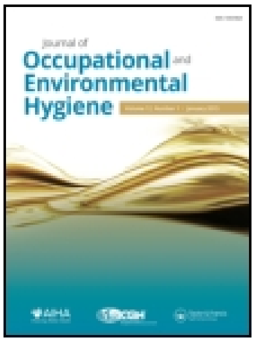

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Correlation Between Respirator Fit and Respirator Fit Test Panel Cells by Respirator Size

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The National Institute for Occupational Safety and Health (NIOSH), recognizing the difficulties inherent in using old military data to define modern industrial respirator fit test panels, recently completed a study to develop an anthropometric database of the measurements of heads and faces of civilian respirator users. Based on the data collected, NIOSH researchers developed two new panels for fit testing half-facepiece and full-facepiece respirators. One of the new panels (NIOSH bivariate panel) uses face length and face width. The other panel is based on principal component analysis (PCA) to identify the linear combination of facial dimensions that best explains facial variations. The objective of this study was to investigate the correlation between respirator fit and the new NIOSH respirator fit test panel cells for various respirator sizes. This study was carried out on 30 subjects that were selected in part using the new NIOSH bivariate panel. Fit tests were conducted on the test subjects using a PORTACOUNT device and three exercises. Each subject was tested with three replications of four models of P-100 half-facepiece respirators in three sizes. This study found that respirator size significantly influenced fit within a given panel cell. Face size categories also matched the respirator sizing reasonably well, in that the small, medium, and large face size categories achieved the highest geometric mean fit factors in the small, medium, and large respirator sizes, respectively. The same pattern holds for fit test passing rate. Therefore, a correlation was found between respirator fit and the new NIOSH bivariate fit test panel cells for various respirator sizes. Face sizes classified by the PCA panel also followed a similar pattern with respirator fit although not quite as consistently. For the LANL panel, however, both small and medium faces achieved best fit in small size respirators, and large faces achieved best fit in medium respirators. These findings support the selection of the facial dimensions for developing the new NIOSH bivariate respirator fit test panel.

Keywords fit test panels, fit testing, respirator size, respirators

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

INTRODUCTION

The consideration of face size and shape has long been a matter of concern to those responsible for respirator testing and certification. Prior to 1972, the U.S. Bureau of Mines (USBM) was responsible for testing and approval of respirators used in the United States. The USBM testing program included the testing of respirators on a panel of human subjects with "varying facial shapes and sizes," a provision that was criticized by many as being too vague.(1)

In 1972, the National Institute for Occupational Safety and Health (NIOSH) took over the USBM's responsibilities for respirator performance testing and certification, with those functions now carried out by the NIOSH National Personal Protective Technology Laboratory (NPPTL). The NIOSH respirator certification regulations currently use language almost identical to that used by the USBM prior to 1972. Certification regulations for three different mask types (42 CFR 84.124(a), 84.205(a), and 84.1156(b)(1)) indicate that the masks are to be tested on a panel of human subjects with varying facial shapes and sizes for a qualitative fit test using isoamyl acetate as the challenge vapor.(2) There has been limited progress in the understanding of how facial shapes and sizes should figure into the certification process.

Los Alamos National Laboratories (LANL) worked under contract with NIOSH in the early 1970s to better define the faces of two panels of subjects (one panel for half-mask respirators and a second panel for full-facepiece respirators). LANL chose to define the panel for half-mask respirators in terms of face length and lip length and a separate panel for full facepiece respirators in terms of face length and face width.[3,4] The LANL specifications were based largely on anthropometric studies using 4325 U.S. military personnel rather than the working population, although LANL did obtain data for a small civilian comparison cohort.[3]

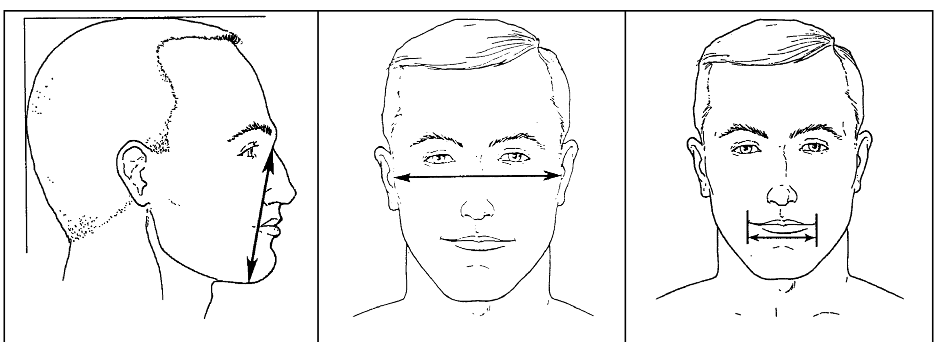
Face length is defined as the straight-line distance from the sellion (deepest point in the hard tissue depression at the top of the nose) to the menton (the lowest and most anterior point on the bony structure of the chin), and lip length is the distance from one end of the fleshy portion of the lips to the other end, with the subject's mouth closed and teeth slightly occluded (Figure 1). The range for face length is 93.5–133.5 mm, and range for lip length is 34.5–61.5 mm in the LANL fit test panel. The panel is divided into 12 categories, based on a 10-mm increment in face length and a 9-mm increment in lip length. Because two cells contained very low percentages of the population (0.2–0.3%), they were deleted from the test panel, leaving a 10-cell panel that represent about 99.5% of the military survey participants (Figure 2). The panel size was determined to be 25 persons based on a subjective decision to minimize time constraints on fit testing, and the number of persons for each cell was determined based on the percentage of the U.S. Air Force survey populations for that cell.

Those specifications, however, when proposed by NIOSH for certification regulations, drew criticism during the public comment period.[5] In response, NIOSH committed to a program of research into fit test methods. Some of that research has been completed and published.[6−8] In more recent years, NIOSH issued performance requirements for self-contained breathing apparatus (SCBA) respirators intended for emergency responses.[9] The LANL panel, which is defined by the face length and face width (for full-facepiece devices), was incorporated into a NIOSH certification facepiece fit test.[9]

Zhuang and Bradtmiller[10] described an anthropometric survey of U.S. civilian workers who had respirator-wearing experience. Based on the NIOSH anthropometric survey, Zhuang et al.[11] developed criteria for two new fit test panels for both half-mask and full-facepiece respirators (Figures 3 and 4). The bivariate panel was defined by face length and face width (previously used by LANL for full face masks). For the other panel, the categorization depends on two principal components, which in turn are functions of 10 facial dimensions.

Before selecting face length and face width for the NIOSH bivariate panel, NIOSH did a thorough review of the literature on correlation between respirator fit and facial dimensions. Four of the eight scientific studies found that face length and/or face width were correlated to respirator fit.[12−19] A recent study by Oestenstad et al.[16] suggested that other facial dimensions including bigonial breadth, biectoorbitale breadth, and bizygomatic breadth be considered when designing half-mask respirators, and that face length and lip width alone may not be appropriate in defining test groups whose fit is intended to be representative of worker populations.Oestenstad et al. concluded that their results are similar to those of Zhuang et al.[19]

The selection of the 10 dimensions for principal component analysis (PCA) was also based on literature review, expert opinions, and correlation analyses between all dimensions.[11,19] Zhuang et al.[11] used PCA to transform 10 dimensions into two principal components, with one component (PC1) describing the overall size of the face and the other component (PC2) describing the faces on an axis that ranges from long/narrow to short/wide. The following formulae describe the two principal



Face length measurement: Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark.	**Face width measurement:** Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches.	**Lip length measurement:** The straight-line distance between the right and left Chelion landmarks at the corners of the closed mouth is measured with a sliding caliper.

FIGURE 1. Description and diagram of key facial dimensions for defining NIOSH bivariate respirator fit test panel and LANL panel

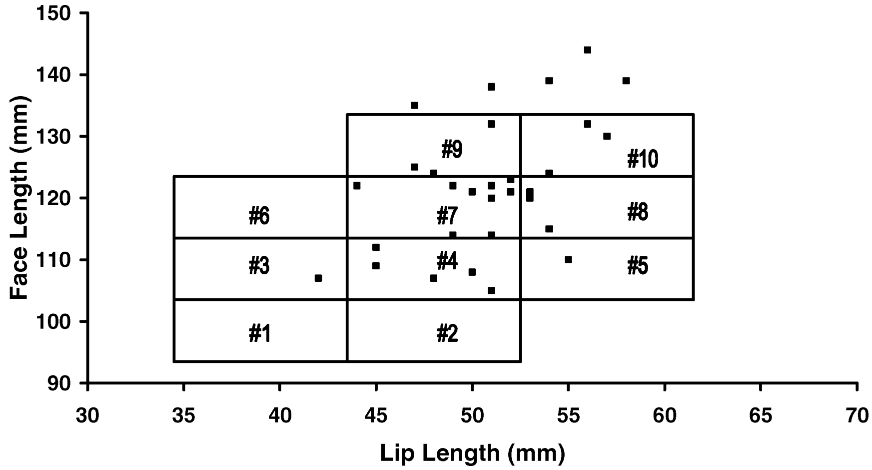


FIGURE 2. Scatter plot of the 30 subjects against the LANL respirator fit test panel with cell number

components (all units are in mm):

$$\begin{aligned} PC1 = {} & 0.343264 * (\text{minimum frontal breadth}) + 0.426498 \\ & * (\text{face width}) + 0.372717 * (\text{bigonial breadth}) \\ & + 0.329648 * (\text{face length}) + 0.363474 \\ & * (\text{interpupillary distance}) + 0.372241 \\ & * (\text{head breadth}) + 0.113578 * (\text{nose protrusion}) \\ & + 0.301125 * (\text{nose breadth}) + 0.202311 \\ & * (\text{nasal root breadth}) + 0.193650 \\ & * (\text{subnasale-sellion length}) \end{aligned} \quad (1)$$

$$\begin{aligned} PC2 = {} & -0.152951 * (\text{minimum frontal breadth}) - 0.039087 \\ & * (\text{face width}) - 0.093279 * (\text{bigonial breadth}) \\ & + 0.359799 * (\text{face length}) - 0.173099 \\ & * (\text{interpupillarydistance}) + 0.013306 \\ & * (\text{head breadth}) + 0.551842 * (\text{nose protrusion}) \\ & - 0.210833 * (\text{nosebreadth}) - 0.341235 \\ & * (\text{nasal root breadth}) + 0.584261 \\ & * (\text{subnasale-sellion length}) \end{aligned} \quad (2)$$

The definitions and diagrams of the dimensions used in the formulae for PC1 and PC2 have been published previously, along with a description of an algorithm for determining to which cell a subject is assigned.[11]

Some questions regarding the new NIOSH panels were raised such as:

- Are the panels appropriate for certification testing?
- How do current manufactured respirators fit different cells of the new NIOSH panels?
- Do manufacturers need to design new sizes of respirators?
- Is there a correlation between manufactured respirator sizes, and the new NIOSH panel cells, i.e., is there a correlation between fit factor and panel cell for different respirator sizes?

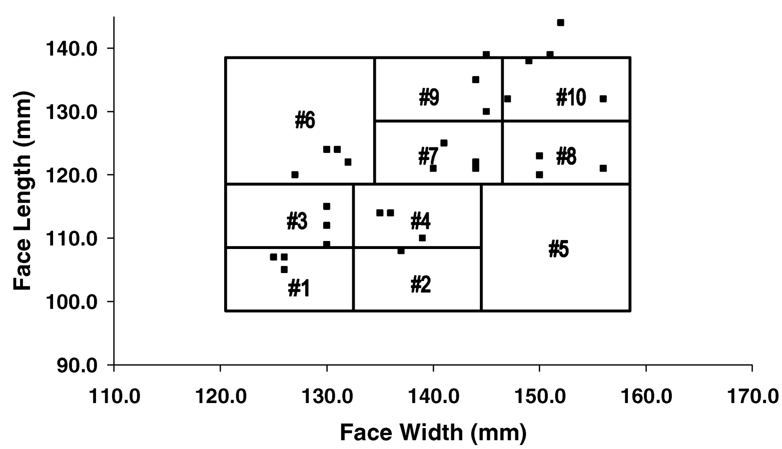


FIGURE 3. Scatter plot of the 30 subjects against the NIOSH bivariate respirator fit test panel with cell number

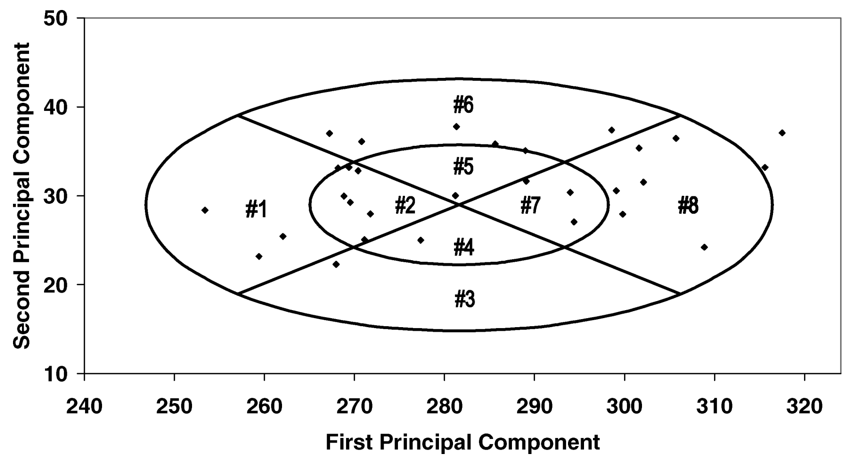


FIGURE 4. Scatter plot of the 30 subjects against the PCA respirator fit test panel with cell number

The objective of this study was to investigate the correlation between respirator fit of different respirator sizes and the respirator fit test panel cells for the NIOSH bivariate, PCA, and LANL panels. Respirator size is defined by the manufacturer's size designation. Manufacturer's sizes are somewhat arbitrary and "small" respirators from two different manufacturers may result in respirator fits associated with different cells of the NIOSH panels. Cell numbers are also arbitrary. For example, they have been chosen such that cells 1–3 of the NIOSH bivariate panel are indicative of small faces, while cells 8–10 are indicative of large faces. This study also investigated whether the current small, medium, and large size respirators fit small, medium, and large faces respectively as defined by the NIOSH panels. Using a pass/fail criterion of fit factor greater than or equal to 100, the fit test passing rate was also calculated.

METHODS AND MATERIALS

Subjects

Thirty subjects were recruited from the metropolitan area of Pittsburgh, Pennsylvania. The recruiters were instructed to select subjects representing the range of face lengths and face widths required by the new NIOSH bivariate respirator fit test panel of Figure 3. Although the subjects did include representatives of the larger and smaller cells, no subjects were identified for cell number 5. The resulting panel of thirty subjects consisted of 13 males and 17 females. All were Caucasian with the exception of two Asian-Americans females and one African-American male. No Hispanics, which account for 12.5% of the U.S. population, participated in the study. However, no significant difference in respirator fit was found between different race groups when they have similar face dimensions.[17] The weight of the subjects ranged from 48.6 kg to 116.0 kg. The stature of the subjects ranged from 1.507 m to 1.900 m.

Measurement of Face Dimensions

The facial measurements were determined by means of a sliding caliper and spreading caliper. Face length was determined with the sliding caliper by measuring the distance from the sellion to the menton. The sellion and menton were both located by means of finger palpation of facial tissue prior to measurement. Once the points were located and marked, the sliding caliper was used to measure the distance to the nearest millimeter.

Face width was measured with a spreading caliper as the maximum distance between the left and right zygomatic arches. The points of maximum distance were located first by finger palpation of the facial tissue on each side of the face. Then the spreading caliper was placed on each of the points, and the distance was read to the nearest millimeter. For both the face length and face width, the caliper was lightly resting on the facial skin, with only slight contact. The face length, face width, and lip length measurements are illustrated in Figure 1. Subjects were placed into the NIOSH bivariate panel cell based on the width and length of their faces. The subjects were measured for lip length to allow assignment to the LANL fit panel size categories. LANL subjects were not grouped for testing as in the NIOSH standard fit test protocols, where small are cells 1 through 4, medium are sizes 3 through 8, and large are sizes 7 through 10. Techniques for measuring the other parameters necessary for calculating the cell number in the PCA panel have been described elsewhere.[11]

Respirators

The respirators were chosen to include one filtering-facepiece respirator and three elastomeric half-mask respirators. All respirators were NIOSH approved and bulk purchased in the United States to ensure consistency in mask characteristics. The elastomeric respirator facepiece designs varied qualitatively in flexibility, elastomeric thickness, and elastomeric finish (glossy, semiglossy, flat). None of these qualities were included in the manufacturers' advertised descriptions nor were these qualities measured after purchase. The qualitative differences are noted here for descriptive purposes only. All respirator filtration media were P100 classification.

Quantitative Fit Testing

Each of the subjects completed quantitative fit tests using a PORTACOUNT device (model 8020; TSI Inc., Shoreview, Minn.) and three exercises on each of four models of half-mask respirators from four different manufacturers, in sizes of small, medium, and large for each respirator model. The fit tests consisted of three one-minute exercises (breathing normally, nodding head, and moving head side to side). These three exercises were chosen primarily to economize on the time commitment of the subjects (thereby increasing continued participation) while still achieving a reasonable diversity of head movements and leak locations, rather than to achieve fit test results comparable to the standard set of OSHA exercises.[20] The nodding and side-to-side movements provide opportunities for the respirators to move in at least two directions if the fit on a given subject is susceptible to such movement. If such susceptibility was present, it would have been reflected in the overall fit factor for that subject, based on the three exercises. The fit tests for each respirator model/size combination were completed three times, with repeated donnings. Subjects were given a 3-min accommodation period before each fit test, and a 3-min rest period after each fit test.

The order of testing the model/size combinations was randomized for each subject, although the repeated donnings were carried out in succession (i.e., all three fit tests on a given model size were completed before going to the next model/size combination).

The PORTACOUNT measures fit by comparing ambient aerosol in the laboratory to aerosol inside the mask, which has presumably entered by means of leaks in the faceseal. For each day of fit testing, the PORTACOUNT was given pre- and post-tests to assure proper function and the adequacy of the ambient aerosol in the laboratory air (i.e., ambient particle concentration >1000 particles per cubic centimeter).

The elastomeric respirators were inspected prior to each use for proper seating of inhalation and exhalation valves. Each subject attempted to achieve an acceptable positive and negative pressure check before each fit test as required and described in OSHA 29 CFR 1910.134 standards,[20] although in some cases the mismatch between respirator and face was so great that an acceptable pressure check could not be achieved. The mismatches were expected, since the intent was to achieve a wide range of fit factors for a range of facial sizes. Fit test data was obtained for those cases with no acceptable pressure check in order that the true trend of the relationship between facial size and respirator fit could be observed.

Statistical Analyses

For each subject/respirator model/size combination, the three fit factors (FF) were log-transformed and then averaged because fit factors are highly variable and usually lognormally distributed.[21] The mean log-transformed fit factors (MLFF) for all four respirator models were further averaged by respirator size to obtain subject MLFF values (SMLFF). This was done to obtain independent observations for correlation analysis. This grouping of data is appropriate, since both elastomeric and filtering-facepiece respirators have an assigned protection factor of 10.

The correlation between SMLFF and panel cells was analyzed using multiple linear regression models. The dependent variable was SMLFF, and the independent variable was center points of panel cells. Cells for each panel are numbered as shown in Figures 2–4. SMLFF was regressed on both face width and face length, i.e., center points of each panel cell. Individual subject face width and face length were not used for each person, since it is the panel that is being evaluated. The center points for each cell of all three panels are given in

TABLE I. Summary of Center Points for Each Respirator Fit Test Panel

	Center Point of Each Cell					
	NIOSH Panel		LANL Panel		PCA Panel	
Cell	Face Width (mm)	Face Length (mm)	Lip Length (mm)	Face Length (mm)	PCA1	PCA2
1	126.5	103.5	39	98.8	255.94	28.99
2	138.5	103.5	48	98.5	273.33	28.99
3	126.5	113.5	39	108.5	281.62	18.52
4	138.5	113.5	48	108.5	281.62	25.61
5	151.2	108.5	57	108.5	281.62	32.37
6	127.5	128.5	39	118.5	281.62	39.46
7	140.5	123.5	48	118.5	289.91	28.99
8	152.5	123.5	57	118.5	307.31	28.99
9	140.5	133.5	48	128.5		
10	152.5	133.5	57	128.5		

Table I. A regression equation was obtained for each panel and each respirator size by using PROC GLM in SAS for Windows (SAS Institute Inc., Cary, N.C.).

Face sizes were then classified into three categories (small, medium, and large faces) for both the NIOSH bivariate panel and LANL panel, and five categories (small, medium, large, short/wide, and long/narrow faces) for the PCA panel. For the NIOSH bivariate panel, small faces were defined as those falling in cells 1–3 of Figure 3, medium faces were those falling in cells 4–7, and large faces were those falling in cells 8–10. For the LANL panel, the categories and cell numbers are similar to the NIOSH bivariate panel. For the PCA panel, small faces were defined as those falling in cell 1 of Figure 4, medium faces were those falling in cells 2, 4, 5, 7, large faces were those falling in cell 8, short/wide faces were those falling in cell 3, and long/narrow faces were those falling in cell 6.

For each panel and face size category, a one-way analysis of variance (ANOVA) was conducted to determine if respirator size affected the MLFF values. The SAS PROC MIXED procedure was used to conduct the analysis with subjects as repeated measure and random effect. Pair-wise comparisons were done using CONTRAST statements to determine if significant differences in geometric mean MLFF values were found between respirator sizes.

For each subject/respirator model/size combination, the fit factors for the three replications were also averaged. The average value was compared to a pass/fail criterion of 100 to determine if the subject wearing a particular model and size passed the fit test. If the average FF was greater than or equal to 100, that subject passed the fit test. Otherwise, that subject failed the fit test. Fit test passing rate was then calculated by respirator size for each face size category of each fit test panel.

RESULTS

Subject Characteristics

Figure 3 shows the distribution of the 30 subjects across the NIOSH panel. Two subjects had face length measurements of 139 mm, which is within the allowable measurement error. However, one subject had a face length of 144 mm, an outlier for the NIOSH bivariate panel. For the purpose of subsequent analysis, these three subjects were considered part of the closest adjacent cell, i.e., cells 9 and 10.

The subjects were categorized using the PCA formulae (Eqs. 1 and 2). It must be noted that subjects were not initially selected by the PCA panel and therefore are not evenly distributed among the PCA size categories. The study population did not consist of many individuals with short/wide faces, with only one subject in cells 3 and 4 (Figure 4). However, of the subjects recruited for this study, all but two fit within a PCA panel size category. Once again, subsequent analysis treated the data points as if they fell within cell number 8.

Subjects' assignment to the LANL fit panel size categories are shown in Figure 2. It must be noted that subjects were not initially selected by the LANL criteria and therefore are not evenly distributed among the LANL face size categories. In fact only one subject fell within the definition of LANL cells 1, 2, or 3. In Figure 2, there are five subjects who did not fit within the LANL panel, demonstrating that almost 17% of the study population could not be placed into a cell. As above, subsequent analysis has been performed with those data points being categorized as falling into the closest adjacent cells. The larger percentage of subjects outside the LANL panel (17%) as compared with the percentage outside the bivariate panel (10%) is in part a reflection of the intent that the bivariate panel would include a larger percentage of the working population.

Two of the subjects did not complete the full sequence of testing. Rather than 360 series of fit tests (30 subjects $\times$ 3 sizes $\times$ 4 models), only 354 series of fit tests were completed. There were 354 MLFF values and 90 SMLFF values for the correlation analyses.

Correlation Between Fit Factors and Panel Cell by Respirator Size

Table II provides a summary of correlation and regression results by fit test panel and respirator size. The best regression model, with the largest R^2 value, for each panel, occurred with the large size respirators. Significant correlations between SMLFF values and center points of panel cells were found in all three panels and small and large sizes (p-value < 0.01). As expected due to the nonlinear nature of the data, no significant correlations between SMLFF values and center points of panel cells were found in medium size for the NIOSH bivariate and LANL panels (p-value > 0.05).

The geometric mean (GM) fit factors for each subject were also calculated using the SMLFF values and are plotted against the center points of the NIOSH bivariate panel for large respirator size in Figures 5 and 6 (3-D view and side view). The regression equations (a plane) are also plotted in Figure 5. For the NIOSH bivariate panel, the GM fit factors increased as face width and face length goes up from cells 1 to 10 for large respirator size. For small respirator size, it is the opposite, i.e., the GM fit factors decreased with face width and face length for small respirator size. Therefore, there was a significant correlation between respirator fit and panel cells for small and large respirator sizes (p-value < 0.01).

Comparison of GM Fit Factors by Panel Face Size Category and Respirator Size

Table III shows the geometric mean of all fit test data within each combination of panel face size category and respirator size for the NIOSH bivariate panel. The results were from all respirator models (e.g., the four small respirator results—one from each model—all contributed to the geometric mean for a given face size category). In addition to the fit test summary statistics, results of pair-wise comparisons are also shown in the table with superscript letters.

The subjects in small face size category of the NIOSH bivariate panel were best fitted (i.e., had the highest geometric mean fit factor) by the small respirators, the medium with

TABLE II. Summary of Correlation Results

Fit Test Panels	Respirator Size	R^2	n	Linear Regression[A]	p-value
NIOSH Bivariate	Small	0.4967	30	$Z = 14.0352 - 0.0363 * X - 0.0539 * Y$	< 0.01
	Medium	0.0913	30	$Z = 1.4313 - 0.0151 * X + 0.0291 * Y$	>0.05
	Large	0.7065	30	$Z = -9.0460 + 0.0320 * X + 0.0575 * Y$	<0.01
PCA	Small	0.4062	30	$Z = 15.5294 - 0.0430 * X - 0.0296 * Y$	<0.01
	Medium	0.2305	30	$Z = 0.4443 - 0.0001 * X + 0.0808 * Y$	<0.05
	Large	0.5336	30	$Z = -10.4449 + 0.0396 * X + 0.0524 * Y$	<0.01
LANL	Small	0.4437	30	$Z = 14.5951 - 0.0192 * X - 0.0936 * Y$	<0.01
	Medium	0.0528	30	$Z = -0.1687 + 0.0086 * X + 0.0219 * Y$	>0.05
	Large	0.5326	30	$Z = -8.8771 + 0.0276 * X + 0.0825 * Y$	<0.01

[A]Z = Mean log-transformed fit factor for all four respirator models for each subject/respirator size combination. NIOSH Bivariate: X = face width of panel cell center; Y = face length of panel cell center (Figure 3).
PCA: X = PC1 of panel cell center; Y = PC2 of panel cell center (Figure 4).
LANL: X = lip length of panel cell center; Y = face length of panel cell center (Figure 2).

medium respirators, and the large faces with large respirators. Subjects in cells 1, 2, and 3 (the small face sizes) had the highest geometric mean fit factor (3464.7, SD = 23.6) for the small respirators, which is significantly different from the next highest GM fit factor (245.5, SD = 19.4) for the medium respirators. Subjects in cells 4, 5, 6, and 7 (the medium face sizes) had the highest geometric mean fit factor (1562.7, SD = 20.6) for the medium respirators, which is also significantly different from the next highest GM fit factor (390.5, SD = 23.5) for the small respirators. Subjects in cells 8, 9, and 10 (the large face sizes) had the highest geometric mean fit factor (1744.1, SD = 24.0) in the large respirators. However, it is not significantly different from the next highest GM fit factor (695.3, SD = 21.3) for the medium respirators. These results are expected and support the use of face length and face width as the criteria for a half-facepiece fit test panel.

The comparisons of GM fit factors within the PCA-determined face size categories and respirator size, as shown in Table IV, indicate that the PCA small, medium, and large face categories achieved the highest GM fit factors for the small, medium, and large respirators, respectively. The long/narrow face category achieved the highest GM fit factor for medium respirator size. The short/wide face category achieved the highest GM fit factor for the small respirators. This is not surprising given that the one subject in that cell was close

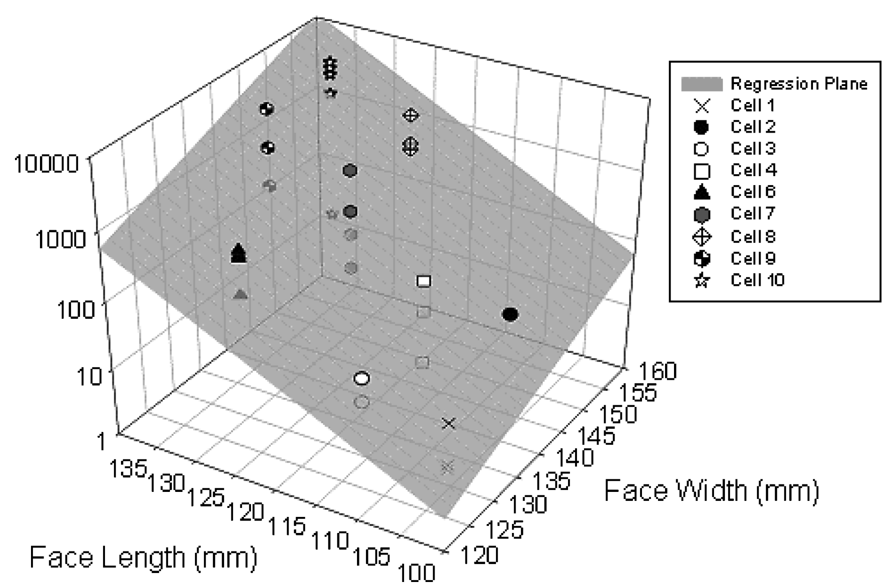


FIGURE 5. Plot of the geometric mean fit factor against center points of NIOSH bivariate panel cells for large respirator size (3-D view). The regression plane is also plotted.

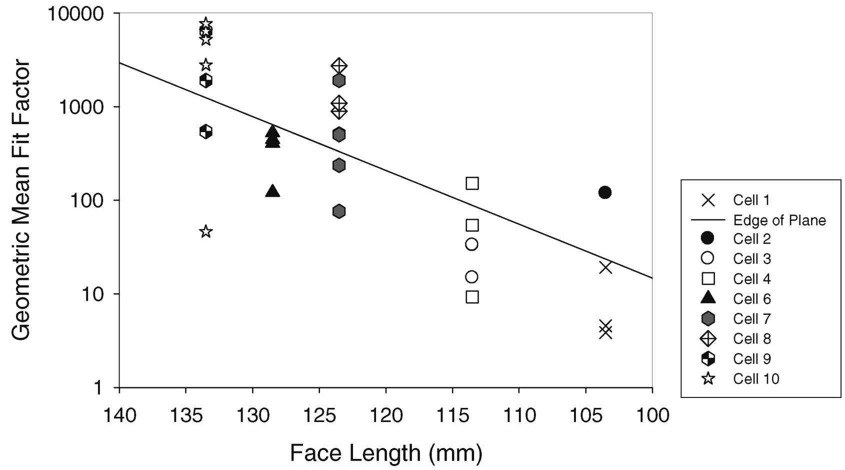


FIGURE 6. Replot of Figure 5 (side view)

to the border with the small face size category. Although the statistical test took consideration of sample size, comparison with cell 3 with only one subject may not be reliable. Only the highest GM fit factor (3679.9, SD = 10.9) for the medium size respirator and long/narrow face category is significantly different from the next highest GM fit factor (516.4, SD = 10.3) for large respirators.

Subjects in the LANL small and medium categories, as shown in Table V, were best fitted by the small respirators, and subjects in the LANL large category were best fitted by the medium respirators. The subject in cell 3 had the highest GM fit factor for small respirators, subjects in cells 4–7 had the highest GM fit factor for the small respirators, and subjects in cells 8 through 10 had the highest GM fit factor for the medium respirators. However, none of these three highest GM fit factors is significantly different from the next highest GM fit factor. They are significantly different from the smallest GM fit factors, respectively for each face size category.

Comparison of Fit Test Passing Rate by Panel Face Size Category and Respirator Size

The fit test passing rates for the NIOSH bivariate, PCA, and LANL panels were analyzed by face size category and respirator size, with results shown in Tables VI through VIII, respectively. For the NIOSH bivariate panel, as expected, each face size category had the highest passing rate with respirators of the same size. Similar results were obtained with the PCA panel. Small, medium, and large faces had the greatest passing rate with small, medium, and large respirators, respectively. Subjects with short/wide faces obtained the highest fit test passing rate with the small respirators, while individuals with long/narrow faces obtained the highest fit test passing rate with medium size respirators.

According to the LANL panel, small and medium face categories had the highest fit test passing rate with small respirators, and large faces had the highest fit test passing rate with medium respirators. Because there was only one subject in the short/wide face category of the PCA panel and small

TABLE III. Geometric Mean of Fit Factors by Respirator Size and the NIOSH Bivariate Panel Face Size Category

		Geometric Mean Fit Factor (GSD) Respirator Size		
NIOSH Face Size Category	Respirator Size with Highest GM Fit Factor	Small	Medium	Large
Small (NIOSH Cells 1–3)	Small	3464.7^{A} (23.6) n = 27	245.5^{B} (19.4) n = 27	18.1^{C} (10.7) n = 27
Medium (NIOSH Cells 4–7)	Medium	390.5^{B} (23.5) n = 48	1562.7^{A} (20.6) n = 48	210.1^{B} (15.3) n = 48
Large (NIOSH Cells 8–10)	Large	30.2^{B} (15.8) n = 43	695.3^{A} (21.3) n = 44	1744.1^{A} (24.0) n = 42

Note: Superscript groupings apply across respirator sizes and within a given NIOSH face size category. Means with the same letter are not significantly different (alpha = 0.05).

TABLE IV. Geometric Mean of Fit Factors by Respirator Size and the PCA Panel Face Size Category

PCA Face Category	Respirator Size with Highest GM Fit Factor	Geometric Mean Fit Factor (GSD) Respirator Size		
		Small	Medium	Large
Small (PCA Cell 1)	Small	9417.9^{A} (12.1) n = 15	1360.4^{A} (20.7) n = 15	20.6^{B} (17.3) n = 15
Medium (PCA Cells 2,4,5,7)	Medium	226.4^{A} (29.0) n = 44	330.0^{A} (19.0) n = 44	142.1^{A} (22.4) n = 44
Large (PCA Cell 8)	Large	47.8^{B} (20.9) n = 31	891.0^{A} (25.2) n = 32	1583.8^{A} (32.3) n = 30
Short/Wide (PCA Cell 3)	Small	1047.3^{A} (36.8) n = 4	18.8^{A} (9.3) n = 4	33.0^{A} (7.2) n = 4
Long/Narrow (PCA Cell 6)	Medium	221.2^{B} (27.7) n = 24	3679.9^{A} (10.9) n = 24	516.4^{B} (10.3) n = 24

Note: Superscript groupings apply across respirator sizes, and within a given PCA face size category. Means with the same letter are not significantly different (alpha = 0.05).

face category of the LANL panel, the passing rates in these two categories may not be reliable.

DISCUSSION

This is the first study to investigate the correlation between fit factors and center points of fit test panels for different respirator sizes. Respirator size was found to significantly affect the fit of subjects in different cells of a fit test panel. Small, medium, and large size respirators have significantly different patterns of respirator fit for the panel cells (Figures 5 and 6). For the small respirator size, respirator fit decreased as the face width and face length increased. For the large respirator size, it was the opposite.

The increase or decrease in fit is also of practical importance. For example, for the large respirator size in Figure 6, the GM fit factors for all except two subjects in cells 1–4 (face length <115 mm) were below 100, which is the pass/fail level of the Occupational Safety and Health Administration (OSHA) standard fit test. (Note: The OSHA standard fit test employs several exercises in addition to those used for this investigation.) The GM fit factors for all except two subjects in cells 6–10 (face length >120 mm) were above 100. This pattern was further supported by the GM fit factors and fit test passing rates for each face size category of a fit test panel. For example, for the large respirator size, the fit test passing rate was 86% for subjects in the large face size category of the NIOSH bivariate panel (Table VI). For the same large respirator size, the fit test passing rate was only 26% for subjects in the small face size category.

Although the fit test passing rate of 86% is high for subjects in the large face size category of the NIOSH bivariate panel, there is still 14% of subjects that could not pass the fit test. This finding further supports the need for individual fit testing as required in the OSHA 29 CFR 1910.134 standards.[20] The fit test passing rates for the PCA panel follow a similar pattern to

TABLE V. Geometric Mean of Fit Factors by Respirator Size and LANL Panel Face Size Category

LANL Face Size Category	Respirator Size with Highest GM Fit Factor	Geometric Mean Fit Factor (GSD) Respirator Size		
		Small	Medium	Large
Small (LANL 1–3)	Small	2933.6^{A} (72.5) n = 4	$68.0^{A,B}$ (17.1) n = 4	4.5^{B} (2.4) n = 4
Medium (LANL 4–7)	Small	801.7^{A} (24.4) n = 58	576.6^{A} (23.8) n = 59	100.3^{B} (17.1) n = 57
Large (LANL 8–10)	Medium	64.5^{B} (26.7) n = 56	1211.7^{A} (18.9) n = 56	879.3^{A} (27.2) n = 56

Note: Superscript groupings apply across respirator sizes, and within a given LANL face size category. Means with the same letter are not significantly different (alpha = 0.05).

TABLE VI. Fit Test Passing Rate by Respirator Size and the NIOSH Bivariate Panel Face Size Category

NIOSH Face Size Category	Respirator Size with Highest Passing Rate	Fit Test Passing Rate Respirator Size		
		Small	Medium	Large
Small (NIOSH Cells 1–3)	Small	$\frac{22}{27} = 81\%$	$\frac{18}{27} = 67\%$	$\frac{7}{27} = 26\%$
Medium (NIOSH Cells 4–7)	Medium	$\frac{32}{48} = 67\%$	$\frac{40}{48} = 83\%$	$\frac{32}{48} = 67\%$
Large (NIOSH Cells 8–10)	Large	$\frac{12}{43} = 28\%$	$\frac{33}{44} = 75\%$	$\frac{36}{42} = 86\%$

that of the bivariate panel (Table VII). The passing rates based on the LANL panel (Table VIII) indicate less correspondence (as compared to the bivariate panel data) between face size and passing rates for a similar respirator size, but the LANL panel data for the small face size are based on only one subject.

The determination of the boundaries for small, medium, and large face size categories by each of the three face size criteria (NIOSH, LANL, and PCA) is somewhat arbitrary. For example, only cells 1 and 2 could have been used as the NIOSH bivariate panel small size category and only cells 9 and 10 as the large category. Further analysis using alternative size groupings could be carried out but is not presented here. When manufacturers designed these respirators, the NIOSH bivariate panel and PCA panel were not available yet. The three elastomeric models were tested by NIOSH on a panel of 10 subjects using the LANL panel with the overlap sizes as noted in the earlier description of the panel before NIOSH approved these respirators.

However, the filtering facepiece model was not tested by NIOSH, since fit testing was not required as part of the certification. Yet these models combined show a very good correlation between respirator fit and the NIOSH bivariate panel cells, i.e., small size respirators best fitted the small faces as classified by the NIOSH bivariate panel. So did the medium size respirators fit best the medium faces as classified by the NIOSH bivariate panel.

For the pair-wise comparisons in Table III, means with the same letter designation are not significantly different when read across the respirator sizes and within a given face size category. The superscript groupings indicate that for alpha = 0.05 and within the small face size category (cells 1–3), the small respirator not only had "best fit" or highest GM fit factor, but the GM fit factor was significantly greater than the other two GM fit factors for medium and large respirator sizes. Likewise, for medium face size category (cells 4–7), the medium respirator not only had best fit or highest GM fit factor, but the GM fit factor was significantly greater than the other two GM fit factors for small and large respirator sizes. Although the large respirator size had the best fit or highest GM fit factor for the large face size category (cells 8–10), the GM fit factor was not significantly greater than the GM fit factor for the medium respirator size.

For the PCA categorizations shown in Table IV, the highest GM fit factor for medium respirator size was significantly greater than the other two GM fit factors for the long/narrow face category. No other highest GM fit factor was significantly greater than the next highest GM fit factor for any of the other categories.

Table V indicates that the faces categorized by the LANL panel never had a best fit or highest GM fit factor that was significantly greater than the next better respirator size. Within the small face size category (cells 1–3), although the small respirator had best fit or highest GM fit factor, the GM fit factor was not significantly greater than the next best fitting respirator size, i.e., medium respirator size, which is not surprising as the single available subject was in an overlap size. This pattern was true for the other two face size categories. Interestingly, the small respirator size had the highest GM fit factors for medium face size category (cell 4–7), and the medium respirator size had the highest GM fit factors for large face size category

TABLE VII. Fit Test Passing Rate by Respirator Size and the PCA Panel Face Size Category

PCA Face Category	Respirator Size with Highest Passing Rate	Fit Test Passing Rate Respirator Size		
		Small	Medium	Large
Small (PCA Cell 1)	Small	$\frac{14}{15} = 93\%$	$\frac{13}{15} = 87\%$	$\frac{4}{15} = 26\%$
Medium (PCA Cells 2,4,5,7)	Medium	$\frac{25}{44} = 57\%$	$\frac{30}{44} = 68\%$	$\frac{25}{44} = 57\%$
Large (PCA Cell 8)	Large	$\frac{10}{31} = 32\%$	$\frac{24}{32} = 75\%$	$\frac{25}{30} = 83\%$
Short/Wide (PCA Cell 3)	Small	$\frac{3}{4} = 75\%$	$\frac{1}{4} = 25\%$	$\frac{1}{4} = 25\%$
Long/Narrow (PCA Cell 6)	Medium	$\frac{14}{24} = 58\%$	$\frac{23}{24} = 96\%$	$\frac{20}{24} = 83\%$

TABLE VIII. Fit Test Passing Rate by Respirator Size and the LANL Panel Face Size Category

LANL Face Size Category	Respirator Size with Highest Passing Rate	Fit Test Passing Rate Respirator Size		
		Small	Medium	Large
Small (LANL Cells 1–3)	Small	$\frac{3}{4} = 75\%$	$\frac{2}{4} = 50\%$	$\frac{0}{4} = 0\%$
Medium (LANL Cells 4–7)	Small	$\frac{43}{58} = 74\%$	$\frac{42}{59} = 71\%$	$\frac{31}{57} = 54\%$
Large (LANL Cells 8–10)	Medium	$\frac{20}{56} = 36\%$	$\frac{47}{56} = 84\%$	$\frac{44}{56} = 78\%$

(cells 8–10). Therefore, it appears that the certification test of 10 subjects recruited from each of the 10 cells of the LANL panel was not the only influence on the respirator design, and the resulting fit in each of the panel size groups may be driven by other factors.

The LANL test panel currently used to test the fit capability of respirators under 42 CFR 84 uses the following sizes based on face length and lip length in the panel: small: cells 1–4; medium: cells 3–8, and large: cells 7–10. Both small and medium respirator sizes that pass the LANL test panel will fit cells 3 and 4, and both medium and large respirator sizes will fit cells sizes 7 and 8. Respirators designed to fit the LANL panel should show some overlap with the small size respirators fitting some medium face sizes, the medium size respirators fitting both some small faces and some large faces, and large size respirators fitting some medium faces.

In this study, the subjects were recruited to represent the NIOSH bivariate panel. Thus, the subjects do not smoothly fill a LANL test panel. There were no subjects in cells 1, 2, or 6. This may skew the LANL panel results slightly, and in fact, the distribution suggests that masks performed as would be predicted by the LANL panel. The subjects in cell 3 had good fit factors in the small size respirators. The subjects in cell 4 did well in the medium and the small size respirators. The subjects in cells 7 and 8 did well in the medium and the large.

Table IX summarizes the correlation coefficients between the mean log-transformed fit factors for each subject/respirator size combination and the parameters that define the fit test panels used in this study. For the small and large size respirators, the correlation coefficients were greater than 0.7 (p-value <0.01) for PC1, face length, and face width. The coefficients were significantly smaller (large, $r \leq 0.52$ and p-value <0.01; small, $r = -0.33$ and p-value>0.05, $r = -0.38$ and p-value <0.05) for PC2 and lip length. For the medium size respirators, only the correlation coefficient ($r = 0.44$ and p-value <0.05) for PC2 was statistically significantly different from zero, which is not surprising given the nonlinear nature of the data from the medium sized respirators. This may suggest that medium respirators can, to some extent, accommodate small and large faces. These observations are consistent with the results from the regression analysis, GM fit factors, and fit test passing rate. Face width and face length are correlated with the fit of small and large sizes of respirators.

The new NIOSH respirator fit test panels show correlation between respirator fit and panel cells for various respirator sizes in this study and previously were found to be more representative of the current U.S. work force than the LANL panel.[10,22] If manufacturers develop new sizes based on the new NIOSH fit test panels, the correlation may be higher and the protection afforded to users could improve for users whose physiognomy does not match current sizes.

TABLE IX. Summary of Correlation Coefficients by Respirator Size

	SMLFF (Large Respirators)	SMLFF (Medium Respirators)	SMLFF (Small Respirators)
PC1	0.76	0.02^B	−0.73
PC2	0.51	0.44^A	-0.33^B
Face Length	0.78	0.15^B	−0.72
Face Width	0.68	-0.02^B	−0.70
Lip Length	0.52	0.15^B	-0.38^A

Abbreviation: SMLFF = mean log-transformed Fit Factors of all four respirator models for each respirator size/subject combination, and each respirator size had 30 subjects (n = 30).
Values without a superscript have p-value <.01.
^{A}p-value <.05.
^{B}p-value >.05.

CONCLUSIONS

This study found that respirator size significantly influenced fit within a given panel cell for the NIOSH bivariate panel. Face size categories also matched the respirator sizing reasonably well, in that the small, medium, and large face size categories achieved the highest geometric mean fit factors in the small, medium, and large respirator sizes, respectively. The same pattern holds for fit test passing rate. Therefore, a correlation was found between respirator fit and the new NIOSH bivariate fit test panel cells for various respirator sizes. These findings support the selection of the facial dimensions for developing the new NIOSH bivariate respirator fit test panel.

Face sizes classified by the PCA panel were less consistent, as compared to the NIOSH bivariate panel classification, in the pattern with respirator fit. For the LANL panel, however, both small and medium faces achieved best fit in small size respirators, and large faces achieved best fit in medium respirators. Since subjects in this study were not recruited to provide uniform representation in each of the categories from the PCA and LANL panels, the comparisons for these panels may not have been evaluated fairly.

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