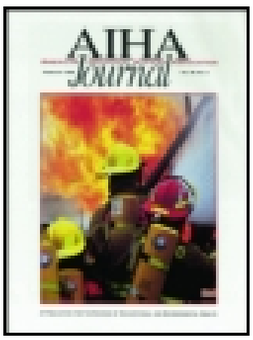

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Comparison of Six Respirator Fit-Test Methods with an Actual Measurement of Exposure in a Simulated Health Care Environment: Part III — Validation

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This article, the last in a series of three, describes the validation phase of a study conducted to test the correlation of respirator fit factors to the subject's actual exposure using biological sampling. The study consisted of three phases: protocol development, method comparison testing, and validation. Six quantitative fit-test methods were evaluated in the method comparison testing phase. The two fit methods with the highest correlation with the wearers' measured exposure were a corn oil method ($R^2 = 0.81$) and an ambient aerosol method ($R^2 = 0.78$). Because the ambient aerosol method is more commonly used in the workplace, it was selected for further analysis. In this validation phase, the fit factors measured during the ambient aerosol fit-test were used to calculate the exposures to Freon®-113 by using the model determined in the method comparison testing phase of the study. The actual Freon-113 exposures were then measured and compared with the predicted exposures. The results verified that the ambient aerosol method fit factors are highly correlated to the total Freon-113 exposure dose and thus that the model had a predictive ability.

Keywords: biological sampling, exposure dose, fit factor, Freon®-113, quantitative fit-test, respirator

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This is the third in a series of three articles describing a study conducted to evaluate and compare the fit factors of half-mask respirators from six quantitative fit-test methods (Table I) against an actual measure of total exposure dose, and therefore, actual respirator performance. The first article in the series described the preliminary studies (chamber characterization, end-exhaled air sampling, skin absorption testing, pharmacokinetic modeling, and subject characterization) on which the validation protocol is based.[1]

The second article described the method comparison testing phase of the study in which 11 subjects wore half-mask respirators in a laboratory test chamber containing a known concentration of Freon®-113 and corn oil aerosol. Fit factors for each subject were obtained with all six methods.[2] A fit factor is a quantitative measure of the fit of a particular respirator facepiece to a particular individual. It is defined under the conditions of quantitative fit-testing as the ratio C_{out}/C_{in}.[3]

The highest R^2 values, 0.81 and 0.78, were associated with the high-flow corn oil (CHD) and the ambient aerosol (AA) methods described in Table I.[2] Since the AA method is more common than the CHD method, it was selected for further analysis.

This third article presents the protocol, results, and findings of the validation phase of the study. The AA method was validated with 32 trials in which the AA fit factors (F) were used to predict the total Freon-113 exposure dose (E) using the following model:

$$\log E = \alpha + \beta * \log F \quad (1)$$

TABLE I. Description of Fit-Test Methods

Fit-Test	Description	Notes
CLF[A] (continuous low flow with flush probe)	Challenge was an oil aerosol with 0.6 MMAD generated in a test chamber. Detector was light scattering photometer. Aerosol was sampled from facepiece cavity at 1 L/min from a probe mounted flush with inside wall.	Similar to the system originally developed for NIOSH.
CHD[A] (continuous high flow with deep probe)	Challenge was an oil aerosol with 0.6 MMAD generated in a test chamber. Detector was light scattering photometer. Aerosol was sampled from facepiece cavity at 5 L/min using a probe deeply inserted into facepiece above upper lip.	Incorporates the deep probe and high sampling rates[10] to minimize sampling bias.
EVD[A] (exhalation valve discharge)	The same as CHD test except sample was taken from a chamber designed to capture the discharge of the exhalation valve at 3 L/min.	
CNP[B] (controlled negative pressure)	Based on the principle of controlled negative pressure in which the volumetric leak rate of air into the facepiece was measured while subject held breath.	Commercially available as the FitTester 3000NPS from Dynatech Nevada Corp.[C] Instrument does not give a specific value for a fit factor less than 11. It is reported as <11.
AA[D] (ambient aerosol)	Ambient aerosol was used as challenge. Aerosol was sampled from facepiece cavity at 0.7 L/min from a probe mounted flush inside facepiece wall.	Commercially available as the Portacount Plus from TSI Inc.[E]
AA1[A] (AA for 30 minutes)	The AA1 test modified to be conducted in Freon-113 chamber simultaneously with the 30-minute exposure to Freon-113.	Oil aerosol was not generated in the chamber during this test.

[A]Fit-testing was conducted simultaneously with Freon-113 challenge of respirator.
[B]Fit-testing was conducted immediately after Freon-113 challenge with respirator being removed and redonned.
[C]DNI Inc., 2000 Arrowhead Drive, P.O. Box 1925, Carson City, NV 89702-1925.
[D]Fit-testing was conducted immediately after Freon-113 challenge of respirator with redonning and care taken to obtain same fit.
[E]TSI Inc., P.O. Box 64394, St. Paul, MN 55164-4394.

where $\alpha = 4.537$ and $\beta = -0.924$.[2] The predicted total exposure was then compared with the actual total exposure dose determined by end-exhaled air analysis.

METHODS AND MATERIALS

The methods and materials for the preliminary studies and the method comparison testing have been described in detail in previous papers.[1,2] Those papers should be referred to for detailed information on the end-exhaled air sampling, skin absorption testing, subject characterization, and method comparison data analysis.

Simulated Health Care Movements

This study employed different motions to simulate movements made by various health care workers as they perform their duties (Table II). These motions were selected based on the professional opinions of three experts knowledgeable in the health care industry regarding the health care workers who would be most likely exposed to patients with tuberculosis (i.e., emergency medical service personnel, emergency room clerks, clinicians, nurses, doctors, and health care workers in prisons).

TABLE II. Simulated Health Care Motions

Motion	Duration (Minutes)	Motion	Duration (Minutes)
Hang IV bag	1	Reach side to side	2
Bending	2	Reaching overhead	2
Insert syringe into IV bag	1	Talking aloud while sitting	2
Carrying weight	2	Nodding and turning head	2
Twisting and turning head	2	Reaching overhead	1
Open and close door	1	Stand and talking aloud	2
Talking aloud	3	Control panel motions	1
Bending	3	Walking	1
Turning head	2		

AA Quantitative Fit-Test Method

The AA method ($R^2 = 0.78$) was chosen over the CHD method ($R^2 = 0.81$) because the majority of quantitative fit-tests conducted in the workplace are done with this method. This method used the TSI Portacount™ 8020 (TSI, St. Paul, Minn.) with six exercises and lasted about 10 minutes. The AA method is done without a chamber and measures the ambient aerosols inside and outside the respirator to determine the fit factor. A condensation nuclei counter is used to detect the aerosols. For this test the subject performed six exercises for approximately 1.5 minutes each: (1) normal breathing while holding the head forward and motionless, (2) deep breathing, (3) normal breathing while turning the head side to side, (4) normal breathing while moving the head up and down, (5) reading aloud the rainbow passage, and (6) normal breathing again while holding the head forward and motionless.

Training of Subjects

The same 11 subjects (6 women and 5 men) who participated in the preliminary research and method comparison phases of the study were used in this phase.[1,2] The subjects were provided with manufacturers' instruction manuals for each of the respirators they wore and were instructed to don the respirator and perform a user seal check (formerly called a fit check, pressure-tightness test, or negative/positive pressure check) per those instructions. In addition, subjects were instructed on how to perform an AA fit-test properly.

Respirators

The respirators used for each validation test were randomly selected from the same eight (seven elastomeric and one disposable

organic vapor/high efficiency) used during the method comparison phase. As in the method comparison testing, no effort was made to find the best fitting respirator for the subject.[2]

Validation Testing

This study was conducted using a (4′ × 4′ × 7′) laboratory chamber (Dynatech Frontier Corp., Model 222–6, Albuquerque, N.M.) that contained a spatially and temporally uniform concentration of 500 ppm Freon-113. The test subjects donned the respirators and performed user seal checks and then entered the chamber. While in the chamber the subjects performed the 17 simulated health care movements listed in Table II. The subjects were in the chamber for 30 minutes. Each of the 11 subjects performed 3 validation tests each with a different respirator model chosen at random.

After exiting the chamber, the subjects proceeded to a clean area (i.e., one removed from the Freon-113 chamber) where the AA method was performed without removing or adjusting the respirator. The ambient particle concentration ranged from 4000 to 6000 particles per cubic centimeter during the testing. After the AA method was completed, the subject removed the respirator and provided an end-exhaled air sample (30 minutes after exiting the chamber) which was analyzed as previously described.[1]

The fit factor obtained from the AA method was entered into the linear regression model in Equation 1 and a predicted total Freon-113 exposure dose was obtained. This predicted total Freon-113 exposure dose was compared with the actual total Freon-113 exposure dose derived from the analysis of the subjects' end-exhaled air. This was done by computing the mean squared prediction error (MSPR) as per Equation 2.

$$\text{MSPR} = \frac{\sum_{i=1}^{n} (Y_i - \hat{Y}_i)^2}{n} \qquad (2)$$

where Y_i is the value of the response variable in the ith validation case, in this case the total Freon-113 exposure dose; $\hat{Y}_i$ is the predicted value for the ith validation case for the total Freon-113 exposure dose from the model; and n* is the number of cases (32) in the validation data set.

During the method comparison phase a mean square error (MSE) was obtained for the model in Equation 1. If the MSPR and MSE are fairly close, then the MSE is not seriously biased and gives an indication of how well the model predicts the wearer's actual total Freon-113 exposure dose. For example, if the MSE equals 0, then all of the actual values fall on the fitted regression line developed from the model. If the MSPR is larger than the MSE for the model, then the MSPR indicates how well the selected model will predict. Ideally, one would want the MSPR to be identical to the MSE of the model. The smaller the value of the MSPR and MSE, the better the model is at predicting actual values.[4]

RESULTS

From the 32 (11 subjects, 3 models/per subject with 1 trial invalidated) AA method fit factors, a predicted total Freon-113 exposure dose was calculated using Equation 1. One trial was invalidated because it was determined that the gas chromatograph was not providing accurate results when this trial was performed and could not be repeated. These predicted total Freon-113 exposure doses along with the actual total Freon-113 exposure doses (Table III) were used to calculate a MSPR using Equation 2. The MSPR based on the 32 tests in Table III was 0.158. The MSE from the AA method comparison testing was 0.159. In addition, the plot of the predicted values versus the actual measured values (Figure 1) indicates a fairly straight line and fairly good correlation with a R^2 value of 0.66. Since the MSPR is nearly identical to the MSE for the model (0.158 versus 0.159), the MSE for the model is not seriously biased and gives an indication of the predictive ability of the model.

Using the same subjects in the model validation testing as in the method correlation testing is a slight limitation. This is because the subjects themselves may have influenced the correlation of the quantitative fit factors from the AA test to the total Freon-113 exposure doses. If this did occur, the model would validate on these subjects and possibly not on others. The possibility of the subjects influencing the correlation was reduced by having the subjects wear randomly selected respirators in both the method comparison and validation phases of the study. Therefore, it was unlikely that a subject would wear the same respirator in both phases, and thereby influence the correlation for the AA method. Hence, the validation results are considered to be unbiased.

The approach in this study of using the subject's exhaled breath as an indication of exposure has advantages over the usual approach of judging new fit-test methods by comparing fit factors

TABLE III. Validation Data

AA Fit Factor	Predicted Total Freon-113 Exposure Dose (ppm-min)	Actual Total Freon-113 Exposure Dose (ppm-min)
9	4219	6627
3	13,173	11,162
7	5493	9418
7	5883	11,590
38	1135	2045
12	3354	4921
5	7497	5976
6	6537	8437
10	3981	6326
4	9204	5306
23	1820	204
691	74	642
299	163	64
330	149	64
7	5968	7371
109	422	285
1470	37	28
534	95	148
766	67	49
20	2075	576
71	631	652
46	948	293
744	69	32
962	54	476
14	2902	3333
962	54	95
1100	48	270
7	5968	12,600
7	5883	1800
17	2418	2127
511	99	42
13	3111	2978

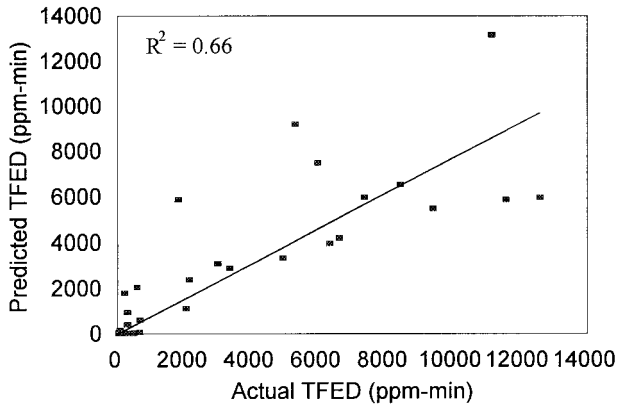

FIGURE 1. Plot of predicted total Freon-113 exposure dose (TFED) as determined by the AA method versus actual total Freon-113 exposure dose measured by analyzing the subject's exhaled breath

from the new method with those from a "standard" method, usually generated aerosol.[5,6] In-facepiece sampling used in generated aerosol methods has associated with it random and systematic errors such as location and depth of the sampling probe, location of face-seal leak, whether the wearer is nose or mouth breathing, and aerosol size-selective features of different leak sites.[7] These errors introduce variation during in-facepiece sampling. Using exhaled breath to estimate the in-facepiece Freon-113 concentration eliminated these errors.

As stated in a previous article, this study provided a plausible explanation for why fit factors do not correlate with workplace protection factors (WPFs).[2] It is not possible for conventional WPF studies to include workers wearing poorly fitting respirators since they must pass a fit-test to be included in the study. However, this laboratory approach does not require the subject population to be prescreened with a fit-test. Therefore, fit factors less than 100 could be included in the analysis. The inclusion of these fit factors resulted in a high correlation between fit factor and total freon exposure dose in this study.[2]

Other researchers have hypothesized that differences between fit factors and WPFs could be caused by the following: (1) the standard quantitative fit-test exercises may not accurately mimic the movements of a worker, (2) the difference between the breathing rate during fit-testing and the breathing rate while performing job tasks could affect correlation, (3) penetration of aerosol quantitative fit-test agents through a respirator face seal could differ from workplace contaminants due to differences in particle size distributions, (4) moisture in the breath could artificially lower quantitative fit-test results, and (5) a short-term fit-test may not predict long-term protection.[8] Others have suggested that the underlying assumptions of the quantitative fit-tests may not be valid. These assumptions are that (1) aerosol fit-test results can be applied to all other types of contaminants, (2) aerosol samples taken inside the respirator are representative of the exposure the wearer is actually receiving, and (3) during the exercise protocols used during quantitative fit-testing, the face seal will be compromised, resulting in a lower fit factor.[9] This study has provided some insight into the validity of some of these assumptions.[2]

In a previous study of in-facepiece sampling bias, the CHD method utilizing a deep probe and a high flow rate had less bias than other methods.[10] Similarly, our study found the CHD fit-test had a higher correlation than the low flow corn oil (CLF) described in Table I and hence less bias. The CHD method had an R^2 value of 0.81, whereas the CLF had an R^2 value of 0.41 when fit factors were correlated with total freon exposure dose.[2] The AA, like the CLF, uses a flush-mounted probe and samples at approximately 1 L/min. These results suggest the performance of the AA method might be improved if the sample rate were increased and if the probe were inserted further into the facepiece. Further research is needed to determine this.

CONCLUSIONS

The results of this validation study indicated that the model in Equation 1 developed during the method comparison testing phase was not seriously biased and predicted the subject's actual exposure as determined by the actual total Freon-113 exposure dose calculated from end-exhaled air analysis. Now that the model has been validated, it is necessary to validate it on other respirator types such as full facepiece. In addition, other studies need to corroborate the results of this study. The study supports the value of some fit-test methods as screening tools to identify workers with poorly fitting respirators.

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