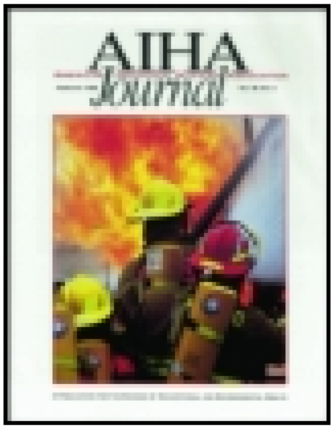

American Industrial Hygiene Association Journal
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/aiha20

A COMPARISON OF CONTROLLED NEGATIVE PRESSURE AND AEROSOL QUANTITATIVE RESPIRATOR FIT TEST SYSTEMS BY USING HUMAN SUBJECTS

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Published online: 04 Jun 2010.

AIHA JOURNAL Applications and Reviews

AM. IND. HYG. ASSOC. J. 54(1):10–14 (1993) 4309

A Comparison of Controlled Negative Pressure and Aerosol Quantitative Respirator Fit Test Systems by Using Human Subjects*

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A quantitative respirator fit test system based on controlled negative pressure was evaluated by comparison testing with a computerized aerosol fit test system. Experiments ranged from multiple sequential tests of a single subject wearing a respirator equipped with a series of fixed leaks to sequential fit tests of 125 U.S. Air Force personnel using both systems. Throughout each test phase, measured negative pressure fit factors were consistently more conservative and less variable than aerosol fit factors. Comparison of subject and fixed leak fit factors indicated significant loss of aerosol during subject fit tests. Negative pressure system results did not show any effect from subject-related losses.

A new method for quantitative fit testing of respirators with elastomeric facepieces by controlled negative pressure has been described.(1) The new technique eliminates several of the major disadvantages of the standard aerosol fit test method. It is noninvasive, so that a worker can be tested with his assigned respirator after replacing the detachable filtering elements with special manifolds. The negative pressure system is also field portable and does not require the generation of a potentially toxic challenge agent.

During a previous study conducted with fixed-leak assemblies instead of human subjects,(2) test results from an automated negative pressure system were highly correlated with results from a computerized standard aerosol system. Controlled negative pressure results were not affected by leak penetration losses that were apparent in the aerosol results.

* This project was supported in part by Grant K01 OHO0068 from the National Institute for Occupational Safety and Health of the Centers for Disease Control.

The same automated negative pressure system was used for this study. The study purpose was to extend the comparison between negative pressure and aerosol systems to include fit testing of respirators on human subjects.

EXPERIMENTAL METHODS AND MATERIALS

Fit tests were conducted with subjects wearing small, medium, or large sizes of half-mask (MSA Comfo II, MSA Corp., Pittsburgh, Pa.) or full-facepiece (MSA Ultra-Vue) probed respirators. High-efficiency particulate air filter cartridges were used during aerosol fit tests. Negative pressure tests were accomplished by removing the cartridges and installing airtight manifolds in the cartridge receptacles. The manifolds were designed to closely approximate the weight of air-purifying cartridges so that substitution of one for the other during comparison testing would not affect the facepiece-to-face seal.

Sequential comparison tests of the two fit test systems were accomplished while the respirator remained in place on the test subject's face. Cartridges were exchanged for manifolds or vice versa between the tests. The effect of cartridge-manifold exchange on the face seal was evaluated by analyzing differences between eight sets of three negative pressure fit tests, with each set separated by a manifold exchange. One-way analysis of variance (ANOVA) showed no significant difference ($p = 0.45$) between the eight sets of three negative pressure fit tests, indicating that cartridges and manifolds could be interchanged without altering the respirator face seal.

Negative pressure tests were initiated by instructing the subject to partially exhale, hold his breath, and plug a breathing port on the manifold. A computerized data acquisition system collected data from the system's pressure and flow transducers at a measured sample rate of 20 Hz. Termination of the fit test

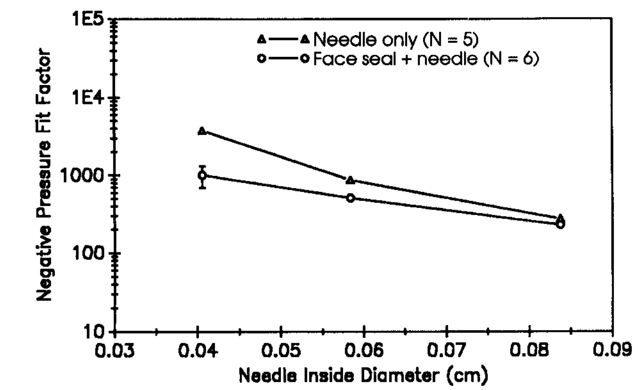

FIGURE 1. Negative pressure fit factors from N repeated tests of various fixed leak and respirator plus fixed leak configurations on Subject A (error bars, when visible on the log axis, represent 95% confidence limits)

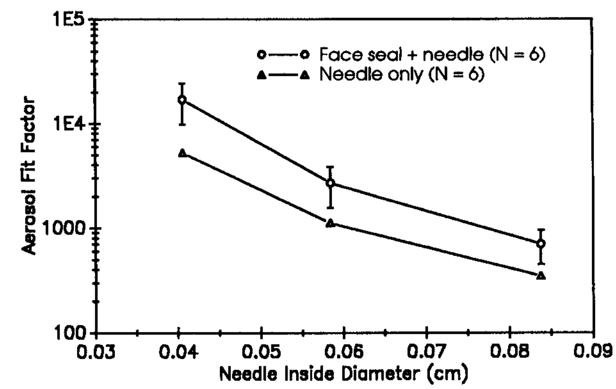

FIGURE 2. Aerosol fit factors from repeated tests of various fixed leak and respirator plus fixed leak configurations on Subject A

was automatically triggered by the pressure spike produced when the subject exhaled into the sealed facepiece after 10–15 sec of breath holding.

Reduction of negative pressure fit test data was also accomplished by computer. The system updated zero drift of pressure and flow transducers immediately before each subject was fit tested. Plots of pressure and leak flow data generated by the computer immediately after each fit test provided a means of judging test quality. Deviations from the test challenge pressure, such as those caused by the subject not fully holding his breath during the test, were readily detected on the plots.

The inspiratory challenge pressure of –1.25 cm H_2O used in this study was determined with a test panel of three male subjects. Mean inspiratory pressure was recorded during normal breathing while the subjects wore a half-mask respirator equipped with two types of cartridges. Negative pressure fit factors were calculated by dividing measured leak rates into a previously derived mean inspiratory flow rate of 431 mL/sec, equivalent to normal breathing at rest.[1]

A Dynatech Frontier (Albuquerque, N.Mex.) Model 260AC computerized aerosol fit test system served as the comparison standard for this study. Following subject entry into the test booth, the system automatically sampled the following sequence at a sampling rate of 2 Hz: booth concentration, photometric baseline, mask concentration for six standard 30-sec exercises,[3] photometric baseline, and booth concentration. A daily check with both chamber and mask sampling lines connected to a common leak source showed variation of less than 2%, indicating consistent photometer response to the two lines.

A series of experiments was conducted to compare the capabilities of the negative pressure and aerosol fit test systems. In order to control subject variability as much as possible, only the normal breathing portions of the fit test exercise protocols were used for comparison purposes during this study.

The first experiment involved repeated sequential fit tests of a single subject using both fit test systems. The subject wore a half-mask respirator that remained in place between each sequential pair of fit tests. The respirator was configured with either no fixed leak (face seal leak only) or with a series of three different fixed leak needles (face seal plus needle leak). Six repetitions of sequential fit test pairs were completed for each respirator leak configuration prior to changing the leak needle.

A second experiment compared the negative pressure and aerosol systems through repeated testing of three subjects wearing both half-mask and full-face respirators over a period of 1 month. No fixed leaks were introduced. One of the subjects made no attempt to maintain consistent day-to-day respirator fit in order to evaluate correlation between aerosol and negative pressure fit factors for a single subject over a broad range of respirator fit.

A final experiment consisted of conducting sequential negative pressure and aerosol fit tests for a population of 125 Air Force military and civilian personnel assigned to a respiratory protection program. A randomized test order between negative pressure and aerosol tests was used to control for possible test order bias.

RESULTS AND DISCUSSION

Equivalent negative pressure and aerosol fit factors for the leak needles used during the first experiment had been previously determined when the same needles were used in a fixed-leak (needle only) comparison study.[2] That study found that negative pressure and aerosol system measurements of leak needles were highly correlated and indicated possible aerosol losses in the leak needles. Figure 1 contrasts the negative pressure fit factors for three leak needles with fit factors for Subject A wearing a half-mask respirator equipped with the same three leak needles. As shown in Figure 1, the combined (face seal plus needle) fit factors were lower than the needle-only fit factors at each leak needle diameter. This finding was expected because the face seal plus needle combination added a second leakage path into the respirator. The measured fit factors graphed in Figure 1 also show more divergence as the needle diameter decreases. This indicates that the negative pressure system had sufficient sensitivity to detect the presence and increasing dominance of the respirator face seal leak as the needles' contribution to total leak decreased with decreasing needle diameter.

Figure 2 contrasts aerosol fit factors determined for the same subject wearing the same respirator/needle combinations. Each pair of aerosol and negative pressure fit factors was measured sequentially without removing or disturbing the respirator. Instead of decreasing as a result of adding the face seal leak path, the combined aerosol fit factors show a dramatic increase (101–225%) with human subject involvement. The addition of the face seal leakage path was completely masked by subject-related aerosol losses. Probable sources of these aerosol losses included leak entry losses, incomplete mixing and streamlining within the respirator facepiece, inconsistent sampling line losses, and respiratory tract deposition.

Particle size–dependent leak entry losses in respirators have been reported by a number of investigators.(4–6) Myers(7) reported a high in-mask sampling bias associated with the inhalation portion of the breathing cycle. A measured fit factor range of 44 to 4728, when the actual fit factor was 87, was attributed in large part to streamlining effects. During the current study, sampling was accomplished over both inhalation and exhalation portions of the breathing cycle. This should have improved in-facepiece mixing and moderated the sampling bias to some extent, although the aerosol subject data indicate otherwise.

Aerosol deposition in the respiratory tract also contributed to the observed aerosol loss.(8,9) The International Commission on Radiological Protection lung retention model predicts an approximate 30% retention rate for the specified corn oil aerosol.

The aerosol photometer could also have contributed to higher aerosol fit factor measurements. The signal-to-mass ratio associated with aerosol detection by forward light scattering is strongly dependent on particle size.(5,10) Changes in challenge aerosol size distributions that result from differential impaction or diffusion losses during leak penetration or from preferential retention in the respiratory tract could significantly alter detector readings. For a particle size distribution closely resembling the size range specified for the corn oil aerosol used in this study (0.5–0.7 μm mass median aerodynamic diameter), Hinds(4) calculated that forward light scattering may underestimate aerosol penetration in half-mask respirators by as much as 23%.

A dramatic increase in variation is also exhibited by the subject data in Figure 2. Needle-only variation (<2%) is too small to be seen on the log scale. In comparing variability between the two systems, it is important to note that aerosol fit tests were based on measurements of both chamber and mask concentrations. Negative pressure results involved single determinations of leakage flow, which were divided into a constant mean inspiratory flow rate to derive a fit factor.

The combined (face seal plus needle) fit factors determined with sequential fit tests of Subject A using both fit test systems

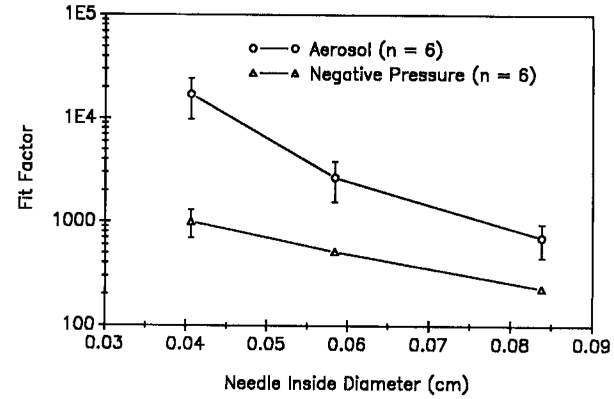

FIGURE 3. Comparison of repeated aerosol and negative pressure fit tests for Subject A wearing the same respirator with various fixed leaks

TABLE I. Negative Pressure and Aerosol System Measurements of Penetration through Various Leak Paths into a Respirator Worn by a Single Subject

		Negative Pressure		Aerosol		
Leak Path	*Leak Needle Diameter (cm)*	*% Pen[A] (A)*	*% COV*	*% Pen (B)*	*% COV*	*% DIFF (B−A)[B]*
Face seal plus needle	0.084	0.437	2.6	0.143	17.8	−67.2
	0.058	0.195	2.9	0.037	21.2	−80.9
	0.041	0.100	15.2	0.006	21.3	−94.2
Needle only	0.084	0.365	0.1	0.287	1.1	−21.3
	0.058	0.115	1.4	0.090	2.0	−22.2
	0.041	0.027	2.5	0.019	1.5	−28.8
Face seal only	—	0.073	19.5	0.009	83.0	−87.9
Calculated face seal only[C]	0.084	0.072	—	−0.144	—	—
	0.058	0.079	—	−0.052	—	—
	0.041	0.073	—	−0.013	—	—

[A]Percent penetration through leak path.
[B]Percent difference in penetration of aerosol versus air through leak path.
[C]Calculated face seal only penetration = (face seal plus needle) − (needle only).

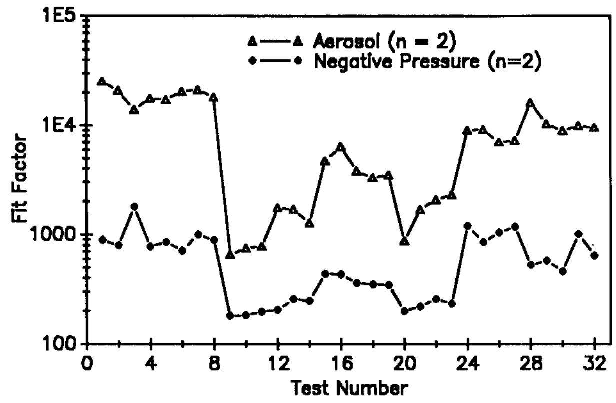

FIGURE 4. Comparison of daily aerosol and negative pressure fit tests for Subject B wearing various respirators. No fixed leaks were used, and no attempt was made to maintain a constant day-to-day fit.

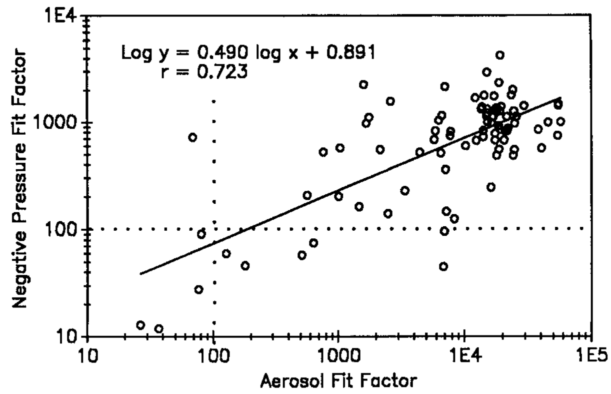

FIGURE 5. Regression of single-aerosol and negative pressure fit tests of an Air Force test population

are shown in Figure 3. Although the log-transformed fit factors are highly correlated (r = 0.989), aerosol fit factors exceed negative pressure fit factors by 205% to 1611%.

Figures 2 and 3 clearly show that penetration of the aerosol challenge agent to the photometer transducer was substantially less than the penetration of air to the negative pressure transducer. A substantial amount of aerosol seems to have been lost enroute. As pointed out by Willeke,[11] any tendency toward incomplete aerosol mixing inside the respirator facepiece is compounded by the fact that the mask sample volume represents only a small fraction of the total inspiratory volume.

Another view of the effect of human subject involvement on the performance of the two systems can be generated by expressing fit factors as reciprocal percent penetrations. Penetration data for the various mask/needle configurations on Subject A are presented in Table I. Face seal–only variation reflects fit test results measured over a period of weeks, whereas each face seal plus needle data set was derived with repeated fit tests on the same day. Needle-only penetration data show aerosol losses in the needles increasing from 20% to 30% as needle diameter decreased. Aerosol penetrations through the respirator face seal were substantially more variable and approached a loss rate of 90%. For the smallest diameter needle, the difference between face seal only and face seal plus needle aerosol penetration was not significant.

Because the driving force for leakage through each mask/needle configuration in Table I was approximately the same for each system, an estimate of face seal penetration can be calculated by subtracting the needle-only penetration from the face seal plus needle penetration. For the negative pressure system, the calculated face seal penetrations for all three leak needle configurations are extremely close to the measured face seal penetration value.

The comparison of calculated versus measured face seal leak did not hold up for the aerosol system. Aerosol leakage that had been consistently detected when the leak needles were plugged directly into the aerosol system's mask sampling line was not detected when the sample was taken from a probed respirator facepiece. Although the driving force for leakage was equivalent, total (facepiece plus needle) leakage was less than needle-only leakage measured without subject-related losses. Aerosol known to be leaking into the respirator facepiece did not penetrate into the mask sampling line.

Figure 4 shows the relationship between negative pressure and aerosol fit factors measured over a period of 1 month for Subject B. The subject was tested sequentially with both systems while wearing both half-mask and full-face respirators without any leak needles. No attempt was made to maintain consistent fit throughout the month. Although the correlation between the systems remained fairly high (r = 0.882), aerosol fit factors consistently exceeded negative pressure fit factors by an approximate order of magnitude.

The regression data for the three subjects given multiple fit tests over a 1-month period exhibited a relationship (slope = 0.45; r = 0.72) very similar to that shown in Figure 5 for the Air Force test population of 125 subjects. Aerosol fit factors were considerably more variable and again exceeded negative pressure fit factors by an approximate order of magnitude. Negative pressure fit factors for the Air Force test population ranged from 12 to 4250; the range of aerosol fit factors was 37 to 194 361. A total of 17.2% of the Air Force test population had measured aerosol fit factors exceeding 40 000. Fit factors greater than 40 000 have a high degree of uncertainty associated with them because of low-level zero drift observed in the log-linear amplifier of the aerosol photometer.

The large difference between fit factors measured by the two systems, with the greatest difference occurring at the better fit conditions, was observed throughout the study. The capability of the systems to detect inadequate fit also differed. By using a fit factor of 100 as a criterion for acceptable fit (indicated by dotted lines in Figure 5), the negative pressure fit test system recognized an inadequate fit in 8.2% of the test population, whereas the aerosol system detected a 4.1% test failure rate.

CONCLUSIONS

A range of air leakage through fixed leaks and respirator face seals was consistently detected by the controlled negative pressure system during this study. Leakage through the same fixed leaks and facepiece seals, as measured by the aerosol system, was generally an order of magnitude lower than negative pressure determinations. Negative pressure–determined fit factors were calculated on the basis of an assumed inspiratory flow of 431 mL/sec. In spite of strong evidence for the existence of substantial air leakage paths into the respirator, relatively low levels of challenge aerosol were detected in the mask sampling line.

Although not directly assessed in this study, factors including leak penetration losses, incomplete mixing because of streamlining, and lung retention may have been significant contributors to the reduced aerosol levels that were detected. The net result of such aerosol reductions are overestimations of respirator fit.

The subject-related losses that appear to have significantly affected aerosol results were not a factor in negative pressure fit determinations. Negative pressure results were not biased by respiratory tract deposition. Streamlining effects were also eliminated because pressure equilibration within the facepiece occurs at sonic velocity. Carpenter and Willeke[12,13] found the results of pressure decay fit tests to be independent of leak site and sampling probe location ($p = 0.99$).

The results of this study indicate that aerosol fit test systems may seriously underestimate air leakage into respirators. The potential for and implications of underestimating all types of contaminant leakage into respirators needs further assessment. The use of a nonvarying gaseous challenge agent such as air would establish a conservative standard for respirator fit testing because contaminant penetration does not occur in the absence of air penetration.

ACKNOWLEDGMENT

The authors thank Col. James E. Peguesse and staff of the Davis-Monthan Air Force Base Environmental Health Office for their support.

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