

Determination of Respirator Fit by an Aerosol Method and a Negative Pressure Method

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Abstract

The purpose of this study was to compare respirator fit as measured by an aerosol and a negative pressure method while accounting for fit variation among subjects, respirators, and repetitions. Replicate fit tests were performed on 15 male subjects while wearing one size of four different brands of half-mask respirator: resulting in a total of 180 fit tests by each method. The natural logarithms of the fit factors ($\ln_FFs$) for both methods were not significantly different from the lognormal distribution. The median aerosol FF was 20,800 with a geometric mean of 15,850 and geometric standard deviation of 2.62. The median negative pressure FF was 1020 with a geometric mean FF of 980 and a geometric standard deviation of 1.93. The mean of the $\ln_FFs$ of the negative pressure method was significantly lower than that for the aerosol method, and the variance of the $\ln_FFs$ for the negative pressure method was significantly smaller than that for the aerosol method. FFs for the two methods had a correlation coefficient of 0.46. An observation in this study was that two subjects were unable to achieve a measurable fit with the negative pressure method while wearing one brand of respirator, while the aerosol method indicated FFs of greater than 3200. This discrepancy could be due to increased sensitivity of the negative pressure system **and/or** failure of the aerosol system to measure leakage because of sampling bias. This study indicates that the negative pressure method provides a more conservative and less variable measure of respirator fit. However, it is not well correlated to results from the aerosol method. These differences may be due, in part, to known bias and variability inherent in the aerosol method.

Background

For many years the accepted method of quantitative fit testing respirators has been to utilize polydisperse aerosols of oil or sodium chloride (NaCl) as test agents. In the United States, aerosols have been most commonly used to meet the quantitative fit testing requirements of the OSHA substance specific standards (29 CFR 1910.1001). In the United Kingdom, methods utilizing sodium chloride aerosols have been adopted (British Standards Institute, 1985). However, a number of studies have found these methods to provide disparate or biased measures of fit factors (FF) due to properties of the aerosols or sampling conditions inside the respirator facepiece (Hinds and Kraske, 1987; Holton and Willeke, 1987; Kolesar et al., 1982; Myers et al., 1986; and Myers et al., 1991).

In an effort to avoid these problems, researchers have investigated alternative methods of quantitative respirator fit testing, including methods that measure air flow through leaks induced by negative pressure within the respirator facepiece. Conceptually, these methods are based on the negative pressure fit check, i.e., when the wearer covers the respirator inlets and inhales, a negative pressure is created within the facepiece; a poor facesal is indicated by perceptible pressure decay due to inward air leakage.

Miller et al. (1987) developed a semi-quantitative field fit test using a slack tube manometer to measure pressure decay in full facepiece respirators. In the test, the wearer inhaled to establish a negative pressure of 51 cm water gauge; an acceptable fit was defined as being able to maintain that pressure for 10 seconds "without a significant loss." The researchers then applied the method to half-mask facepieces at 35.5 cm negative pressure, and compared the negative pressure results to corresponding FFs on 2 x 2 tables. The negative pressure pass/fail determinations produced good values for sensitivity and false negatives, but poor values for specificity and false positives at critical FFs of 10, 90, and 100.

As part of the rationale for developing safety factors to transfer laboratory FFs to the workplace, Williams (1983) demonstrated that the ratio of total air flow into the respirator and flow through face-seal leaks was equivalent to a concentration FF.

$$\frac{Q_b}{Q_l} = \frac{C_a}{C_b} \quad (1)$$

where:

Q_b = total volumetric breathing rate

Q_l = air flow through leaks

C_a = challenge concentration

C_b = concentration inside the facepiece

In this model, flow rate through facesal leaks (Q_l) is a function of pressure drop across the facepiece (Δp), and is described by Equation 2 where K and a are constants for a given leak.

$$Q_l = K\Delta p^a \quad (2)$$

These relationships were incorporated into subsequent respirator leak models (Campbell, 1984; Hinds and Kraske, 1987) and are the theoretical basis for negative pressure fit test methods.

Carpenter and Willeke (1988) proposed a negative pressure decay method which applied these principles. Through a series of equations based on limited empirical data, the researchers defined air leakage as a function of the slope of pressure decay, respirator facepiece volume, and facepiece pressure differential. Corresponding air flow through air purifying elements at the same challenge pressure was calculated, and an index of fit was expressed as the ratio of the purified air flow and the leak air flow. This index of fit was represented as being equivalent to an aerosol-measured FF. The researchers subsequently compared pressure decay slopes to aerosol leakage for three leak sizes in three respirators worn by a test subject. They observed a slope of about one for aerosol leakage and leak slope over a range of three decades. To avoid the effects of respirator cavity volume and pliability, Han et al. (1991) developed a simplified version of the pressure decay method. This method used empirically derived flow coefficients for leaks and cartridges for a given brand of respirator to define the flow ratio (Q_b/Q_l) rather than to express leakage in terms of leak slope. Flow ratios measured on two brands of respirators worn by three subjects were found to be lower than corresponding FFs measured by particle counting and light scattering methods.

Crutchfield et al. (1991a) proposed an alternative negative pressure method to determine flow ratio (Q_b/Q_l). This method used a micro-sampling pump controlled by a pressure transducer to induce a predetermined negative pressure in a respirator facepiece. A mass flow meter measured the volume of air exhausted to maintain that pressure while the wearers held their breath: this exhaust rate was equivalent to leak flow rate (Q_l). The preset facepiece pressure was defined by a gender-specific mean inspiratory flow rate (Q_b) at a representative work rate, and a type of filter resistance. The researchers found that flow ratios determined by the negative pressure method and FFs determined by a Freon-12 QNFT method were highly correlated ($r > 0.99$). In a subsequent study Crutchfield et al. (1991b) compared negative pressure flow ratios to corn oil aerosol FFs measured on a mechanical assembly simulating a respirator with hypodermic needles used as fixed leaks. They found that the aerosol FFs were

significantly lower than the flow ratios, but were highly correlated ($r > 0.99$).

Previous work indicates that FFs measured with test agents may be biased due to sampling conditions within the facepiece and sample losses at the leaksite. An alternative approach which utilizes the ratio of total flow and leak flow has a sound theoretical basis, and has been shown to be highly correlated to FFs. However, these comparisons have been limited to a small number of subjects wearing respirators with artificial leaks. Comparisons under these closely controlled conditions do not account for the substantial intra- and inter-subject variation in respirator fit (da Roza et al., 1983) and fit differences among respirators (Hyatt et al., 1972). The purpose of this study was to compare respirator fit measured by a negative pressure and an aerosol method for a panel of test subjects wearing one size of four brands of half-mask respirators.

Materials and Methods

Tests were performed on 15 white males between 20 and 50 years of age. The subjects were clean shaven, and without facial features that could result in facepiece leaks. Respirator sizes for each subject and brand were selected on the basis of the subjects' perception of which size fit best, and confirmed by a manual positive or negative pressure check and the ability to attain a minimum FF of 100 as measured by the aerosol method. Each subject was tested three times by each method while wearing each respirator brand. The sequence of testing by method and respirator type was randomized by the blind selection of labeled cards. The respirators were removed at the end of each test.

All sizes of the four brands of half-mask respirators were probed between the nose and mouth at the midline of the facepiece to allow for aerosol sampling. This line was closed with a valve during the negative pressure test. HEPA filters were attached to the respirator cartridge holders for the aerosol tests and replaced with testing manifolds for the negative pressure tests.

The aerosol test method utilized the Portacount™ Model 8010 condensation nuclei counter (CNC). The negative pressure method utilized the Dynatech Fit Tester 3000™ negative pressure system (NPS). This device worked on the

principle of establishing and maintaining a constant negative pressure within the respirator developed by Crutchfield et al. (1991a). Both devices were calibrated and operated according to the manufacturers' instructions. The challenge pressure for the NPS was -1.47 centimeters of water, and was selected on the basis of a half-mask respirator equipped with HEPA filters worn by males with an average inspiratory flow rate at a work rate of 200 kilocalories per hour (Crutchfield et al., 1993).

The negative pressure test protocol required the subjects to hold their breath for approximately ten seconds while holding their head in six positions:

- 1) head forward (hfl),
- 2) head left (hl),
- 3) head right (hr),
- 4) head up (hu),
- 5) head down (hd), and
- 6) head forward (hf2).

At the end of each test, the respirator was removed and cleaned. This process was repeated for the three repetitions by method and respirator brand. The overall FF for each test was calculated by Equation 3.

$$FF = \frac{6}{\frac{1}{FF_{hf1}} + \frac{1}{FF_{hl}} + \frac{1}{FF_{hx}} + \frac{1}{FF_{hu}} + \frac{1}{FF_{hd}} + \frac{1}{FF_{hf2}}} \quad (3)$$

The protocol for the CNC included four head movement exercises:

- 1) normal breathing while holding the head forward and motionless (nbl),
- 2) normal breathing while turning the head side to side (ss),
- 3) normal breathing while moving the head up and down (ud), and
- 4) normal breathing while holding the head forward and motionless (nb2).

As with the NPS method, the respirator was removed after each test. The overall FF for each test was calculated by Equation 4.

$$FF = \frac{4}{\frac{1}{FF_{nbl}} + \frac{1}{FF_{ss}} + \frac{1}{FF_{ud}} + \frac{1}{FF_{nb2}}} \quad (4)$$

The mean of the natural logarithms for the three overall FFs ($\ln_FF$) was used as the estimate of average fit for each respirator/subject combination (Selvin and Rappaport, 1989).

Since the purpose of this study was to compare fit measured by the two methods, the exercises included in the two protocols were selected to provide test conditions that were as similar as possible. Therefore, the aerosol test protocol does not reflect penetration during the deep breathing and talking exercises.

It might be argued that this would result in an underestimation of the penetration measured by the aerosol method. However, an analysis of variance (ANOVA) of data from a study to assess the significance of movements during a fit test (Revoir, 1979) found that there were no significant differences among penetrations measured during the six test exercises, including talking, and the average test penetration. Among the pair-wise differences, penetration during talking was only significantly greater than that for the first normal breathing exercise. Also, Crutchfield (1989) has pointed out the inconsistency of positive facepiece pressure during the talking exercise and increased measured penetration.

Data were entered into a data file and statistical analysis performed with SOLO™ statistical software to an alpha value of 0.05 ($\alpha = 0.05$) (Hintze, 1991). The $\ln_FF$ data were tested for normality with the Kolmogorov-Smirnov test (Rosner, 1990). The difference between the mean FFs measured by the two methods was tested by a two-sample t-test. The difference between the variance of FFs measured by the two methods was tested by Bartlett's F-test (Winer, 1971). A three-way, repeated measures analysis of variance (ANOVA) was performed to determine the effect of subject, respirator, and test method on measured FFs (Winer, 1971). Association between the two methods was determined by correlation, and the extent to which method, respirator, and subject affected variation if FFs were determined by multiple linear regression (Winer, 1971).

Results and Discussion

Summary statistics of the FF data are shown in Table 1. The mean $\ln_FF$ s for both methods were not significantly different from the normal distribution. Therefore, subsequent analysis was by parametric statistics. The mean $\ln_FF$ for each subject, respirator and method are shown in Table 2. The mean $\ln_FF$ for the CNC method was 9.64 (geometric mean FF = 15400) and that for the NPS method was 6.89 (geometric mean FF = 980). The difference between the mean of the $\ln_FF$ s by the two methods was 2.75, and was significantly different from zero ($p < 0.0001$). The variance of the log FFs for the CNC method of 0.93, was significantly greater than that of 0.43 for the NPS method.

The observation of FFs measured by the CNC method being significantly greater than those for the NPS method conflict with the initial study by Crutchfield et al. (1991a), which found no significant difference between FFs measured by the Freon-12 QNFT and the NPS. However, it is in agreement with the second study by Crutchfield et al. (1991b) which found that aerosol FFs were significantly higher than those for the NPS, and the study of Han et al. (1991). The significantly greater variance of the CNC method found in this study also agrees with the results observed by Carpenter and Willeke (1988) and Crutchfield et al. (1991a).

Table 1. Descriptive statistics of protection factor data.

	CNC	NPS
Median	20,300	1,020
Geometric Mean	15,400	980
Geometric Std Dev	2.62	1.9

Table 2. Mean $\ln_{FF}$ data.

SUB NO.	RESP 1		RESP 2		RESP 3		RESP 4	
	CNC	NPS	CNC	NPS	CNC	NPS	CNC	NPS
1	11.32	6.68	9.61	6.68	10.52	6.96	10.91	6.92
2	10.24	6.30	10.08	6.34	9.08	8.23	9.79	7.98
3	10.09	6.80	8.44	6.48	7.00	6.13	9.97	6.16
4	10.11	7.47	8.71	6.19	8.89	7.69	8.82	7.10
5	9.27	6.31	9.67	6.40	9.40	5.98	9.86	6.78
6	9.93	7.48	11.24	7.27	8.91	7.06	10.35	7.15
7	9.66	6.46	10.45	7.46	8.19	6.67	9.88	7.64
8	10.44	7.27	11.23	7.65	8.87	7.08	9.74	7.21
9	9.77	7.66	8.87	6.51	6.14	4.91	9.02	5.25
10	9.92	6.56	9.95	6.80	8.57	6.54	9.67	7.06
11	10.21	8.13	9.10	6.39	8.95	6.52	10.20	6.93
12	9.52	6.93	9.80	7.48	8.60	7.22	9.49	6.50
13	10.22	7.04	9.79	7.12	9.14	7.13	8.63	6.93
14	11.48	7.98	10.49	6.50	10.02	6.64	9.41	5.36
15	10.58	7.31	10.73	7.29	8.71	7.05	10.74	7.64
Mean*	10.18	7.09	9.88	6.84	8.73	6.79	9.76	6.84
Std Dev*	0.60	0.58	0.86	0.49	1.06	0.77	0.64	0.77

Resp 1 = North, 7700 Series

Resp 2 = American Optical, 5 Star

Resp 3 = Survivair, Series 2000

Resp 4 = U.S. Safety, Comfort Air

*Mean and standard deviation of $\ln_{FF}$ for all fit tests with each respirator (n = 60)

A scatter plot of the mean $\ln_{FF}$ s for the two methods is shown in Figure 1. Pearson's correlation coefficient for the mean $\ln_{FF}$ s by the two methods was 0.47. These results indicated a weak association between the two methods: much less than that found in the two studies by Crutchfield et al. (1991a, 1991b), and that of Han et al. (1991). A possible reason for this difference could be that the previous studies employed few subjects, or utilized fixed leaks, while this study used 15

subjects with repeated measures by each method on each respirator. The use of several humans would be expected to increase the variability of measured FFs among subjects (da Roza et al., 1983) as measured by each method: thus lowering the observed strength of association between the two methods.

Three-way repeated measures ANOVA found that respirator ($p < 0.001$) and method ($p < 0.001$)

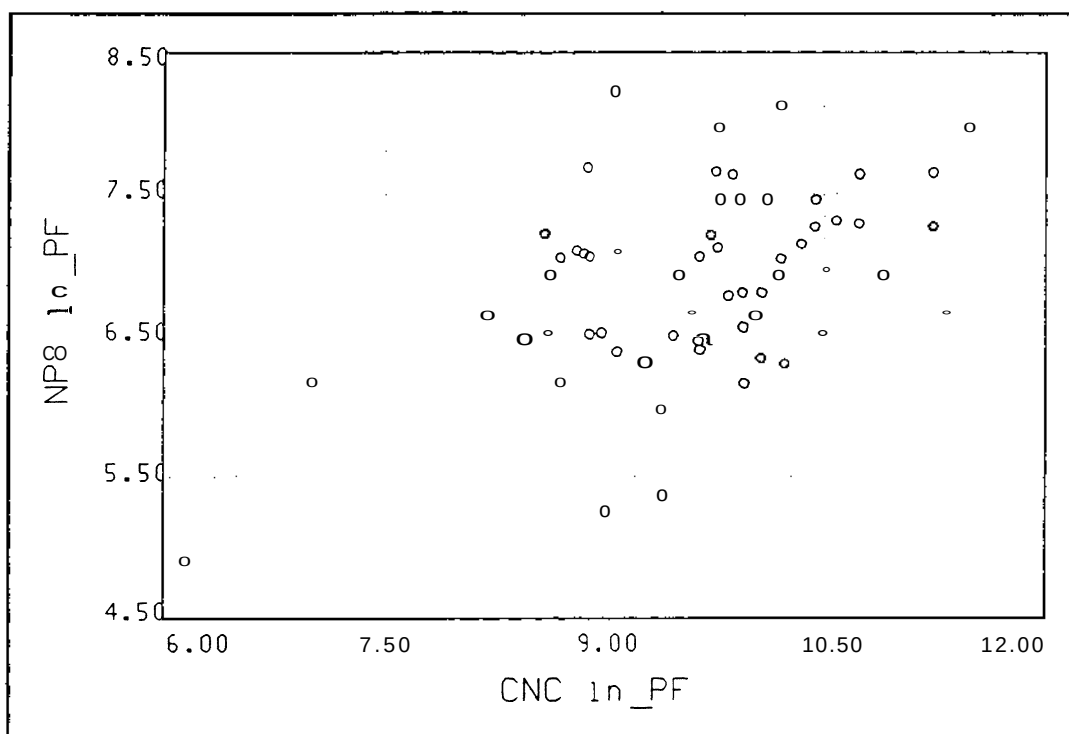


Figure 1. Plot of NPS ln_FF and CNC ln_FF.

had significant effects on mean ln_FF; there was also a significant interaction between these two variables ($p < 0.001$). Subsequent simple effects analysis of ln_FF within the two methods and the four respirators found no significant differences among the ln_FF for the four brands of respirators as measured by the NPS method (Winer, 1971). However, a significant difference was observed between one brand and the other three as measured by the CNC method. These results are illustrated in Figure 2. Note that if Respirator #3 was not significantly different from the other respirators measured by the CNC method, the two lines would have been essentially parallel, indicating no interaction (Winer, 1971). Thus, the interaction between respirator/method could be attributed to Respirator #3.

Multiple linear regression was performed using method, respirator, and subject as the independent variables, and mean Log FF as the dependent variable. The analysis found that only the method independent variable had a significant ($p < 0.001$) coefficient of determination of 0.87—which indicates that 87% of the observed variation in ln_FF was due to differences between methods. The coefficients of determination for subject and respirator were 0.00 and 0.01 respectively. This analysis confirmed the results of the repeated three-way ANOVA.

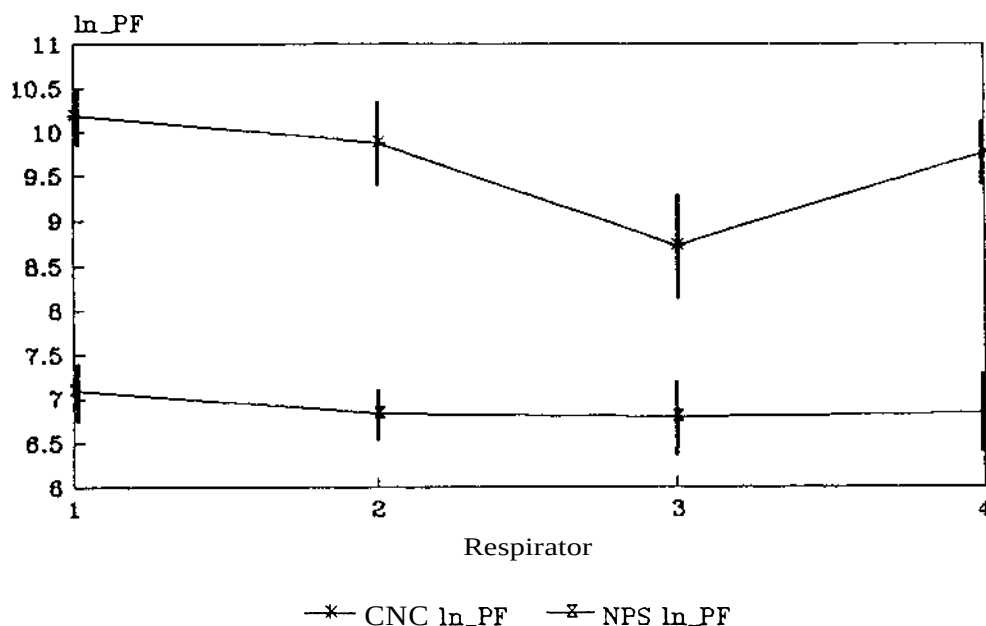


Figure 2. Mean and 95% confidence interval for ln_FF for brands of respirator by method.

Conclusions

This study found that FFs measured by the NPS method were significantly lower than those measured by the CNC method. The geometric mean FF for the CNC method was over 15 times greater than that of the NPS method. The NPS method measured lower FFs than the CNC method on virtually every subject, which is in agreement with the study by Crutchfield et al. (1991b). Unlike previous studies, which found correlation coefficients greater than 0.9 (Carpenter and Willeke, 1988b, and Crutchfield et al., 1991a and 1991b) the correlation coefficient of FFs measured by the two methods was only 0.47. However, repeated three-way ANOVA and multiple linear regression found that measurement method accounted for most of the variation in the pooled FFs.

An observation made during testing was that two subjects were not able to achieve measurable FFs with the NPS while achieving FFs greater than 3200 with the CNC method. During the NPS test, they were unable to achieve a challenge pressure high enough (-1.47 cm H₂O) for the instrument to conduct a negative pressure test. This would indicate that the FF was less than eight, which is the lower end of the dynamic range

of the NPS (Crutchfield et al., 1991b). If this were the case, a low FF measured by the CNC would also be expected. These contradictory observations could have been due to aerosol streamlining inside the respirator, thus the CNC method would not have sampled the particles that were actually leaking into the facepiece (Myers et al., 1986). Both subjects were retested at a later date and did achieve measurable NPS fits that were used in statistical analysis.

These results and observations indicate that while the two methods are not highly correlated, the NPS method provides a more conservative measure of fit for the brands of respirators worn by this group of subjects. The significantly lower variance of the NPS method may indicate that previously noted variability in respirator fit as measured by aerosols (da Roza et al., 1983) may be, in part, due to variability in the sampling method. These findings would indicate that the NPS method should be further evaluated as an alternative fit testing method to overcome the known limitations of methods utilizing test agents (Myers et al., 1986, Kolesar et al., 1982, Holton and Willeke, 1987, and Myers et al., 1991).

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- 29 CFR 1910.1001 "Asbestos, Tremolite, **Anthophyllite**, and **Actinolite**," Appendix C—Qualitative and Quantitative Fit Testing Procedures.