

Exhalation Valve Leakage Measured by a Negative Pressure Fit Test Method and its Effect on the Measurement of Human Subject Fit Factors

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ABSTRACT

Studies comparing condensation nuclei counter and dynamic negative pressure methods have found that the negative pressure method consistently measures lower and less variable fit factors. It has been suggested that this is, in part, due to the negative pressure method measuring exhalation valve leakage in addition to faceseal leakage. To test this premise, leakage through exhalation valves from three brands of halfmask respirators was measured with a commercially available dynamic negative pressure fit tester. The valves were fitted to a sealed canister and thirty tests performed at each challenge pressure of -9.9, -14.7, -19.6 and -22.1 mm H₂O programmed in the device corresponding to work rates of 140, 280, 420 and 490 kg-m min⁻¹. Average leak rates were found to be 1.7, 1.0, 1.2 and 1.7 ml min⁻¹ for all tests at the respective challenge pressures. These leak rates accounted for an average of between 1.16×10^{-3} to 1.1×10^{-2} percent of the corresponding programmed inspiratory flows. When the average valve leakage at a normal work rate was subtracted from the total leakage measured by the negative pressure method in a previous human subject fit test study, it was found that the adjusted fit factors were not significantly different from the measured fit factors. The results of this study indicate that the leakage measured by the negative pressure device on these valves was extremely low, and their effect on overall fit factors was negligible.

Keywords: Exhalation valve, leakage, negative pressure fit test, fit factor, bias

INTRODUCTION

NIOSH requires that leakage through exhalation valves not exceed 30 ml/min at a challenge pressure of 25 mm H₂O (42 CFR Part 84, 1995). Although the method that NIOSH uses to test valves measures volumetric flow rate (NIOSH, 2005), most studies of respirator valve leakage have relied on the measurement of aerosol leakage. Burgess and Anderson (1967) found that aerosol leakage through mushroom-shaped exhalation valves ranged from 0.002 to 0.05% at a work rate of 830 kg-m min⁻¹ which was a 19-fold increase over that for a sedentary work rate. They also found that having the valve cover in place improved valve performance 2.5 fold. Held (1974) measured aerosol leakage through exhalation valves during the inspiration cycle of a breathing machine and reported leak rates of 6 ml min⁻¹ for clean mushroom-shaped valves. Douglas (1975) measured aerosol penetration through clean exhalation valves using a breathing machine operating at a 622 kg-m min⁻¹ work rate and found average leakage of 0.04% without the cover in place and < 0.01% with the cover in place, and concluded that properly functioning exhalation valves contributed little to respirator leakage. Bellin and Hinds (1990) tested aerosol penetration through normal valves and valves compromised by spray paint on the valve seat

using a breathing machine at work rates of 0, 208, 415 and 622 kg-m min⁻¹. Average leakage through the clean exhalation valves with the cover in place was found to be less than 0.01%. Three valves from discarded respirators with paint between the valve and valve seat had leakage that ranged from 0.28 to 0.66%. They also found that penetration increased by 10-fold between the lowest and highest work rates (challenge pressure), and that measured penetration through leaky valves decreased as particle size increased from 0.5 to 4 µm. Brosseau (1998) tested three manufacturer's valves with 0.3 and 0.8 µm aerosols at work rates of 415 and 622 kg-m min⁻¹ at a challenge pressure of 25 mm H₂O, and found leak rates to range from 0.0 to 0.03%. No significant differences among manufacturer's valves or among valve lots, and no failure of exhaust valves were observed. Penetration did not vary by particle size at the low work rate, but small particles were less penetrating than large particles at the higher work rate. Kuo *et al* (2005) used a leakage meter to measure volumetric leak rate through seven valves from four brands of respirators with and without two types of induced leaks (fiber insertion and arched) at pressures ranging from 15 to 45 mm H₂O. They found that leakage could increase or decrease with increasing pressure for different valves. Although no actual values were reported, graphs indicate that leak rates ranged from 8 – 12 ml min⁻¹, 15 – 34 ml min⁻¹, 0 – 12 ml min⁻¹ and 2–7 ml min⁻¹ at 25 mm H₂O for the four types of valves. Leak rates of 5–11 ml min⁻¹, 10–24 ml min⁻¹, 0–15 ml min⁻¹, and 2–11 ml min⁻¹ were reported at a pressure of 15 mm H₂O.

Quantitative fit testing is usually performed by methods using ambient aerosols (AA) or controlled negative pressure (CNP). The AA method measures the penetration of an ambient aerosol into the respirator during a series of head movement exercises, and a fit factor (FF) is calculated as the harmonic mean of the ratio of the aerosol concentration outside the respirator to that inside the respirator during each exercise. CNP fit testing is based on exhausting air from a temporarily sealed respirator to generate and maintain a constant pre-set negative pressure, then continuing to exhaust air at a rate sufficient to maintain that pressure (Crutchfield *et al*, 1993a). The challenge pressure is selected to represent the mean inspiratory pressure under normal use conditions. With the negative pressure being kept constant inside the facepiece, exhaust flowrate is equal to leakage flowrate. FF is then the ratio of a programmed inspiratory flow rate for a given work rate to the measured leak rate. Comparison studies have shown that the CNP method consistently measures lower and less variable FFs than the AA method (Crutchfield, *et al*, 1993b; Oestenstad and Graffeo, 1993; Janssen, *et al*, 2002; Delaney, *et al*, 2003). It has been suggested that this may be, in part, due to the fact that leakage into the facepiece measured by the CNP method includes flow through the exhalation valve as well as face seal leaks (Clayton and Vaughn, 2005). The purpose of this study was to measure volumetric leak rates through respirator valves by the CNP method and determine their effect on CNP FFs measured in a previously reported human subjects fit factor study comparing the CNP and AA methods (Oestenstad and Graffeo, 1993).

MATERIALS AND METHODS

Leak rates through three exhalation valves from each of three brands of half-mask respirators were randomly measured with a FitTester 3000 (Occupational Health Dynamics, Pelham, AL) at the four challenge pressures of -9.9, -14.7, -19.6, and -22.1 mm H₂O, that are programmed into the instrument representing the negative pressure inside a half mask respirator worn by males at work rates of 140, 280, 420 and 490 kg-m min⁻¹. Corresponding programmed inspiratory flow rates for these work rates are 3.31x10⁴, 5.38x10⁴, 7.45x10⁴, 8.45x10⁴ ml min⁻¹. The valves tested were from MSA 200LS (flat with center hole), 3M 6200 (flat with center stem), and North 7700 (mushroom with center stem) half-mask respirators. The valve bodies with covers in place were mounted on a sealed canister fitted with a 20 gauge hypodermic needle (Figure 1) and ten leak rate measurements were performed on each valve at each challenge pressure. This procedure was repeated at random three times resulting in a total of 30 leak measurements on each valve at each challenge pressure. The needle was used to provide a baseline flow rate into the canister above the detection limit of the instrument. The average of 30 leak rate measurements through the needle only (26.45, 37.08, 45.39 and 48.97 ml min⁻¹) at the four challenge

pressures was subtracted from the leak rate measured through the needle and the valve to provide a net leak rate through the valve. A zero was assigned to cases where the needle and valve leak rate was less than the average leak rate through the needle alone. Percent leakage was calculated as net leak rate divided by the programmed inspiratory flow rate.



Figure 1. Sealed canister fitted with exhalation valve and hypodermic needle.

The FitTester 3000 default challenge pressure for testing half mask respirators according to the OSHA fit test protocol is -14.7 mm H₂O (OSHA, 1998). As a measure of the effect that valve leakage would have on the measurement of overall FFs as postulated by Clayton and Vaughn, (2005), mean leak rates for each manufacturer's valves at this pressure were subtracted from total leak rates for FFs measured on human subjects by the CNP method in a previous study (Oestenstad and Graffeo, 1993) to obtain an adjusted FF for face seal leakage only. It was thought that this was an appropriate exercise since one the respirators in that study was the same as in the present study (North 7700) and the three others had the same type of exhalation valves as those in the present study (flat with center hole, flat with center stem, and mushroom with center stem). The adjusted FFs were compared to the original values as a measure of the possible bias that may be caused by valve leakage on measured FFs (Equations 1 – 3).

$$\text{Measured FF} = \frac{\text{Breathing Rate (ml} \cdot \text{min}^{-1})}{\text{Faceseak Leak Rate (ml} \cdot \text{min}^{-1}) + \text{Valve Leak Rate (ml} \cdot \text{min}^{-1})} \quad (1)$$

$$\text{Adjusted FF} = \frac{\text{Breathing Rate (ml} \cdot \text{min}^{-1})}{\text{Faceseak Leak Rate (ml} \cdot \text{min}^{-1})} \quad (2)$$

$$\text{Bias} = \left(\frac{\text{Adjusted FF} - \text{Measured FF}}{\text{Measured FF}} \right) \times 100 \quad (3)$$

Data were entered into an Excel worksheet then imported into SPSS® (v.12.0) Statistical Software for analysis of leak rate data that included descriptive statistics with the Shapiro-Wilk test for normality, three-way ANOVA with Bonferroni post hoc tests. Although some of the data were not normally distributed, ANOVA was used because it allows for post-hoc multiple comparisons and it is considered to be robust to nonparametric data (Norušis, 2003). As a check on the stability of the analysis, the results of the ANOVA were compared to the results of a Kruskal-Wallis non-parametric test (Norušis, 2003) and found to be the same. FF data were tested by descriptive statistics with the Shapiro-Wilk test for normality, and paired t-tests. All tests of significance were at an alpha-value of 0.05 ($\alpha = 0.05$).

RESULTS AND DISCUSSION

Descriptive statistics for the leak measurements are shown in Table I. The maximum leak rate for all measurements on all valves at all pressures was 6.5 ml min^{-1} , well below the 30 ml min^{-1} allowed by NIOSH (42 CFR Part 84, 1995). The maximum leak percentage was 1.1×10^{-2} , which is on the same order of those reported in previous studies (Burgess and Anderson, 1967; Held, 1974; Douglas, 1975; Bellin and Hinds, 1990; Brosseau, 1998; Kuo *et al.*, 2005). Some of the valve leak measurements were not normally distributed and were skewed to the right. Observation of stem and leaf and normality plots indicated that non-linearity was probably due to the number of zero values or values close to zero. Mean leak rates and mean percent leakage for the three brands of valves are illustrated in Figures 2 and 3 respectively. ANOVA (Norušis, 2003) found that leak rates through MSA valves were significantly higher than 3M and North valves at all challenge pressures, and leak rates through North valves were significantly greater than 3M valves only at $-9.9 \text{ mm H}_2\text{O}$. Mean leak rates for each of the three manufacturer's valves are illustrated in Figures 4a through 4c. ANOVA found that leak rates for MSA valves were significantly different at all challenge pressures; all the 3M valves were significantly different at $-9.9 \text{ mm H}_2\text{O}$, and leakage through valve 4 was significantly greater than valves 5 and 6 at -19.6 and $-22.1 \text{ mm H}_2\text{O}$; leakage through North valve 7 was significantly greater than valve 9 at $-9.9 \text{ mm H}_2\text{O}$, and valve 9 was significantly greater at $-19.6 \text{ mm H}_2\text{O}$. All of these results were confirmed by the Kruskal-Wallis test. This is different from the results reported by Brosseau that there were no significant differences among manufacturers' valves (1998).

It was also observed that there was not a consistent increasing or decreasing trend in leak rate as challenge pressure increased as reported by Kuo *et al.* (2005), contradicting Bellin and Hinds (1990) observation that aerosol penetration increased with increasing work rate. Examination of Figure 2 indicates that mean leak rates for all three brands decreased as challenge pressure increased from -9.9 to $-14.7 \text{ mm H}_2\text{O}$, then gradually increased as pressure increased to -19.6 and again to $-22.1 \text{ mm H}_2\text{O}$. This phenomenon may be due to the challenge pressure of $-9.9 \text{ mm H}_2\text{O}$ not being sufficient to adequately seat the valves, thus allowing greater leakage. Whereas less leakage occurred as the valves were progressively better seated as the challenge pressure increased further.

Descriptive statistics for measured FFs by the AA and CNP methods from the study by Oestenstad and Graffeo (1993), CNP FFs adjusted for mean valve leakage, and the resulting FF bias are summarized in Table II and illustrated in Figure 5. Although the adjusted FFs were lower than the measured FFs, as postulated by Clayton and Vaughn (2005), a two-sample t-test found that the adjusted CNP FFs were not significantly different from the measured CNP FFs for any of the respirator brands. It is noted that only the bias for the maximum CNP measurement on one MSA valve significantly exceeded 10%. As can be seen from the AA and CNP FFs in Table II, the bias in the CNP FFs caused by exhalation valve leakage does not account for the order on magnitude difference with the AA FFs. That difference could be due to sampling bias as a result of flow streaming within the facepiece identified by Myers, *et al.* (1986) and Oestenstad, *et al.* (1990).

Table I. Exhalation Valve Leak Descriptive Statistics

	Challenge Pressure (mm H ₂ O)											
	-9.9			-14.7			-19.6			-22.1		
	Leak Rate (ml min ⁻¹)											
	MSA	3M	North	MSA	3M	North	MSA	3M	North	MSA	3M	North
Mean	2.2	1.2	1.7	1.8	0.6	0.6	2.0	0.8	0.8	2.6	1.1	1.3
Std Dev	0.53	0.86	0.62	1.07	0.45	0.65	1.77	0.48	0.51	0.97	0.70	0.63
Minimum	1.0	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.9	0.0	0.0
Median	2.1	1.1	1.7	1.6	0.5	0.5	1.2	0.7	0.8	2.8	1.0	1.2
Maximum	3.8	2.6	2.7	4.7	1.8	1.9	5.1	1.9	2.5	6.5	2.8	2.8
	Percent Leak (x 10 ⁻³)											
	MSA	3M	North	MSA	3M	North	MSA	3M	North	MSA	3M	North
Mean	6.6	3.5	5.2	3.4	1.1	1.2	2.7	1.1	1.1	3.1	1.3	1.6
Std Dev	1.6	2.6	1.9	2.0	0.7	1.2	2.4	0.7	0.7	1.2	0.8	0.7
Minimum	3.2	0.0	1.4	0.0	0.0	0.0	0.0	0.0	0.0	1.1	0.0	0.0
Median	6.5	3.3	5.3	3.0	1.0	1.2	1.6	1.0	1.1	3.3	1.2	1.5
Maximum	11.3	8.0	8.3	8.8	3.3	3.6	6.9	2.6	3.4	7.7	3.4	3.4

Table II. Fit Factor Descriptive Statistics

	Measured		Adjusted FF for Mean Exhalation Valve Leak			CNP FF Bias		
	AA FF	CNP FF	MSA	3M	North	MSA	3M	North
Mean	26496	1257	1361	1288	1288	4.55	1.44	1.44
Std Dev	28053	1057	1347	1136	1136	4.51	1.27	1.27
Minimum	142	112	112	112	112	0.38	0.13	0.13
5th %ile	1349	225	227	226	226	0.76	0.25	0.25
10th %ile	3053	481	488	483	483	1.63	0.54	0.54
Median	20550	1020	1056	1032	1032	3.53	1.15	1.15
90th %ile	55130	2271	2458	2330	2330	8.22	2.60	2.60
95th %ile	86805	2931	3250	3030	3030	10.87	3.38	3.38
Maximum	216000	8810	12492	9770	9770	41.80	10.90	10.90

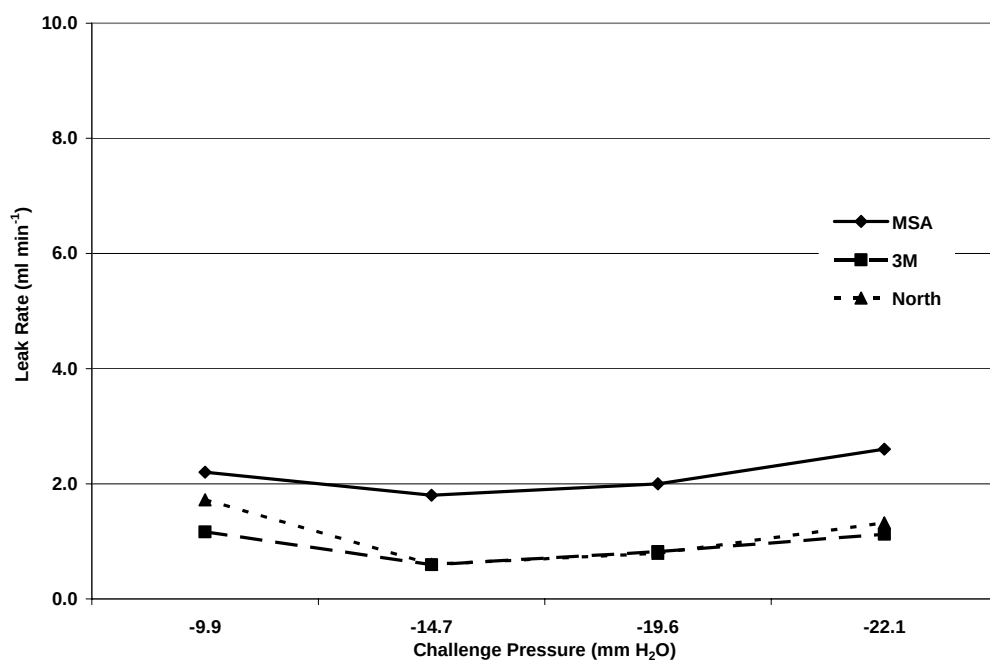


Figure 2. Mean Leak Rates for Manufacturer's Valves.

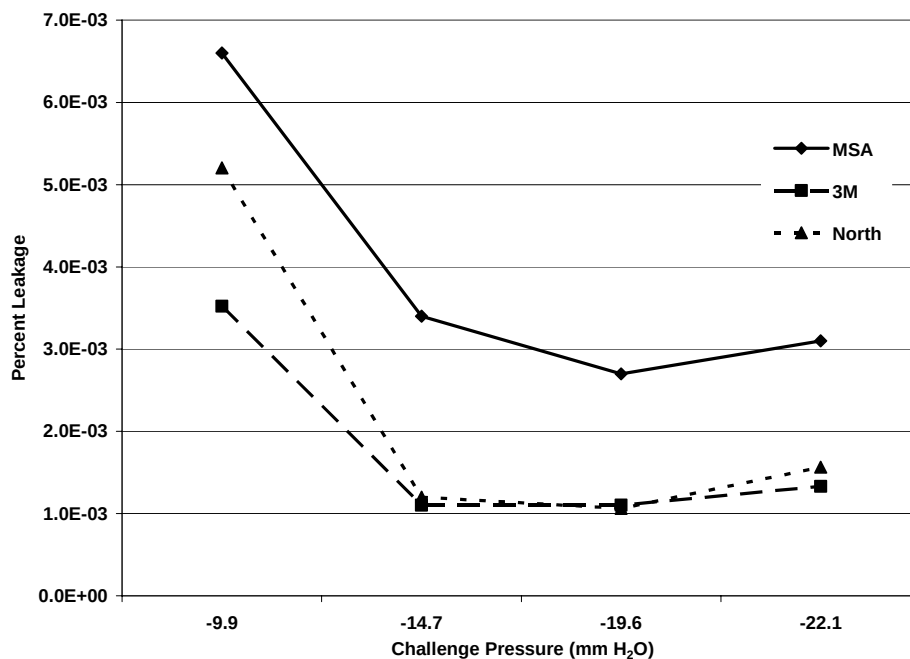


Figure 3. Mean Percent Leakage for Manufacturer's Valves.

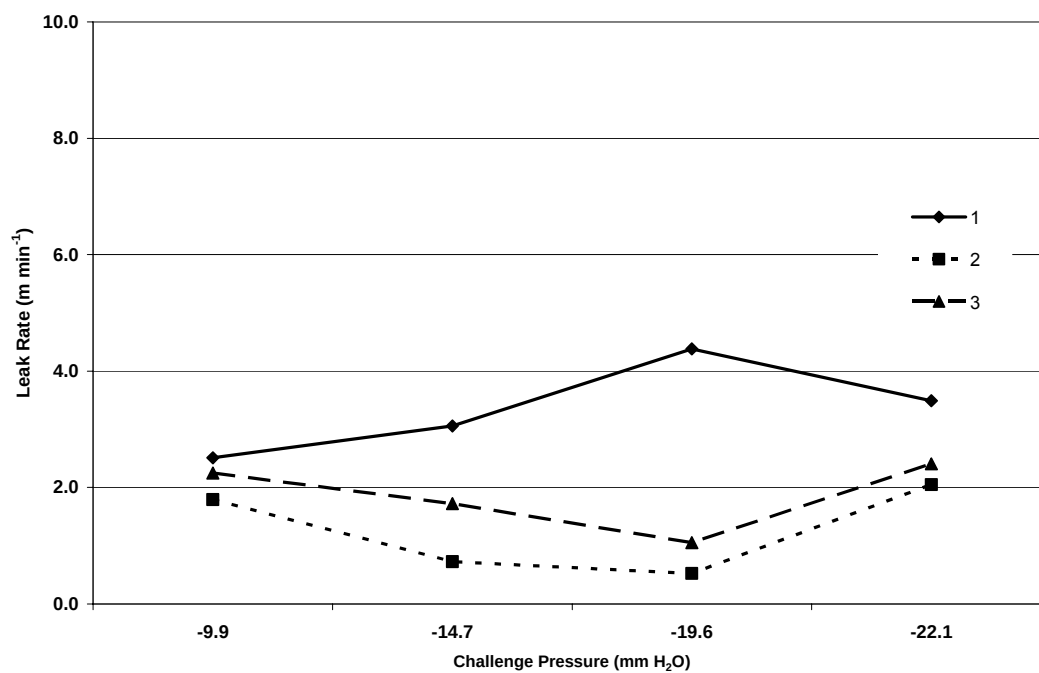


Figure 4a. MSA Valves Mean Leak Rates.

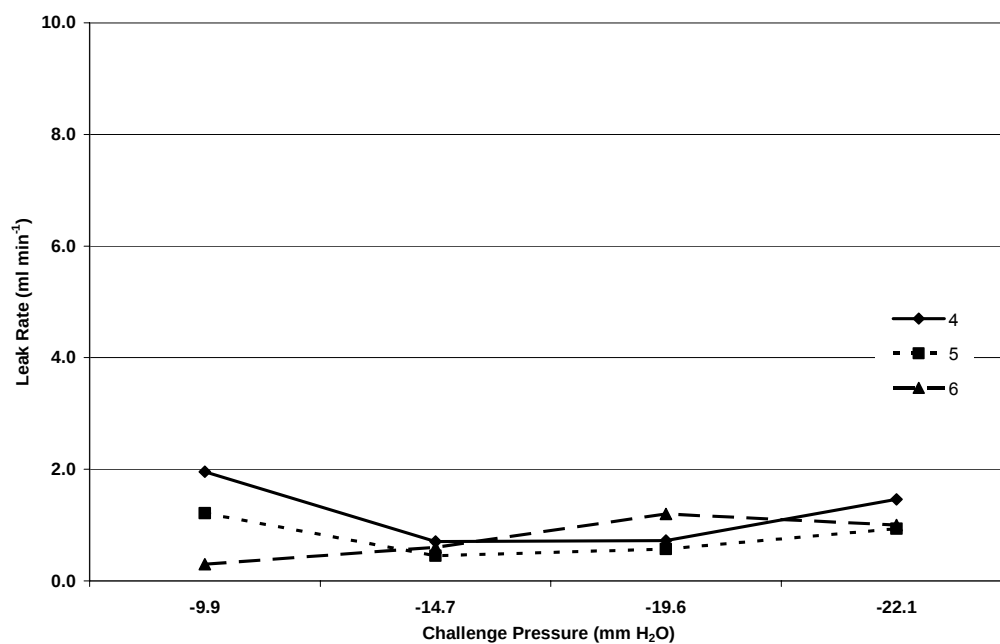


Figure 4b. 3M Valves Mean Leak Rates.

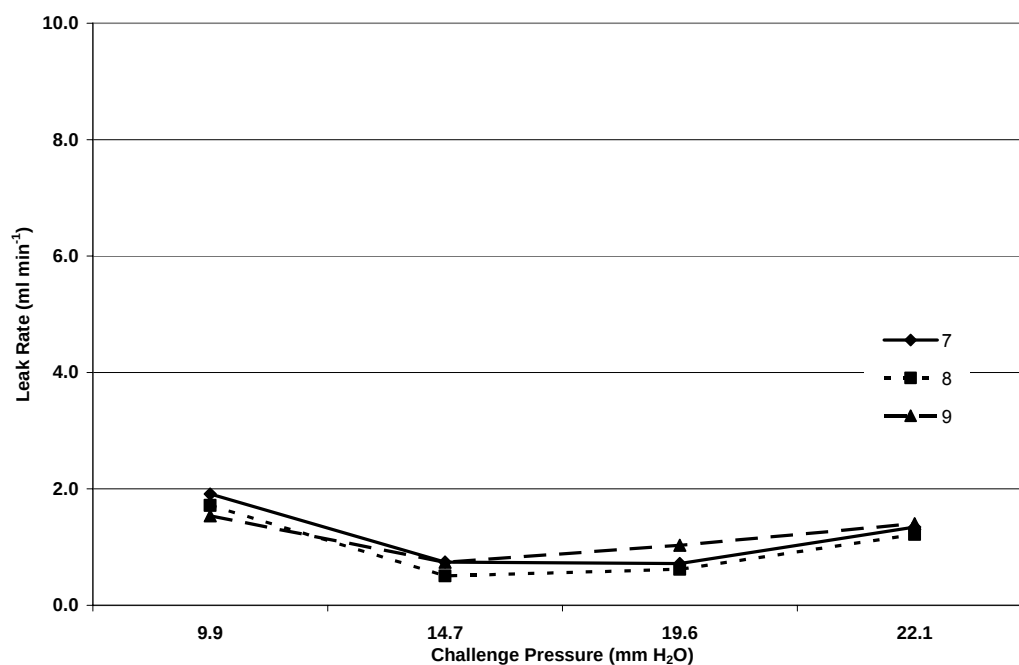


Figure 4c. North Valves Mean Leak Rates.

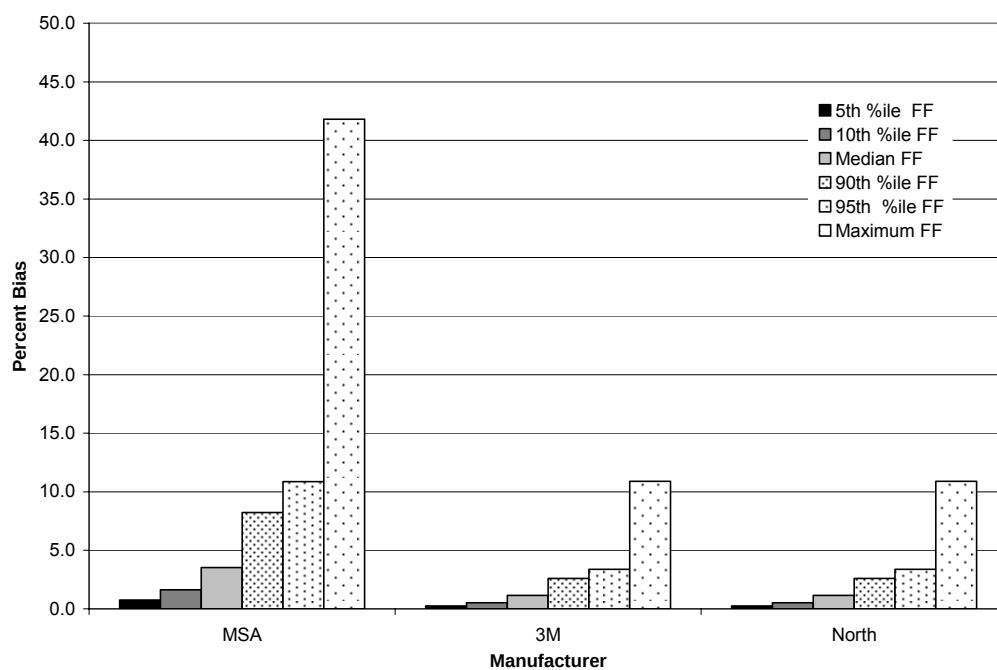


Figure 5. Fit Factor Bias from Mean Exhalation Valve Leak Rates.

CONCLUSIONS

Leak rates measured through MSA, 3M and North valves by the CNP method were very low, and resulted in percent of breathing rates on the order of 10^{-3} . There were significant statistical differences in leak rates among the three manufacturer's valves and within the MSA and 3M valves. However, these differences were so small as to not be practically significant. Measured leak rates did not significantly bias FFs measured on human subjects. There was not a consistent trend in leak rates as challenge pressure increased. However, this may have been due to the valves not adequately seating at the lowest pressure whereas they progressively seated better as pressure increased.

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