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FACESEAL LEAK IDENTIFICATION ON HALF-MASK RESPIRATORS

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IDENTIFICATION OF FACESEAL LEAK SITES ON A HALF-MASK RESPIRATOR*

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A method has been developed to identify the location and shape of respirator face seal leak sites by the deposition of a fluorescent tracer. An aerosol generation, conditioning and exposure system to provide a test environment with stable aerosol concentration and size distribution of 4-methyl-7-diethylaminocoumarin was designed and tested. Face seal leak sites on a respirator mounted on a mannequin and worn by human subjects were identified by deposition of the tracer aerosol and subsequent observation under longwave ultraviolet lighting. Test parameters were identified for the optimal definition of leaks. Photographic techniques were developed to document the identified leak sites.

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INTRODUCTION

This is the first of two papers which report the development and application of a technique to identify faceseal leak sites on half-mask, air-purifying respirators. This paper describes the aerosol and methods which were developed for this purpose, and the tests conducted to identify faceseal leak sites on mannequins and human subjects. A subsequent paper discusses the distributions of leak sites and shapes, and their association with facial dimensions for a panel of subjects wearing one brand of half-mask respirator.⁽¹⁾

The past two decades have brought significant advances in respirator research. Most of those have been directed toward the quantification of respirator leakage through the use of quantitative fit testing. That technology has resulted in the development of the assigned protection factor concept and its incorporation into the ANSI Z88.2 American National Standard for Respiratory Protection⁽²⁾ and OSHA comprehensive health standards such as those for lead and asbestos.⁽³⁾

However, few studies have been reported in which the investigators attempted to identify leak sites on respirators. In an early qualitative fit test, coal powder was sprayed around the facepiece of a respirator and leakage was identified by observing the coal deposited at leak site(s).⁽⁴⁾

Later, a quantitative fit test which could be modified to indicate leak sites was reported.⁽⁵⁾ This method used freon gas as a test agent and a halide meter to measure leakage. To identify leaks, a small capillary tube attached directly to a freon supply was moved around the

facepiece. When the capillary was near a leak site, a strong deflection of the meter was noted.

Using this method, the authors found that the leakage of half-mask respirators varied substantially, even on multiple tests with the same individual wearing the same mask. They stated that the differences in fit were due to variability of leaks around the nose. No indication as to the amount of this variance, the degree of penetration, or the prevalence of leakage around the nose was provided, and no other leak sites were indicated.

Leak sites could also be identified by a method which utilized photosensitive paper placed beneath the facepiece and light as a test agent.⁽⁶⁾ In this method, the paper was cut into templates and placed inside the facepiece in a darkroom with photosafe 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 grey or black areas. Eight subjects wearing a half-mask respirator and a disposable respirator were tested with this method. It was noted that most leaks occurred around the nose and chin, and that leaks occurred over a large area of the face. A limitation of this method was that since light travels in straight lines, it may not detect leaks that change direction.

Identification of respirator leak sites with a fluorescent tracer has also been reported.⁽⁷⁾ In that method, a trace aerosol of optical brightener was applied to the immediate area of the respirator seal, and aerosol deposition at leak sites was documented by photographs taken under ultraviolet (UV) lights. Several types of half-mask respirators

with imposed leaks were tested on a small number of subjects. Quantitative fit testing conducted immediately prior to the fluorescent aerosol test. The method was able to identify imposed leaks with corresponding fit factors up to about 200. Aerodynamic streamlining within the respirator facepiece was also observed in mannequin tests using static (noncyclic) airflow, but not on any of the human subjects.

The purpose of this work was to develop a method to identify face seal leak location and shape on human subjects while wearing a well-fitting half-mask respirator by deposition of a test aerosol at the leak and subsequent visual detection and photographic documentation. Feasibility of this approach was based on studies which had demonstrated particle deposition at respirator leak sites^(8,9,10) and others which demonstrated the ability to detect very small quantities of fluorescent tracers deposited on the skin.⁽¹¹⁾ Utilizing these findings, the authors selected a suitable test material, constructed an aerosol exposure system, and developed photographic techniques and a test protocol.

MATERIALS AND METHODS

The primary considerations for selection of a test agent were: 1) that it be essentially non-toxic, 2) that very small quantities be visible on the skin, and 3) that it could be generated in concentrations and particle sizes used in current quantitative fit test methods which employ aerosols. After a review of the physical, toxicological and optical properties of a number of fluorescent compounds, the fluorescent

whitening agent 4-methyl-7-diethylaminocoumarin (MDC) was selected for use in the study. (11,12,13,14,15)

MDC is a member of a family of fluorescent whitening agents which absorb energy from long-wave UV light (320-400 nm) and convert it to visible light in the blue region (430-500 nm). It binds strongly to proteins on the outermost layers of the stratum corneum, and is very highly visible under UV lights. Visible concentrations of MDC on the skin may be as low as $10 \mu\text{g}/\text{cm}^2$. (11)

The aerosol generation, conditioning and exposure system used in the study was patterned after that of Burgess *et al.* (16) A schematic diagram of this system is shown in Figure 1. This system nebulized an ethanol solution of MDC which was dried to produce a residual aerosol. The static charge on the aerosol and ethanol vapor in the carrier air were reduced before introduction into the exposure chamber.

The nebulizer was a modification of a design by Liu and Lee. (17) It allowed for the constant feed of fresh solution to be nebulized, thus avoiding an increase in solute concentration and a corresponding increase in the size of the residual aerosol. (18) The mass and size distribution output of the nebulizer was found to be very stable, but it required a relatively high liquid feed rate of about 2 ml/min.

Spatial and temporal measurements of chamber aerosol concentrations were made with a Dynatech-Frontier forward light-scattering photometer. Photometer outputs measured across the chamber in perpendicular 8-point traverses were within $\pm 4\%$ of the mean value. Photometer outputs measured at 1 minute intervals over a 2 hour test run were found to decrease slightly with time, but the value at the end of the test was

within 10% of the value at the beginning of the test. Aerosol mass concentrations in the test chamber were measured by gravimetric methods. Concentrations were found to range from 18 to 50 mg/m³ under various system operating conditions.

The aerodynamic size distributions of the aerosol produced under a variety of nebulizer operating conditions were measured with a Marple Personal Cascade Impactor. The Impactor was operated at the upper limit of its operating range (5 L/min) with coated mylar substrate. The sampling conditions used were within the limit recommended for coated mylar to control particle bounce.⁽¹⁹⁾

The sampling data from 17 tests were analyzed by a cascade Impactor data reduction program which summarized Cunningham Correction Factor, aerodynamic cut size, cumulative frequency, and Reynolds Number values for each stage. It also tested for a log-normal distribution and calculated a least squares regression curve, an aerodynamic mass median diameter, and geometric standard deviation.⁽²⁰⁾ The results of these analysis revealed that the test aerosol had an average aerodynamic mass median diameter of 0.55 μm and an average geometric standard deviation of 1.6. These values were within those recommended in Appendix A of ANSI Z88.2-1980 for quantitative fit testing,⁽²⁾ and would include particles shown to be deposited in respirator leaks by previous studies.^(8,9,10)

The liquid aerosol was dried in a heated tube, and static charge on the particles was reduced by passing them through a neutralizer constructed to specifications of Carsey.⁽²¹⁾ Static charge remaining on the particles was not measured. However, it was noted that there was no

observable accumulation of particles on the chamber walls as would be expected if there were a high residual static charge.

The aerosol and carrier air then passed through two diffusion columns packed with 8-12 mesh activated carbon to reduce the concentration of ethanol vapor. The concentration of ethanol vapor in the test chamber remained at about 700 ppm which required respirators worn by test subjects to be equipped with combination HEPA filters and organic vapor cartridges.

After leaving the diffusion driers, the conditioned aerosol was injected into the chamber dilution air. The dilution air, which was filtered through a tower packed with 8-12 mesh activated carbon and a HEPA filter, was blown into the exposure chamber at 0.2 to 0.25 m³/min with a variable speed high volume blower.

The chamber was constructed of clear plexiglass and clear, flexible vinyl. It consisted of a rigid top 55 cm in diameter on which two concentric plexiglass rings were attached. The diameter of the inner ring, which formed the chamber wall, was 46 cm. Walls of the chamber and the exhaust plenum were formed by flexible vinyl which hung from the rings. A plastic shroud was added to outer wall to prevent aerosol from escaping into the laboratory environment in uncontrolled air currents around test subjects seated in the test chamber.

Dilution air and aerosol were introduced through the two inlet ports in the top of the chamber and were distributed into a shallow plenum by impaction plates. They then passed through a 2 cm layer of open cell polyurethane foam to insure a homogeneous distribution within the test chamber. Air velocity through the test chamber was calculated

to be between 2 and 3 cm/sec at the dilution air flow rates of 0.2 and 0.25 m³/min. Since these velocities were below the range of available anemometers, they were not verified. However, smoke tube checks of air flow within the chamber indicated that flow was evenly distributed across the chamber and was laminar. Air was exhausted to the outside through the annulus formed at the bottom of the chamber wall and the outside wall.

MANNEQUIN TESTS

The aerosol generating and exposure system was used with the MDC aerosol to conduct a series of quantitative fit tests on a mannequin to determine if the method of identifying leak sites was feasible. The tests consisted of a pre-exposure photograph under ultraviolet lights, fitting the mannequin head form with a half-mask respirator equipped with high efficiency cartridges, exposure of the mannequin to the MDC aerosol, and a post-exposure photograph under ultraviolet lights.

Air flow through the respirator was by both simulated respiration and continuous flow. Respiration was approximated with a pulmonary resuscitator connected to the mannequin head. A respiratory minute volume of about 9 L/min was produced using this system. This was below the average respiratory minute volume of about 14 L/min for an adult at a work rate of 0 kilogram-meter (0 Kg·M).⁽²²⁾ As a result, a series of tests was also conducted at continuous flow of 15 l/min through the mannequin.

The mannequin head was prepared by coating with an opaque latex film to eliminate fluorescent interference. The pre-exposure photograph

was made to confirm the absence of any interfering materials. Lighting for the photographs was with 2 Spectroline Model XX-15N lights with UV transmitting filters. Maximum emission wavelength for these lights was 365 nm with a range of about 300 to 430 nm. The light provided about 1.8 μ W of ultraviolet irradiation when placed at a distance of 35 cm from the mannequin face.

The photographs were taken with a Nikon FE camera using an RMC Tokina 35-105 mm zoom lens and a Kodak 2E Gelatin Filter to remove ultraviolet light. Kodak Tri-X-Pan 400 ISO black and white film pushed to 1200 ISO was exposed at 5.6f for 1.0 second for the pre-exposure photograph and 0.5 second for the post-exposure photograph. The exposed film was developed and printed with Kodak chemicals. Special attention was given to proper time, temperature, agitation, and chemical dilution to enhance film contrast.

A respirator was mounted on the mannequin with a wire placed between the facepiece and the headform to produce an artificial leak. The mannequin was placed in the test chamber, the generator was started and the aerosol concentration in the test chamber was allowed to equilibrate. Quantitative fit tests were conducted using a Dynatech-Frontier Model 264 Quantitative Fit Test System. At the conclusion of the tests, the respirator was carefully removed and the mannequin head again was illuminated with ultraviolet light and photographed.

The post-exposure photographs showed clear evidence of aerosol deposition at the location of the artificial leaks. An example of post-exposure photographs of the mannequin is shown in Figure 2. It illustrates artificial leaks on both sides of the face with continuous

air flow of 15 L/min through the facepiece. Note the aerosol deposition patterns indicating aerodynamic streamlining inside the facepiece.

HUMAN SUBJECT TESTS

Before human subject tests were initiated, minor modifications were made to the generation and exposure system to provide higher and more consistent aerosol concentrations. Test duration to obtain visible deposition of aerosol was estimated from chamber aerosol concentration, measured penetration, and respiratory minute volume. Using these factors, human tests were conducted for about 40 minutes at an average MDC concentration of about 38 mg/m^3 . UV lighting and photographic techniques were the same except that a darkroom with mounted UV lights and a camera tripod were used to provide more consistent exposure conditions.

Test procedures for human subjects were developed from experience gained in conducting the mannequin tests. The protocol included: 1) screening of potential subjects, 2) anthropometric measurements, 3) pre-exposure photographs, 4) respirator fitting, 5) quantitative fit test, and 6) post-exposure photographs. Criteria for selection of test subjects were: 1) age between 21 and 50, 2) absence of any facial features which may have resulted in obvious respirator leakage (creases or folds in the skin, scars, sunken cheeks, or beards), and 3) absence of any medical conditions which would put subjects at risk as a result of wearing a respirator or being exposed to the test aerosol.

Facial anthropometric dimensions to be measured were developed from a review of previous research on respirator anthropometry, (23,24,25,26)

and consultation with the staff of Anthropology Research Projects, Inc., of Yellow Springs, Ohio. Those dimensions are illustrated in Figure 3. (27)

Prior to the pre-exposure photographs, subjects' faces were wiped with with alcohol swabs to remove fluorescent materials, and their clothing was covered with a black shroud to eliminate interference from clothing. Their eyes were covered with opaque goggles while exposed to the UV lights.

After the pre-exposure photograph, the subjects were fitted with a respirator, and a negative pressure fit check performed. Care was taken not to disturb the facepiece until after completion of the fit test. The respirator used in the study was the U.S. Safety Series 200 Half-Mask which was available in small, medium, and large sizes. The facepiece configuration was thought to be typical of most half-mask respirators. The size worn by each subject was determined by their face length and lip width. The respirators were probed for fit testing at a point on the vertical midline between the subject's nose and mouth.

The aerosol generating system was started and the chamber aerosol concentration allowed to equilibrate. The subjects were carefully fitted with the appropriate size respirator to insure the best possible fit. After it was observed that the subjects could breath through the respirators without difficulty, they were seated on a chair with their heads and shoulders in the test chamber.

Real-time aerosol concentration in the test chamber and beneath the respirator were measured with a Dynatech Model 264 Quantitative Fit Test Photometer. An initial check was made of the aerosol concentration

inside the respirator to insure that the leakage was less than 10%. The test was stopped if leakage of less than 10% could not be attained after adjustment of the facepiece. A standard quantitative fit test which included head movement exercises and talking was performed.⁽²⁾

Integrated photometer output for measurements in the test chamber and beneath the respirator were used to calculate fit factors. Under these sampling conditions, the measured concentration inside the respirator would be less than that expected from leakage alone due to aerosol measurement during exhalation. As a result, the measured fit factor would be higher than the true fit factor. Fit factors were not corrected for this bias, which has been estimated to be about 5% to 12% by previous studies.^(28,29)

At the conclusion of the test, the subjects were removed from the test chamber, and the respirator was carefully removed. Post-exposure photographs to document visible aerosol deposition were immediately taken by the same procedure used for the pre-test photograph.

DISCUSSION

Leak sites which could be detected visually and by photographic methods were classified as to their location (nose, cheek or chin) and their one-dimensional shape (point or diffuse). Examples of post-exposure photographs are shown in Figures 4 and 5. Note that the deposited aerosol on the subject in Figure 5 follows a streamlining pattern from the leak to the subject's nostril. Streamlining was hypothesized as being the cause of sampling bias in the determination of fit factors.⁽³⁰⁾ This observation confirms that this phenomenon occurs

within the respirator facepiece worn by human subjects, and could account for the very high measured fit factor for this subject.

This study demonstrates the feasibility of identifying respirator face seal leak sites with an aerosol of MDC using the described generation, conditioning and exposure system. The system was found to be capable of providing a constant output of an aerosol with the desired size distribution characteristics. Sufficient deposition of the fluorescent tracer to allow visual detection of face seal leak sites on a mannequin and human subjects was obtained. Photographic documentation of identified leak sites is presented.

This method could be used to determine the distributions of leak sites and shapes for groups of wearers, for types of respirators, for various breathing rates and interactions of these variables. This information may identify an association of critical facial dimension(s) with respirator fit or facial shapes which might be accommodated by a specific respirator type or configuration.

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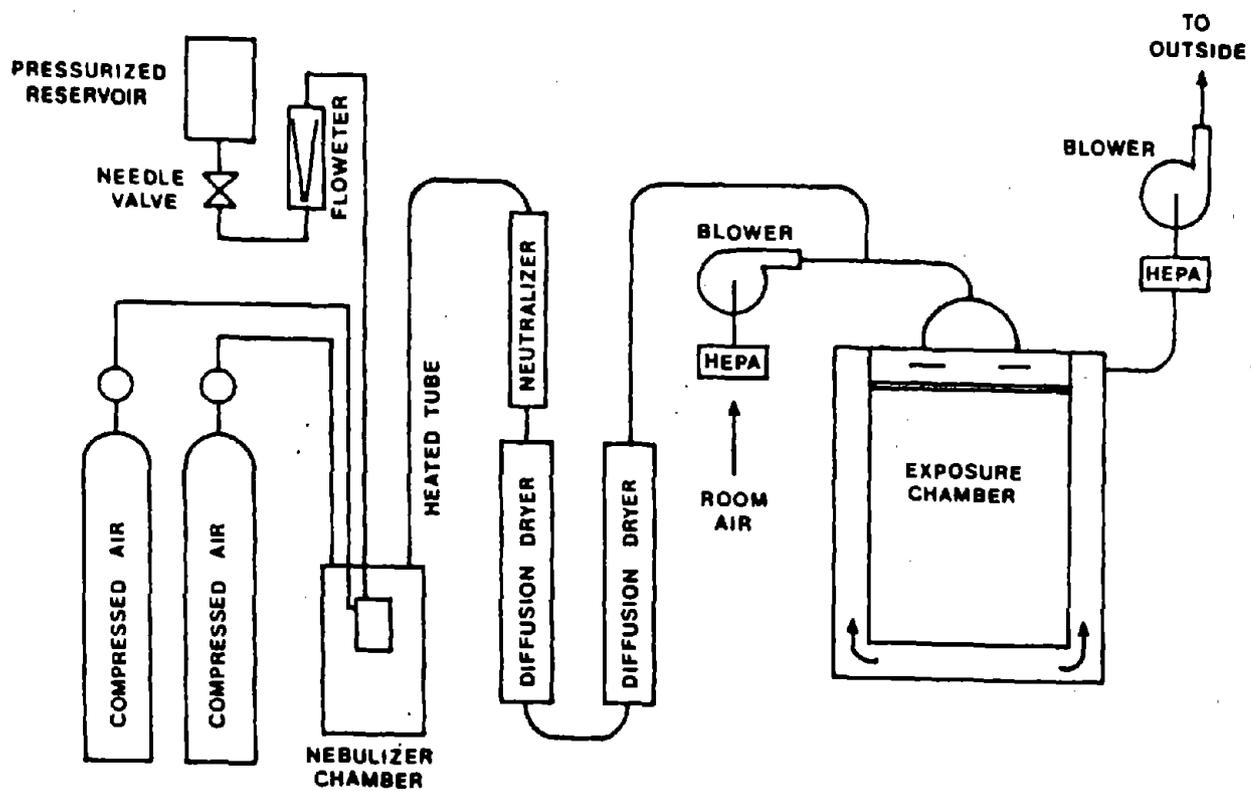
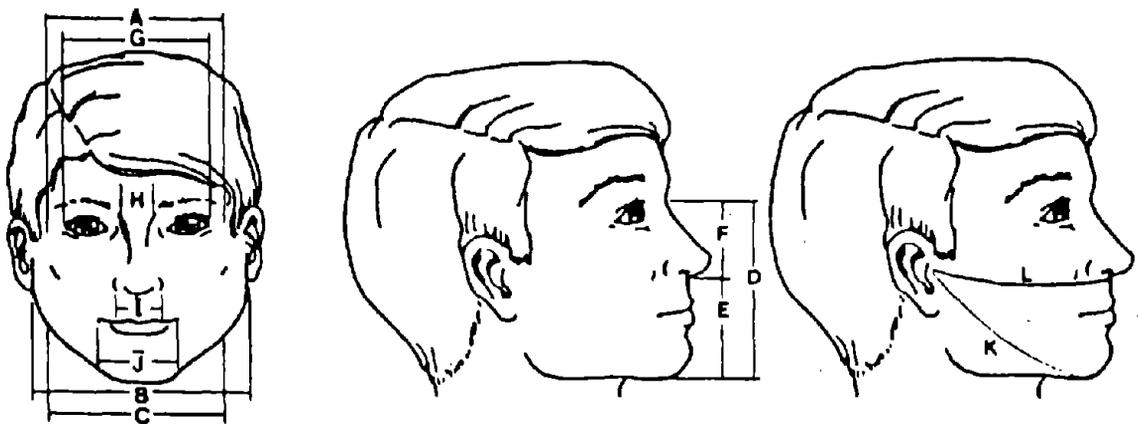


Figure 1 -- Aerosol generation, conditioning and exposure system.



Figure 2 -- Aerosol deposition on mannequin after exposure with continuous air flow.



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

Figure 3 -- Facial dimensions.



Figure 4 -- Aerosol deposition on a subject with a diffuse chin leak. (fit factor = 600).

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Figure 5 -- Aerosol deposition on a subject with streamlining from a point nose leak (fit factor = 2300).

DISTRIBUTION OF FACESEAL LEAK SITES ON HALF-MASK RESPIRATORS
AND THEIR ASSOCIATION WITH FACIAL DIMENSIONS*

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Face seal leaks on one brand of half-mask respirator worn by 73 human subjects wearing were identified by deposition of a fluorescent tracer aerosol during a standard quantitative fit test. The identified leaks were categorized according to their facial location and shape. The distributions of those categories were determined and the association of anthropometric facial dimensions with leak sites were tested. It was found that about 79% of all observed leaks occurred at the nose or were multiple leaks which included the nose. About 73% of all leaks approximated the shape of a slit rather than a round orifice. Males were much more likely to have slit-like leaks than females. Significant associations were found for 25% of the tests between facial dimensions

and leak site subsets. Only two significant associations were found for the facial dimensions used to define the Los Alamos respirator test panel. Gender was a factor in many of the significant associations. The amount of leakage through chin leaks was found to be higher than leaks at other sites. Significant correlation of facial dimensions and fit factor was found for three facial dimensions; none of which are used to define the respirator test panel. Evidence of air flow streamlining within the facepiece was observed on 22% of the subjects. This study indicates that gender is a factor in how a respirator fits, and that other facial dimensions should be considered in defining a respirator test panel and selecting a respirator for an individual wearer.

INTRODUCTION

While there has been extensive work conducted to quantify respirator leakage, very little has been reported on the size and shape of respirator leaks. Yet recent developments in respirator research have been based, in part, on assumptions about these parameters. Also, a significant association of respirator leakage with facial dimensions used to define respirator test panels has not been supported in previous studies. This would indicate that other facial dimensions may be critical in defining a good respirator face seal. A better understanding of this relationship is critical since NIOSH has proposed to include the use of facial dimensions test specifications for certifying respirators.⁽¹⁾ A method developed to identify respirator leak sites has been used to study these parameters for human subjects wearing one brand of half-mask, air-purifying respirator.

Recently, several models to predict respirator leakage have been developed.^(2,3,4,5) In these models, protection factors are predicted by the ratio of total air flow into the respirator facepiece to air flow through face seal leaks. In general, air flow through the leaks is determined by the equation $Q = K \times P^a$, where Q = flow rate and P = resistance. The flow coefficient (K) represents the dimensions of the leak and various unit conversion factors. The exponent (a) characterizes the type of flow and ranges from 1.0 for laminar flow to 0.5 for turbulent flow.

The values of both the flow coefficient and the exponent for a given leak are determined by its size and shape. These parameters for facesal leaks on humans are not known, but have been approximated by capillaries in some studies.^(6,7,8) A study using capillaries as artificial leaks found these models to be accurate within the restrictions of assumptions about values of the coefficient and exponent for laminar flow.⁽⁶⁾

In the landmark paper on sampling bias in the determination of protection factors, capillaries were used as artificial leaks.⁽⁷⁾ Location of leaks was selected only on the basis of experience, and was one of the factors found to have a significant association with sampling bias.

Round tubes and wires placed in the facesal were used to represent leaks in a study to determine flow characteristics in respirator leaks.⁽⁸⁾ It was observed that pressure drop vs. flow rate through these types of leaks was nonlinear, indicating that flow was changing from laminar to turbulent. Therefore, the value of the flow exponent was changing. These changes were attributed to leak path geometry. They noted also that flow rate was strongly influenced by leak size, being proportional to the 2.7 power of leak diameter for the leaks tested.

A method to estimate respirator fit by pressure decay is also based on predicted air flow through round leaks.⁽⁹⁾ In this study, the size of respirator leaks is predicted from the respirator cavity volume and the rate of pressure decay. Air flow into the facepiece is then determined from flow equations using the same coefficients and exponents used in leak models. The authors acknowledge that flow is dependent, in

part, on leak shape and additional work is needed to show the extent of this dependence.

Anthropometric dimensions are an important consideration in the design of respirator facepieces.⁽¹⁰⁾ The effect of respirator design and facial dimensions on respirator leakage was recognized by researchers at Los Alamos.⁽¹¹⁾ From extensive quantitative fit test data, they concluded that one type or size of facepiece could not be expected to provide an adequate fit for an entire working population. As a result, anthropometric test panels defined by face length and lip width were established for conducting quantitative fit testing on half-mask respirators.⁽¹²⁾ Data from subsequent fit tests utilizing these panels were used to establish assigned protection factors.⁽¹³⁾

The relationship between these facial dimensions and respirator fit was accepted but never validated by association with respirator leakage. The association of these dimensions with protection factors was tested, and a significant correlation for lip width ($p = 0.30$) was found but not for face length.⁽¹⁴⁾ However, the correlation coefficient was relatively low (0.22), and the findings probably were limited by the assumption that differences in face seals did not contribute significantly toward variance in protection factors.

The association of lip width with respirator leakage was also tested as part of a study of workplace protection factors in a copper smelter.⁽¹⁵⁾ No significant association was found between this dimension and the average protection factor for each worker. However, this result was limited in that it was based on a small sample size ($n = 9$).

MATERIALS AND METHODS

The purpose of this study was to determine the distribution of face seal leak sites on a group of 73 subjects wearing one brand of half-mask respirator, and to test the association of the identified leaks with the subjects' facial dimensions. Each subject was tested one time according to a protocol developed to identify leaks by the deposition of a fluorescent tracer aerosol at the leak site.⁽¹⁶⁾ The test protocol included: 1) measurement of facial dimensions, 2) pre-exposure photograph, 3) fitting with a respirator and pressure check, 4) performing a quantitative fit test according to an ANSI recommended method,⁽¹⁷⁾ and 5) post-exposure photographs and classification of observed leak sites.

The respirator used in the study was the U.S. Safety Series 200 Half-Mask which was available in small, medium, and large sizes. The facepiece size was selected for each subject according to their face length and lip width. The respirators were carefully fitted to assure the best possible face seal. Subjects who had facial features which would result in obvious leak sites or who could not attain a protection factor greater than 10 were not used in the study.

The facial dimensions illustrated in Figure 1 were measured with sliding and spreading calipers and steel measuring tape. Identification of facial landmarks and measurements were made by one investigator according to training provided by the staff of Anthropometry Research Projects, Inc. of Yellow Springs, Ohio. Before any measurements were made in the study, three sets of measurements of the 12 selected dimensions were performed on a panel of 10 subjects. The purpose of

these measurements was to develop experience in locating facial landmarks and making measurements, and to determine the reliability of the investigator's measurement techniques.

Data for each dimension were analyzed by a two-way analysis of variance (two-way ANOVA).⁽¹⁸⁾ As expected, the between-subject variation was significant for all dimensions. There was also significant between-test variation for biectoorbitale breadth ($p = 0.049$), subnasale-nasion length ($p = 0.013$), and lip width ($p = 0.042$). A graph of the residuals for these dimensions indicated that, in each case, one subject had observations which deviated from the mean more than any of the other subjects. These results were considered adequate relative to expected inter-observation variability identified in anthropological studies.^(19,20)

Measurement consistency was also evaluated during the study by measurements of the 12 dimensions performed on a control subject at selected intervals. These observations were plotted on Shewhart Quality Control graphs, and no trends or values outside the two standard deviation control limits were noted.⁽¹⁸⁾

Identified leaks were classified according to their location and shape. Leak site categories were around the nose, on the cheeks, under the chin, or a combination of more than one of those sites. There were eight possible categories of single or multiple leak sites. Leak shapes were either point or diffuse: point leaks were those on which the aerosol was deposited on a small cross sectional area (less than 1 cm.) of the face, and diffuse leaks were those where the aerosol was deposited over a large area (greater than 1 cm.)

Data recorded on each subject included respirator size, subject demographic information, facial dimensions, quantitative fit test results, and leak site and shape classifications. Data were entered into a spreadsheet, and appropriate parametric and nonparametric statistical analysis performed using True Epistat Statistical Software.⁽¹⁸⁾ Two-tailed tests of hypothesis were performed using an alpha value of 0.05.

Designation of leak sites was considered as a multinomial random variable. The sample distribution was compared to 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 $i = 1, 2, \dots, 8$).⁽²¹⁾ With 73 subjects, a minimum difference of 0.115 could be detected between the null proportion and an observed proportion of one type of leak shape at an alpha value of 0.05 and a power of 0.85. Given that a leak occurred, leak shape was a dichotomous variable whose distribution was assumed to be binomial.

RESULTS

Subjects included university students, staff and faculty who volunteered to participate in the study. Their average age was 30.6 years, and ranged from 21 to 50. Ten of the subjects had experience in wearing respirators in workplace settings. The gender and race distribution of the sample is shown in Table 1.

Figure 2 is a plot of the dispersion of test subjects according to their face length and lip width relative to the Los Alamos respirator test panel.⁽¹²⁾ Although it follows the same general pattern, facial

dimension distribution of the sample is skewed to the upper right of the test panel. This difference could be attributed to true differences between the populations used to establish the panel and the sample population, or to systematic differences in measurement technique by the investigator.

Table II summarizes observed respirator leak sites for all subjects and gender subsets. Statistical analysis of race subsets was not considered appropriate because of the small number of subjects in these groups. It is very obvious that, for all subjects, the leak categories with the highest proportions were those at the nose and those which were multiple leaks involving the nose and chin. The chi-square goodness-of-fit test verified that all categories were not equally likely to occur ($p < 0.0001$).⁽¹⁸⁾ Frequencies for all other categories were less than their expected values. About 79% of all subjects tested had leaks at the nose or multiple leaks which included the nose. Approximately 51% of the subjects had leaks at the chin or multiple leaks that included the chin. Only about 19% of the subjects had leaks at the cheek or multiple leaks which included the cheek.

The leak site distributions for males and females also were tested by the chi-square goodness-of-fit test.⁽¹⁸⁾ As in the overall results, significant differences existed in the categories of nose leaks and nose\chin leaks. Male and female leak site distributions also were compared to each other using an extended Fisher's exact test and were found not to be significantly different.⁽²²⁾

Observed leak shapes are summarized in Table III. A total of 110 leaks were observed on 73 subjects. When more than one leak occurred on

the same subject, the shape of one was found to be independent of the other leak by Fisher's exact test ($p = 1.000$).⁽¹⁸⁾ For all subjects, it was found that the proportion of diffuse leaks (0.727) was significantly greater than 0.5 by the one-sample binomial test ($p < 0.0001$).⁽¹⁸⁾ The proportion of diffuse leaks for males was 0.822 and for females was 0.630. However, only the observed proportion of diffuse leaks on males was significantly different than 0.5 ($p < 0.0001$). A chi-square test for independence found that that males were significantly more likely to have diffuse leaks than females ($p = 0.041$).⁽¹⁸⁾

Subsets were formed of subjects with a primary leak type in common. All of the subjects without the leak site(s) of interest were combined to form comparison subsets. Because of small numbers, some subsets were not tested, and only limited tests could be performed on others. The leak site subsets tested are listed in Table IV.

A subset of subjects with air flow streamlining was added to the faceseal leak site categories. Streamlining was hypothesized by Myers *et al.* as being the cause of the bias which they had identified in their mannequin study of in-facepiece sampling factors.⁽⁷⁾ Visual evidence of streamlining was found from aerosol deposition patterns on 16 subjects in this study (13 females and 3 males). All but one of the streamlining leaks were nose leaks. These patterns originated at the faceseal leak site and followed relatively straight lines to the subjects' noses or mouths. Subjects with these patterns were treated as a separate subset because of the implications of this phenomenon on the validity of in-facepiece sampling for the determination of fit factors.

The means for each facial dimension of subjects in a leak site subset were compared to the mean of all other subjects using a Student's t-test⁽¹⁸⁾ or Wilcoxin's Rank Sum Test.⁽¹⁸⁾ In addition a two-way ANOVA was performed for each dimension using gender, leak site, and their interactions as the independent variables, and facial dimension as the dependent variable.⁽¹⁸⁾ By deduction, it was assumed that a difference in a dimension was attributed to gender if a significant difference was found in the two-sample test but not in the two-way ANOVA. The results of these analysis are shown in Table V.

Because of small sample numbers, race was not included in the analysis. However, an extended Fisher's exact test found that race distributions were not significantly different for any of the comparison subsets.⁽²²⁾ Therefore, it was assumed that race would not affect the outcome of the two-sample tests or the two-way ANOVA.

In summary, only nose width was found to be significantly different in the comparisons of the single leak subsets of nose only, cheek only, and chin only. Nose width was found to be significantly different in four of the eight comparisons. Significant differences in three sets of comparisons were found for biectorbitale breadth, biygomatic breadth, bigonial breadth, bitragon-menton arc, and bitragon-subnasale arc. Only two significant differences were observed for the two dimensions used to define the Los Alamos respirator test panel.⁽¹²⁾ Face length (menton-nasion length) was found to be significant in only two comparisons, and lip width was not significant in any of the comparisons.

Of the 24 significant differences observed, 17 were attributed to differences in gender. These results would indicate that gender is an important factor in the location of respirator leak sites. In most cases, the significant dimension was smaller thus indicating the difference was related to female dimensions.

Measured fit factors were recorded for each subject as part of the quantitative fit test and exposure to the fluorescent aerosol. Observed values ranged from 21 to greater than 50,000 with a geometric mean of 3060. The distribution of these values was found to be log-normal by the Kolmogorov-Smirnov one-sample test.⁽¹⁸⁾ These data indicate that the subjects were able to obtain exceptionally good face seals and in all cases the values exceeded the assigned fit factor of 10.⁽²³⁾ However, interpretation of these data are conditional because of the possibility of bias in fit factor measurements due to aerodynamic streamlining identified by Myers et al.⁽⁷⁾ and the evidence of that phenomenon observed on some subjects in this study.

The significance of differences between fit factor geometric means of various groups were tested by Student's t-test.⁽¹⁸⁾ There were differences between the geometric means for males and females, subjects with point leaks and those with diffuse leaks, and subjects with air flow streamlining and those without, but none were significant.

Results of comparisons of mean fit factors for subjects in the various leak site subsets are shown in Table VI. The geometric means for the chin leaks only and nose/chin leaks were significantly lower than their comparison subsets. This would indicate that aerosol penetration through chin leaks is much greater than through leaks at

other sites. These results are similar to those found in a study of particle size-dependent losses at leak sites.⁽²⁴⁾

The association of each facial dimension and fit factor was measured by Pearson's or Spearman's correlation coefficients.⁽¹⁸⁾ Coefficients were calculated for all subjects, by gender, for subjects with air flow streamlining, and for all of the leak site subsets. Coefficients which were significantly different from 0.0 were found in only six groups. Those results are summarized in Table VII. Menton-subnasale length and nasal root breadth were found to have significant coefficients in four groups. It is noted that no significant correlations were found for the dimensions used to define the Los Alamos respirator test panel.⁽¹²⁾

DISCUSSION

Results of this study indicate that about 79% of all subjects wearing one brand of half-mask respirator had face seal leaks at the nose or multiple leaks which included the nose. About 51% of all the subjects tested had leaks at the chin or multiple leaks which included the chin, while only about 19% had leaks at the cheek or multiple leaks which included the cheek. The distribution of leak sites on male and female subjects were not significantly different. Approximately 73% of leaks on all subjects were diffuse, although females were found to have a significantly smaller proportion of diffuse leaks than males (63% vs. 82%).

The association of the 12 measured facial dimensions with eight leak site subsets were also tested. Statistically significant associations were found in 24 of the 96 tests. Of these dimensions, 75%

were smaller than their comparison groups. About 71% of the significant differences were attributed to differences in gender. About 58% of the dimensions with significant association were face width measurements, about 17% were face length measurements, and about 17% were arc measurements.

Of the two dimensions used to define respirator test panels (face length and lip width) only face length was significantly associated with two leak site subsets. This indicates that these dimensions may not be good criteria for selecting respirators or predicting respirator leakage. Previous studies also failed to indicate an association between respirator leakage and these dimensions. (14,15)

The prevalence of nose leaks observed in this study (78%) followed the limited observations of two previous studies which identified face seal leak sites by other methods. (25,26) In addition, nose dimensions (subnasale-nasion length, nasal root breadth, and nose width) comprised 25% of the significant associations of facial dimension to leak site category. Nasal root breadth also had significant correlation coefficients with fit factors for four groups of subjects. These results would indicate that nasal dimensions should be considered in defining respirator test panels and in the sizing and selection of respirators for individual wearers.

Based on observed deposition patterns, diffuse leaks were considered to approximate slits, and point leaks to approximate round holes. These shapes would have implications on the leak flow equations used in respirator leak models, (2,3,4,5) and the pressure decay through face seal leaks. (9) Due to the high prevalence (73%) of diffuse leaks,

appropriate equations may be those that represent flow through slits rather than round holes.

A significant observation in this study was the presence of very heavy aerosol deposition along air flow streamline patterns on about 22% of the subjects tested. All of these patterns originated from point leaks and followed a relatively straight line to the subjects' nostril or mouth, and all but one were nose leaks. It is not known if streamlining does not occur with diffuse leaks or, if it does, that the test was not sensitive enough to detect it. Subjects with streamlining leaks were significantly smaller in 10 of the 12 facial dimensions measured, and 81% were female. Streamlining was hypothesized as causing bias in the measurement of fit factors in laboratory mannequin studies.⁽⁷⁾ This study confirms that this phenomenon occurs on human subjects.

Certain conditions known to affect the faceseal leakage of respirators were not addressed in this study. These conditions limit conclusions which can be made from this study and should be addressed in further research. Conditions which may affect leak location or shape are: 1) different brands and models of half-mask respirators, 2) intrasubject leak variability, and 3) subject breathing rates at higher work rates.

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TABLE I

Gender and Race Distribution of Test Subjects

Race	Male	Female	Total
Asian	7	2	9
Black	3	6	9
White*	25	25	50
Other	4	1	5
Total	39	34	73

* The race category of "Other" included Hispanics and Asian Indians.

TABLE II
Observed Respirator Leak Sites for All Subjects
and Gender Subsets

Leak Site	All		Gender			
	Subjects	(%)	Male (%)	Female (%)		
Nose	24	(32.9)	13	(33.3)	11	(32.4)
Cheek	6	(8.2)	4	(10.2)	2	(5.9)
Chin	6	(8.2)	3	(7.7)	3	(8.8)
Nose & Cheek	4	(5.5)	3	(7.7)	1	(2.9)
Nose & Chin	26	(35.6)	11	(28.2)	15	(44.1)
Cheek & Chin	1	(1.4)	1	(2.6)	0	(0.0)
Nose, Cheek & Chin	4	(5.5)	2	(5.1)	2	(5.9)
None Detected	2	(2.7)	2	(5.1)	0	(0.0)
Total	73		39		34	

TABLE III
Observed Leak Site Shapes

Subset	Leak Shape		Total
	Point (%)	Diffuse (%)	
All Subjects	30 (27.3)	80 (72.7)	110
Male	10 (17.8)	46 (82.2)	56
Female	20 (37.0)	34 (63.0)	54
Black	2 (18.2)	9 (81.8)	11
Oriental	3 (23.1)	10 (76.9)	13
White	24 (30.0)	56 (70.0)	80
Other	1 (16.7)	5 (83.3)	6

TABLE IV

Leak Site Subsets Tested for Differences in Facial Dimensions

Test Subset	Leak Sites Included in the Subsets	Number of Subjects
Nose Leaks Only	Nose	24
All Nose Leaks	Nose Nose-Cheek Nose-Chin	56
Cheek Leaks Only	Cheek	6
All Cheek Leaks	Cheek Nose-Cheek Cheek-Chin	15
Chin Leaks Only	Chin	6
All Chin Leaks	Chin Nose-Chin Cheek-Chin	37
Nose-Chin Leaks	Nose-Chin	26
Streamlining	Subjects with Aerodynamic Streamlining	16

TABLE V

Facial Dimensions with Significant Association with Leak Sites

Dimension	Nose Leaks Only	All Nose Leaks	Cheek Leaks Only	All Cheek Leaks	Chin Leaks Only	All Chin Leaks	Nose- Chin Leaks	Stream- lining Leaks
Blectorbitale Breadth						G ²		G ²
Bizygomatic Breadth						G ²	G ²	G ²
Bigonial Breadth				A ¹			G ²	G ²
Menton-Nasion Length				G ¹				G ²
Menton-Subnasale Length								G ²
Subnasale-Nasion Length				A ¹				
Biocular Breadth								G ²
Nasal Root Breadth								G ²
Nose Width	A ¹					A ²	G ²	G ²
Lip Width								
Bitragion-Menton Arc				G ¹			A ²	G ²
Bitragion-Subnasale Arc				G ¹			A ²	A ²

A - Significant difference for all subjects in the test group.

G - Significant difference for subjects in the test group affected by gender.

¹ Dimension in the test group was significantly larger than the comparison group.

² Dimension in the test group was significantly smaller than the comparison group.

TABLE VI

Fit Factor Geometric Means of Leak Site Subsets

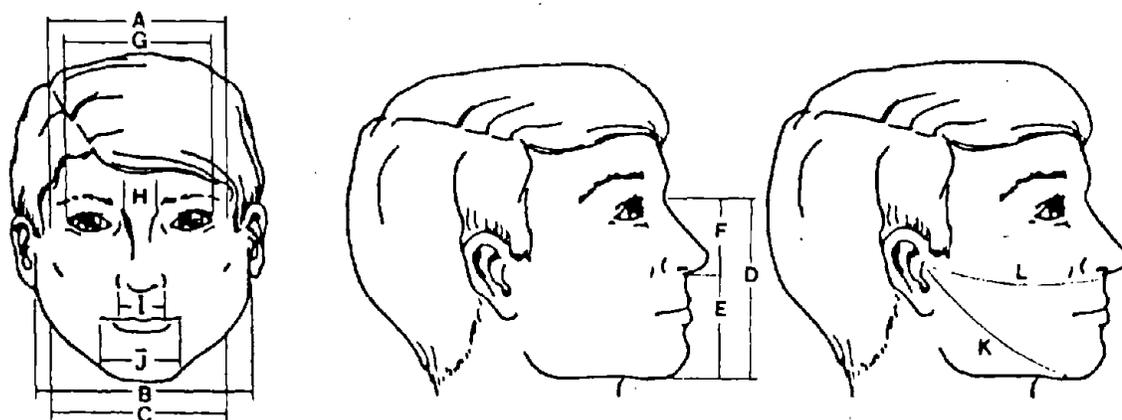
Subset	Number In Subset	Subset Geometric Mean	Comparison Subset Geometric Mean	t-test p value
Nose Leaks Only	24	5210	2360	0.066
All Nose Leaks	58	2640	5460	0.148*
Nose/Chin Leaks	26	1590	4400	0.015*
Cheek Leaks Only	6	4020	2980	0.659
All Cheek Leaks	15	2830	2830	0.998
Chin Leaks Only	6	2930	3080	0.950*
All Chin Leaks	37	1810	4580	0.019
Streamlining Leaks	15	1410	3810	0.148

* Significantly different at $\alpha = 0.05$

TABLE VII

Facial Dimensions with Significant
Correlation Coefficients to Fit Factors

Facial Dimension	All Subjects	Males	Females	Nose Leaks Only	All Nose Leaks	All Chin Leaks
Menton-Subnasale Length	0.322	0.431			0.290	0.361
Bilocular Breadth	0.234				0.250	
Nasal Root Breadth	0.285		0.336	0.467	0.306	



- | | |
|--|--|
| A. Bleptoorbitale Breadth | F. Subnasale-Nasion Length
(Nose length) |
| B. Bilzygomatic Breadth
(Face Width) | G. Bilocular Breadth |
| C. Bigonial Breadth | H. Nasal Root Breadth |
| D. Menton-Nasion Length
(Face Length) | I. Nose Width |
| E. Menton-Subnasale Length
(Lower Face Length) | J. Lip Width |
| | K. Bitragion-Menton Arc |
| | L. Bitragion-Subnasale Arc |

Figure 1 -- Facial dimensions.

B270
10

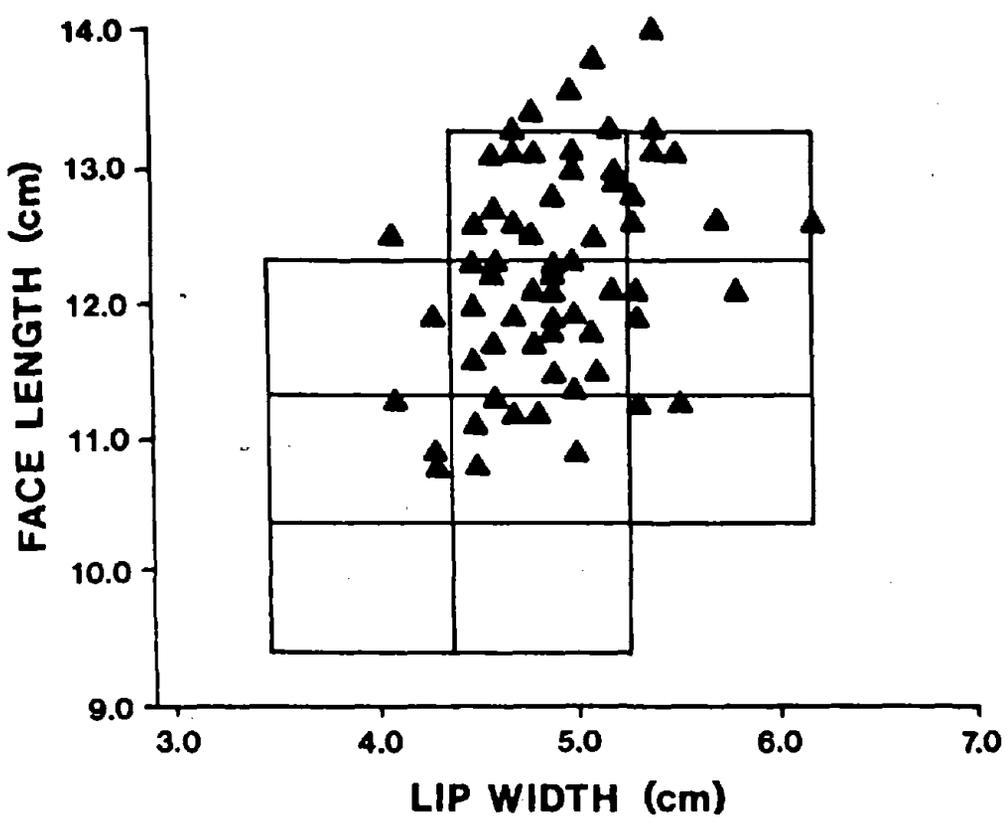


Figure 2 -- Distribution of test subjects on the fit test panel.

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