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Effect of Leak Location on Measured Respirator Fit

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A significant difference in leak detection as a function of leak location was observed during a study assessing how well current models of quantitative fit-test systems detect leakage. Known sources of leakage (matched hypodermic needles) were introduced at three fixed locations into factory-probed half-mask and full-face respirators mounted on a headform-breathing machine system. The leak locations were the bridge of the nose, the cheek, and the chin. Baseline leakage into each respirator was determined by conducting a fit-test with all fixed leak sources capped. Fit tests were repeated with each individual source uncapped. Study objectives included determining (1) how well each system measured the leakage, and (2) whether leak location had any effect on leak measurement. An ambient aerosol fit-test system (Portacount Plus) and a controlled negative pressure (CNP) fit-test system (FitTester 3000) were used. The ambient aerosol system detected an overall average of 37.2% of the known leakage, with a coefficient of variation of 44.7%. An analysis of variance showed significant differences in aerosol system measurements of leakage as a function of leak location and mask type ($p<0.001$). A different pattern of aerosol leak detection as a function of leak location was observed between half-mask and full-face respirators, which appears to be related to differences in in-mask airflow dynamics. The CNP system detected an overall average of 97.9% of the known leakage through the same hypodermic needles, with a coefficient of variation of 4.3%. CNP system results were not affected by leak location ($p>0.43$) or mask type ($p>0.32$).

Keywords: fit-testing, respirators

Respirators are used to limit respiratory system exposures to airborne contaminants. In general, any contaminant that leaks into a respirator during inspiration has a high probability of being carried by the inspiratory airstream into the respiratory system. The level of contaminant control achieved with a respirator is therefore a direct function of respirator leakage. Respirator fit is an inverse function of respirator face-seal leakage, which has historically been quantified as the penetration of an aerosol challenge agent into a respirator during a fit-test.

Leak geometry has been shown in laboratory experiments to be an important determinant of aerosol penetration into a respirator.[1–5] The location and depth of sampling probes used to collect in-mask samples during a fit-test have also been shown to significantly affect results.[6–8] Phenomena related to aerosol streamlining past the sampling probe can add positive or negative bias to in-mask sample results. Aerosol deposition in the lungs decreases the likelihood that penetrating aerosol will be collected by the sample probe and consequently detected as leakage by an aerosol system's detector. Although such phenomena can reduce the amount of aerosol leakage detected, they have little or no effect on the actual penetration of contaminant into the respiratory system. The presence of such biasing factors during aerosol fit-testing can produce inflated fit factors relative to actual lung exposures.

Leak location may also affect the accuracy of aerosol-based measurements of respirator leakage. Studies indicate that the ability of aerosol-based systems to detect respirator leakage may depend on where the leak occurs.[2,6,9–12] This study was designed to examine fundamental leak detection efficiencies of ambient aerosol and controlled negative pressure (CNP) fit-test systems, as well as the effect of leak location on leak

detection. Study objectives included determining (1) how well each quantitative fit-test system could measure the known leakage introduced into the respirator, and (2) whether the location of the leak had any effect on the leak measurement.

METHODS AND MATERIALS

The basic study design consisted of introducing known leaks at three fixed locations into factory-probed half-mask and full-face respirators mounted on a headform-breathing machine system. The flush-mounted sampling probes were located on the respirator centerline midway between the nose and mouth. Full-face respirators were probed through the lens. Of the four full-face respirator models tested, one incorporated a nosecup. The sampling probe for this respirator did not extend into the nosecup. Therefore, the sampling probe locations for all full-face respirators were the same.

Caulk was used to minimize face-seal leakage when the respirators were strapped to the headform. Baseline leakage into each respirator was determined by each fit-test system by making fit-test measurements with the fixed leak sources capped. Measurements were repeated with each individual fixed leak source uncapped in turn. The leakage rate through each fixed leak source was determined as the difference between the measured baseline plus needle leakage and the baseline-only leakage.

A Posichek I (Biosystems, Rockfall, Conn.) was used in its breathing machine mode to provide two highly repeatable respiration rates, as described in Table I. Four different brands of both half-mask and full-face elastomeric respirators were used during the study. A series of three hypodermic needles (0.084 cm i.d., 3.5 cm long) with closely matched characteristics were selected as fixed leak sources. Each needle was fitted with a 3-cm length of rubber tubing at its base that could be selectively doubled and clamped off. Each of the three matched needles was inserted in the same relative location of each respirator tested. The needles were inserted through the respirator facepiece at (1) the right side of the nose bridge, (2) midpoint of the right cheek, and (3) at the left base of the chin. On the full-face respirators, the top leak needle was inserted through the respirator body above the lens so that it extended down to the area of the bridge of the nose.

TABLE I. Tidal Volumes and Inspiratory Flow Rates Produced by the Posichek I Breathing Machine at Standard and Hard Work Rates

	Standard Work Rate	Hard Work Rate
Tidal volume, L	1.66	2.53
Inspiratory period, sec	1.40	1.17
Inspiratory flow rate, L/min	71.2	129.6

An ambient aerosol fit-test system (Portacount Plus, TSI, St. Paul, Minn.) and a CNP fit-test system (FitTester 3000, Dynatech Nevada, Carson City, Nev.) were used to make repeated measurements of the fixed respirator leakage. At the initiation of the study the pressure and flow rate transducers of the FitTester device were calibrated against primary pressure (water manometer) and flow rate (Gilibrator, Gilian Instrument Corp., Caldwell, N.J.) calibration standards. Daily internal system calibrations of the FitTester probe orifice produced a mean coefficient of variation of 1.3% over 19 test days.

A daily operational check of the Portacount device consisted of exposing both mask and ambient aerosol sample lines to room air and checking for a reported fit factor of 1. The high efficiency particulate air (HEPA) filter supplied with the Portacount was used to check detector zero each time a new mask was affixed to the headform. The instrument consistently reported a zero particle count with the filter attached. An ambient aerosol concentration check was performed prior to the initiation of each test series, as well as during each fit-test. A daily maximum fit factor check using the HEPA filter was not performed since proper operation of the Portacount could be verified by the results of the previously described checks. Respirator background aerosol counts were monitored in the Portacount's count mode during the mask-mounting process to minimize baseline leakage. Actual baseline leakage measurements for each mask were made in the standard fit-test mode.

A 10-L water spirometer (Collins Inc., Braintree, Mass.) and kymograph were used to verify the mean inspiratory flow rates and tidal volumes of the breathing machine, which are shown in Table I. Mean inspiratory pressures and periods for each respirator equipped with HEPA filters were determined by connecting a pressure transducer (Omega PX-163, Stamford, Conn.) to the respirator sample probe. The in-mask pressure profile generated by the breathing machine at each breathing rate was recorded at a transducer sampling rate of 32 Hz. The mean inspiratory pressure measured for each respirator was used as the challenge pressure during fit-tests conducted with the CNP device.

Leakage measurements were made by conducting individual fit-tests with each system that consisted of six sequential measurements of respirator fit. Portacount measurements were based on a system default setting of 60 sec for the in-mask sample period. Since the headform remained stationary throughout the fit-test sequence, each of the six fit measurements made during each fit-test was expected to be identical. The first test sequence for each respirator was conducted with the ambient aerosol system. Six measurements of baseline respirator fit were recorded with all three fixed leak sources capped. Leak Source 1 (bridge of the nose) was then uncapped and another six fit measurements were recorded. After Leak Source 1 was recapped, the same procedure was used to record individual fit measurements for the remaining two fixed leak sources. The aerosol test sequence was completed by conducting a second baseline fit-test with all fixed leak sources capped.

After completion of the ambient aerosol fit-test sequence at each breathing rate for a given respirator, the headform was removed from the breathing machine without disturbing the respirator seal. It should be noted that, even if respirator seals were disturbed during this procedure, test results would not be invalidated because fixed leak measurements made by each system were relative to the baseline respirator leakage determined by that system. For CNP fit-tests, HEPA filters were replaced by CNP test manifolds, and a rubber cap was used to seal the factory-mounted sample probe. A rubber stopper was used to seal the base of the headform, which simulated test subject breath-holding. This procedure removed the large dead space of the breathing machine bellows from the CNP fit-test.

A means for determining a known leakage rate through a fixed leak source into a respirator has been previously described.[13] In essence, the leakage rate of air through a fixed leak geometry is fully described as a function of the pressure gradient across the leak source. Airflow rates through the fixed leak sources used in this study were determined to be in the laminar flow region. Laminar flow implies a linear relationship between flow rate through the leak needle and the pressure gradient across it. The linear relationship between pressure and flow allowed the leakage flow measurements made under both cyclic and constant pressure conditions to

be directly compared. Determination of the mean inspiratory pressure for each respirator/HEPA filter combination allowed specification of the mean air leakage rate into the respirator when the leak needle was uncapped. The leakage rate through each needle at each measured mean inspiratory pressure was verified with the Gilibrator.

The FitTester reported respirator leakage directly in mL/min. The fit factors reported by the Portacount were translated into estimates of leakage flow rates by multiplying the measured penetration rate (reciprocal of fit factor) by the measured inspiratory flow rate of the breathing machine. In the absence of aerosol losses, aerosol penetration rates would equal air penetration rates.

A Leak% variable, defined in Equation 1, was derived to describe the percentage of the known leakage introduced into each respirator that was detected by each fit-test system.

$$\text{Leak\%} = 100*[((R+L_m)-R)/L_k] \quad (1)$$

where: Leak% = percent of known leak accounted for by difference between L_m and R leak measurements
R = baseline respirator leakage measured with all fixed leak sources capped, mL/min
$R+L_m$ = measured leakage with individual fixed leak source uncapped, mL/min
L_k = calibrated (known) flow rate through fixed leak source, mL/min

RESULTS

An analysis of variance (Number Cruncher Statistical Systems 6.01, Kaysville, Utah) showed significant differences in aerosol system measurements of leakage as a function of leak location and mask type ($p<0.001$). No significant differences in Leak% were detected as a function of respirator brand ($p>0.51$) or breathing rate ($p>0.09$). These data were pooled for subsequent analysis. The percentages of the known leakage (Leak%) detected by each fit-test system were calculated for each test respirator using the procedures outlined in Equation 1 and illustrated in Tables II and III. Leak% values for half-mask respirators are shown in Figure 1. Mean values of Leak% at each fixed leak location are shown, along with measurement variation (error bars represent one standard deviation). The same information is presented in Figure 2 for the full-face respirators tested.

The ambient aerosol system detected an overall average of 37.2% of the known leakage introduced into test respirators, with a coefficient of variation of 44.7%. The CNP system detected an overall average of 97.9% of the known leakage through the same hypodermic needles, with a coefficient of variation of 4.3%. CNP system measurements of Leak% were not affected by leak location ($p>0.43$) or mask type ($p>0.32$)

DISCUSSION

The ambient aerosol system detected an overall average of 37.2% of the known leakage introduced into test respirators. Any aerosol lost to diffusion during penetration through the leak needles would result in reduced detection of the known leaks by the aerosol system. The potential for such losses is strongly dependent on the aerodynamic diameter of the ambient aerosol challenge agent and the flow rate through the leak needles. Although the size distribution of the ambient aerosol in the test room was not characterized, an estimate of potential aerosol diffusion losses in the fixed leak needles was made.[14] For the fixed leak geometries

Table II. Example of Data Collected for One Brand of Half-Mask Respirator at Breathing Rate of 71.2 L/min

Trial No.	Baseline	Position 1	Position 2	Position 3
Measured CNP leak rates, mL/min				
1	8.1	79.7	78.6	78.2
2	7.7	80.1	78.3	78.5
3	9.0	80.7	77.6	78.6
4	8.2	79.4	77.9	79.8
5	7.7	79.7	78.4	78.7
6	9.0	80.7	78.2	78.2
Mean	8.3	80.1	78.2	78.7
COV,%	6.5	0.6	0.4	0.7
Measured aerosol fit factors				
1	>50000	5090	2210	2090
2	>50000	4550	2820	1730
3	>50000	5550	2250	1860
4	>50000	5940	2570	2170
5	>50000	5090	2400	1830
6	>50000	4050	2860	1700
Calculated aerosol penetration, (1/fit factor)				
1	<2.0E-05	1.96E-04	4.52E-04	4.78E-04
2	<2.0E-05	2.20E-04	3.55E-04	5.78E-04
3	<2.0E-05	1.80E-04	4.44E-04	5.38E-04
4	<2.0E-05	1.68E-04	3.89E-04	4.61E-04
5	<2.0E-05	1.96E-04	4.17E-04	5.46E-04
6	<2.0E-05	2.47E-04	3.50E-04	5.88E-04
Mean	<2.0E-05	2.01E-04	4.01E-04	5.32E-04
COV, %	—	12.8	10.0	8.9

Note: Measured mean inspiratory pressure for this mask was 0.71 in H_2O.

TABLE III. Determination of Leak% Variable Using Measured Leak Rate and Fit Factor Data From Table II

	Leak Rate, mL/min		
	Source 1	Source 2	Source 3
Calibrated leak rate through leak source at pressure differential of 0.71 in H_2O	71.6	70.1	70.5
Mean total leak rate (baseline plus leak source) measured with CNP system	80.1	78.2	78.7
Net CNP leak rate (total minus mean baseline of 8.3 mL/min)	71.8	69.9	70.4
Calculated CNP Leak% variable (100* [net/calibrated])	100.3%	99.7%	99.9%
Mean total penetration measured with aerosol system	2.01E-4	4.01E-4	5.32E-4
Net aerosol penetration (total minus mean baseline of 1.37E-5)	1.87E-4	3.87E-4	5.18E-4
Estimated aerosol leak rate, mL/min (net penetration times inspiratory flow rate)[A]	13.3	27.5	36.9
Calculated aerosol Leak% variable (100*[estimated/calibrated])	18.6%	39.2%	52.3%

[A]Measured inspiratory flow rate=71,200 mL/min.

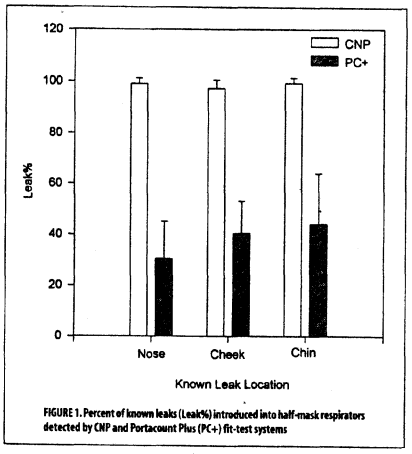

FIGURE 1. Percent of known leaks (Leak%) introduced into half-mask respirators detected by CNP and Portacount Plus (PC+) fit-test systems

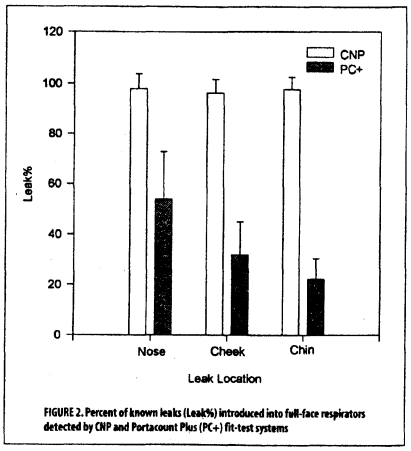

FIGURE 2. Percent of known leaks (Leak%) introduced into full-face respirators detected by CNP and Portacount Plus (PC+) fit-test systems

and leak rates (>70 mL/min) used in this study, potential diffusion losses for aerosols of 0.1, 0.05, and 0.01 microns aerodynamic diameter were calculated to be 0.4%, 0.8%, and 6.0%, respectively. Potential aerosol losses in the leak needles can explain only a fraction of the observed differences between the known leak rates introduced into test respirators and the leak rates detected by the aerosol system.

The Portacount's detection of known leakage during this study increased in comparison with results from a similar study conducted with human subjects.[13] In that study a Portacount Plus detected an average of 21.8% of the fixed leakage introduced into subjects' respirators at the bridge of the nose. As expected, greater variability was observed with human subjects. The increase in Portacount leak detection observed during this study may be due in part to the lack of aerosol lung deposition. The loss of aerosol to lung deposition that was experienced during the human subject study would not be expected to occur in the bellows of the breathing machine used in this study. Subject-generated aerosols have also been shown to affect ambient aerosol system measurements.[15] Subject-generated aerosols are interpreted by the Portacount as increased respirator leakage. The effects of any subject-generated aerosol associated with the previous human subject study should have been effectively canceled out as a result of being included in both the needle-closed and needle-open sequential measurements made during that study.

As shown in Figures 1 and 2, a different pattern of aerosol leak detection as a function of leak location was observed between half-mask and full-face respirators. This difference may be related to differences in basic airflow dynamics between the two types of masks. The pattern of leak detection as a function of mask type is consistent with the in-mask flow dynamics of each mask type. In half-mask respirators, the predominant airflow path is through the purifying elements, through the inhalation valves, and directly to the nose or mouth. In these flow conditions, leakage introduced into the chin area should be picked up and mixed more readily than leakage introduced at the bridge of the nose. For the half-mask respirators tested in this study, the highest percentage of leakage was detected at the chin, while the lowest percentage was detected at the bridge of the nose.

The pattern of aerosol leak detection as a function of leak location was reversed in the full-face respirators. Each of the four brands of full-face respirators tested incorporates a deflector immediately downstream from the inhalation valve to deflect air up across the face shield to keep it defogged. This airflow pattern should more readily pick up and mix leakage introduced at the bridge of the nose, as is indicated in the results. The aerosol leak detection patterns evident in Figures 1 and 2 support the theory of aerosol streamlining that has been proposed[6] and supported[9] by other researchers.

CONCLUSIONS

An ambient aerosol system detected less than half of the fixed leakage introduced into half-mask and full-face respirators mounted on a breathing machine. Aerosol leak detection was found to differ significantly as a function of leak location and respirator type. Detection of the same leakage by a CNP system was consistently close to 100% and was not affected by leak location or mask type.

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