	E,F	2.8	4.6	21.9	4.2	28.6	3.9	21.4	2.8
TN01	21.1	F,G	3.0	3.4	11.3	3.3	29.6	3.2	35.9	3.3
2747	19.5	G	2.8	3.6	NP[B]	3.6	13.9	3.5	12.7	3.2
910	19.5	G	1.9	6.8	5.4	7.0	NP[B]	6.8	NP[B]	6.8
Piccola	10.6	H	2.2	3.0	10.2	2.9	NP[B]	3.0	12.6	2.9
M-12	9.1	H	1.6	4.1	3.2	4.3	2.9	4.2	NP[B]	4.1
FR200 Affinity	8.8	H	2.3	2.3	NP[B]	2.3	NP[B]	2.3	NP[B]	2.3
MAS695	3.0	I	1.9	1.1	2.8	1.0	1.2	1.1	NP[B]	1.1

Note: Dash indicates fit testing not done.
[A] All means having the same Duncan Grouping letter are statistically the same.
[B] Not applicable.
[C] No subjects passed the fit test.

TABLE V. Summary Statistics for SWPF Values Without and With Fit Testing by Fit-Test Method for N95 Elastomeric-Facepiece Respirators

Model	GM Without Fit Testing	Duncan Grouping of the GM[A]	GSD Without Fit Testing	5th Percentile Without Fit Testing	5th Percentile by Fit-Test Method					
					Bitrex		Saccharin		Companion	
					Pass	Fail	Pass	Fail	Pass	Fail
All elastomeric facepieces	35.5	—	2.6	7.3	11.1	6.3	11.7	6.2	13.0	4.4
3M 7000	161.1	A	3.1	25.3	22.9	28.5	50.0	16.9	50.7	11.8
2000	73.1	B	2.0	23.4	27.3	21.8	31.1	17.3	30.7	9.6
1490/1590	49.1	C	1.7	20.8	24.6	18.9	30.7	16.8	26.0	15.8
7700	41.5	C,D	1.6	19.0	20.3	17.9	18.1	19.9	22.3	8.7
Survivair 7000	40.3	D	2.8	7.5	15.1	5.0	47.6	5.9	13.8	3.8
6800	36.7	D	2.0	11.5	9.8	13.7	11.9	12.0	10.8	18.1
66	30.3	E	2.9	5.3	19.5	4.2	27.6	4.6	27.9	2.9
5 Star	29.9	E,F	3.5	3.8	39.8	3.4	13.8	2.6	17.8	2.3
11291	26.4	E,F,G	2.2	7.3	25.3	6.0	12.9	5.6	15.8	2.0
6100	25.5	E,F,G	1.7	7.0	13.0	5.8	14.9	5.7	15.1	4.4
Comfo Classic	25.3	E,F,G	1.7	10.9	13.6	9.8	12.0	10.1	15.4	7.9
1200	24.5	E,F,G	1.7	9.8	13.2	9.3	7.7	10.0	10.2	9.7
8000	24.4	E,F,G	1.8	9.1	10.9	8.3	11.0	8.6	14.0	7.2
2900	24.2	F,G	2.7	4.7	7.8	3.6	7.1	4.0	18.5	2.3
Comfo Elite	22.2	G	1.8	8.1	17.0	7.1	15.3	7.5	13.8	7.4

Note: Dash indicates fit testing not done.
[A] All means having the same Duncan Grouping letter are statistically the same.

than it was after the Companion fit-test method. Testing was conducted to determine if the level of protection between the two types of respiratory devices varied when using the same fit-test method. For the Bitrex and saccharin fit-test methods, no significant difference was found between the two types of respirators ($p = 0.0595$ and $p = 0.7079$, respectively). For the Companion fit-test method, a significant difference was found ($p = 0.0291$), with the level of protection afforded by the elastomeric respirators being lower than the filtering-facepiece respirators.

To determine if the level of protection given by the three types of respiratory protective devices was the same, a Duncan's Multiple Range test was performed on the GMs for the three types (Table II). The test revealed that surgical masks did not perform as well as filtering-facepiece respirators, which do not perform as well as elastomeric facepieces; all three GMs were significantly different from each other ($\alpha = 0.05$). To determine if the 5th percentiles also were significantly different, a Fisher Exact test was conducted. First, the SWPFs for all three types were combined and a 5th percentile for these data was calculated. This combined 5th percentile value was calculated to be 2.0. The 5th percentiles for each subject/respiratory protective device combination were then determined to be greater than, less than, or equal to this value and a 2×2 contingency table was developed. For the SWPF testing, 69 of the 896 (7.7%) 5th percentiles were less than or equal to 2.0. Of these, only one was with an elastomeric facepiece, six were with filtering facepieces, and 62 were with surgical masks. The Fisher Exact test revealed that there was a significantly higher ($p < 0.0001$) incidence of SWPFs falling on or below 2 for the surgical mask than there was for the other two types of respiratory protective devices.

Next, the SWPF data for all the surgical masks were removed from the above data set, and a new 5th percentile was computed using only the SWPF data from the N95 filtering-facepiece and elastomeric half-facepiece respirators. The new 5th percentile was 4.5, with the fraction of SWPF tests at or below 4.5 being 39 out of 746 (5.2%) (five from elastomeric respirators and 34 from filtering facepiece respirators). There is a significantly higher ($p < 0.0001$) incidence of SWPFs falling on or below 4.5 for filtering facepiece respirators than there is for elastomeric respirators.

Table V contains the Duncan's Multiple Range test results on the GMs for the elastomeric respirators. As with the other two respiratory protective devices, the Duncan's Multiple Range test indicates a statistically significant difference between the GMs. The Fisher Exact test on the 5th percentiles did not indicate a significantly higher ($p = 0.0990$) incidence of SWPFs falling on or below 7.3 between the different elastomeric models.

An indication of the fitting characteristics of the various respiratory protective device models is provided by the h-value. A half-facepiece respiratory protective device is considered to have good fitting characteristics when 95% of the wearers obtain a SWPF $\geq$10 (i.e., an h-value $\geq$ 0.95).[5] The h-values for the 36 models tested are contained in Table VI.

TABLE VI. h-Values and Passing Rates

		Pass Rate		
Model	**h-Value**	**Bitrex**	**Saccharin**	**Companion**
All surgical masks	0.003	—	—	—
1818	0.010	—	—	—
Nexcare Surgical	0.000	—	—	—
Surgine 4238	0.005	—	—	—
48237	0.000	—	—	—
Aseptex 1800+	0.000	—	—	—
Prohibit	0.000	—	—	—
All filtering-facepiece respirators	0.74	42/374	43/374	82/374
8511	0.98	2/24	4/24	4/24
9210	0.96	9/25	5/25	11/25
3945	0.93	4/25	6/25	15/25
1913	0.93	2/25	1/25	5/25
1730	0.90	8/25	8/25	11/25
910	0.89	2/25	0/25	0/25
8515	0.88	4/25	5/25	13/25
9211	0.88	2/25	4/25	6/25
2600/2601	0.79	2/25	4/25	10/25
TN01	0.72	1/25	2/25	2/25
2747	0.71	0/25	1/25	3/25
Piccola	0.56	1/25	0/25	2/25
M-12	0.49	4/25	1/25	0/25
FR200 Affinity	0.49	0/25	0/25	0/25
MAS695	0.05	1/25	2/25	0/25
All elastomeric	0.92	119/372	129/372	227/372
3M 7000	0.99	10/25	13/25	17/25
2000	0.99	8/25	14/25	21/25
1490/1590	0.99	10/24	12/24	17/24
7700	0.99	11/25	13/25	22/25
6800	0.97	8/25	12/25	21/25
Comfo Classic	0.96	9/25	10/25	14/25
8000	0.96	11/25	7/25	12/25
1200	0.94	5/24	2/24	13/24
11291	0.90	5/25	9/25	19/25
Survivair 7000	0.89	11/25	5/25	15/25
6100	0.89	7/25	7/25	13/25
Comfo Elite	0.88	6/25	5/25	5/25
66	0.85	5/25	3/25	13/25
5 Star	0.82	3/25	9/25	11/25
2900	0.79	10/25	8/25	14/25

Note: Dashes indicate fit testing not done.

For surgical masks as a group, the h-value was 0.003. Out of the 900 SWPF tests, only three SWPFs were equal to or greater than the expected level of protection. One model had two of these SWPFs and a second model had the third SWPF. Four models of surgical masks had an h-value of 0.00. No surgical mask had good fitting characteristics. As a group, the N95 filtering-facepiece respirators had an h-value of 0.74. The h-value for the N95 elastomeric half-facepiece

respirators as a group was 0.92. The h-values for the 15 individual filtering facepiece models ranged from 0.05 to 0.98, and the range for the 15 elastomeric models was from 0.79 to 0.99. For filtering facepiece respirators, only two models had good fitting characteristics, whereas seven models of elastomeric respirators did. Six filtering facepiece models had an h-value that was lower than 0.79. This is another indication that, as a group, elastomeric N95 models have better fitting characteristics and may provide higher levels of protection than filtering facepiece respirators.

DISCUSSION

Level of Protection

One reason surgical masks provided the lowest level of protection may be their original purpose. The intent of a surgical mask was to catch the bacteria and other droplets shed from the wearer's mouth and nose and prevent them from entering the open surgical field and causing infection.[14] Catching droplets from the wearer's nose and mouth may not depend on a tight seal against the wearer's face. Thus, surgical masks could have been designed without close attention to fitting characteristics. They were not designed to protect the wearer from inhaled particles. Therefore, filter media of surgical masks may have a low efficiency against the ambient particles used in the SWPF tests.

Differences in design features could be the reason elastomeric half-facepiece respirators as a whole provided a higher level of protection than the filtering-facepiece respirators. All the elastomeric respirators were equipped with adjustable head straps, whereas some of the filtering-facepiece respirators had only elastic, nonadjustable straps. Adjustable straps may allow a more customized seal (i.e., having one strap tighter than the other strap) resulting in greater protection. Another design difference is that the filtering-facepiece respirators came in two configurations, cup-shaped and folding (Table I). It may be that one configuration does not provide as much protection as the other one.

A third difference is that some of the filtering-facepiece respirators had a moldable nosepiece. For those respirators with moldable nosepieces, the wearer may not have remolded the nosepiece the same way during each donning, causing different SWPF values between tests. All of these factors could have contributed to the assessment that the filtering-facepiece respirators had a lower level of protection than the elastomeric respirators. The study was not designed to determine which of these variables contributed to the difference in protection. The effect of design characteristics on the level of protection needs further investigation.

The Duncan's Multiple Range and Fisher Exact tests also were used to determine if there was a difference in protection between the different models of respiratory protective devices. Table III shows the results of the Duncan's Multiple Range test on the GMs of the surgical masks. The GMs of most models are statistically different. The 5th percentiles of all six models are significantly different as well ($p < 0.0001$). Surgical masks both as a class and individually provided very little protection. The best-performing models only had 5th percentiles of 1.9. These models reduced the concentration inside the mask to only 53% of the outside concentration. One model did not provide any protection (i.e., a 5th percentile of 1). A half-facepiece respirator is expected to provide a 5th percentile of at least 10 (i.e., it should reduce the concentration inside by at least 90 percent).[4]

The Duncan's Multiple Range test results on comparing the GMs for the filtering facepiece models are contained in Table IV. There are statistically significant differences between the GMs of the various models. A Fisher Exact test on the 5th percentiles had the same results. There is a significantly higher ($p < 0.0001$) incidence of SWPFs falling on or below 3.3 between the different filtering facepiece respirator models.

Effect of Fit Testing on Level of Protection

In addition to the 5th percentiles without fit testing, Tables IV and V contain the 5th percentiles for passing and failing each of the three fit-test methods for both filtering facepiece and elastomeric respirators, respectively. Without fit testing, only three of the filtering facepiece respirator models (Table IV) and six of the elastomeric respirator models (Table V) had 5th percentiles meeting the expected level of protection.

In general, passing any of the three fit-test methods resulted in a higher level of protection when compared with no fit testing for both filtering- and elastomeric facepiece respirators. For filtering-facepiece respirators, the 5th percentile went from 3.3 without fit testing to a minimum of 7.9 after passing the Bitrex fit-test method. After passing either the saccharin or Companion fit-test methods, filtering-facepiece respirators as a class provided at least the minimum level of protection. For elastomeric facepiece respirators as a class, the 5th percentile increased from 7.3 without fit testing to a minimum of 11.1 after passing a fit test. Tables IV and V indicate that with some models of both filtering- and elastomeric-facepiece respirators passing a fit test, a wearer may not have a respirator that provides adequate protection. After passing the Bitrex fit-test method, three models of filtering-facepiece respirators had 5th percentiles substantially below the expected level of protection (Table IV). After passing the saccharin test, two models of filtering-facepiece respirators did not meet the expected level of protection. One of the models had a 5th percentile of 1.2, which is essentially no protection and just 0.1 higher than the 5th percentile without fit testing. Two models of elastomeric half-facepiece respirators did not provide the expected level of protection after passing a fit-test method (Table V). When the Companion method was the fit-test method, the passing 5th percentiles for all respirator models met the expected level of protection. The 5th percentiles of the elastomeric facepieces passing a fit-test method but not meeting the expected level of protection tended to be higher than those for the filtering-facepiece respirators. This is another indication that the elastomeric half-facepiece respirators may

provide a higher level of protection than the filtering-facepiece respirators.

There appear to be inconsistencies in the 5th percentiles of subjects passing and failing a fit-test method for both filtering-facepiece and elastomeric facepiece respirators. For some models, the 5th percentile for those failing a given fit-test method is higher than the 5th percentile for those passing that particular fit-test method. In some instances, those subjects failing a particular fit-test method did so with a respirator that provided an adequate level of protection. An example is the Wilson 6800 elastomeric-facepiece respirator using the Companion fit-test method (Table V). The 5th percentile for those subjects failing the Companion fit-test method with that model is 18.1, almost twice that of those passing that fit-test method. In other cases, the 5th percentile of those passing a fit-test method indicated an inadequate level of protection, whereas the failing 5th percentile indicates adequate protection for those subjects (e.g., the model 1200 using the saccharin fit-test method [Table V]).

This inconsistency could be due to the high alpha (α) errors (the rate of false inadequate protection conclusions) for each of the fit-test methods.[2] The α errors for the three fit-test methods used in this study were approximately 50 percent. If these false conclusions of inadequate protection were removed from the data set of subjects failing a fit-test method, then the resulting 5th percentile could be much lower. A possible reason for the α error being high with the qualitative fit tests may be that they are subjective in nature (i.e., relying on the subject's subjective response). A subject may report tasting the agent when he or she actually is unsure of whether he or she tastes it.

Another inconsistency is that between the elastomeric- and filtering-facepiece models, the three fit-methods did not give the same level of protection order. That is, the model providing the highest level of protection for subjects passing the Bitrex fit-test method did not necessarily provide the highest level of protection for the saccharin or Companion fit-test methods. This may imply that the α and the β errors may be model dependent.

The data suggest that passing a fit test does not mean a wearer will receive adequate protection, especially with certain models of filtering-facepiece respirators. The level of protection achieved after passing a fit-test method may depend on the fit-test method used.

Since the data from this study were analyzed, another method (a random effects model) for determining the level of protection provided by a respiratory protective device has been proposed.[15] The 5th percentile method aggregates all the data (i.e., treats all the data the same without regard to any inter-individual variation). The random effects method takes into account the inter- and intra-wearer variability. By doing this, one can estimate the percentage of wearers having inadequate fits (i.e., their individual 5th percentile values are less than 10), where the 5th percentile of the aggregate protection factor distribution is greater than 10. To determine the effect of inter-individual variability on the results of this study, the data presented here will be analyzed using the random effects method with those results presented in a future article.

Limitations

This study had several limitations. The levels of protection afforded by the respiratory protective devices used may not be representative of those that could be achieved in the actual workplace. In this study, subjects were given a particular size of a multi-size respirator model based on the subject's face size, rather than having the subject try on multiple sizes to determine which fit the best, as is done in an actual respiratory protection program. This may have led to subjects not having the size that provided the highest level of protection. In addition, if a subject failed a fit test with a given size, the data were included and the subject was not retested with another size, also as is done in actual practice.

It has been shown that the fit factors provided by the PORTACOUNT Plus may overestimate the exposure of a respirator wearer under actual working conditions.[12] Another limitation was the subject panel. Because the panel was selected without regard to a particular facial size distribution, the subjects who participated in this study may not be representative of all respirator wearers.

Still another limitation is that the SWPF exercise regime used in this study consisted of seven exercises that may not be representative of work activities in actual work environments. Actual workplace movements may stress the seal of the respiratory protective device more than the SWPF exercises, causing the device to have to reseal in order to continue to provide protection. The SWPF exercises may not cause the respiratory protective devices to have to reseal. Therefore, the results obtained in this study provide the relative performance of each respirator model compared with 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 36 respiratory protective device models tested in this study may not be representative of all models available at the start of the study. When the study began, there were more than 160 models of surgical masks, 92 models of N95 filtering-facepiece respirators, and 56 models of elastomeric N95 half-facepiece respirators commercially available. Only 15 each of randomly selected filtering-facepiece and elastomeric respirators and 6 surgical mask models were tested in this study. The models not tested may include ones that would have tested better or worse than any or all of those tested. In addition, respirator manufacturers are continually evaluating and redesigning their products but keeping the same model numbers. The respirator models tested in this study may not be representative of models currently on the market. The "all" combined results may not be representative of all N95 filtering-facepiece and elastomeric half-facepiece respirators and surgical masks now being manufactured.

Qualitative tests are perceived to be cheaper and faster than quantitative fit tests. The data in Table VI indicate that this may not be true. The two qualitative fit tests have lower pass rates

than the Companion (22% for the Bitrex, 23% for the saccharin, and 41% for the Companion). In addition, the overall pass rate for the three fit-test methods is higher for the elastomeric respirators than for the filtering-facepiece respirators (43% vs. 15%). Lower pass rates would lead to a larger number of people being retested with the qualitative tests, if the fit testing is being performed correctly (e.g., no force fitting, etc.). This retesting would increase the cost and the time needed to perform a qualitative test.

Another interesting aspect of the data contained in Table VI is the fact that some models had very high h-values but rather low pass rates for the various fit-test methods. For example, the model 2000 elastomeric facepiece respirator had an h-value of 0.99, which indicates it has good fitting characteristics. Only 32% of the subjects passed the Bitrex fit-test method. This is in contrast to 84% of the subjects passing the Companion test with it. Another example is the model TN01 filtering-facepiece respirator, which had an h-value of 0.72, but only 8% of people passed with the saccharin and Companion tests, and only 4% passed with the Bitrex test. Further research is required into why respirators with high h-values have low pass rates, even when using the Companion fit-test method. Again, the method error rates are responsible, and perhaps an improved fit test with lower error rates would provide a better correlation between h-values and passing rates.

CONCLUSIONS

This study has shown that there is a difference between the three types of respiratory protective devices, particularly with the level of protection afforded by surgical masks being lower than that afforded the wearer by the other two types of devices. The data demonstrates a difference in the level of protection provided by elastomeric and filtering-facepiece respirators. The 5th percentile SWPF for filtering-facepiece respirators was statistically lower than that for elastomeric respirators. When the levels of protection among models of a given respiratory protective device type were compared, a significant difference was found in two of the three types (surgical masks and filtering-facepiece respirators). In addition, the number of subjects passing the fit-test methods was investigated. The qualitative fit-test methods had lower pass rates than the quantitative fit-test method. Therefore, using a qualitative fit test may not be less expensive and time-consuming due to the increased number of repeat fit testings that may have to be done. Overall, elastomeric respirators had higher pass rates than filtering-facepiece respirators. Elastomeric respirators may provide a higher level of protection as well as being easier to fit, possibly reducing the overall costs of a respiratory protection program. It was found that passing a fit test generally improves the protection afforded the wearer. The data support fit testing as an essential element of a complete respiratory protection program. To have the greatest level of protection, a wearer should pass a fit test with a respirator that has good fitting characteristics (i.e., h-value ≥ 0.95).

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REFERENCES

1. **U.S. Department of Labor/Bureau of Labor Statistics, Department of Health and Human Services, CDC, NIOSH:** *Respirator Usage in Private Sector Firms, 2001.* Washington, D.C., 2003.
2. **Coffey, C.C., R.B. Lawrence, Z. Zhuang, D.L. Campbell, P.A. Jensen, and W.R. Myers:** Comparison of five methods for fit testing N95 filtering-facepiece respirators. *Appl. Occup. Environ. Hyg. 17*:1–8 (2002).
3. **National Institute for Occupational Safety and Health (NIOSH):** *NIOSH Respirator Selection Logic 2004*. DHHS (NIOSH) Publication No. 2005-100. Cincinnati, Ohio: NIOSH, 2004.
4. **Industrial Safety Equipment Association:** *Use and Selection Guide for Non-Powered Air Purifying Particulate Respirators.* Industrial Safety Equipment Association, Arlington, Va., 1996.
5. **American National Standards Institute (ANSI):** *American National Standard for Respiratory Protection* (ANSI-Z88.2). [Standard]. New York: ANSI, 1992.
6. **Coffey, C.C., D.L. Campbell, and Z. Zhuang:** Simulated workplace performance of N95 respirators. *Am. Ind. Hyg. Assoc. J. 60*:618–624 (1999).
7. **Coffey, C.C., R.B. Lawrence, D.L. Campbell, Z. Zhuang, C.A. Calvert, and P.A. Jensen:** Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J. Occup. Environ. Hyg. 1*:262–371 (2004).
8. **Los Alamos Scientific Laboratory:** *Respirator Protection Factors* by E.C. Hyatt (LA-6084-MS). Los Alamos Scientific Laboratory, Los Alamos, N.M., 1976.
9. **Lenhart, S.W., and D.L. Campbell:** Assigned protection factors for two respirator types based upon workplace performance testing. *Ann. Occup. Hyg. 28*:173–182 (1984).
10. **Los Alamos Scientific Laboratory:** *Selection of Respirator Test Panels Representative of U.S. Adult Facial Sizes* by A. Hack, E.C. Hyatt, B.J. Held, T.O. Moore, C.P. Richards, and J.T. McConville (LA-5488). Los Alamos Scientific Laboratory, Los Alamos, N.M., 1974.
11. "Respiratory Protection," *Code of Federal Regulations* Title 29, Part 1910.134. 2002. pp. 434–440.
12. **Coffey, C.C., D.L. Campbell, W.R. Myers, and Z. Zhuang:** Comparison of six respirator fit-test methods with an actual measurement of exposure in a simulated health care environment: Part II—Method comparison testing. *Am. Ind. Hyg. Assoc. J. 59*:862–870 (1998).
13. **National Institute for Occupational Safety and Health (NIOSH):** *NIOSH Guide to Industrial Respiratory Protection*, DHHS (NIOSH) Publication No. 87-116. Cincinnati, Ohio: NIOSH, 1987.
14. **Beck, W.C.:** The surgical mask: Another "sacred cow"? *AORN J. 55*:9555–9557 (1992).
15. **Nicas, M., and J. Neuhaus:** Variability in respiratory protection and the assigned protection factor. *J. Occup. Environ. Hyg. 1*:99–109 (2004).