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Factors Affecting the Location and Shape of Face Seal Leak Sites on Half-Mask Respirators

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While there have been a number of studies on the effect of leak site and shape on the magnitude of measured leakage through respirator face seals, there have been very few studies to identify the location and size of these leaks. In a previous study we used a method of identifying the location and shape of respirator leaks on a half-mask respirator by the deposition of a fluorescent tracer during a fit test, and testing for their association with facial dimensions. The purpose of this study was to apply that methodology to conduct multiple fit tests to determine if gender, respirator brand, repeated fit tests, and test exercises affected the location and shape of face seal leak sites. Categorical analysis found that none of these factors had a significant effect on the location and shape of leaks. General linear model analysis found some significant effects of the study factors on leaks, but facial dimensions had a greater effect, and there were significant differences between facial dimensions of subjects with a leak and those without. Significant differences in leak site distributions between this and the previous study may have been due to differences in facial dimensions and racial/ethnic composition. Twice as many diffuse leaks as point leaks were observed in both studies, indicating that slit-like leaks would be most appropriate on mannequins used in laboratory respirator leakage studies, and in respirator flow and penetration models. That the study factors had no significant effects in the categorical analysis, significant effects for facial dimensions were found in the linear analysis, and leak site distribution differences between this and our previous study may have been affected by differences in facial dimensions, indicate that, in addition to size, the shape of an individual's face may be an important determinant of leak sites on a half-mask respirator. This would have implications for the design of respirator facepieces and in the selection of respirators for individual wearers.

Keywords aerosol, anthropometry, facial dimensions, fit test, fluorescent tracer, gender

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INTRODUCTION

Leakage of contaminants through face seals has long been recognized as a major limitation of the level of protection that could be provided by half-mask respirators. Many authors have reported studies on the influence of the size, shape, and location of face seal leaks on the measurement of in-facepiece concentrations of aerosols, gases, and vapors. Hinds and Kraske[(1)] evaluated the performance of half-mask and filtering facepiece respirators with circular and slit-like leaks made by placing wires between the facepiece and test mannequin. Penetration of aerosols in the range of 0.1 to 11.3 μm were measured in tests performed over seven steady flow rates from 2 to 150 l min^{-1}. Aerosol penetration through circular and slit-like leaks was similar and found to depend strongly on leak size and less strongly on pressure drop. They also observed that penetrations through leaks at the nose, cheek, and chin were very similar.

Chen and Willeke[(2)] measured leakage of aerosols at five inhalation flow rates through four types of leaks with different shapes but with the same cross-sectional area — single round hole, four small holes, sixteen smaller holes, and a slit. They found that slit-like leaks and multiple circular leaks passed fewer aerosols than a single circular leak of the same cross-sectional area because leak flow rate decreases with an increase in leak shape complexity. Vaughan et al.[(3)] also studied the loss of monodisperse aerosols in the range of 1.5–9.0 μm through circular and slit leaks. While the losses in circular leaks were erratic, they were found to be even more so in slit leaks. The authors concluded that losses of aerosols will depend on the shape and site of a leak and the flow path of leaked air.

Krishnan et al.[(4)] compared aerosol fit factors (FFs) measured on human subjects wearing a half-mask respirator with flow FFs measured on a mannequin fitted with the same respirator, with one to three artificial leaks of the same internal diameter. Although the aerosol FFs were much higher than the flow FFs, the coefficient of variation for both methods was of the same order of magnitude. From this, the authors postulated

that variations in the aerosol FF measurements were due to changes in the size of the face seal leaks, and they estimated that the human leak sizes ranged from 0.5 mm^2 to 1.3 mm^2.

Leak location has been shown to affect bias in the measurement of in-facepiece aerosol concentrations. Crutchfield and Park[5] compared leakage into a half-mask respirator through artificial leaks at the nose, cheek, and chin by controlled negative pressure (CNP) and condensation nuclei counter (CNC) methods. They found that the CNC method measured different percentages of known leakage among the three sites, with the lowest percentage through nose leaks followed by cheek then chin leaks. Lee et al.[6]obtained similar results when they used a newly developed real-time sampling system to measure protection provided by filtering facepiece respirators. Based on mannequin and human tests, they found that measured leakage through nose leaks on a filtering facepiece respirator was significantly less than that through cheek or chin leaks.

While there have been a number of studies on the effect of leak site and shape on the magnitude of measured leakage through respirator face seals, there have been very few studies to identify the location and size of face seal leak sites. Beginning in 1934, the Bureau of Mines used a qualitative "coal dust tightness test" in which three subjects having full, average, and lean facial features donned eye protection and a test respirator; then, a high concentration of fine coal dust was blown around the edges of the facepiece. Passing the test required that there be no visible coal dust on the face or in forced nasal discharge.[7]

Adley and Wisehart[8] developed a quantitative fit test method using a Freon gas as a test agent and a halide meter to measure leakage. A small capillary tube attached to the Freon supply was moved around the facepiece, and a strong deflection was noted when the capillary was near a leak site. Using this method, the authors found that the leakage of half-mask respirators varied substantially and that differences in fit were caused by variability of leaks around the nose. Cohen[9] developed a method to identify leak sites that utilized photosensitive paper placed beneath the facepiece and light as a test agent. The paper was cut into templates and placed inside the facepiece in a darkroom with ultraviolet lights. The subject then donned the respirator, and a high-intensity light was moved around the facepiece. After the paper was developed, the location and degree of leakage was indicated by the presence of gray or black areas. By using this method on eight subjects, it was found that most leaks occurred around the nose and chin, and they covered a large area of the face.

We previously reported a method to identify the location and shape of respirator face seal leak sites by the deposition of a fluorescent tracer.[10] An aerosol generation, conditioning, and exposure system was developed and tested to provide a test environment with a stable fluorescent aerosol concentration and size distribution. Face seal leak sites on 73 human subjects wearing a single brand of half-mask respirator during a standard quantitative fit test were identified by deposition of the aerosol on their faces and subsequent observation and photographic documentation under ultraviolet lighting.

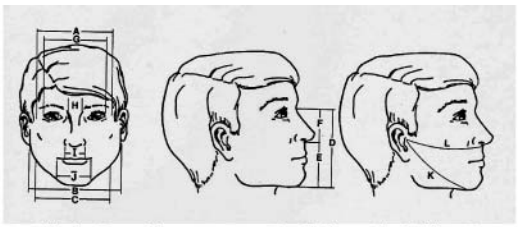
Identified leaks were classified according to their location and shape. About 89% of all observed leaks occurred at the nose or chin or were multiple leaks that included these sites; about 73% of all leaks approximated the shape of a slit rather than a round orifice, and the prevalence of these leaks was affected by gender. Significant association of facial dimensions and leak sites were found, most of which were attributed to gender. Evidence of airflow streaming within the facepiece was observed on 22% of the subjects.

Although that study made a significant contribution to the knowledge of respirator leak sites, it was limited in that it did not address certain conditions known to affect the face seal leakage of half-mask respirators. These conditions include variation of leakage among different brands of respirators,[11] variation of leakage among different fittings of a half-mask respirator on the same person, and variation of leakage among the exercises of a respirator fit test.[12] The purpose of this study was to determine if the distribution of respirator leak sites and shapes on half-mask respirators were affected by respirator brand, repetition of fit test, fit test exercise, or gender. This was done by conducting multiple fit tests using a fluorescent tracer aerosol and observing aerosol deposition at leak sites.

METHODS AND MATERIALS

The aerosol generation system and exposure chamber used in this study was an expansion of the system used in our previous study.[10] It consisted of four Liu-type nebulizers[13] connected in parallel in a plenum, a heated drying tube, a particle neutralizer, two diffusion drying tubes in series, and an Air Techniques System 2.5 m^3 exposure chamber with air lock (model TDA-71; Air Techniques International, Owings Mills, Md.). Tinopal CBSX (Ciba Specialty Chemicals, Tarrytown, N.Y.) was used as the test agent. It was dissolved in water to a concentration that would result in residue particles of the desired size.[14] The test aerosol was measured by a TSI Model 3320 Aerodynamic Particle Sizer (APS; TSI Inc., Shoreview, Minn.) and had a mass median aerodynamic diameter of 0.9 μm and a geometric standard deviation of 1.2. By optimizing nebulizer and chamber operating parameters, chamber aerosol concentrations were in the range of 15 to 20 mg m^{-3}.

Prospective subjects for the study included Caucasian females and males, between the ages of 20 and 60, recruited from the student and staff population of the University of Alabama at Birmingham (UAB). Prospective subjects completed a medical questionnaire and informed consent form prior to acceptance into the study. Measurements of key facial dimensions were made by one investigator, with anthropometric sliding and spreading calipers (GPM Instruments, Zurich, Switzerland) and a Lufkin steel measuring tape (Cooper Tools, Apex, N.C.). Measurement consistency was evaluated during the study by repeated measurement of the facial dimensions on a



A. Biectoorbitale Breadth
B. Bizygomatic Breadth (Face Width)
C. Bigonial Breadth
D. Menton-Sellion Length (Face Length)
E. Menton-Subnasale Length
F. Subnasale-Sellion Length
G. Biocular Breadth
H. Nasal Root Breadth
I. Nose Breadth
J. Lip Length
K. Bitragion-Menton Arc
L. Bitragion-Subnasale Arc

FIGURE 1. Measured facial dimensions.

control subject. Measured facial dimensions are illustrated in Figure 1.

The subjects' skin was pretreated with sunscreen to lower natural skin fluorescence and improve detection of leaks, and a pretest frontal photograph under ultraviolet lighting (300–430 nm) was taken before fitting with a respirator. Based on facial size and shape as observed by the investigators, each subject was fitted with an appropriate sized, probed, half-mask, air-purifying respirator equipped with high-efficiency particulate filters; fit checks were performed to indicate adequacy of fit.

A quantitative fit test with the fluorescent tracer aerosol using a model 264 forward light scattering photometer (Dynatech Frontier Corp., Albuquerque, N.M.) was then performed. Each test consisted of the six-exercise sequence of normal breathing (NB), deep breathing (DB), moving the head from side to side (SS), moving the head up and down (UD), talking, and normal breathing for 4 min each with an interval of 30 sec between exercises to measure chamber concentration.

After the test, the respirator was carefully removed, leak sites identified and measured under UV lighting, and a post exposure photograph taken. Identified leaks were classified into the leak site location categories shown in Table I. Leak shapes were classified as either point or diffuse; point leaks were those on which the aerosol was deposited on a small cross-sectional area of less than 1 cm, and diffuse leaks were those where the aerosol was deposited over an area greater than 1 cm. This protocol was approved by the University of Alabama at Birmingham Institutional Review Board.

TABLE I. Leak Site Categories

Leak Category	Description
0	No observed leaks
1	Nose leaks only
2	Cheek leaks only
3	Chin leaks only
4	Nose and cheek leaks
5	Nose and chin leaks
6	Cheek and chin leaks
7	Nose, cheek, and chin leaks (all)

The effects of respirator brand, gender, and test repetition on leak sites and shapes were determined by conducting three fit tests with the same subject wearing one size of three different brands of half-mask respirators (1) AO 5-Star Series, AOSafety, Indianapolis, Ind.; (2) North 7700 Series, North Safety Products, Cranston, R.I.; and (3) Survivair Series 2000, Survivair, Santa Ana, Calif.), resulting in a total of nine fit tests per subject. Respirator brands used for each test were selected at random. The effect of fit test exercise on leak site and shape was evaluated by conducting a series of five fit tests in which a subject repeated one of the above exercises selected at random throughout the entire test session while wearing the North respirator. This sequence resulted in five tests on each subject.

Collected data were entered into a computer spreadsheet and descriptive and categorical statistical analyses were performed using SPSS version 12.0 (SPSS, Chicago, Ill.). Tests of significance were at an alpha value of 0.05 ($\alpha = 0.05$). Designation of leak sites was considered as a multinomial random variable, and their distribution was compared with the multinomial distribution using the Chi-square goodness-of-fit test with the null hypothesis that each of the eight leak site categories was equally likely to occur ($p_i = 0.125$ for $i = 1,2, \cdots 8$).[15] Given that a leak occurred, leak shape was a dichotomous variable whose distribution was assumed to be normal. A Fisher-Freeman-Halton exact Chi-square test was used to test for differences in the distribution of leaks in cases where there were fewer than five observations in a cell.[16]

The association of leak sites and shapes with gender, respirator brand, test sequence, and facial dimensions was determined by a Generalized Linear Model using the PROC GENMOD in SAS version 9.2 (SAS, Cary, N.C.). This procedure uses generalized estimating equations to analyze correlated data arising from repeated measurements when the measurements are assumed to be multivariate normal. Because GENMOD was being used as an exploratory analysis, tests of significance were at an alpha value of 0.10 ($\alpha = 0.10$). GLM univariate ANOVA[15] was used to test for differences between the 12 measured facial dimensions of subjects with a specific leak (nose, cheek, or chin) and all others without that leak while controlling for gender. The independent variables were facial dimensions and gender, and the dependent variables were differences between the facial dimensions of subjects with the leak and those without. These tests were at an alpha value of 0.05 ($\alpha = 0.05$).

RESULTS

Descriptive Statistics

Initially, 67 subjects were admitted to the study; however, 26 were dropped because they failed to complete any of the fit tests. The resulting sample used in the analysis included

TABLE II. Test Subject Facial Dimensions

Facial Dimension (cm)	Mean (Standard Deviation)		
	All Subjects (n = 41)	Females (n = 20)	Males (n = 21)
Biectoorbitale breadth	11.13 (0.82)	10.73* (0.70)	11.53 (0.72)
Bizygomatic breadth (face width)	13.34 (0.73)	12.98* (0.77)	13.68 (0.48)
Bigonial breadth	10.23 (0.58)	10.05* (0.62)	10.41 (0.47)
Menton-sellion length (face length)	11.84 (0.64)	11.56* (0.63)	12.11 (0.52)
Menton-subnasale length	6.95 (0.51)	6.81* (0.46)	7.11 (0.52)
Subnasale-sellion length	5.24 (0.38)	5.16 (0.38)	5.32 (0.37)
Biocular breadth	8.73 (0.38)	8.58* (0.31)	8.89 (0.38)
Nasal root breadth	1.59 (0.16)	1.54* (0.17)	1.65 (0.13)
Nose breadth	3.39 (0.34)	3.20* (0.20)	3.56 (0.35)
Lip length	4.96 (0.37)	4.84* (0.38)	5.07 (0.31)
Bitragion-menton arc	29.06 (2.63)	27.45* (1.91)	30.70 (2.19)
Bitragion-subnasale arc	26.42 (1.47)	25.80* (1.26)	27.07 (1.39)

*Significant difference between genders.

20 females and 21 males. Nine of these subjects did not complete all of the tests required for the inter-respirator or the inter-exercise variation evaluations; however, the statistical tests utilized would accommodate unequal numbers of tests for each subject, so they were retained in the analysis. The subjects' age ranged from 20 to 55 years with an average of 30 years. Their facial dimensions are shown in Table II. As expected, facial dimension data were normally distributed, and all but one dimension for females were significantly smaller than those for males. Figure 2 shows that all but two subjects

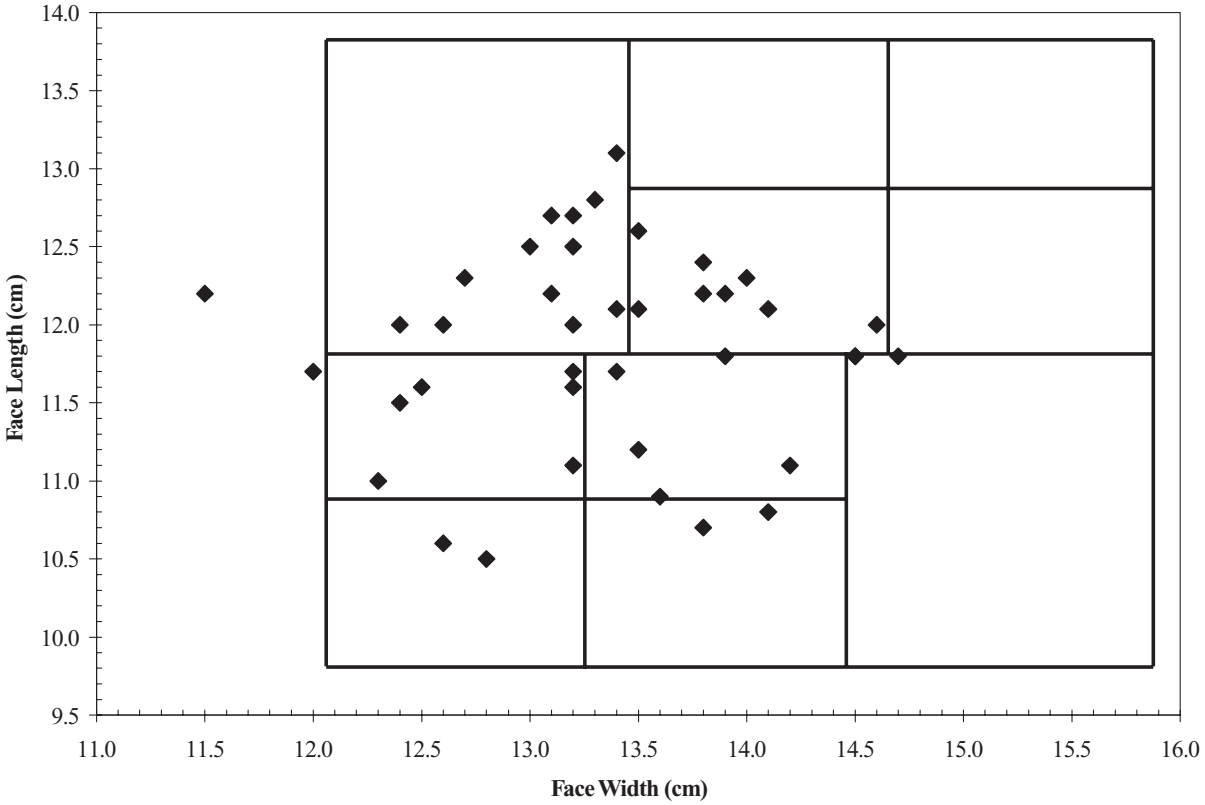


FIGURE 2. Subject's facial dimensions on the NIOSH test panel.

TABLE III. Leak Site Distribution

	Leak Category (Percent)								
Gender	None	Nose	Cheek	Chin	Nose-Cheek	Nose-Chin	Cheek-Chin	All Sites	Total Count
Female	3.0	13.6	18.9	6.5	22.5	14.2	13.0	8.3	169
Male	2.5	15.0	20.6	2.5	27.5	9.4	11.3	11.3	160
All	2.7	14.3	19.8	4.6	24.9	11.9	12.2	9.7	329
Brand									
AO	2.7	14.5	17.3	4.5	26.4	12.7	12.7	9.1	110
North	3.6	15.2	23.2	8.0	18.8	12.5	10.7	8.0	112
Survivair	1.9	13.1	18.7	0.9	29.9	10.3	13.1	12.1	107
Fit Test									
1	1.8	11.6	24.1	6.3	16.1	13.4	12.5	14.3	112
2	4.6	16.5	14.7	1.8	29.4	13.8	14.7	4.6	109
3	1.9	14.8	20.4	5.6	29.6	8.3	9.3	10.2	108
Shape									
Point	0.0	6.2	10.9	3.3	25.6	15.6	15.6	22.7	211[A]
Diffuse	0.0	10.2	12.6	2.4	32.9	13.5	14.1	14.4	334[A]
Exercise									
NB	0.0	10.0	30.0	20.0	20.0	0.0	20.0	0.0	10
DB	11.1	11.1	22.2	11.1	0.0	11.1	33.3	0.0	9
SS	11.1	22.2	22.2	11.1	11.1	11.1	11.1	0.0	9
UD	12.5	12.5	37.5	0.0	0.0	0.0	37.5	0.0	8
Talk	12.5	0.0	12.5	25.0	12.5	0.0	37.5	0.0	8

[A]The number of shape observations exceeds the number of tests because some tests resulted in multiple leaks.

were within the National Institute for Occupational Safety and Health (NIOSH) Fit Test Panel[17] indicating that this group was representative of a U.S. working population.

Categorical Analysis

A total of 329 tests were performed for the inter-respirator evaluation in which 546 individual leaks were identified. The number of leak sites exceeded the number of tests because some of the leak site categories included more than one leak (i.e., nose–cheek, nose–chin, cheek–chin, and all sites). Nine tests resulted in not identifying any leak sites. Forty-four tests were performed for the inter-exercise evaluation in which 58 individual leaks were identified. Identified face seal leak sites were classified as to their site and shape as previously defined. Because of a high subject dropout rate for the exercise fit tests the numbers were so low that no attempt was made to analyze those data.

The distribution of leak sites by gender, respirator brand, fit test, leak shape, and fit test exercise are summarized in Table III. Leak site distributions by gender and for all subjects are illustrated in Figure 3 in which it is obvious that the largest proportion of leaks were those at the nose and cheek (24.9%). Leaks at the cheek were the next most prevalent category (19.8%), followed by nose leaks (14.3%). Leaks at the cheek accounted for 40.2% of all the identified leaks, 36.7% leaks were at the nose, and 23.1% were at the chin. A Chi-square test found the distribution of observed leak sites for all subjects to be significantly different from the uniform distribution ($p < 0.001$), while the distributions for males and females were not significantly different ($p = 0.476$).[15] Leak site distributions by respirator brand and fit test were also not significantly different ($p = 0.549$ and $p = 0.079$, respectively).

The distributions of leak shapes by gender, leak site, respirator brand, fit test, and test exercise are summarized in Table IV. A Chi-square test found the distribution of observed leak shapes for all subjects to be significantly different from the uniform distribution ($p < 0.001$),[15] with 39% being point leaks and 61% being diffuse leaks. The number of leaks identified on females and males was almost equal, 276 and 269, respectively, and the distributions of their shapes were not significantly different ($p = 0.198$). The distributions of leak shapes for respirator brand and fit test were also not significantly different ($p = 0.782$ and $p = 0.244$, respectively).

Generalized Linear Analysis

The GENMOD analysis of the association of leak sites and shapes with gender, respirator brand, test sequence, and facial dimensions was performed at two levels — one by the test factors of gender, respirator brand, and test sequence, and the other by facial dimensions. The first level resulted in 41 clusters with a maximum cluster size of 9, so the Empirical Standard Error Estimates were used as a measure of association. The facial dimension analysis resulted in 41 clusters and a

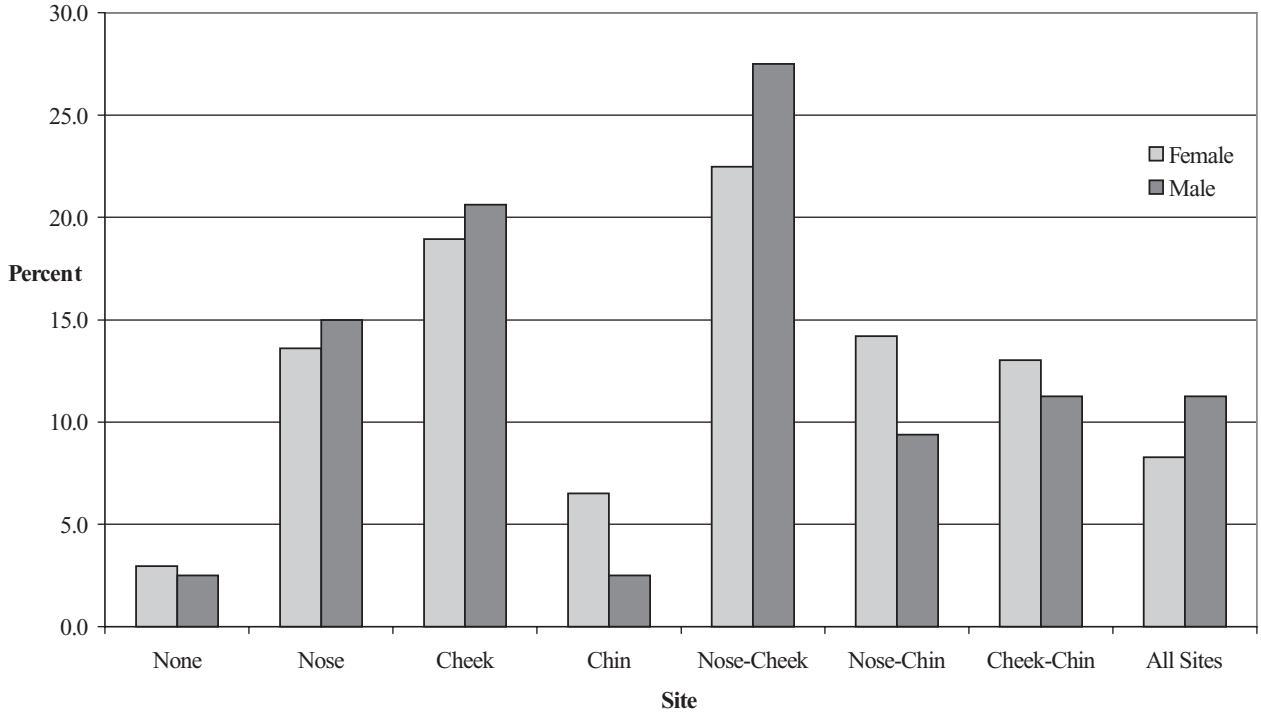


FIGURE 3. Leak site distribution by gender.

maximum cluster size of 21, so the Model Standard Error Estimates were used as a measure of association.

Significant parameter estimates for the analyses are shown in Table V. These parameter estimates are analogous to coefficients in linear regression, so the value of the parameter estimate indicates the magnitude of the effect of the factor on the outcome variable. While GENMOD defines a model of the relationship between dependent and independent variables, it does not estimate a coefficient of determination (R^2) for that model. Therefore, the significant parameter estimates in Table V were linked to PROC LOGISTIC, and a R^2 was estimated by binomial logistic regression. These values are shown at the bottom of Table V.

Differences between facial dimensions of subjects with and without a given leak site (nose, cheek, or chin) and those without that leak were tested by GLM univariate ANOVA[15] because the GENMOD procedure does not calculate a difference value per se. The p-values for the facial dimensions that had significant differences between subjects with a specific leak location and those without that leak are summarized in Table VI.

TABLE IV. Leak Shape Distribution (Percent)

Gender	Point	Diffuse	Total
Female	35.9	64.1	276
Male	41.6	58.4	269
Brand			
AO	40.8	59.2	184
North	37.6	62.4	173
Survivair	37.8	62.2	188
Fit Test			
1	43.4	56.6	189
2	37.3	62.7	177
3	35.2	64.8	179
Exercise			
NB	42.9	57.1	14
DB	25.0	75.0	12
SS	18.2	81.8	11
UD	50.0	50.0	10
Talk	36.4	63.6	11

DISCUSSION

The categorical analysis of leak site distributions found no significant differences between genders and leak shapes or among respirator brands and fit tests. The nonsignificant difference between genders was the same as in our previous study to test the association of face seal leak sites and facial dimensions.[18] As illustrated in Figure 4, we did observe significantly different leak site distributions between this study and that study in which only one fit test was performed on each subject. A test for independent proportions found that the distributions in the two studies for both genders and all subjects were significantly different ($p < 0.001$).[15] The leak sites with the greatest differences were Nose-Chin with 23.8% fewer leaks in this study, followed by Nose-Cheek with 19.4%

TABLE V. GENMOD Analysis

	Significant Parameter Estimates ($p < 0.10$)					
	Leak Site			Leak Shape		
	Nose	Cheek	Chin	Nose	Cheek	Chin
First Level						
Gender	0.139					
Test			−0.055	0.100		
Brand					−0.220	
Size					0.480	
Second Level						
Biectoorbitale breadth						
Bizygomatic breadth (face width)		−0.139			−0.244	
Bigonial breadth	0.228	−0.167		0.442	−0.325	
Menton-sellion length (face length)			−0.660			−1.044
Menton-subnasale length			0.500			0.789
Subnasale-sellion length			0.646			1.013
Biocular breadth						
Nasal root breadth			0.392			0.570
Nose breadth			−0.215			−0.469
Lip length						
Bitragion-menton arc		0.037			0.100	
Bitragion-subnasale arc			0.113			0.177
R^2 for facial dimension	0.073	0.104	0.123	0.144	0.065	0.082
Logistic regression[A]						

[A]Logistic regression using facial dimensions with significant parameter estimates as independent variables in the model.

more leaks in this study, Nose with 18.6% fewer leaks, and Cheek with 11.5% more leaks (three of the four involving the nose and two involving the cheek).

In the previous study, we found that about 52.7% of the 110 identified leaks where at the nose, 13.6% were at the cheek, and 33.6% were at the chin; whereas in this study 36.7% of the 545 identified leaks were at the nose, 40.2% were at the cheek, and 23.1% were at the chin. The subjects in the previous study were of mixed racial origin (Asian, South Asian, African-American, Caucasian, and Hispanic) and had significantly larger biectorbitale breadth, bigonial breadth, menton-sellion length, menton-subnasale length, bitragion-menton arc, and bitragion-subnasale arc than the all-Caucasian subjects in this study. The differences between the percentages of nose and cheek leaks in the two studies may have been related to the differences in these dimensions, implying that leak location may vary among racial or ethnic groups.

That leak site distributions by respirator brand were not significantly different ($p = 0.549$) was not an unexpected result, since the facepieces were basically of the same shape. The Survivair respirator did have a flat sealing surface, whereas the other two respirators had a more rounded surface, indicating that the type of sealing surface may not affect leak location. When the leak site distributions for respirator brand were broken down by size (small, medium, large) it was found that the site distributions for the three AO sizes were significantly different ($p = 0.015$), while those for the North and Survivair respirators were not ($p = 0.453$ and 0.171, respectively).[15]

Of all of the factors tested, only leak site distributions among fit tests were nearly significantly different ($p = 0.079$). When these data were sorted by gender, distributions for females were significantly different ($p = 0.044$), while those for males were not ($p = 0.090$), indicating that gender may affect differences in leak location among fit tests.

The categorical analysis of leak shape distributions also found no significant differences between genders, among respirator brands, or among fit tests. As with leak sites, the nonsignificant difference in leak shapes between genders was the same as in our previous study.[18] However, the nonsignificant differences among fit tests was unexpected. Crutchfield et al.[12] found that much of the variation in fit test results could be attributed to repeated mask donnings. It would be reasonable to assume that variation in fit during repeated donnings could be attributable to variation in leak size and shape as described by Krishnan et al.[4]

TABLE VI. P-values for Significant Differences Between Facial Dimensions of Leak Site Subsets by GLM ANOVA

	Leak Site		
Facial Dimension	Nose	Cheek	Chin
Biectoorbitale breadth			
Bizygomatic breadth (face width)			
Bigonial breadth	0.044		
Menton-sellion length (face width)		0.067	
Menton-subnasale length			
Subnasale-sellion length	0.017		
Biocular breadth			
Nasal root breadth			
Nose breadth		0.080	
Lip length			
Bitragion-menton arc	0.028	0.028	
Bitragion-subnasale arc	0.038		0.038

When comparing categorical results with our previous study,[18] it was interesting to note that the number of leaks identified on females and males was almost equal in both studies, 50.6% and 49.3%, respectively, in the current study and 49.1% and 50.1% in the previous study. A test for independent proportions[15] found that the distributions of shapes for females and all subjects in the two studies were not significantly different ($p = 0.872$ and $p = 0.118$, respectively); however, those for males were significantly different ($p < 0.001$). The distribution of leak shapes for all subjects in this study included 38.7% point leaks and 61.3% diffuse leaks, which was not significantly different from the previous study in which 27.3% were point leaks and 72.7% were diffuse leaks ($p = 0.086$). These results are similar to those reported by Cohen.[9] These consistencies further support the suggestion that equations for leak flow and aerosol penetration models would be best described by those for complex shapes.[1–3]

While the categorical analysis did not find any significant leak site or shape distributions among the primary factors tested, the GENMOD analysis identified a number of significant parameter estimates for leak sites and shapes among the test factors and facial dimensions (Table V). Only gender and bigonial breadth affected the probability of observing nose leak sites, while no test factors and only three facial dimensions (bizygomatic breadth, bigonial breadth, and bitragion-menton arc) affected the probability of observing a cheek leak. The probability of observing a chin leak was affected by fit test sequence and 6 of the 12 facial dimensions (menton-sellion length, menton-subnasale length, subnasale-sellion length, nasal root breadth, nose breadth, and bitragion-subnasale arc). The shape of a nose leak was affected by fit test sequence

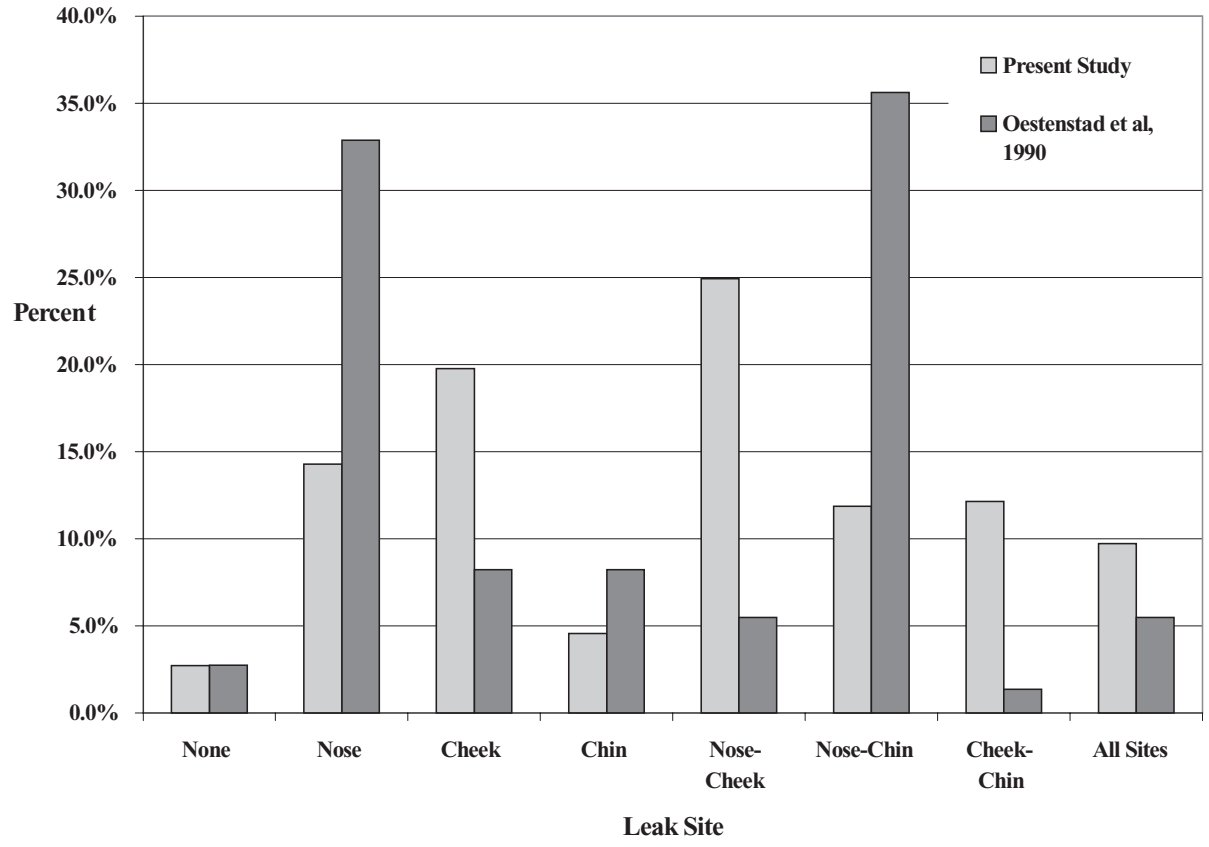


FIGURE 4. Leak site distributions for all subjects in the present study and in Oestenstad et al.[18]

and bigonial breadth; the shape of a cheek leak was affected by respirator brand and size, and by three facial dimensions (bizygomatic breadth, bigonial breadth, and bitragion-menton length); the shape of a chin leak was affected by the same facial dimensions that affected the probability of observing a chin leak. It is interesting to note that more factors and facial dimensions had significant parameter estimates for chin leak sites and shapes despite the fact that they were the least prevalent leak type (23.1%). Also, facial dimensions that affected nose and/or cheek leak sites and shapes, and chin leak sites and/or shapes were mutually exclusive.

Of the two dimensions used to define the NIOSH respirator test panel,[17] decreasing bizygomatic breadth (face width) increased the probability of observing a cheek leak and that it would be more likely to be diffuse in shape; decreasing menton-sellion length (face length) would increase the probability of observing a chin leak and that it would be more likely to be diffuse in shape. These effects would tend to support the utility of the NIOSH panel dimensions[17] in that they are predictive of the occurrence of leaks at these sites and their shape. The relatively large number of significant parameter estimates for facial dimensions compared with the test factors may imply that the shape of the wearer's face is more important in predicting leak location and shape than the test factors. However, logistic regression models using facial dimensions with significant parameter estimates as independent variables and leak site or leak shape as the dependent variables produced very low R^2 values (Table V). Therefore, the above associations must be interpreted with some circumspection.

When comparing facial dimensions between subjects with and without a given leak, those with the leak had facial dimensions greater than those without the leak in 29 of 36 comparisons, and in seven of the eight comparisons with significant p-values, dimensions of subjects with the leak were greater than those without. However, when the data were sorted by gender, there was essentially no difference between those with a leak and those without. These results would again indicate that facial dimensions may be more important factors in identifying where a face seal leak would occur and that they would be affected by gender.

CONCLUSIONS

The study factors of gender, respirator brand, and test repetition failed to show any significant effect on leak location or shape in the categorical analysis. However, there was a significant difference in leak site distributions for the different sizes of AO respirators and a significant difference in fit test leak site distributions for females, indicating that there may be an interaction of size within respirators and gender within fit test that could not be evaluated by this study design. Interpretation of the GENMOD analysis implies that facial dimensions may be more important in defining the location and shape of leak sites than the study factors, and that gender may have an effect.

Comparisons between the results of this and our previous study,[18] were instructive for both leak shapes and sites. Based on the large proportion of diffuse leaks in both studies, slit-like leaks would be most appropriate on mannequins used in laboratory studies of respirator leakage and in the development of flow and penetration models.[1–3] That we observed significantly different leak site distributions between the two study groups, and the groups were significantly different in racial/ethnic composition and facial dimensions, would again indicate that facial dimensions would be more important in determining leak sites and that race/ethnicity and gender may also be a factor. This and the results of the GENMOD analysis would indicate that an individual's facial structure, possibly influenced by gender and race/ethnicity, may be an important determinant in the location and shape of leak sites on half-mask respirators. If this is the case, respirator manufactures should consider facial shapes as well as size when designing respirators. Likewise, they should be considered by respirator program administrators when selecting a specific respirator for an individual. These results also indicate that current work using three-dimensional scanning of facial features may be the best approach in determining where and how a respirator worn by an individual might leak.

In their pioneering work on human variability and respirator sizing, McConville and Churchill[19] discussed the many design challenges of gender and racial and ethnic variability. In regard to gender, they noted, "In addition to the difference in size, the female head and face has been described as usually more rounded and relatively more gracile so that in sexing a skull the initial impression of descriptive features, rather than size per se, is often the deciding factor."[p.12] Such differences among groups and individuals can be best assessed by three-dimensional scanning rather than traditional anthropometric measurements.

The results of this study are limited to Caucasian respirator wearers, the sample size may have been too small to detect differences that actually existed (Type II error), and it was too small to provide any information on age-related variability of facial dimensions. Although all anthropometric measurements were made by one investigator and measurement consistency was tested throughout the study, it is possible that there was systematic error in measurements that could have affected the results.[20]

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