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

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An automated version of a new method for quantitative respirator fit testing by controlled negative pressure was compared with a computerized aerosol fit test system. The controlled negative pressure technique eliminates many of the problems associated with aerosol and pressure decay fit test methods. A series of fixed leaks was used to compare the leak measurement capabilities of the controlled negative pressure system against a standard computerized aerosol fit test system. Negative pressure and aerosol fit factors determined for a series of fixed leaks through hypodermic needles were highly correlated with each other ($r = 0.998$) and with the cross-sectional areas of the leak needles ($r > 0.995$).

A new technique for quantitative respirator fit testing has been developed. The new method is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of exhaust is controlled so that a constant negative pressure is maintained in the mask while the wearer's breath is held. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. Measurement of the exhaust stream yields an airflow rate equivalent to the leakage flow rate into the respirator.

The controlled negative pressure technique eliminates several of the major disadvantages of the standard aerosol method. It is noninvasive so that a worker can be fit tested with an assigned respirator after replacing the detachable filtering element(s) with special manifolds. The negative pressure system is also field portable and does not require the generation of a potentially toxic challenge agent.

A feasibility study comparing a manually controlled negative pressure fit test system with a system in which Freon®-12 is used as a challenge agent demonstrated the potential of the controlled negative pressure concept.[1] The current consensus standard method for quantitative respirator fit testing is based on generated aerosol challenge agents.[2] To further investigate the capabilities of the controlled negative pressure technique, an automated negative pressure system was developed for comparison testing against a computerized aerosol system.

EXPERIMENTAL MATERIALS AND METHODS

A schematic of the automated negative pressure fit test system is shown in Figure 1. Automation was achieved by using feedback from the pressure transducer (Omega [Stamford, Conn.] PX-163; 0 ± 12.5 cm H_2O) to control the electronic valve of a fast mass flow controller (Tylan [Torrance, Calif.] FC-280S; 0–3 L/min). The dynamic range of the flow transducer allowed determination of fit factors covering an approximate range of 8 to 12 000. The pressure and mass flow transducers were calibrated with primary standards and exhibited consistent performance throughout the course of the study. The computerized data acquisition system collected data from the pressure and flow transducers at a measured sample rate of 20 Hz. Reduction of fit test data was also accomplished by computer.

A Dynatech (Albuquerque, N.Mex.) Frontier Model 260AC computerized aerosol fit test system[3] served as the comparison standard. Corn oil (specified mass median aerodynamic diameter of 0.5–0.7 μm) was used to generate the challenge aerosol. Fit test sequence, sample stream management, data acquisition, and fit factor calculations were software-controlled. Automated sampling of the following sequence was accomplished at a sampling rate of 2 Hz: booth concentration, photometric baseline, mean mask sampling line concentration for six 30-sec intervals, photometric baseline, and booth concentration. A daily operations check was performed to ensure that both booth and mask sampling lines gave identical photometer readings when both lines were sampling the same source. The ratio of the paired sampling line check measurements over a period of 30 days was 1.0029 ± 0.0164, indicating consistent photometer response to the two sampling lines.

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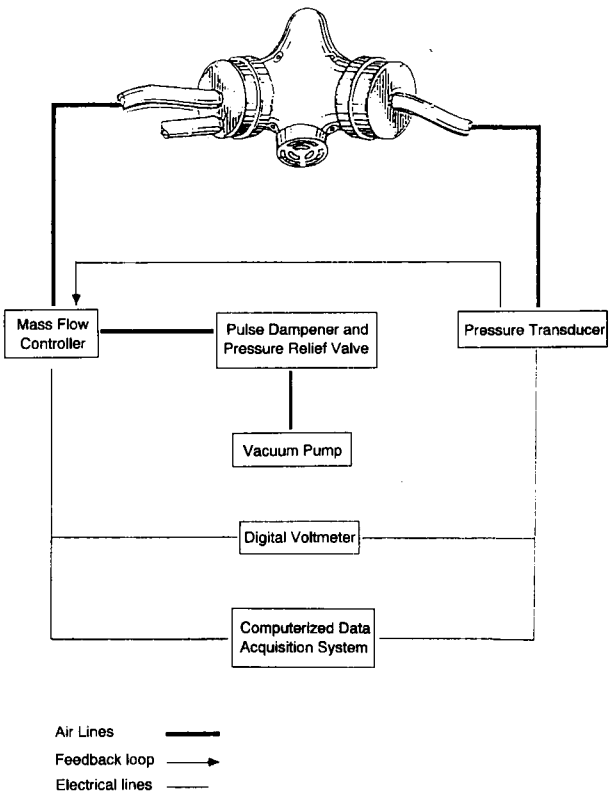

FIGURE 1. Components of a negative pressure fit test system

This initial comparison study of the negative pressure and aerosol fit test systems was accomplished without human subjects. Mechanical, fixed-leak assemblies were used to eliminate the variability associated with respirator donning and wear by humans.

The negative pressure system was tested with a 1-L canister configured to simulate a sealed respirator with manifolds installed. A reference pressure of –1.50 cm H_2O was used as the challenge pressure during negative pressure tests. This matched the pressure measured in the throat of the aerosol fixed-leak assembly, which made the driving force for leakage into both systems identical.

A series of four hypodermic needles, described in Table I, provided nonvarying leak sources during the comparison study. Equivalent negative pressure fit factors were calculated for the canister/needle by dividing measured leak rates into a previously derived mean inspiratory flow rate of 431 mL/sec.[1] This procedure allowed the determination of canister fit factors equivalent to fit factors for a normally breathing human subject wearing a respirator with the same amount of leakage as the needle.

TABLE I. Characteristics and Measured Leak Rates of Hypodermic Needles Used as Fixed Leaks

Gauge	ID (cm)	Length (cm)	Leak Rate[A] (mL/min)
18	0.084	4.5	108
20	0.058	4.5	32
22	0.041	4.5	9
26	0.025	2.5	3

[A]Measured with negative pressure system at challenge pressure of –1.50 cm H_2O.

The aerosol system was also evaluated with a fixed-leak assembly. An air-purifying cartridge receptacle was removed from a respirator and used to connect a HEPA filter cartridge directly to the system's mask sampling line through a Y fitting. Fixed leaks were introduced by inserting the same series of needles through a septum mounted on the opposing arm of the Y fitting. A dilution effect correction was required to make these fit factors equivalent to those of a subject wearing a respirator equipped with HEPA filters and the same amount of leakage. The correction involved multiplying measured aerosol fit factors by the ratio of mean inspiratory flow rate to mask sample line flow rate (431/47 = 9.17).

The potential for losses of the aerosol challenge agent relative to a gaseous (air) challenge agent during sampling was assessed by comparing predicted versus measured aerosol fit factors for the leak needles. Predicted fit factors were estimated by calculating the ratio of mask sampling line flow rate to needle leakage flow rate. Leak rates for each needle were determined at the pressure measured in the mask sampling line at the throat of the fixed-leak assembly (–1.5 cm H_2O).

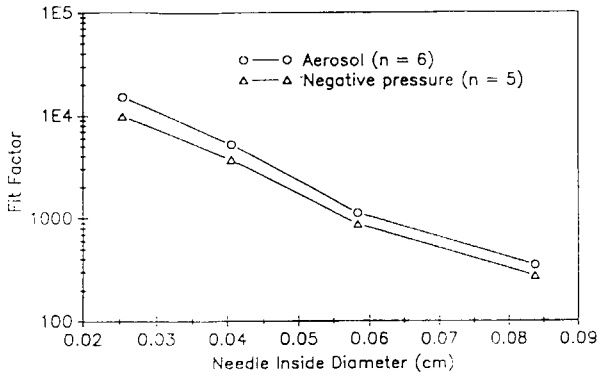

FIGURE 2. Aerosol and negative pressure fit factors for mechanical assemblies with identical fixed-leak diameters (n = number of fit test repetitions)

RESULTS AND DISCUSSION

Figure 2 shows the comparison between negative pressure fit factors and aerosol fit factors determined for the fixed-leak assemblies outfitted with the same four leak needles. Error bars representing 95% confidence intervals are too small with respect to the log axis to be visible. The mean percent coefficient of variation (PCOV) for negative pressure fit factors ranging from 274 to 9901 was 2.2%. The mean PCOV for the range of aerosol fit factors (348 to 15 165) was 1.5%. Corrected aerosol fit factors exceeded equivalent negative pressure fit factors by an average of 37%, indicating potential aerosol losses in the needles. Aerosol penetration through the HEPA filter installed in the aerosol fixed-leak assembly would have tended to reduce the observed differences.

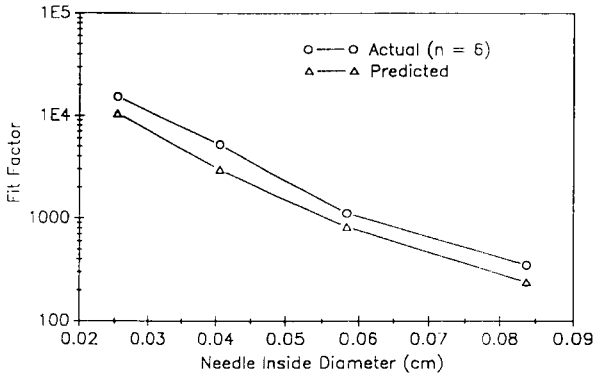

FIGURE 3. Predicted and actual aerosol fit factors at various leak diameters for a mechanical, fixed-leak assembly

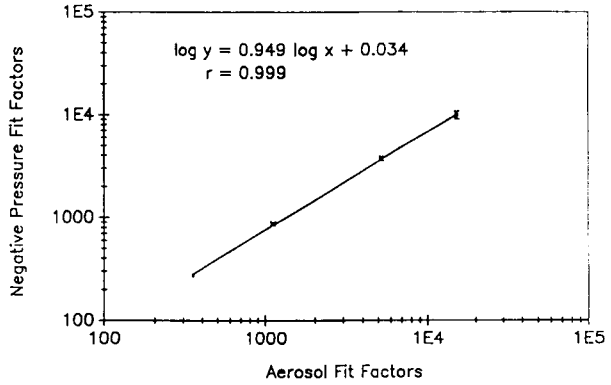

FIGURE 4. Correlation between corrected aerosol fit factors and equivalent negative pressure fit factors for mechanical, fixed-leak assemblies (error bars represent 95% confidence levels)

The apparent aerosol losses were inversely related to needle diameter. Data from the smallest diameter needle fall below the general curvilinear plots because the smallest needle was half as long as the rest, resulting in higher penetration rates and lower fit factors. Student's t-tests indicated that aerosol and negative pressure fit factors differed significantly ($p < 0.001$) at each needle diameter. Second-order regression analysis of the data accomplished prior to log transformation for plotting revealed a high correlation between needle cross-sectional area and both aerosol ($r = 0.995$) and negative pressure ($r = 0.997$) data.

Aerosol fit factors predicted by the ratio of mask sample line flow rate to needle leak rate are compared to measured aerosol fit factors for the needles in Figure 3. Measured fit factors exceeded predicted fit factors by an average of 51% with the differences again being inversely related to needle diameter. Error bars are too small with respect to the log axis to be visible. Student's t-tests conducted at each needle diameter showed significant differences between predicted and measured aerosol fit factors ($p < 0.001$), a further indication of significant aerosol sample loss in the needles. Any aerosol lost during respirator face seal leak penetration would cause an overestimation of respirator fit.

As shown in Figure 4, negative pressure fit factors and aerosol fit factors determined for the fixed-leak assemblies were highly correlated ($r = 0.998$). Both systems measured the range of fixed leaks with good consistency.

CONCLUSIONS

An automated respirator fit test system based on controlled negative pressure showed a high degree of correlation with a computerized aerosol fit test system while a series of fixed leaks were measured. Aerosol losses in the leak needles were evident when aerosol system results were compared to both negative pressure results and to predicted aerosol results based on measured flow rates through the needles. Aerosol leak penetration losses during actual respirator fit testing would result in overestimations of fit. Because air molecules are not subject to leak penetration losses, negative pressure appears to have been a more rigorous challenge agent than the corn oil aerosol used during this limited comparison study. Additional study is needed to assess these findings relative to measuring actual respirator fit for human subjects.

ACKNOWLEDGMENT

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