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**FACTORS AFFECTING RESPIRATOR LEAK SITES AND SHAPES**

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## SIGNIFICANT FINDINGS

This study resulted in significant findings related to the correlation of facial dimensions and respirator fit, the distribution of leak sites and shapes, facial dimension differences for subjects with specific types of leaks, and the persistence of streamlining patterns at elevated breathing rates. Although seven facial dimensions were found to have significant correlation coefficients with respirator fit, they were poor predictors of fit in both linear and logistic regression models. Correlation was found to be strongly affected by gender. Of the dimensions currently used to define the half-mask respirator test panel, only face length was found to be significantly correlated to fit. Also, neither of the dimensions were included in any of the linear or logistic models for predicting respirator fit.

Analysis of leak site data found a very high proportion of cheek leaks and multiple leaks that included the cheek, and a high proportion of nose leaks. The distribution of leak sites was not affected by gender, respirator brand, or fit test repetition. There was no significant difference between leak shape distributions for gender, respirator brand, or fit test exercise.

Facial dimensions for subjects in leak site categories were significantly different in only one dimension for all subjects and females; however, ten dimensions were significantly different for males. There were few significant differences in the two-way comparisons of dimensions for subjects in a leak site category and their comparison groups. Logistic regression analysis found that subject, test repetition, and respirator brand were not significant in any of the models to predict the probability of a leak at any of the primary sites; and gender was only significant in the model for cheek leaks.

The fit tests on a mannequin fitted with a half-mask respirator over a range of work rates, and corresponding inspiratory flow rates, resulted in less developed visual streamlining patterns at the higher rates. In addition, bias associated with in-facepiece sampling was found to significantly decrease as inspiratory flow rate increased.

#### USEFULNESS OF FINDINGS

The results of this study will contribute to the understanding of the distribution of respirator leak sites and shape, and will have both theoretical and practical applications. Knowledge of these parameters may contribute to more accurate theoretical modeling of respirator leakage. Determination of the persistence of streamlining flow at high breathing rates may partially explain the lack of correlation between laboratory and workplace fit factors. Based on the results of the association of anthropometric dimensions with leak sites and respirator fit observed in this study and in our previous work, it appears that the facial dimensions currently used to define half-mask respirator test panels needs to be re-evaluated. These associations could be useful to respirator program administrators in the selection of a model or size of respirator for an individual wearer. They may also contribute to the improvement of facepiece design, thus providing greater protection to the user.

## ABSTRACT

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, by fit test exercise, or by gender, to determine the association these study factors and facial dimensions with respirator fit, and to determine if air flow streamline patterns persist at elevated breathing rates. This was accomplished by developing an exposure system for a fluorescent tracer aerosol, conducting 329 quantitative fit tests on human subjects wearing three different brands of half-mask respirator, and conducting 44 tests on subjects performing one of the five fit test exercises. Tests with the fluorescent aerosol were performed on a mannequin fitted with a half-mask respirator at a range of breathing rates. At the conclusion of these tests, the respirators were removed and leak sites and evidence of streamlining were visually identified. Inferential and regression statistical methods were used to test the effect of the study factors and facial dimensions on the distribution of the observed leak sites and shapes and respirator fit. Only one of the facial dimensions used to define the respirator test panel was found to be significantly correlated to fit; and neither of the dimensions were included in regression models to predict fit. About 67% of the observed leaks occurred at the cheek of multiple sites which included the cheek. Point leaks accounted for only 38% of the leaks. The distributions of leak sites and shapes were found not to be affected by gender, respirator brand, test repetition, or test exercise. Few of the comparisons of facial dimensions for subjects in leak categories were found to be significant, and regression models found that none of the study factors had a significant effect on the probability of a leak occurring at a specific site. Evidence of

streamlining was observed on about 44% of the test subjects, and mannequin tests indicated that streamlining patterns decayed as breathing rates increased. The results of this study indicates that leak sites and shapes do not vary between genders, among respirator brands, or among repeated fitting of a respirator. Facial dimensions were found to be poor predictors of respirator fit, and that dimensions other than those currently used may be more appropriate to define test panels whose fit is intended to be representative of worker populations.

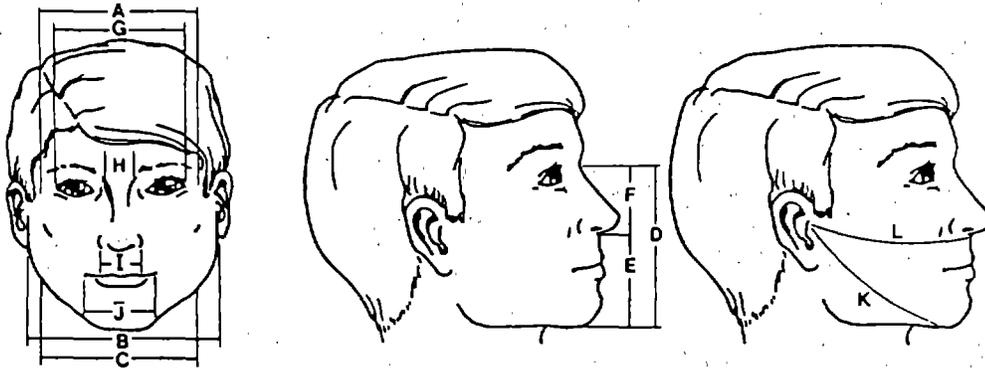
## PURPOSE

The purpose of this research project was to study factors which may affect leak site and shape on half-mask respirators, and air flow patterns within the respirator facepiece. This was accomplished by performing respirator fit tests on human subjects using a fluorescent tracer aerosol to identify face seal leak sites and shapes. The fluorescent aerosol was also used to observe the persistence of streamlining deposition patterns on a mannequin headform at increased breathing rates. The visual evidence of streamlining on the mannequin was supplemented by measuring sampling bias at different breathing rates. Specific objectives of the study were to: 1) determine the intra-subject variability of leak sites and shapes by performing multiple tests on the same subject wearing the same respirator, 2) determine the variability of leak sites and shapes for different respirators by performing multiple tests with different respirators on the same subjects, 3) determine if leak sites and shapes change between the exercises of a fit test, 4) confirm characteristic facial dimensions of subjects who are identified with the streamlining phenomenon, and 5) determine if streamlining persists at higher breathing rates.

## MATERIALS AND METHODS

This work was completed by constructing an aerosol generation system and exposure chamber, and evaluating the size distribution and concentration characteristics of the aerosol. After selection of the fluorescent test material and evaluation of the exposure system, exposure studies on human subjects were initiated using the following protocol: 1) prospective subjects reviewed the respiratory questionnaire and informed consent forms, 2) facial dimensions of selected subjects were measured with sliding and spreading anthropometric calipers and metal

tape, 3) a pre-test frontal photograph of the subject was taken, 4) the subject was fitted with the appropriate size of respirator, 5) a quantitative fit test (QNFT), using a forward light-scattering photometer, was performed with the fluorescent tracer aerosol, 6) after the test the respirator was carefully removed, leak sites identified and measured, and a post exposure photograph taken. The protocol was approved by the UAB Institutional Review Board, and a detailed description is given in Appendix I. The facial dimensions measured are illustrated in Figure 1.



- |   |   |
|---|---|
| A. Bletoorbital Breadth                           | F. Subnasale-Nasion Length<br>(Nose length) |
| B. Bizygomatic Breadth<br>(Face Width)            | G. Bicocular Breadth                        |
| C. Bigonial Breadth                               | H. Nasal Root Breadth                       |
| D. Menton-Nasion Length<br>(Face Length)          | I. Nose Width                               |
| E. Menton-Subnasale Length<br>(Lower Face Length) | J. Lip Width                                |
|   | K. Bitragion-Menton Arc                     |
|   | L. Bitragion-Subnasale Arc                  |

FIGURE 1. - Facial Dimensions

Observation and documentation of leak sites was performed under ultraviolet lighting. The subjects' skin was pre-treated with sun screen to lower natural skin fluorescence to improve the detection of some light, diffuse leaks. Identified leaks were classified into the leak site categories given in Table I. Leak shape were classified as either point or diffuse; point leaks were those on which the aerosol was

deposited on a small cross-sectional area (less than one centimeter) of the face, and diffuse leaks were those where the aerosol was deposited over a wider area of the face (greater than one centimeter).

Leak Category	Description
0	No Observed Leaks
1	Nose Leaks Only
2	Cheek Leaks Only
3	Chin Leaks Only
4	Nose & Cheek Leaks
5	Nose & Chin Leaks
6	Cheek & Chin Leaks
7	Nose, Cheek, & Chin Leaks

Steps 3 through 6 of the protocol were also performed for the mannequin tests to observe the persistence of streamlining patterns. In addition, a series of fit tests was performed on the mannequin fitted with one brand of respirator to measure sampling bias at the different breathing rates. These tests were performed with a condensation nuclei counter fit test device which used room aerosols as the test agent.

The effects of intra-subject fit variability and respirator configuration on leak sites and shapes was determined by conducting three tests with the same subject wearing one size of three different brands of half-mask respirators; resulting in a total of nine fit tests. This approach follows that of daRoza et al. (1983). The respirator brands selected were the AO 5-Star Series<sup>®</sup>, The North 7700 Series<sup>®</sup>, and the Survivair Series 2000<sup>®</sup> respirators. Each test consisted of the six-exercise sequence of normal breathing, deep breathing, moving the head from side-to-side, moving the head up-and-down, talking, and normal breathing. The effect of fit test exercise on leak site and shape was

evaluated by conducting a series of five tests in which the subject repeated one of the above exercises throughout each fit test with the North respirator. This sequence resulted in five tests on each subject.

Breathing rate tests were performed on a mannequin headform fitted with the North half-mask respirator. The headform was plumbed to breath through the mouth only, and was connected to a NIOSH-type breathing machine. The machine is designed to simulate breathing patterns at various work rates. Work rates and corresponding minute volumes and maximum inspiratory flow rates which were initially tested are shown in Table II. (Nelson et al., 1972) Leaks were simulated by a 1 X 10 millimeter slit positioned at the nose, cheek, and chin.

Work Rate (kg•m/min)	Breathing Rate (resp/min)	Minute Volume (liters)	Max. Inspiratory Flow (l/min)
Sedentary	15	10	40
208	21	21	70
415	23	30	94
622	23	37	114
830	30	55	152
1107	40	75	185

Sampling bias determinations were made on the mannequin fitted with the North respirator, but with leaks simulated by 20, 18, and 14 gauge hypodermic needles located at the nose, cheek, and chin. Particle counts were measured in the mannequin ( $C_i$ ), inside the respirator ( $\hat{C}_i$ ), and outside the respirator ( $C_o$ ); bias was calculated as the difference between  $C_i$  and  $\hat{C}_i$  divided by  $C_i$ .

Data collected from the human subject tests were entered into a computer spreadsheet and organized into the general data categories: 1) demographic information, 2) anthropometric data, 3) leak site

classifications and size, and 4) fit test data. The data analysis was performed using SOLO<sup>2</sup> and EPISTAT<sup>3</sup> statistical software. Two-tailed tests of hypothesis was used at an alpha value of 0.05.

Prior to analysis, basic summary statistics were calculated for all variables. After making appropriate transformations, differences between protection factors (PFs) of subjects with a leak type and those without the leak was tested by parametric and non-parametric two-sample tests and 2-way ANOVA. Correlation between facial dimensions and PFs was determined by parametric correlation coefficients, and dimensions with significant correlations were modeled using step-wise multiple linear regression. The categorical distribution of leak sites and shapes by gender and respirator brand was tested by two-way chi-squared or exact tests. The categorical distribution of leak shapes by exercise was also tested by an exact test.

For the primary objectives of the study, conditional logistic regression was used to test for the effect of intra-subject variability, between-respirator variability, and facial dimensions on the probability of observing a leak. The probability of observing a leak (i.e., outcome = leak at a site; YES or NO), was modeled using the independent variables respirator brand, subject, test replication (1, 2, 3), and other important factors such as gender and facial dimension. This method was applied to test the independent variables on the probability of observing a leak shape (point or diffuse) and streamlining (yes or no).

## RESULTS AND DISCUSSION

### Aerosol and Exposure Chamber

Tinopol CBS-X<sup>o</sup> was selected as the test agent in this study. This compound is water soluble, non-mutagenic, non-carcinogenic, and of low toxicity. It also has a much higher fluorescent efficiency than the

coumarin-type used in our previous studies (Oestenstad et al., 1990a) and provided better definition of leak sites. Tinopol-CBS-X's solubility (up to 2.5%) allowed sufficient flexibility in controlling the particle size of the test aerosol, for the output size characteristics of the Liu nebulizer (Liu and Lee, 1975) used in the aerosol generating system.

The aerosol generating and exposure system consisted of four Liu-type nebulizers connected in a parallel configuration, a heated drying tube, two diffusion drying tubes in series, a distribution plenum, and a Air Techniques System, Model TDA-71,<sup>®</sup> 2.5 m<sup>3</sup> exposure chamber with air lock. The test aerosol introduced into the exposure chamber had a mass median aerodynamic diameter of 0.9  $\mu\text{m}$  and a geometric standard deviation of 1.2. By optimizing nebulizer and chamber operating parameters, chamber aerosol concentrations in the range of 15 to 20 mg/m<sup>3</sup> were achieved.

#### **Descriptive Statistics**

Initially, 67 subjects were admitted to the study; however, 26 were dropped because they had failed to complete any or even a portion of the required tests. This attrition not only reduced the absolute number of subjects included in the study, but also consumed time and resources which could have been better utilized on more cooperative subjects.

The resulting sample used in the analysis included 20 white females and 21 white males. Some of these subjects did not complete all of the tests required for the inter-respirator ( $n = 9$ ) 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. A total of 329 tests were performed for the inter-respirator evaluation, and 44 for the inter-exercise evaluation.

The age range of the subjects was from 20 to 55 years with an average of 30 years. The facial dimensions measured for the subjects in

this study are shown in Table III, and a plot of their distribution on the half-mask test panel (Hack and McConville, 1978) is shown in Figure 2. As expected, these data were normally distributed, and most dimensions for females were significantly smaller than those for males (McConville et al., 1972). Figure 1 indicates that the subjects were within the face length and lip width size ranges thought by Hack and McConville (1978) to be representative of a working population.

TABLE III - Facial Dimensions of Test Subjects			
FACIAL DIMENSION (cm)	Mean (Standard Deviation)		
	All Subjects (n = 41)	Females (n = 20)	Males (n = 21)
Biectoorbitale Breadth (BIECTO)	11.13 (0.82)	10.73 <sup>3</sup> (0.70)	11.53 (0.72)
Bizygomatic Breadth (BIZYGO)	13.34 (0.73)	12.98 <sup>3</sup> (0.77)	13.68 (0.48)
Bigonial Breadth (BIGON)	10.23 (0.58)	10.05 <sup>3</sup> (0.62)	10.41 (0.47)
Menton-Nasion Length (MEN_NAS) <sup>1</sup>	11.84 (0.64)	11.56 <sup>3</sup> (0.63)	12.11 (0.52)
Menton-Subnasale Length (MEN_SUB)	6.95 (0.51)	6.81 (0.46)	7.11 (0.52)
Subnasale-Nasion Length (SUB_NAS)	5.24 (0.38)	5.16 (0.38)	5.32 (0.37)
Biocular Breadth (BIOC)	8.73 (0.38)	8.58 <sup>3</sup> (0.31)	8.88 (0.38)
Nasal Root Breadth (NAS_RB)	1.59 (0.16)	1.54 <sup>3</sup> (0.17)	1.65 (0.13)
Nose Width (NOS_W)	3.39 (0.34)	3.10 <sup>3</sup> (0.20)	3.56 (0.35)
Lip Width (LIP_W) <sup>2</sup>	4.96 (0.37)	4.84 <sup>3</sup> (0.38)	5.07 (0.31)
Bitragion-Menton Arc (BIT_MEN)	29.06 (2.63)	27.45 <sup>3</sup> (1.91)	30.70 (2.19)
Bitragion-Subnasale Arc (BIT_SUB)	26.42 (1.47)	25.80 <sup>3</sup> (1.26)	27.07 (1.39)

1 - Face Length: used to define half-mask respirator test panel  
2 - Lip Width: used to define half-mask respirator test panel  
3 - Significant difference between genders for this dimension.

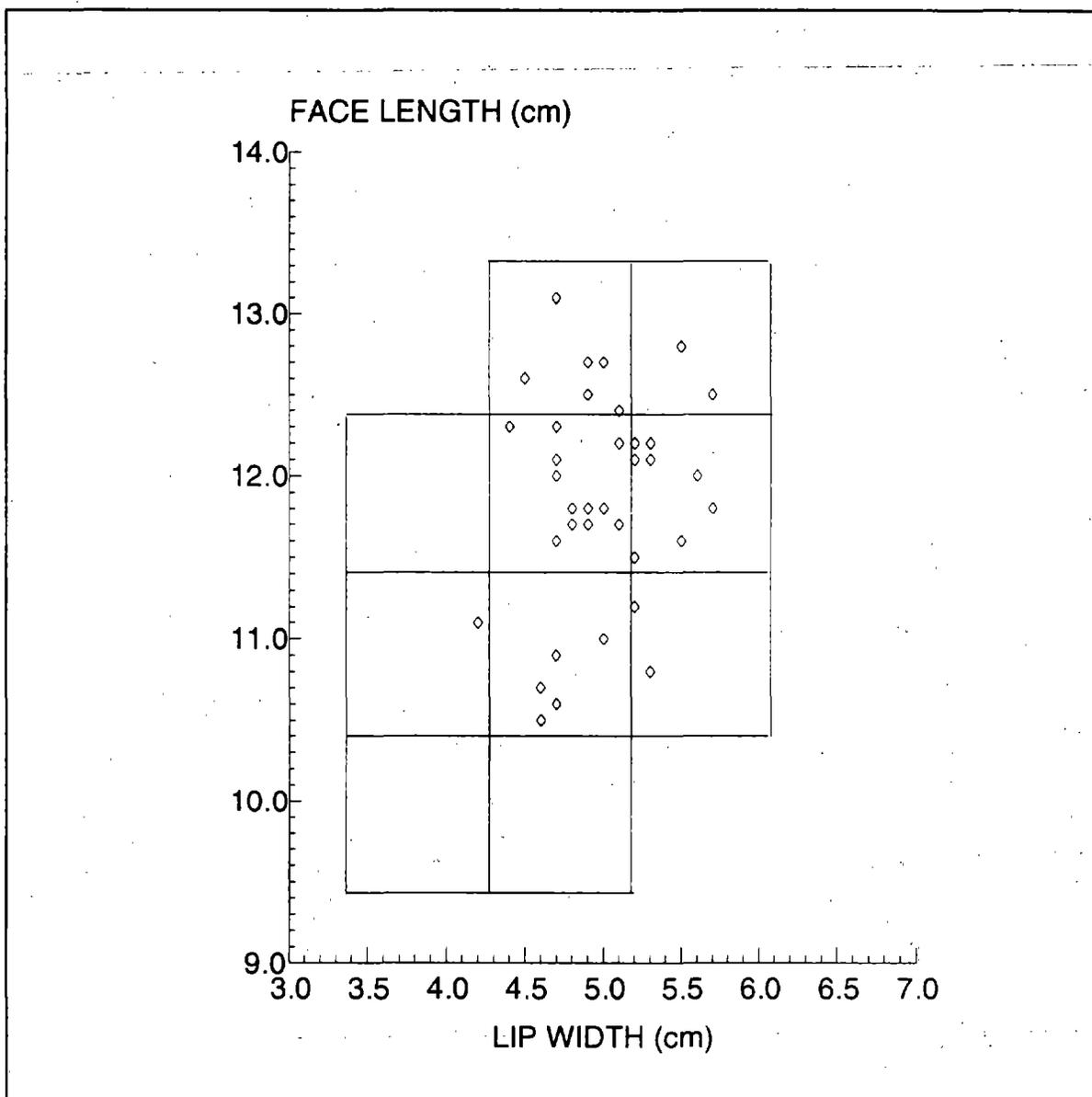


FIGURE 2 - Distribution of Test Subjects on Respirator Test Panel

The protection factors (PFs) for all of the tests for inter-respirator variation ( $n = 329$ ) ranged from 6 to 39820 with a median of 2005. These data were not normally distributed (Hintze, 1991); therefore, a log-transformation was performed to achieve normality. However, the goodness of fit test found the natural logarithms of the protection factors (LN\_PFs) were not normally distributed. An examination of the histogram of these data showed that the data followed

a normal distribution function, but were truncated on the right, i.e. appeared to have an upper limit. The photometer output from the fit tests was analyzed to determine the maximum PF that could be determined given the limit of detection of the instrument and the chamber concentrations during the fit tests. The average maximum PF was found to be about 33580. Since this value approximated the upper limit of the measured PFs, it was concluded that the truncation in the data was due to the detection limit of the photometer and that the true distribution of LN\_PFs could be assumed to be normal.

The log-transformed data had a geometric mean of 1210 with a geometric standard deviation of 6.81. A two-sample t-test (Hintze, 1991) found the mean LN\_PF for females of 6.854 (geometric mean = 950) was significantly lower than the mean LN\_PF of 7.334 (geometric mean = 1560) for males. A one-way ANOVA and Newman-Keuls post-hoc test (Hintze, 1991) found that the mean LN\_PF of 7.708 (geometric mean = 2225) for the North respirator was significantly greater than the mean LN\_PF of 6.824 (geometric mean = 920) for the Survivair respirator, and the mean LN\_PF of 6.750 (geometric mean = 855) for the AO respirator.

#### **Association Between Facial Dimensions and Fit**

The correlation matrix for the measured facial dimensions and LN\_PF is shown in Table IV. Bizygomatic breadth, menton-nasion length, menton-subnasale length, nasal root breadth, nose width, bitragion mentonarc, and bitragion subnasale arc all had significant positive correlation coefficients with LN\_PF; these results are similar to those we found in our previous study. (Oestenstad and Perkins, 1992) It was noted that of the two dimensions used to define the respirator test panel (Hack and McConville, 1978), only face length (MEN\_NAS) had a significant correlation coefficient with LN\_PF. However, a number of the facial dimensions were also highly correlated. Multicollinearity between facial

dimensions limits the interpretation of individual variables in subsequent regression models. Therefore, facial dimensions not included in those models should not be interpreted as not necessarily being related to fit.

Correlation between measured facial dimensions and LN\_PF for all subjects and by gender are compared in Table V. Inspection of this table shows that the dimensions with significant correlations for females closely matches those for all subjects; indicating that gender is an important factor in the association between facial size and fit. These results support the findings of Johnson (1987) and Gross and Horstman (1990).

It is also apparent from Table V that the sign of five of the coefficients is different by gender. Females have positive coefficients for BIGON, MEN\_NAS, SUB\_NAS, BIOC, and BIT\_MEN while those for males are negative. These results would indicate that respirator fit improves for females as these dimensions get larger, and fit for males deteriorates as they get larger. This observation and the fact that the mean LN\_PF for females was significantly lower than that for males would suggest that, despite being in the same cells of the respirator test panel, the size of the respirator facepieces used in this study were too large for the females. This outcome again is in agreement with Johnson's (1987) observation of the importance of differences in facial dimensions for females and males in the same cell.

The association between facial dimensions and fit was also tested by linear and logistic regression models. Multiple linear regression was performed by the forward, stepwise method, using LN\_PF as the dependent variable and the 12 measured facial dimensions as the dependent variables. (Hintze, 1991) This method assigned weights to outlying

TABLE IV - Correlation Coefficients of Facial Dimensions and LN PF

	BIECTO	BIZYGO	BIGON	MEN NAS	MEN SUB	SUB NAS	BIOC	NAS RB	NOS W	LIP W	BIT MEN	BIT SUB	LN PF
BIECTO	1.000												
BIZYGO	0.579	1.000											
BIGON	0.622	0.567	1.000										
MEN NAS	0.239	0.225	0.280	1.000									
MEN SUB	0.010	0.105	0.008	0.776	1.000								
SUB NAS	0.188	0.164	0.246	0.632	0.166	1.000							
BIOC	0.665	0.545	0.422	0.316	0.377	-0.029	1.000						
NAS RB	0.058	0.082	0.226	0.354	0.143	0.251	0.114	1.000					
NOS W	0.494	0.501	0.408	0.263	0.302	0.043	0.515	0.184	1.000				
LIP W	0.549	0.550	0.527	0.266	0.081	0.266	0.434	0.125	0.519	1.000			
BIT MEN	0.520	0.537	0.504	0.690	0.568	0.294	0.524	0.338	0.590	0.407	1.000		
BIT SUB	0.545	0.817	0.587	0.176	0.092	0.093	0.617	0.114	0.645	0.528	0.538	1.000	
LN PF	-0.042	0.188*	0.059	0.126*	0.111*	0.046	0.078	0.153*	0.188*	0.069	0.150*	0.201*	1.000

\* - Significant Pearson correlation coefficient between facial dimension and LN PF

TABLE V - Correlation Coefficients of Facial Dimensions and LN PF by Gender

	BIECTO	BIZYGO	BIGON	MEN NAS	MEN SUB	SUB NAS	BIOC	NAS RB	NOS W	LIP W	BIT MEN	BIT SUB
ALL SUB	-0.042	0.188*	0.059	0.126*	0.111*	0.046	0.078	0.153*	0.188*	0.069	0.150*	0.201*
LN PF												
FEMALE	-0.084	0.154*	0.133	0.228*	0.181*	0.152*	0.084	0.194*	0.015	0.050	0.264*	0.203*
LN PF												
MALE	-0.174	0.130	-0.119	-0.089	0.001	-0.105	-0.008	0.016	0.214	0.002	-0.089	0.114
LN PF												

\* - Significant Pearson correlation coefficient between facial dimension and LN PF

points to reduce their effect on the estimation of regression coefficients by iterative procedures: it then utilized a heuristic algorithm to select the variables that resulted in the highest coefficient of determination (sequential  $R^2$ ) value for the regression model. The regression coefficients for the dimensions retained in the models developed by these procedures are summarized in Table VI.

TABLE VI - Linear Regression Coefficients			
Independent Variable	Dependent Variable = LN_PF		
	All Subjects	Females	Males
BIECTO	-0.848*	-1.020*	-0.732*
BIZYGO	0.660*	0.939*	
BIGON			
MEN_NAS			
MEN_SUB		-0.793*	
SUB_NAS			
BIOC			
NAS_RB		1.702*	
NOS_W	0.910*		1.90*
LIP_W			
BIT_MEN	0.114*	0.252*	
BIT_SUB		0.122	
Adjusted $R^2$	0.30	0.40	0.31
* - Regression coefficient $\neq 0$			

The results for all subjects was very similar to our previous work (Oestenstad and Perkins, 1992); it included common facial dimensions and the  $R^2$  was about the same. However, unlike the previous work, the  $R^2$  of the gender-specific models in this study did not substantially improve. Again, the facial dimensions used to define the respirator test panel (Hack and McConville, 1978) were not included in any of these models. These results would indicate that facial dimensions are not highly predictive of respirator fit for either gender.

Correlation and linear regression are limited to analysis of data that are in an interval scale. Therefore, conditional logistic regression was utilized to test for the effect of the categorical variables of gender, respirator brand, respirator size, and test and the interval variables of facial dimensions on the probability that PF would be above some critical value. (Hintze, 1991) Since logistic regression requires a dichotomous dependent variable, the measured values of PF were classified as being above or below 2000; i.e., if  $PF \leq 2000$ , then  $PF_{2000} = 0$  and if  $PF > 2000$ , then  $PF_{2000} = 1$ . The critical value of  $PF = 2000$  was chosen because it was very close to the median of the measured PFs, and would provide approximately the same number of observations above and below that value.

The results of the conditional logistic regression analysis are shown in Table VII. Of the categorical variables, only respirator size was included in the model for all subjects. This would seem contradictory to the observation that  $LN\_PF$  was significantly different between genders and among respirator brands. It was also noted that  $BIECTO$ ,  $BIZYGO$ ,  $NAS\_RB$ , and  $NOS\_W$  were facial dimensions common to both the linear and logistic models. For all of these models, the coefficients of determination (sequential  $R^2$ ) and the efficiencies were very low; indicating that fit was correctly classified by the independent variables only 61 to 66% of the time. (Gustafson, 1991)

TABLE VII - Logistic Regression Coefficients			
Independent Variable	Dependent Variable = PF2000		
	All Subjects	Female	Male
Gender		.1	.1
Test			
Respirator			
Size	0.322		
BIECTO	-1.016 <sup>2</sup>	-1.436 <sup>2</sup>	-0.8792 <sup>2</sup>
BIZYGO	0.893 <sup>2</sup>	1.0332 <sup>2</sup>	0.946 <sup>2</sup>
BIGON		0.846	
MEN_NAS			
MEN_SUB			
SUB_NAS			
BIOC			
NAS_RB		2.640 <sup>2</sup>	
NOS_W	0.997 <sup>2</sup>	-2.723 <sup>2</sup>	1.498 <sup>2</sup>
LIP_W		1.000	
BIT_MEN			
BIT_SUB			
Model R <sup>2</sup>	0.120	0.168	0.128
Efficiency <sup>3</sup>	0.611	0.669	0.650
1 - Gender was not included in these models 2 - Coefficient $\neq$ 0 3 - Proportion of predicted PF2000 being correctly classified in comparison to observed values			

### Respirator Leak Sites and Shapes

Faceseal leak sites which were visually identified after the fit test were classified as to their site and shape as previously defined. The observed distribution of leaks for all subjects and by gender is illustrated in Figure 3, and the data are summarized in Table VIII. The distribution of observed leak sites for all subjects was found to be significantly different from the uniform distribution by the Chi-square goodness-of-fit test. (Gustafson, 1991)

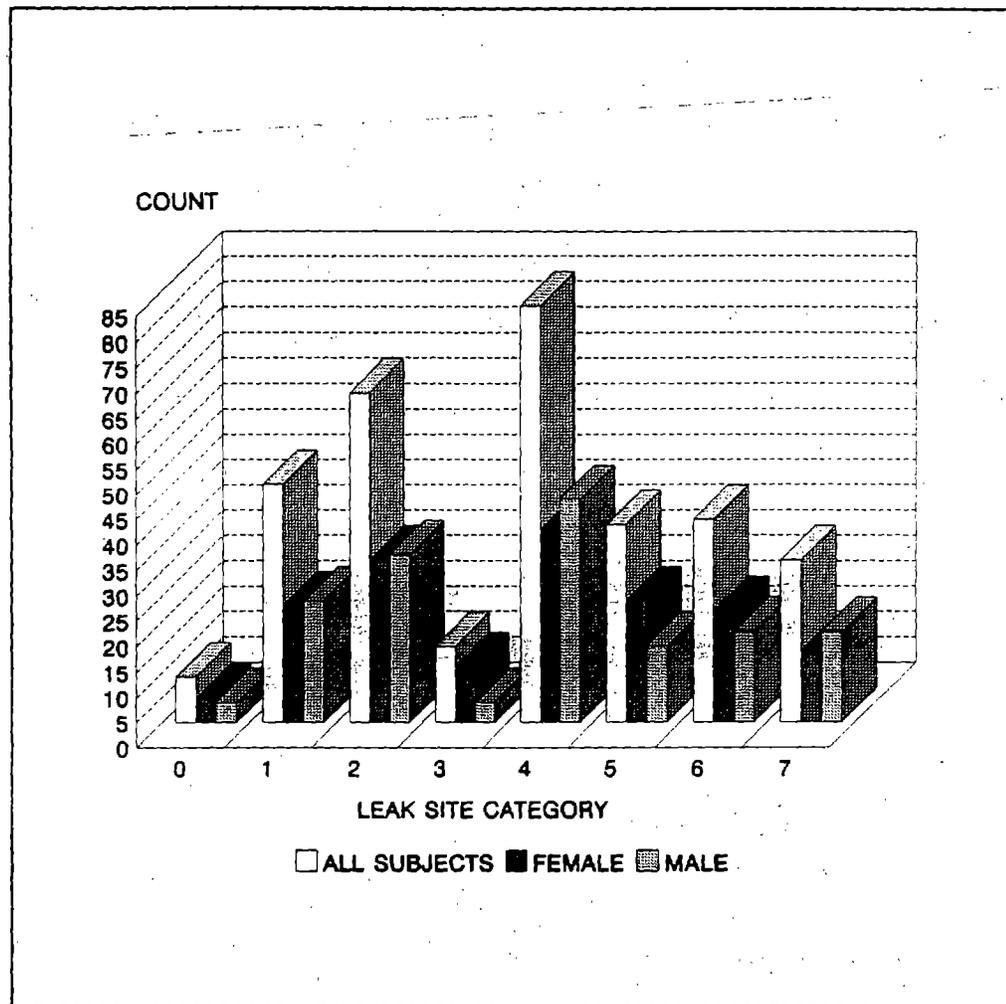


FIGURE 3 - Distribution of Leak Sites by Gender

Gender	Leak Category								Total
	0	1	2	3	4	5	6	7	
Female	5	23	32	11	38	24	22	14	169
Male	4	24	33	4	44	15	18	18	160
Total	9	47	65	15	82	39	40	32	329

$\chi^2 = 6.58 < \chi^2_{0.05,7} = 14.07$ , therefore accept  $H_0$ .

From Figure 3 it is obvious that the largest proportion of leaks were those at the nose and cheek (Leak Category 4), leaks at the cheek was the next most prevalent category (Leak Category 2), followed by nose leaks (Leak Category 1). About 67% of all the tests resulted in leaks

at the cheek or multiple leaks which include the cheek; while about 61% of the tests resulted in leaks at the nose or multiple leaks which included the nose. The high percentage of cheek leaks or multiple leaks which included the cheek is the converse to what was observed in our previous work. (Oestenstad et al., 1990b) A Chi-square test (Gustafson, 1991) found the leak site distributions by gender not to be significantly different.

Leak site categories were also sorted by respirator brand as a test of the variation of leak sites among respirators. These distributions are illustrated in Figure 4, and the data are summarized in Table IX.

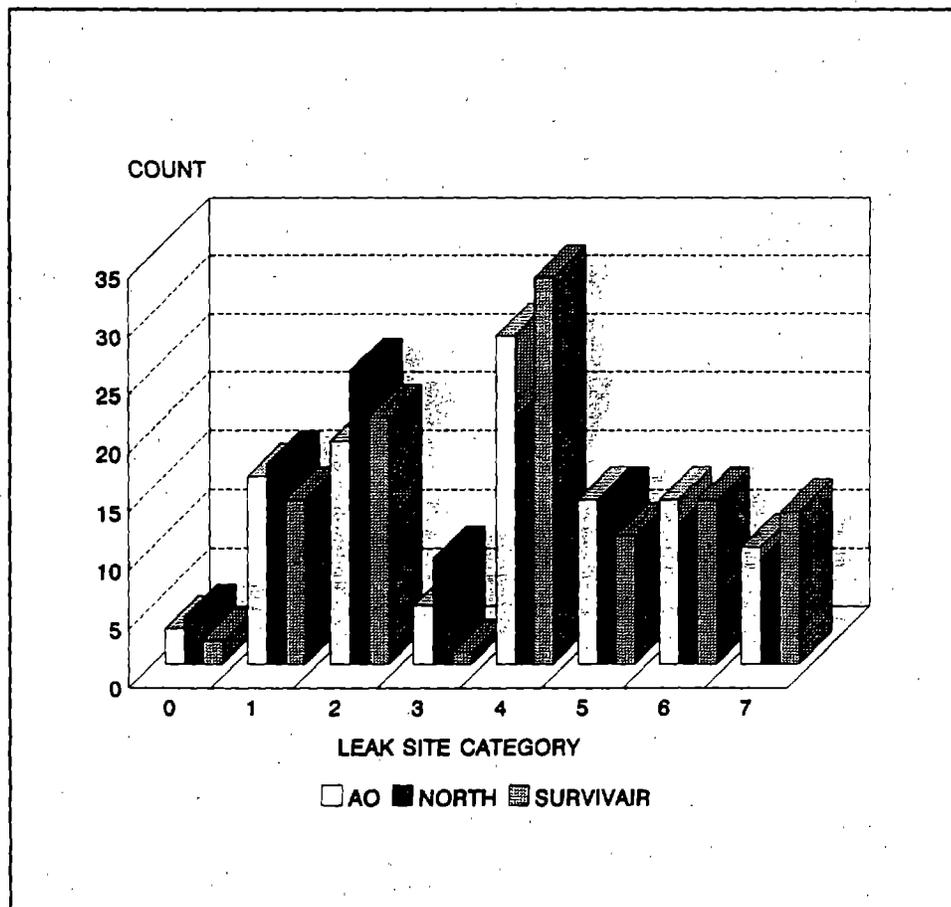


FIGURE 4 - Distribution of Leak Sites by Respirator Brand

Inspection of Figure 4 would indicate that the observed frequencies in each leak categories was fairly consistent among the three respirators.

A Chi-square test found the leak sites not to be significantly different among the three respirators. However, this result may be suspect because the expected count in some cells was less than five. (Gustafson, 1991) An exact test would have been more appropriate in this analysis, but was not included in the available software.

Respirator Brand	Leak Category								Total
	0	1	2	3	4	5	6	7	
AO	3	16	19	5	28	14	14	10	109
North	4	17	25	9	21	14	12	9	111
Survivair	2	14	21	1	33	11	14	13	109
Total	9	47	65	15	82	39	40	32	329

$\chi^2 = 12.28 < \chi^2_{.05,14} = 23.68$ , therefore accept  $H_0$ . May be suspect because expected count < 5

Leak site categories were also sorted by test as a measure of the variation of leak sites among the three repetitions of fit tests with the three brands of respirators. These distributions are illustrated in Figure 5, and the data are summarized in Table X. Again, this result may be suspect because the expected count in some cells was less than five. (Gustafson, 1991)

Inspection of Figure 5 again indicates that the observed frequencies in each leak categories was fairly consistent among the three fit tests. A Chi-square test found the distribution of leak sites not to be significantly different among the three tests. However, this result may be suspect because the expected count in some cells was less than five. (Gustafson, 1991)

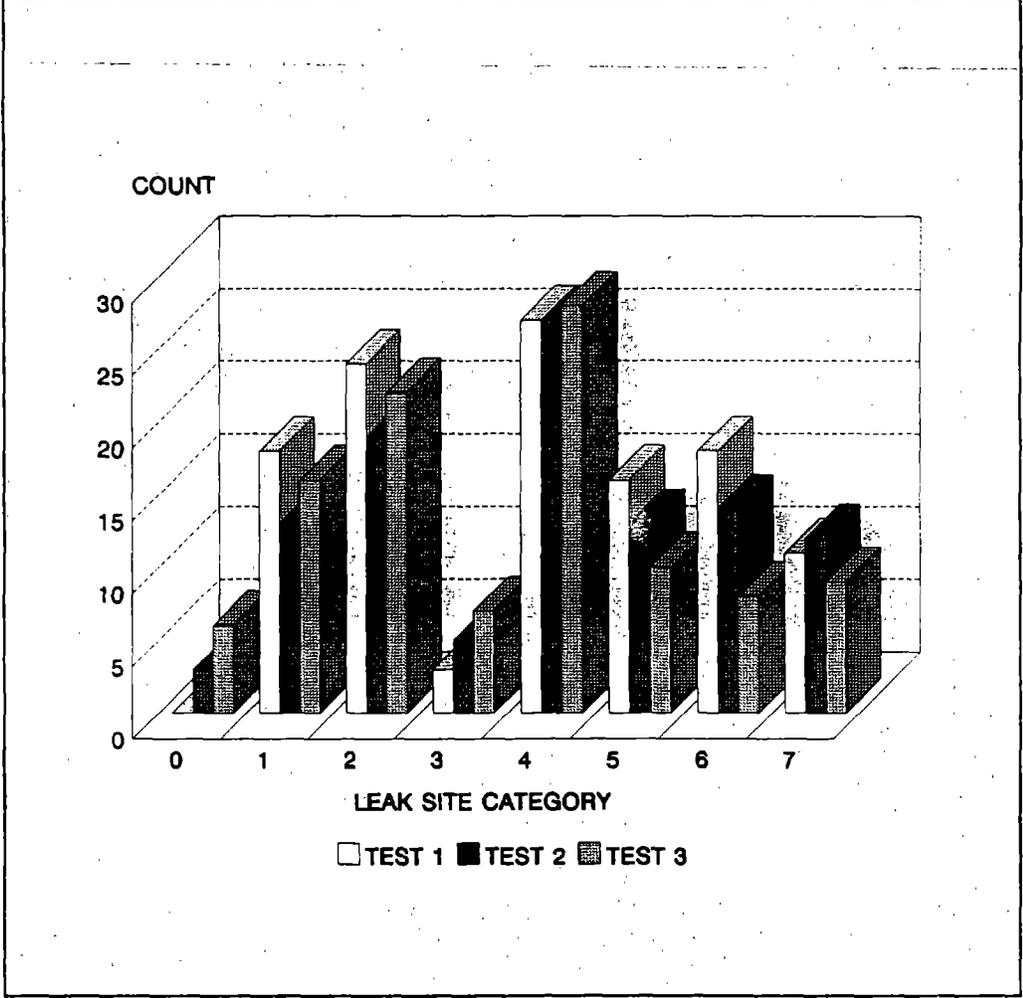


FIGURE 5 - Leak Site Distribution by Fit Test

TABLE X - Leak Site Distribution by Fit Test									
Fit Test	Leak Category								Total
	0	1	2	3	4	5	6	7	
1	0	18	24	3	27	16	18	11	117
2	3	13	19	5	27	13	14	12	106
3	6	16	22	7	28	10	8	9	106
Total	9	47	65	15	82	39	40	32	329

$\chi^2 = 13.78 < \chi^2_{0.05, 14} = 23.68$ , therefore accept  $H_0$ . May be suspect because expected count  $< 5$

Leak site categories were summarized for the fit tests in which subjects repeated the same exercise throughout the test as a measure of the variation of leak sites among the exercises within a fit test; these

results are shown in Figure 6. The very low frequencies in the cells area result from the fact that only 4 of the 41 subjects completed any of the five single-exercise tests. The problem of subject cooperation and attrition was been previously discussed. No comments or statistical tests are presented because of the very small numbers in this part of the study.

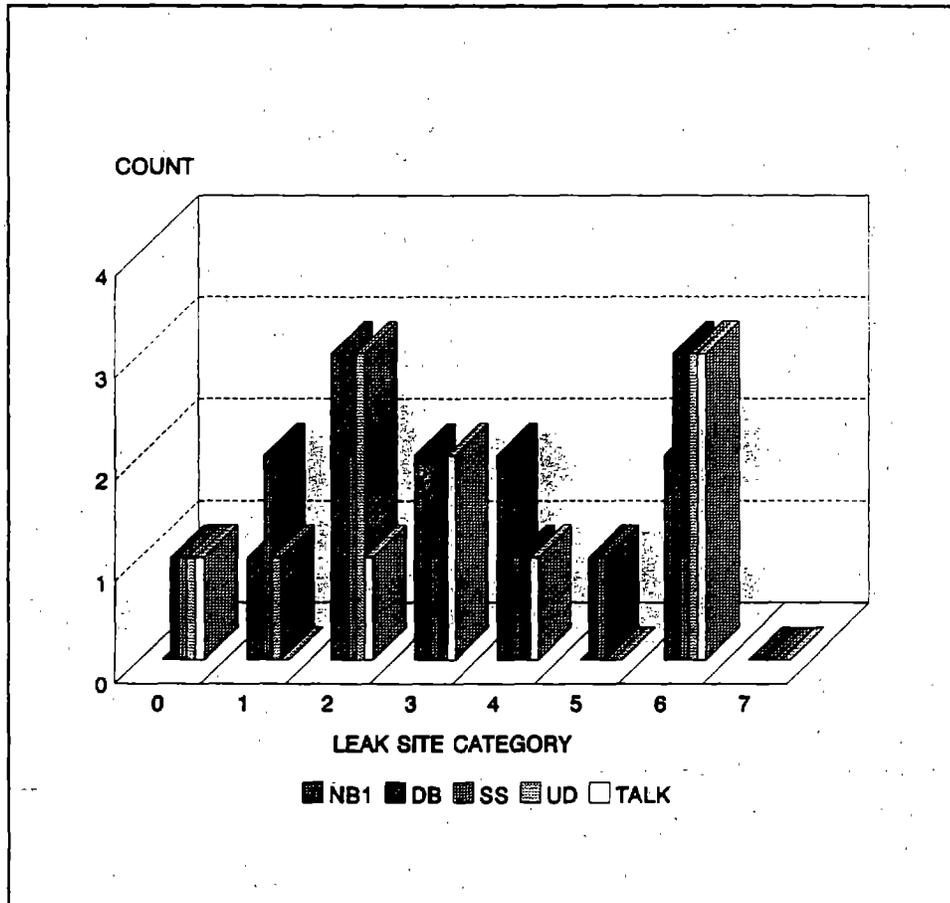


FIGURE 6 - Leak Site Distribution by Fit Test Exercise

Observed leak shapes were classified by gender, respirator brand, and fit test exercise; the data are summarized in Tables XI, XII, and XIII. It should be noted that for the tests to measure inter-respirator variation, there were 545 leaks observed on 41 subjects because many of the subjects had more than one leak site, i.e. nose and cheek (Leak Category 4), nose and chin (Leak Category 5), cheek and chin (Leak

Category 6), and nose, cheek, and chin (Leak Category 7). In the tests to measure exercise variation, there were 58 leaks observed on 4 subjects. The shape of individual leaks was assumed to be independent on subjects with multiple leaks.

Leak shape distributions for all subjects and each gender were tested by the one-sample binomial test. (Gustafson, 1991) The proportion of point leaks of 0.387 for all subjects was found to be significantly less than 0.5 ( $p < 0.001$ ). The binomial test on the data for females found the proportion of point leaks of 0.358 to be significantly less than 0.5 ( $p < 0.001$ ); and the test on the data for males found the proportion of point leaks of 0.416 to also be less than 0.5 ( $p = 0.007$ ). A Chi-square test found the distributions of leak shapes for females and males shown in Table XI not to be significantly different. (Gustafson, 1991) These results differ from those in our previous work (Oestenstad et al., 1990b) in that the proportions of point leaks for both genders was significantly different from 0.5, and in this study there was not a significant difference between genders in the proportion of point leaks.

Leak Shape	Gender		Total
	Females	Males	
Point	99	112	211
Diffuse	177	157	334
Total	276	269	545
$\chi^2 = 1.674 < \chi^2_{.05, 1} = 3.841$ , therefore accept $H_0$ .			

The distributions of leak shapes by respirator brands shown in Table XII were tested by the one-sample binomial test (Gustafson, 1991), and the proportions of point leaks for all brands were found to be significantly less than 0.5. Differences among the shape distributions among the three brands were tested by the Chi-square test and found not

to be significantly different. The distributions of leak shapes by repetition of fit test for each brand were also tested by the Chi-square test, and none were found to be significantly different: although the calculated Chi-square value for the three tests on the AO brand was very close to the critical value resulting in a p-value of 0.056.

Leak Shape	Respirator Brand			Total
	AO	North	Survivair	
Point	73	63	72	208
Diffuse	105	107	114	326
Total	178	170	186	534

$\chi^2 = 0.578 < \chi^2_{0.05, 2} = 5.991$ , therefore accept  $H_0$ .

Despite the small number of observed leaks, the distributions of leak shapes by fit test exercise were compiled and are shown in Table XIII. The binomial test found none of the proportions of point leaks for each exercise to be significantly different from 0.5. (Gustafson, 1991) However, this may have been due to the small numbers of trials rather than the true distribution of leak shapes. Distributions of leak shape for the exercises was tested by an extended exact test (Freeman and Halton, 1951) and found not to be significantly different.

Leak Shape	Test Exercise					Total
	Normal Breathing	Deep Breathing	Side-to-Side	Up-and-Down	Talking	
Point	6	3	2	5	4	20
Diffuse	8	9	9	5	7	38
Total	14	12	11	10	11	58

Exact test p-value = 0.529, therefore accept  $H_0$ .

### Association of Facial Dimensions and Leak Sites

An objective of this study was to determine if there were significant differences between the facial dimensions of subjects in a specified leak site category and those not in that category, and to determine if subject, gender, respirator brand, or fit test repetition would affect the probability of observing leaks at the three primary sites, i.e. the nose, cheek, or chin. Each dimension for all subjects and gender subsets was initially tested for differences among the seven leak site categories by the Kruskal-Wallis ANOVA. (Hintze, 1991) Differences among facial dimensions of subjects in a leak category and those not in that category were tested by two-way ANOVA and two-sample t-tests. (Hintze, 1991) Since the ANOVA allows comparisons to be adjusted for the effect of gender, it was assumed that a difference in a dimension was attributed to gender if a significant difference was found in the t-test but not the ANOVA. The affect of subject, gender, respirator brand, fit test repetition, and facial dimensions on the probability of observing a leak at the nose, cheek, or chin was also modelled by conditional logistic regression.

These tests were also performed for subjects with aerodynamic streamlining. Visual evidence of this phenomenon was found from fluorescent aerosol deposition patterns on 18 subjects after one or more of their fit tests. These patterns originated at leak sites and followed relatively straight lines to the subjects' nose or mouth. Myers et al. (1986) hypothesized that this phenomenon contributed to in-facepiece sampling bias for the determination of protection factors. Subjects with these patterns were treated as a separate subset because of the implications on the validity of in-facepiece sampling. Streamlining was observed on about 19% of the subjects in our previous study (Oestenstad et al., 1990b), and about 44% of the subjects in this study. The

prevalence of subjects with streamlining observed in this study is thought to more accurately reflect real usage conditions since this study involved repeated tests on the same subject.

The results of the comparisons of facial dimensions between the leak site categories are summarized in Tables XIV and XV. It was interesting to note that for all subjects the Kruskal-Wallis ANOVA found significant variation for biectoorbitale breadth, and for females only subnasale-nasion length; while significant variation was found among males for all dimensions except bigonial breadth and lip width. This would suggest that subsequent analysis might be affected by gender.

Facial Dimension	All Subjects	Females	Males
BIECTO	0.006*	0.269	0.150*
BIZYGO	0.780	0.280	0.013*
BIGON	0.202	0.559	0.070
MEN_NAS	0.159	0.108	0.035*
MEN_SUB	0.142	0.222	0.004*
SUB_NAS	0.063	0.020*	0.039
BIOC	0.127	0.855	0.042*
NAS_RB	0.391	0.111	0.063*
NOS_W	0.115	0.965	0.003*
LIP_W	0.284	0.272	0.334
BIT_MEN	0.056	0.725	0.029*
BIT_SUB	0.323	0.162	0.002*

\* - Significant variation of this dimension among subjects in the seven leak site categories

The results of the two-sample t-tests and two-way ANOVAs for subjects in leak categories and their comparison groups are summarized in Table XV. Facial dimensions in only 16 of the 108 comparisons were found to be significantly different. As expected, when differences were

affected by gender, the subjects in the leak category were always smaller than those in the comparison group. In fact, for all but three cases, subjects in the leak category had dimensions that were significantly smaller than the comparison group.

Facial Dimension	Leak Category							Streamlining	
	0	1	2	3	4	5	6		7
BIECTO	< G			< G		< G		>	
BIZYGO									< G
BIGON				< G					
MEN_NAS						<			
MEN_SUB						<			<
SUB_NAS		<						>	
BIOC									
NAS_RB									
NOS_W				<					
LIP_W	<								
BIT_MEN					< G	>			< G
BIT_SUB									

< Dimension of subjects in Leak Category significantly less than comparison group  
 > Dimension of subjects in Leak Category significantly greater than comparison group  
 G Difference affected by gender

Biectoorbitale breadth (BIECTO) was significantly different in four of the nine comparisons, and bitrignon-menton arc (BIT\_MEN) was significantly different in three; while biocular breadth (BIOC), nasal root breadth (NAS\_RB), and bitrignon-subnasale arc (BIT\_SUB) were not significantly different in any of the comparisons. It was noted only three dimensions were significantly different for subjects which had streamlining when compared to those who did not. This was not expected because our previous work (Oestenstad et al., 1990b) found significant differences for ten of the twelve dimensions.

The results of the logistic regression analysis are shown in Table XVI: The dichotomous variables included in these models were: 1) Gender, subject, fit test repetition, respirator brand, and respirator size. Fit test repetition was intended to be a measure of variation of leak site on an individual over repeated tests (intra-subject variability). Respirator brand was a measure of leak site variation among respirators (inter-respirator viability). Coefficients of the variables which the

Independent Variable	Dependent Variables								
	Nose Leak			Cheek Leak			Chin Leak		
	All	Female	Male	All	Female	Male	All	Female	Male
Gender	0.542	1	1	-0.730 <sup>2</sup>	1	1		1	1
Subject									
Test									-0.340
Respirator				0.227					1.062
Size			-0.510						
BIECTO				0.744 <sup>2</sup>		0.835 <sup>2</sup>			
BIZYGO				-0.415	-0.433				-1.814 <sup>2</sup>
BIGON	1.103 <sup>2</sup>	1.031 <sup>2</sup>	0.944 <sup>2</sup>	-0.848 <sup>2</sup>		-1.186 <sup>2</sup>			
MEN_NAS	-0.430 <sup>2</sup>	-1.239 <sup>2</sup>			1.656 <sup>2</sup>		-2.563 <sup>2</sup>		-1.697 <sup>2</sup>
MEN_SUB		1.189			-1.110		1.700 <sup>2</sup>	0.691	
SUB_NAS							2.808 <sup>2</sup>		1.783 <sup>2</sup>
BIOC			0.823						
NAS_RB		2.677 <sup>2</sup>	-2.839 <sup>2</sup>						2.150
NOS_W			-1.748 <sup>2</sup>	1.154 <sup>2</sup>		1.143			
LIP_W								-0.694	
BIT_MEN				0.267 <sup>2</sup>		0.401 <sup>2</sup>			
BIT_SUB	-0.389 <sup>2</sup>	-0.536 <sup>2</sup>					0.155		0.681 <sup>2</sup>
Model R <sup>2</sup>	0.064	0.115	0.106	0.104	0.095	0.155	0.087	0.030	0.175
Efficiency <sup>3</sup>	0.641	0.657	0.644	0.684	0.633	0.750	0.643	0.562	0.744

1 - Gender was not included in these models  
2 - Value of coefficient was significantly different from zero  
3 - Proportion of correct prediction of leak at the designated site in comparison to observed values

computer program (Hintze, 1991) retained in the logistic regression model are shown in the table; those which are highlighted indicate the values that were significantly different from zero; or variables which had a significant affect on the probability of observing a leak at the designated site.

The  $R^2$  for the analyses was very low in all cases and the efficiencies were only marginal, indicating that the models were not very good predictors of the occurrence of a leak at the designated site. Of all the dichotomous variables, only gender had a significant coefficient in the model for predicting cheek leaks on all subjects. This indicates that leak location does not significantly vary between genders, among subjects, among the respirator brands, or among repeated tests on the same individual. These results confirm the previous Chi-square analysis of the 2 X k tables. Of the dimensions used to define the respirator test panel (Hack and McConville, 1978), face length (MEN\_NAS) had significant coefficients in five of the nine models; while lip width (LIP\_W) had a coefficient in the model for chin leaks on females but was not significant.

#### **Effect of Breathing Rate on Streamlining**

The effect of breathing rate on aerodynamic streamlining was evaluated qualitatively and quantitatively. The qualitative method was to observe aerosol deposition patterns indicating streamlining on a mannequin headform after fit tests in which a breathing machine was operated at different breathing rates. The quantitative method was to measure sampling bias during fit tests on the mannequin while the breathing machine was operated at different breathing rates. The tests and breathing rates were described earlier.

Visual streamlining patterns were classified in three categories according to the extent of their development: 1) None - aerosol

deposition patterns at the leak site only, 2) Slight - aerosol deposition at the leak site and some evidence of a streamline formation extending from the leak, and 3) Developed - uniform aerosol deposition from the leak site to the mouth of the mannequin. The results of the classification of deposition patterns from 21 mannequin fit tests are summarized in Table XVII and illustrated in Figure 7.

Work Rate (Kg-m/min)	Aerodynamic Streamline Development			Total
	None	Slight	Developed	
Sedentary	0	0	5	5
208	0	0	7	7
622	3	2	0	5
830	3	1	0	4
Total	6	3	12	21

These data resulted in a Spearman's rho correlation coefficient of -0.869; (Gustafson, 1991) indicating that as the breathing rate increased, the streamlining patterns became less developed. An approximate randomization test for contingency tables also found the two variables to be highly related ( $p < 0.0001$ ). (Gustafson, 1991) These results would indicate that streamlining patterns are more likely to develop at low breathing rates.

Three quantitative measurements of bias were performed by the method previously described for each combination of leak sites and leak locations at the work rates listed in Table II; resulting in a total of 162 tests. The data, which are summarized in Table XVIII, were analyzed by a general linear model ANOVA (Hintze, 1991). That analysis found the sampling bias measured at the four lowest work rates were significantly lower than those measured at the two highest rates. The mean and 95%

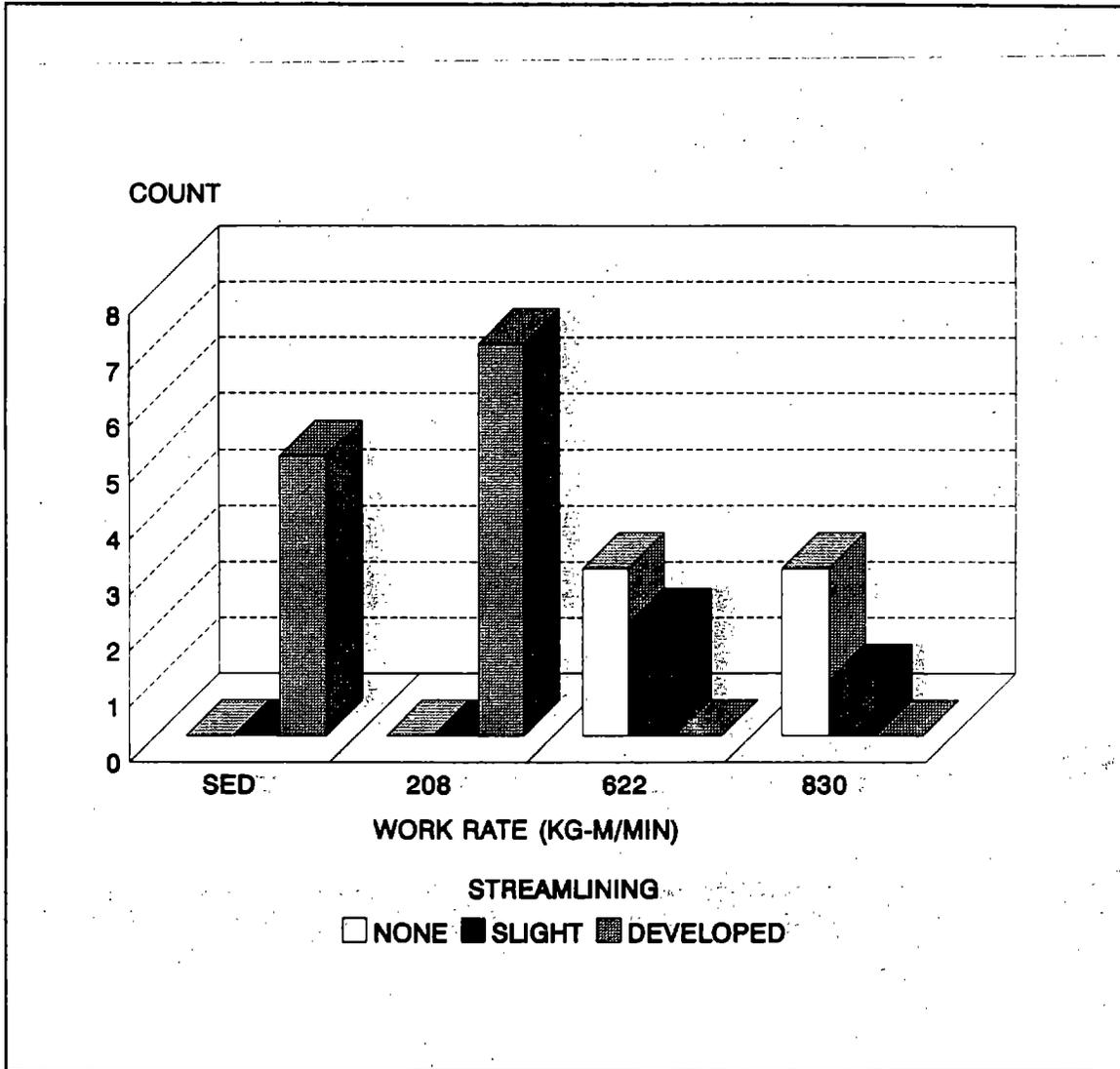


FIGURE 7--- Observed Streamlining Patterns at Different Breathing Rates

confidence interval of bias measured at each work rate are shown in Figure 8. It was noted that as the work rate increased, the means followed a trend toward lower values while the confidence intervals tended to become wider.

It is hypothesized that these phenomenon are a result of the air flow within the facepiece becoming more turbulent at the higher inspiratory flow rates. (Hinds, 1982) As air flow becomes more turbulent there is greater mixing of the aerosol in the facepiece, and a sampling probe at this location collects a sample that is more representative of

the true concentration. The turbulent flow may also cause the measured concentration to be more variable because of the instability of air flow patterns at higher velocities.

TABLE XVIII - Sampling Bias			
Factor		Mean	Std Dev
All		86.5	8.02
Run			
1		86.5	8.26
2		87.4	7.14
3		85.5	8.62
Work Rate (kg-m/min)	Ins Flow Rate (L/min)		
Sedentary	26.2	89.1	4.40
208	47.1	90.4	5.98
415	64.1	87.4	6.54
622	77.1	88.0	7.68
830	112.5	83.0	8.66
1107	154.6	81.0	9.78
Leak Size			
20 ga		87.5	5.26
18 ga		82.8	10.70
14 ga		90.4	3.27
Leak Location			
Nose		89.8	4.12
Cheek		89.1	5.39
Chin		77.8	9.21

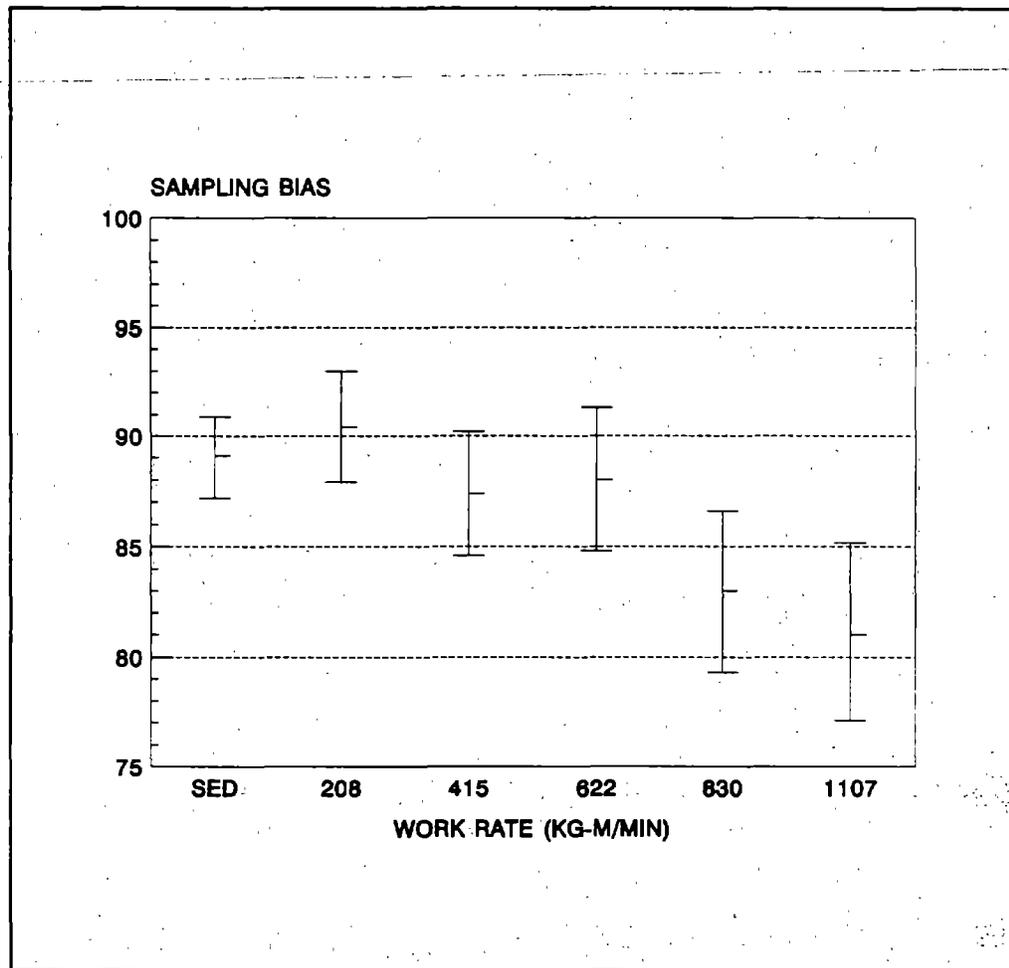


FIGURE 8 - Sampling Bias

## CONCLUSIONS

### Significant Findings

This study resulted in significant findings related to the correlation of facial dimensions and respirator fit, the distribution of leak sites and shapes, facial dimension differences for subjects with specific types of leaks, and the persistence of streamlining patterns at elevated breathing rates. Although seven facial dimensions were found to have significant correlation coefficients with respirator fit, they were poor predictors of fit in both linear and logistic regression models. Correlation was found to be strongly affected by gender; females

had seven facial dimensions that were correlated to fit while males only had one. Of the dimensions currently used to define the half-mask respirator test panel (Hack and McConnville, 1978), only face length was found to be significantly correlated to fit. Also, neither of the dimensions were included in any of the linear or logistic models for predicting respirator fit. These results support our previous findings that these dimensions may not be appropriate to define test groups whose fit is intended to be representative of worker populations. (Oestenstad and Perkins, 1992)

Analysis of leak site data found a very high proportion of cheek leaks and multiple leaks that included the cheek. This result contradicts our previous observation of a low proportion of these types of leaks. (Oestenstad, et al., 1990b) However, this study also found a high proportion of nose leaks as was found in the previous work. (Oestenstad, et al., 1990b) This study found that the distribution of leak sites was not affected by gender, respirator brand, or fit test repetition. This would indicate that leak sites would be consistent for all brands of half-mask respirators, and would not vary among repeated fittings of the same respirator on an individual.

A significantly low proportion of point leaks was found for all subjects and for each gender. Unlike our previous results, (Oestenstad, et al., 1990b) this study found no significant difference between the gender leak shape distributions. It was also found that there was no significant difference among the leak shape distributions by respirator brand or among the fit test exercises.

The tests for differences among facial dimensions for subjects in leak site categories found only one dimension to be significantly different for all subjects and for females; however, ten dimensions were significantly different for males. Of the 108 two-way comparisons of

subjects in a leak site category and those with visual evidence of streamlining to their comparison groups, only 16 were found to be significantly different. In all but three of these cases, the dimension of subjects in the leak site category were significantly smaller than the comparison group; and only seven were affected by gender. Logistic regression analysis found that subject, test repetition, and respirator brand were not significant in any of the models to predict the probability of a leak at any of the primary sites (nose, cheek, and chin); and gender was only significant in the model for cheek leaks.

The fit tests on a mannequin fitted with a half-mask respirator over a range of work rates, and corresponding inspiratory flow rates, resulted in less developed visual streamlining patterns at the higher rates. In addition, bias associated with in-facepiece sampling was found to significantly decrease as inspiratory flow rate increased. It is thought that these phenomena are a result of increasing turbulence and better mixing in the facepiece at the higher flow rates.

#### **Usefulness of Findings**

The results of this study will contribute to the understanding of the distribution of respirator leak sites and shape, and will have both theoretical and practical applications. Knowledge of these parameters may contribute to more accurate theoretical modeling of respirator leakage. Leak location, shape, and size have been shown to affect leak flow, yet are subject to assumptions in prominent leak models. Leak size and shape or both also be important factors in the methods used to predict respirator fit by facepiece pressure decay rates. Determination of the persistence of streamlining flow at high breathing rates may partially explain the lack of correlation between laboratory and workplace fit factors.

Based on the results of the association of anthropometric dimensions with leak sites and respirator fit observed in this study and in our previous work, it appears that the facial dimensions currently used to define half-mask respirator test panels needs to be re-evaluated. Also, these associations could be useful to respirator program administrators in the selection of a model or size of respirator for an individual wearer. They may also contribute to the improvement of facepiece design, thus providing greater protection to the user.

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## APPENDIX I - TEST PROTOCOL

Human subjects were used in tests to determine the effects of test exercise, intra-subject variability, and respirator brand on the distribution of respirator leak sites and shapes. Paid volunteer subjects for this study included white females and males between the ages of 21 and 60, recruited from the student and staff population of the UAB Medical Center. A detailed description of subject participation in the study follows.

1. Prospective subjects were asked to complete a questionnaire to determine if they had any pre-existing condition which might prevent them from being able to wear a respirator during the test. Individuals who did not satisfactorily complete the questionnaire were not used in the study.
2. Prospective subjects were screened to determine if they had any facial features which would result in obvious leakage while wearing a respirator. Such features might include creases or folds in the skin, scars or sunken cheeks. Individuals with these features were not be used in the study.
3. An informed consent form was be reviewed and signed by all subjects accepted into the study.
4. Measurement of key facial dimensions was made with anthropometric sliding and spreading calipers and a metric tape. Those dimensions were: 1) biectoorbitale breadth, 2) bizygomatic breadth, 3) bigonial breadth, 4) menton-nasion length, 5) menton-subnasale length, 6) subnasale-nasion length, 7) biocular breadth, 8) nasal root breadth, 9) nose width, 10) lip width, 11) bitragion-menton arc, and 12) bitragion-subnasale arc.
5. A pretest frontal photograph of the subjects' faces were obtained under illumination from longwave ultraviolet lamps with a spectral

range of 300 to 400 nm and maximum emission at 365 nm. Irradiance was about  $1.8 \text{ mW/cm}^2$ . The subjects' eyes were closed at all times while the lamps are on.

6. The subjects was fitted with a probed, half-mask, air-purifying respirator equipped with high efficiency particulate filters. They were observed to ensure that they were able to breath without difficulty while wearing the respirator before proceeding with the test.
7. The subjects entered the test chamber and connected the sample line for in-facepiece measurements. Before beginning the test, the aerosol concentration beneath the respirator was measured to ensure that the penetration did not exceed 10% of the chamber concentration. The subjects were asked to perform appropriate head and facial exercises which included one or all of the following: 1) normal breathing while holding the head still, 2) deep breathing while holding the head still, 3) normal breathing while turning the head from side to side, 4) normal breathing while moving the head up and down, 5) normal breathing while holding the head still and talking and 6) normal breathing while holding the head still. Aerosol concentrations were measured inside the respirator during these exercises. The test was terminated if the aerosol concentration inside the respirator exceeded 10% of the chamber concentration for more than 15 consecutive seconds.
8. At the conclusion of the test, the subjects exited the test chamber and the respirator was carefully removed. A post-test frontal photograph of the subjects' face was taken while illuminated with ultraviolet light.
9. Steps 5 through 8 were repeated for each test in which the subjects participate.

**LIST OF POSSIBLE PUBLICATIONS**

It is anticipated the papers on the following topics will be published from the data generated by this study:

1. The effect of gender, respirator brand, and test repetition on the association of respirator fit with facial dimensions. An additional topic in this paper will be the lack of association of the fit test panel dimensions (MEN\_NAS and LIP\_W) with fit.
2. The effect of gender, respirator brand, exercise, and test repetition on leak site and shape distributions.
3. The decay of streamlining patterns and the decrease of in-facepiece sampling bias with increasing breathing rates.