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New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force

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The fit test panels currently used for respirator research, design, and certification are 25-subject panels developed by Los Alamos National Laboratory (LANL) and are based on data from the 1967 and 1968 anthropometric surveys of U.S. Air Force personnel. Military data do not represent the great diversity in face size and shape seen in civilian populations. In addition, the demographics of the U.S. population have changed over the last 30 years. Thus, it is necessary to assess and refine the LANL fit test panels. This paper presents the development of new respirator fit test panels representative of current U.S. civilian workers based on an anthropometric survey of 3997 respirator users conducted in 2003. One panel was developed using face length and face width (bivariate approach) and weighting subjects to match the age and race distribution of the U.S. population as determined from the 2000 census. Another panel was developed using the first two principal components obtained from a set of 10 facial dimensions (age and race adjusted). These 10 dimensions are associated with respirator fit and leakage and can predict the remaining face dimensions well. Respirators designed to fit these panels are expected to accommodate more than 95% of the current U.S. civilian workers. Both panels are more representative of the U.S. population than the existing LANL panel and may be appropriate for testing both half-masks and full-facepiece respirators. Respirator manufacturers, standards development organizations, and government respirator certification bodies need to select the appropriate fit test panel for their particular needs. The bivariate panel is simpler to use than the principal component analysis (PCA) panel and is most similar to the LANL panel currently used. The inclusion of the eight additional facial measurements allows the PCA panel to provide better criteria for excluding extreme face sizes from being used. Because the boundaries of the two new panels are significantly different from the LANL panel, it may be necessary to develop new respirator sizing systems. A new five-category sizing system is proposed.

Keywords civilian workers, fit test panels, respirator sizing, respirators

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INTRODUCTION

In the early 1970s, the Respirator Research and Development Section of the Los Alamos National Laboratory (LANL) was asked by the National Institute for Occupational Safety and Health (NIOSH) to develop anthropometric specifications for fit testing full- and half-facepiece respirators. Because no survey of face dimensions of U.S. workers was available at that time, the LANL team decided to develop these specifications based on the 1967 and 1968 U.S. Air Force (USAF) anthropometric surveys.[1,2]

Prompted by concerns over the possible inapplicability of military data to civilian workers, the Los Alamos team surveyed 200 civilians on 13 face dimensions, including menton-nasal root depression length (face length), bizygomatic breath (face width) and lip length—three face dimensions critical for the development of respirator fit test panels. The survey found close agreement to approximately 2 mm between the USAF and Los Alamos surveys. Therefore, it was concluded that the USAF survey could be used for developing fit test panels that represent facial dimensions of U.S. industrial workers.

The full-facepiece panel was based on the bivariate distribution of face length and face width.[3,4] The upper limit of the panel was defined by the mean value of male population plus two standard deviations, and the lower limit was defined by the mean value of the female population minus two standard deviations. The resulting range for face length was 93.5–133.5 mm and for face width was 117.5–153.5 mm.

The panel was then divided into 16 categories, based on a 10-mm increment in face length and a 9-mm increment in face width. Because six cells contained very low percentages of the population (<0.1–1.8%), they were deleted from the panel, leaving a 10-category panel representing about 91% of the total population. Twenty-five subjects were selected for the panel size, as suggested by NIOSH as a practical limit of expense and time to perform tests. The number of subjects for each cell was determined based on the percentage of the USAF survey populations for that cell. Thus, the test panel is usually referred to as the 25-member panel for testing full-facepiece respirators.

The half-facepiece panel was based on the bivariate distribution of face length and lip length.[3,4] The upper and lower limits were defined in the same way as for the full-facepiece panel. The resulting range for face length was 93.5–133.5 mm, and for lip length was 34.5–61.5 mm. The panel was 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-category panel that represented about 95% of the population. Twenty-five subjects were selected as the panel size, and the number of subjects for each cell was determined based on the percentage of the USAF survey populations for that cell.

Both the full- and half-facepiece panels have been used as anthropometric specifications for respirator fit testing research since they were developed in 1973. Recommendations were that 25 subjects be recruited according to the face dimension criteria in the LANL panels for half- or full-facepiece respirators. The pass/fail criteria for the panel suggested that a single respirator model designed to fit 95% of the user population should have only a single failure for the 25 subjects tested.[3]

Concern was raised about the applicability of military data and test panels based on military data to civilian workers. The demographics of the U.S. population have changed over the last 30 years. Military personnel have to meet strict entry and fitness criteria; they also tend to be younger than the general civilian work force. Military population may not represent the great diversity in face size in civilian population. As a result, personal protective equipment designed and sized for a military population may not provide the same level of fit to civilian workers.

There is also scientific evidence questioning the panel applicability.[5–7] As early as 1975, Leigh[5] measured 1467 employees (127 females) of DOW Chemical USA, Rocky Flats Division in Colorado. Out of the 1467 Rocky Flats employees tested, 12.6% had measurements falling outside of the selection area established by the LANL panel for full-facepiece respirators. The author concluded that a change in the LANL panel selection area would be advantageous.

The United States Bureau of Mines[6] surveyed 48 male mine rescue workers in 1978 and found that a more extensive survey of the industrial populations who used PPE was needed. In a recent NIOSH study, the manual measurements of 2391 civilian subjects (only two face dimensions, i.e., face length and face width, were measured) from the project titled "Civilian American and European Surface Anthropometry Resource (CAESAR)," were analyzed.[7] The analyses found that the LANL panel for full-facepiece respirators included only 84% of the CAESAR subjects.

In 2001, the NIOSH National Personal Protective Technology Laboratory recognized the difficulties inherent in using the old military data and initiated a study to develop an anthropometric database of the heads and faces of civilian respirator users.[8] The new database was also used to evaluate the ability of the LANL respirator fit test panels to represent the current U.S. civilian workers in a companion study.[9] The 1967 and 1968 USAF anthropometric survey data of 4325 military persons (on which the LANL fit test panels were based) and the current NIOSH survey of 3997 civilian respirator users (weighted to match the 2000 U.S. census population) were used in that companion study.

Comparisons were made on age and race distributions as well as key face dimensions (face length, face width, and lip length) between the USAF and NIOSH surveys. Age and race distributions of the USAF data were different from those of the NIOSH data. The bivariate distribution of face length and face width for full-facepiece applications and the face length and lip length for half-facepiece applications were different between the two surveys.

Furthermore, the LANL full-facepiece panel excluded 15.3% of NIOSH survey subjects. Subjects in the NIOSH survey had larger key face dimensions (face length and face width) than the subjects in the 1967–1968 USAF survey. Thus, it was concluded that the LANL respirator fit test panels did not represent the current U.S. civilian work force well. The NIOSH survey on face anthropometry of respirator users is more representative of the age and racial/ethnic distributions of the current civilian population. It was recommended that the LANL panels be revised.

The NIOSH database was then used to develop new respirator fit test panels. This paper presents the development of the new panels.

METHODS AND MATERIALS

NIOSH Anthropometric Database

The 2003 NIOSH survey was a nationwide anthropometric survey of respirator users across the United States.[8] The subjects were recruited from various industries, including manufacturing, construction, health care, law enforcement, and firefighting. These workers rely on respirators to prevent work-related respiratory illnesses and injuries.

A stratified sampling plan was used with an equal sample size in each stratum. The survey consisted of three age strata (18–29, 30–44, 45–65 years), two gender strata (male and female), and four racial/ethnic group strata (White, African American, Hispanic, and Others). Height, weight, 19 face dimensions, and neck circumference were measured with traditional methods. A total of 3997 subjects (2543 male and 1454 female) was measured. Two subjects had missing values for face width and another subject had missing value for interpupillary distance. Thus, 3994 subjects provided usable data for the analyses in this study.

The sampling strategy called for equal representation in each of the sampling cells. This was done to ensure that the anthropometric variability in all segments of the population had been adequately captured. People in the work force did not fall into those cells in equal proportion; therefore, the sample needed to be proportionately weighted to be accurately representative of the U.S. respirator users. Because demographic statistics are not available for the respirator wearing population, the proportionality was weighted to the U.S. 2000 census,[10] which is a complete enumeration of population and housing as of April 1, 2000. A limited number of questions were asked of every person and housing unit. Information is available on: name, household relationship, sex, age, Hispanic or Latino origin, race, and tenure (whether the home is owned or rented).

The present analysis was based on the demographic information on age, sex, and race distribution (including Hispanic or Latino origin) of the 2000 U.S. census data. Weighting factors were calculated from the U.S. census data and NIOSH data. Detailed calculation of the weights is found in a companion paper.[8]

Bivariate Distribution Approach

The bivariate distribution approach was used originally by LANL to develop respirator fit test panels. However, face length and lip length have not consistently correlated with fit factor in every study of half-masks in the literature whereas other dimensions such as nasal root breadth have been shown to correlate with fit factor in some of the studies.[11–17]

Thus, a recent NIOSH study was conducted to investigate the appropriateness of face dimensions for defining fit test panels including a systematic review of the literature on respirator fit and face dimensions.[18] In 16 of the 33 respirator model/size combinations studied, subsets of 1 to 6 face dimensions of the 12 face dimensions measured in that previous study were identified from multiple linear regression analyses between face dimensions and simulated workplace protection factors (SWPFs) at a significance level of 0.05. The frequency of face dimensions that were included in the 16 subsets was determined. Bigonial breadth appeared in the most subsets (6) with regression coefficients significantly different from zero at a significance level of 0.05. Face width, face length, and nose protrusion each appeared in five subsets. Lip length was found in only one subset.

A systematic literature review found that eight studies had been conducted to investigate face dimensions and respirator fit for half-facepiece respirators.[11–18] Face length and/or face width had significant correlation with fit in six of the eight studies for half-facepiece respirators.[18] Thus, face length and face width are recommended for defining the panel for half-facepiece respirators. Recall that these two dimensions were selected for defining the LANL panel for full-facepiece respirators rather than half-facepiece respirators. So far, no study has reported the correlation between face dimensions and the fit of full-facepiece respirators. Thus, face length and face width are also recommended for defining the panel for full-facepiece respirators.

The new panel was also divided into 10-cell categories. The number of subjects remained at 25, and at least 2 subjects for each cell are specified. Then the number of subjects to be sampled from each cell was determined by matching the percentage of subjects in each cell to the distribution of the U.S. work force as close as possible.

Principal Component Analysis Approach

Multivariate statistical methods are valuable techniques for analysis of anthropometric data.[19] In a recent example, multivariate statistical methods were recently used to examine anthropometric differences between biologically admixed U.S. Army male soldiers and single racial groups of Black male soldiers and White male soldiers.[20] One popular multivariate statistical technique, principal component analysis (PCA), is widely used by scientists and engineers for data reduction and analysis of large datasets. PCA defines a new coordinate system using linear combinations of the original variables to describe trends in the data.

Although PCA can handle any number of input variables, variable selection was performed in this application to remove known noisy variables and to reduce the dataset to a more manageable size. The number of principal components used in the model was chosen using standard methods.[20] The PRINCOMP procedure (SAS Institute Inc., Cary, N.C.) was used to perform the PCA and create eigenvalues and eigenvectors using the 3994 subjects in the survey with usable data. The weighting factors were used by using a WEIGHT statement in the SAS PRINCOMP procedure.

The scores from the principal component analysis were used to develop the PCA panel. The panel was divided into 8-cell categories. The number of subjects remained at 25, and at least 2 subjects for each cell are specified. The number of subjects to be sampled from each cell was determined by matching the percentage of subjects in each cell to the distribution of the U.S. work force as close as possible.

RESULTS

Bivariate Panel

The new fit test panel based on face length and face width is shown in Figure 1. Percentage of population and number of subjects by cell and gender for this panel are summarized in Table I. The layout of cells is different from the LANL panel. This panel covers 96.7% male and 98.7% female civilian work force. This panel has limits of 98.5 to 138.5 mm for face length and 120.5 to 158.5 mm for face width. These limits are significantly different from the limits of the LANL panel. These limits were first based on the male mean plus two standard deviations (SDs) and the female mean minus two SDs. Cell boundaries were then adjusted so that the population can be distributed among cells as uniformly as possible. The boundaries were set so that at least 95% of the population was included in the panel.

Figure 2 shows the scatter plot of the bivariate distribution of NIOSH subjects and the boundaries of the new panel based on the new NIOSH survey data. More than 95% of the NIOSH subjects are within the boundary of the panel.

The panel size is 25 subjects for testing one-size-fits-all models. This sample size is the same as the LANL panel. It

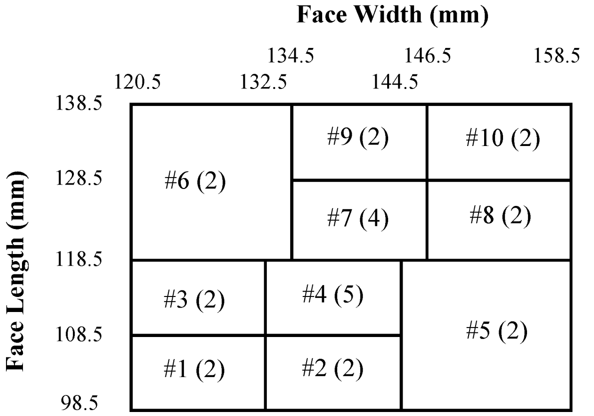

FIGURE 1. NIOSH panel based on face length and face width is shown. The cells are numbered 1–10 and the numbers in parentheses indicate the number of subjects to be sampled from each cell. When the subject's face length or face width fall on the boundaries, the subject is classified into the higher number cells with greater face dimensions.

TABLE I. Percentage of Population and Number of Subjects for the Panel Based on Face Length and Face Width

Cell	Male (%)	Female (%)	Total (%)	Male	Female	Total
1	0.3	10.6	5.5		2	2
2	1.0	9.5	5.3		2	2
3	1.9	19.0	10.5		2	2
4	15.5	34.3	25.0	2	3	5
5	9.7	4.5	7.1	1	1	2
6	4.9	6.5	5.7	1	1	2
7	30.7	12.0	21.3	3	1	4
8	15.9	1.7	8.7	2		2
9	9.9	0.6	5.2	2		2
10	6.9	0.1	3.5	2		2
Total	96.7	98.7	97.7	13	12	25

is a compromise between the need for a sufficient number of tests to develop good statistics and the requirement to test all devices submitted for approval in a reasonable length of time. The standards development organizations can decrease or increase the panel size using the percentages in Table I.

For two-size systems such as small/medium and medium large, it is recommended that the small/medium is tested on subjects from Cells 1–6 and medium/large is tested with subjects from Cells 5–10. The total number of subjects becomes 29 for two-size systems. For three-size systems such as small, medium, and large, they are tested with subjects from Cells 1–4 for small, Cells 4–7 for medium, and Cells 7–10 for large, respectively. The total number of subjects becomes 34 for three-size systems.

Another option is to test each size (e.g., small, medium, or large) with the same 25 subjects from whichever cells manufacturers determine have good fit. For example, if manufacturers determine that a small size respirator fits Cells 1–7 better, 25 subjects from Cells 1–7 are selected to test this small size respirator. The number of subjects in each cell can be based on the percentages for Cells 1–7 in Table I.

PCA Panel

For this application, the selection of which dimensions to include in PCA was based on four criteria: (1) the dimensions are relevant to respirator fit; (2) the dimensions excluded from PCA have good correlation with, and can be predicted by, the dimensions included in the PCA; (3) the number of dimensions

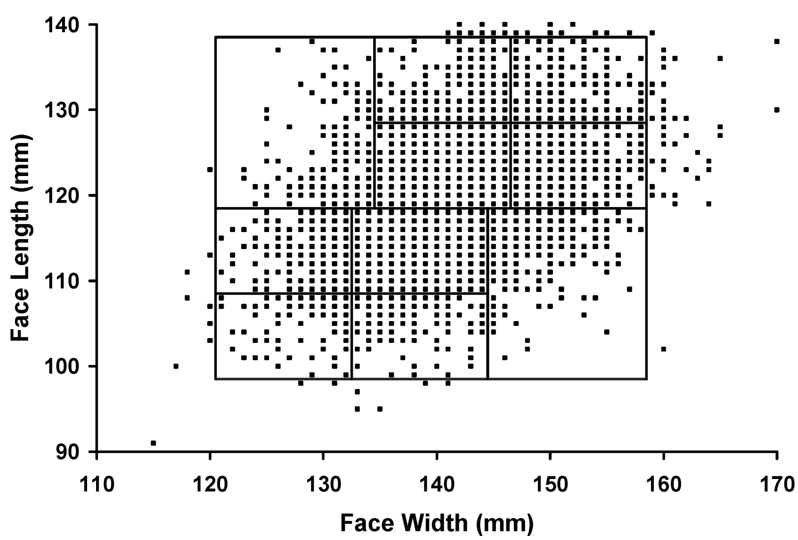

FIGURE 2. Bivariate distribution is shown along with the NIOSH bivariate panel.

TABLE II. Summary of Correlation Coefficients Between One Dimension and the Rest of Dimensions

Face Dimensions	N	Mean Correlation Coefficients	Standard Deviation	Minimum	Maximum
Bitragion chin arc	18	0.5375	0.18	0.19	0.88
Bitragion subnasale arc	18	0.5237	0.19	0.07	0.88
Bitragion frontal arc	18	0.5021	0.16	0.18	0.77
Face width	18	0.5020	0.18	0.17	0.71
Neck circumference	18	0.4903	0.15	0.20	0.77
Head circumference	18	0.4675	0.15	0.23	0.78
Maximum frontal breadth	18	0.4675	0.19	0.03	0.86
Head length	18	0.4216	0.15	0.21	0.78
Minimum frontal breadth	18	0.4203	0.17	0.07	0.86
Face length	18	0.4199	0.12	0.19	0.60
Head breadth	18	0.4180	0.15	0.16	0.71
Interpupillary distance	18	0.4134	0.16	0.01	0.64
Bigonial breadth	18	0.4107	0.17	0.11	0.71
Bitragion coronal arc	18	0.3781	0.14	0.13	0.63
Nose breadth	18	0.3360	0.14	0.02	0.56
Lip length	18	0.3310	0.13	0.04	0.56
Subnasale-sellion length	18	0.2393	0.14	0.02	0.60
Nasal root breadth	18	0.2290	0.08	0.08	0.40
Nose protrusion	18	0.1677	0.11	0.01	0.42

is reasonable so that users of the PCA fit test panel can realistically make the measurements without undue burden on the test subjects; and (4) dimensions that are difficult to obtain and/or highly variable are excluded. Based on these criteria, 10 dimensions were included in the PCA (Table II). A summary of the rationale for selection of these variables using the criteria is given below.

The identification of variables that are considered related to respirator fit was done using a combination of expert opinion and literature analysis. Members from International Organization for Standardization (ISO) Technical Committee 94/Subcommittee 15 (TC94/SC15), Respiratory Protective Devices, Working Groups 2–3, Joint Project Group 2[21] considered minimum frontal breadth, face width, bigonial breadth, face length, interpupillary distance, nose protrusion, nose breadth, nasal root breadth, and subnasale-sellion length to be relevant to the fit of half-facepiece and full-facepiece respirators with the exception of head breadth. Lip length was also considered important for mouth bite devices.

A similar set of variables is found from the literature analysis. Face length and/or face width correlated with fit in six of eight previous studies.[18] Many other dimensions such as nose length, nose protrusion, bigonial breadth, and nasal root breadth also correlated with the fit of half-masks.[18]

Studying the correlation structure of data can yield clues to help determine which variables to exclude. The correlation coefficients between each face dimension and each of the remaining 18 dimensions were examined. These are also summarized in Table II. The results are sorted by the mean of all 18 correlation coefficients. Four variables had mean correlation coefficients greater than 0.5 meaning they had high correlation with a number of other dimensions. Because face width is important in respirator fit, we retained it, but the other three dimensions were excluded from the PCA.

The next five dimensions with mean correlation coefficients greater than 0.42 were then excluded from PCA. Because minimum frontal breadth is more relevant to respirator fit than bitragion coronal arc, bitragion coronal arc was excluded from PCA. This rationale excluded a total of nine dimensions as shown in Table III and included 10 dimensions for the PCA. Table III shows the R^2 values for multiple regression analyses between each of the nine face dimensions excluded in the PCA and the 10 face dimensions included in the PCA. The relatively high values, especially for the first five dimensions, suggest that not much information is being lost by excluding them, which is not surprising given the high degree of correlation found among human body dimensions.[1,2]

The selection of 10 dimensions for developing the PCA panel based using four criteria yield a manageable number of variables. Current practice using the LANL panel requires measurement of only two dimensions. To use the PCA panel, eight additional measurements will need to be done for each subject in the panel. With eight additional variables, variability is increased and facial characteristics can be better described.

TABLE III. Summary of R^2 Values for Multiple Regression Analyses Between Each of the Face Dimensions Excluded from the PCA Model and the 10 Face Dimensions Included in the PCA Model

Face Dimensions	R^2	p-value
Maximum frontal breadth	0.83	<0.01
Bitragion chin arc	0.69	<0.01
Bitragion subnasale arc	0.66	<0.01
Neck circumference	0.66	<0.01
Bitragion frontal arc	0.61	<0.01
Head circumference	0.44	<0.01
Lip Length	0.43	<0.01
Head Length	0.42	<0.01
Bitragion coronal arc	0.38	<0.01

TABLE IV. Summary Statistics Principal Component Analysis Weighted to U.S. Population

Principal Component	Eigenvalue	Cumulative Eigenvalue	Percentage Total Variance	Cumulative (%)
1	4.205	4.205	42.1	42.1
2	1.640	5.845	16.4	58.5
3	0.859	6.705	8.6	67.0
4	0.804	7.509	8.0	75.1
5	0.634	8.142	6.3	81.4
6	0.598	8.741	6.0	87.4
7	0.419	9.159	4.2	91.6
8	0.356	9.515	3.6	95.2
9	0.302	9.818	3.0	98.2
10	0.182	10.000	1.8	100.0

It is interesting to note that the correlation analysis was almost identical to the expert selection of dimensions relevant to respirator fit at a ISO technical committee/working group meeting. Neck circumference, head length, and head circumference were excluded from the PCA model because they were obviously irrelevant to respirator face seal. This exclusion is not applicable to neck dam hoods. For the four arc measurements, they were excluded not only because of the high correlation coefficients but also because they have large inter- and intrameasurer errors. Including them will bring significantly highly variable data into the PCA model. In addition, they are not in the area of traditional face seal. Lip length was excluded because it did not have significant correlation with fit of half-masks and was considered irrelevant to the fit of full-facepiece respirators.[13,14,21]

The number of principal components (PCs) to use in developing the PCA model was selected based on the following criteria: (1) retaining any component with an eigenvalue greater than 1.00 (Kaiser criterion); (2) the proportion of variance accounted for; (3) interpreting the substantive meaning of the retained components; and (4) practicality. Based on these criteria, the first two PCs were selected. A summary of the rationale for selecting the first two components using the criteria are given below.

The summary statistics from the PCA weighted to match the U.S. civilian work force are shown in Table IV. The first two PCs explained 42% and 16% of the total variation, respectively. The third PC accounted for only 8.6%. The Kaiser criterion (i.e., only PCs with eigenvalues greater than 1) was used to determine how many PCs to retain.[22] In essence, this is like saying that unless a PC extracts at least as much variation as the equivalent of one original variable, it is dropped. Using this criterion, two PCs should be retained.

Furthermore, the use of two components provides for simpler interpretation. The PCA scores calculated from the two components will allow the panel to be based on two-dimensional scatter plots and thus can be easily compared with the previous LANL panel and the new bivariate panel. If additional PCs were retained, the scatter plots would be more challenging to interpret, which ultimately would limit the usefulness of the PCA panel.

The new fit test panel based on the PCA scores is shown in Figure 3. Percentage of population and number of subjects by cell and gender for this panel are summarized in Table V. This panel covers 95.2% of the male and 97.6% of the female civilian work force. The layout of cells is different from the bivariate panel. The limit of this panel is based on an ellipse in which more than 95% of the population is included. The inner ellipse includes about one-half of the population.

The rationale for the rest of the PCA configuration is to have uniform distributions for each cell. Thus, two lines were used to divide the two ellipses into four quadrants resulting in eight cells. The population is then uniformly distributed among cells. Figure 4 shows the scatter plot of the distribution of the

TABLE V. Percentage of Population and Number of Subjects for the Panel Based on Two Principal Components

Cell	Male (%)	Female (%)	Total (%)	Male	Female	Total
1	1.1	22.0	11.6	0	3	3
2	5.7	21.6	13.7	1	3	4
3	5.6	17.8	11.7	1	2	3
4	9.1	15.5	12.3	1	2	3
5	16.7	8.1	12.4	2	1	3
6	17.9	6.6	12.2	2	1	3
7	18.4	5.1	11.7	2	1	3
8	20.8	1.0	10.8	3	0	3
Total	95.2	97.6	96.4	13	12	25

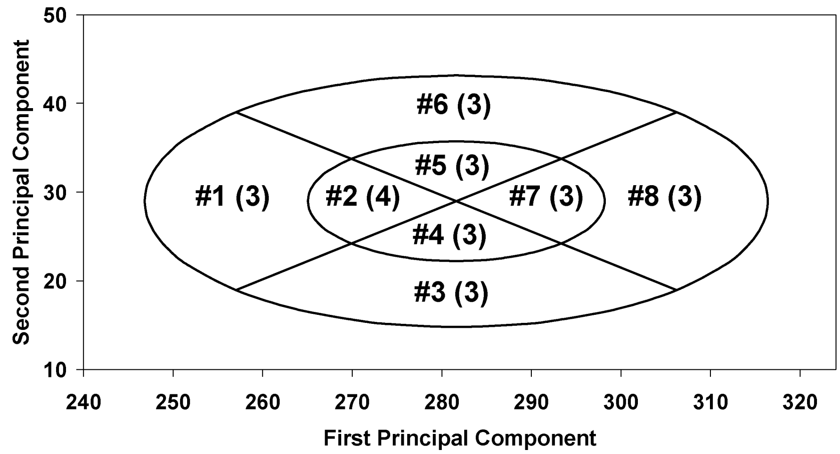

FIGURE 3. NIOSH panel based on two principal components is shown. The cells are numbered 1–8 and the numbers in parentheses indicate the number of subjects to be sampled from each cell. The fourth subject from cell 2 can be replaced with a fourth subject from cell 4, 5 or 7 if it is easier to get the fourth subject from these cells.

scores from the first two PCs for the NIOSH subjects and the boundaries of the new PCA panel.

The panel size is 25 subjects for testing one-size-fits-all models. For two-size systems such as small/medium and medium/large, it is recommended that the small/medium is tested on subjects from Cells 1-4 and medium/large is tested with subjects from Cells 5–8. The total number of subjects is also 25 for two-size systems. Three-size systems such as small, medium, and large are tested with subjects from Cells 1 and 3 for small; Cells 2, 4, 5, and 7 for medium; and Cells 6 and 8 for large, respectively. The total number of subjects is still 25 for three-size systems.

Another option is to test each size (e.g., small, medium, or large) with the same 25 subjects from whichever cells manufacturers determine have good fit. For example, if manufacturers determine that a small size respirator fits Cells 1–5 better, 25 subjects from Cells 1–5 are selected to test this small size respirator. The number of subjects in each cell can be based on the percentages for Cells 1–5 in Table V.

The eigenvectors from the PCA are provided in Table VI. The eigenvectors for each PC are used to multiply the original face dimensions to obtain the scores for each PC. A rotation was performed using variance maximizing method, but the loadings are similar to the original loadings; therefore, the original loadings were used to develop the PCA panel.

Interpretation of the magnitudes of the eigenvectors provides insight into the relationships among the facial dimensions and their contributions to the PCA scores. The ability to interpret scores is further evidence that the selected components are relevant for developing the PCA fit test panel. The eigenvectors for PC1 are all positive. As each dimension increases, the PC1 score is also increased. Face width, bigonial breadth, and head breadth contribute the most to the first PC. Thus, the first PC captures the overall size of the face. Subjects with larger faces

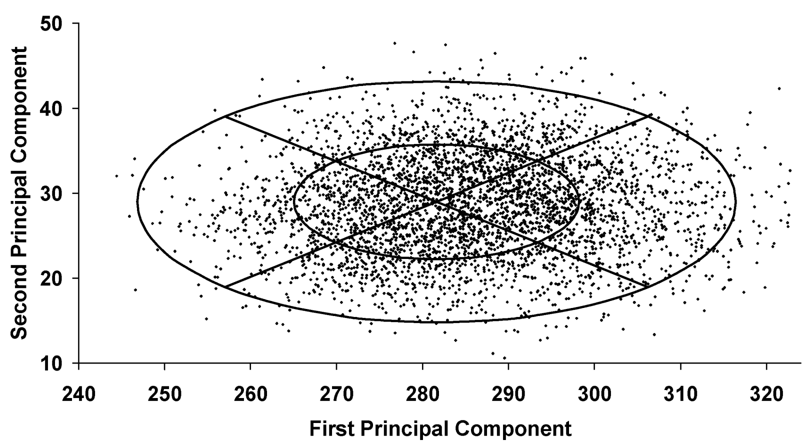

FIGURE 4. Scatter plot of principal components scores is shown along with the PCA panel.

TABLE VI. Eigenvectors from Principal Component Analysis Weighted to U.S. Population

Face Dimensions	PC1	PC2
Minimum frontal breadth	0.343264	−0.152951
Face width	0.426498	−0.039087
Bigonial breadth	0.372717	−0.093279
Face length	0.329648	0.359799
Interpupillary distance	0.363474	−0.173099
Head breadth	0.372241	0.013306
Nose protrusion	0.113578	0.551842
Nose breadth	0.301125	−0.210833
Nasal root breadth	0.202311	−0.341235
Subnasale-sellion length	0.193650	0.584261

(e.g., Cell 8 in Figure 4) will fall into the rightmost portion of the PCA scores plot shown in Figure 4, while those with smaller faces (e.g., Cell 1 in Figure 4) will fall into the left side of the plot.

The magnitudes of the eigenvectors for the second PC are more diverse. The eigenvectors for PC2 are negative with the exception of face length, nose protrusion, and subnasale-sellion length. Nasal root breadth and nose breadth had the largest negative eigenvectors. Face width and head breadth were close to zero and have little impact on PC2. Thus, the second PC captures face shape, primarily key nose features. As dimensions with negative eigenvectors increase, their PC2 score is decreased. For the three dimensions with positive eigenvectors, it is the opposite. For subjects with large narrow noses and long face lengths, their PC2 scores are large. These subjects will fall primarily into Cell 6. For subjects with short, broad noses and short face lengths, their PC2 scores are small, so they will be found in the lower portion of the scores plot (e.g., near Cell 3).

To investigate the appropriateness of the PCA panel based on the 10 face dimensions, one additional variable selection approach was investigated. A PCA fit test panel was developed using all 18 head and face dimensions (neck circumference was not included in this analysis). For this PCA panel, all NIOSH subjects were classified into Cells 1, 3, 6, and 8 in the same way as the 10-dimension PCA panel. For simplicity, Cells 2, 4, 5, and 7 were combined into a single cell for this analysis. For the subjects in each cell based on the 18-dimension PCA panel, the percentage of those subjects in cells based on the 10-dimension PCA panel was determined. The results are summarized in Table VII.

The Kappa statistic is used as a measure of the degree of association or reproducibility between the 10-dimension PCA panel and 18-dimension PCA panel.[23] The Kappa statistic was 0.57 ($K > 0.75$ denotes excellent reproducibility; $0.4 <= K <= 0.75$ denotes good reproducibility; $0 <= K <= 0.4$ denotes marginal reproducibility). For the large faces (Cell 8) based on the 18-dimension PCA panel, 57.2% of them were also placed into Cell 8 based on the 10-dimension PCA panel, and the rest of them were placed into Cell 3 (6.2%), Cell 6 (6.2%), and Cells 2, 4, 5, and 7 (25.4%).

About 70% of the time, both the 18-dimension and 10-dimension panels classified subjects into the same cells. The reason for such a good agreement for Cells 1–8 is the high correlation between the 10 dimensions and the other nine dimensions excluded. For outliers, agreement was only 40.6% between the two panels because of large values in the eight additional dimensions. However, within each panel only less than 5% of the population are considered outliers. In addition, with only 10 dimensions, the two PCs explained more of the total variation (58%) as compared with 18 dimensions (55%); therefore, the selection of 10 face dimensions is appropriate.

To use the PCA panel, the 10 face dimensions need to be first measured as described in Appendix A. The first and second principal components (PC1 and PC2) are then calculated as follows:

PC1 = 0.343264* (minimum frontal breadth) + 0.426498* (face width) + 0.372717* (bigonial breadth) + 0.329648* (face length) + 0.363474* (interpupillary distance) + 0.372241* (head breadth) + 0.113578* (nose protrusion) + 0.301125* (nose breadth) + 0.202311* (nasal root breadth) + 0.193650* (subnasale-sellion length)

TABLE VII. Percentage of Population for Each Cell Based on 10-Dimension PCA Panel by the Cell Based on 18-Dimension PCA Panel

Cell Based on 18-Dimension PCA Panel	Cell Based on 10-Dimension PCA Panel 1 (%)	3 (%)	6 (%)	8 (%)	2, 4, 5, 7 (%)	Outliers (%)	Total (%)
1	64.2	4.4	8.4	0.0	21.5	1.4	100.0
3	0.7	66.9	0.0	4.3	23.9	4.3	100.0
6	1.6	0.0	67.1	1.4	22.3	7.6	100.0
8	0.0	6.2	6.2	57.2	25.4	5.1	100.0
2, 4, 5, 7	4.7	7.2	6.2	3.5	78.4	0.0	100.0
Outliers	19.6	4.4	8.0	23.4	4.0	40.6	100.0

PC2 = −0.152951* (minimum frontal breadth) −0.039087*(face width) −0.093279* (bigonial breadth) + 0.359799* (face length) −0.173099* (interpupillary distance) +0.013306* (head breadth) +0.551842* (nose protrusion) −0.210833* (nose breadth) −0.341235* (nasal root breadth) + 0.584261* (subnasale-sellion length)

Then the algorithm in Appendix B can be used to determine which cell the subject is in.

A video tape was prepared to demonstrate the landmarking and measuring techniques with the traditional tools. A computer program was also developed to assist in measuring new subjects and to determine the cell number for each subject.

DISCUSSION

New respirator fit test panels have been developed using the traditional bivariate approach and a new approach based on PCA. The bivariate panel based on face length and face width is easy to use and is expected to cover more than 95% of the U.S. civilian work force. The boundary limits of the new panel are significantly different from the LANL panel. The new bivariate panel can be used for full-facepiece respirators and for half-masks.

The PCA panel is complicated and requires more measurements but may provide a more representative selection of face sizes for the test panel, which may lead to better fitting respirators for the population as a whole. Similar to the new bivariate panel, a single PCA panel can be used for testing both half-masks and full-facepiece respirators.

The nine dimensions that were excluded in the PCA model have good correlation with the 10 dimensions selected and can be well predicted by the 10 dimensions (Table III). For example, maximum frontal breadth was excluded, but the R^2 was 0.83 for the multiple regression model between maximum frontal breadth and the 10 dimensions. If it is more relevant to the fit of full-facepiece respirators in the future, its variation has already been well described by the 10 dimensions and there is no need to revise the PCA panel. Thus, the PCA model provides a strong framework that can take into account future developments more easily than the simpler bivariate panel.

To help respirator manufacturers, standards development organizations, and government respirator certification bodies select the appropriate fit test panel for their application, it is important to compare the new bivariate and PCA panels. The use of more than two face dimensions for the development of the PCA fit test panels is appealing and can be supported by the following analyses. Of the 3994 subjects with usable data in the NIOSH database, 182 (∼5%) were outliers according to the PCA panel. Of these 182 subjects, 124 subjects were in Cells 1 to 10 of the bivariate panel. The other 58 subjects were also outliers for the bivariate panel.

For the 44 subjects outside the ellipse for Cell 8 of the PCA panel (i.e., large faces), bigonial breadth, nose breadth, and interpupil distance were usually greater than the mean values plus two standard deviations. However, they were in Cells 8 and 10 of the bivariate panel. Thus, the two dimensions used in the bivariate panel (i.e., face length and face width) did not pick up the unusual values of other dimensions. For the 42 subjects outside the ellipse for Cell 3 of the PCA panel (i.e., short faces and broad noses), nose length and nose protrusion were usually smaller than the mean values plus two standard deviations, while bigonial breadth and nose breath were usually greater than the mean values plus two standard deviations. Yet they were in Cells 1 to 8 of the bivariate panel.

For the six subjects with too small faces according to the PCA panel, bigonial breadth, nose length, and head breadth were too small, but they were in Cell 1 of the bivariate panel. For the 32 subjects with too long faces, nose protrusion and nose length were usually too large. However, they were in Cells 6–10 of the bivariate panel. Therefore, two dimensions are not adequate to pick up any unusual face dimensions of a subject. Increasing the number of dimensions used in the development of a fit test panel increases the likelihood that face shapes with one or more extreme values will be excluded.

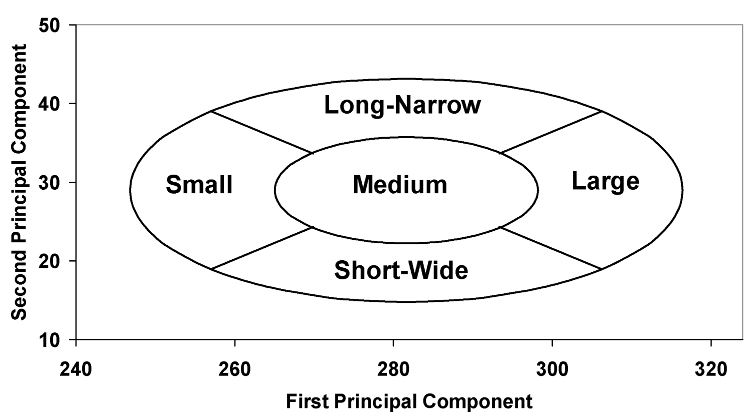

FIGURE 5. A five-size sizing system is proposed based on principal component analysis.

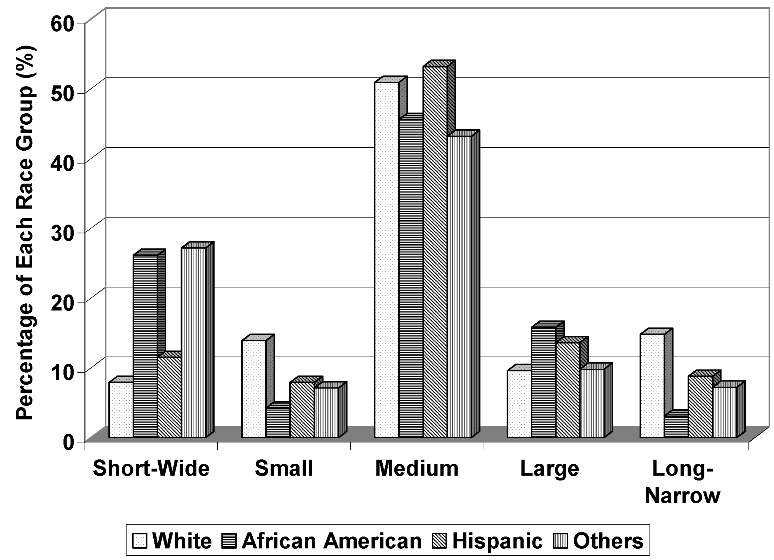

FIGURE 6. Distribution of face size according to the sizing scheme from Figure 5 is shown for each race group.

The bivariate panel excluded 107 of the 3994 subjects as outliers. Of these 107 subjects, 58 were also outliers for the PCA panel. The other 49 subjects were classified into Cells 1, 3, 6, and 8 of the PCA panel. These 49 subjects had face length and face width values that were just outside the boundaries of the NIOSH bivariate panel. The other eight dimensions had normal values usually within two standard deviations from their mean values.

It is also useful to consider the relative difficulty in recruiting subjects to fill the fit test panel. If a fit test panel contained one or more cells that represent a very small segment of the population, it will be difficult to find subjects whose facial dimensions fall within those cell boundaries (e.g., Cells 1, 2, and 6 in the current LANL panels). A simulation study was conducted to estimate the relative difficulty in recruiting subjects for the two panels. The 3994 subjects with usable data in the anthropometric database were used. For each simulation experiment, the order of subjects in the database was randomly changed.

Next, the algorithm described in Appendix B was applied to place each recruited subject one by one into the appropriate cell for each panel. This is equivalent to recruiting a subject and making the appropriate measurements on them to determine which cell they belong to. During the simulation, if a subject was placed into a cell that already contained the desired number of subjects, then that person was put on a waiting list, and the next subject was tested. This process was continued until all of the cells in the panel were filled. This simulation was conducted 1000 times and summary statistics describing the number of subjects recruited were calculated.

For the bivariate panel, the minimum, maximum, and median numbers of subjects recruited were 34, 264, and 91, respectively. For the PCA panel, the minimum, maximum, and median numbers of subjects recruited were 28, 168, and 58, respectively. In general, the PCA panel was much easier to fill than the bivariate panel (i.e., fewer subjects needed to be recruited). This result is not surprising since the PCA panel has two fewer cells than the bivariate panel and according to Tables I and V, the cell with the smallest % of the population in the bivariate panel was 3.5% compared to 10.8% in the PCA panel. This also may be associated with the cell boundaries selected for the bivariate panel.

The interpretation of the eigenvectors and the distribution of the facial sizes within and outside the PCA and bivariate panels suggest that new sizing systems for respirator designs may be needed. The variation of respirator fit in each cell has not been investigated in the past; however, at least one study found that a single size facepiece does not fit the population well.[18] Two or more respirator sizes may be necessary to cover the five size categories identified in the PCA panel as illustrated in Figure 5. The five sizes are: small, medium, large, long-narrow, and short-wide. The distribution of face size for each race group is shown in Figure 6. African and Asian Americans have more short faces with broad noses. White Americans have more long faces with large narrow nose protrusions and small faces.

CONCLUSIONS

Using the 2003 NIOSH facial anthropometric survey, weighted to match the age and race distribution of the U.S. population as determined from the 2000 census, two new respirator fit test panels were developed. One fit test panel (bivariate panel) was developed using the bivariate approach with cells based on face length and face width.

Another panel (PCA panel) was developed using the scores from the first two principal components obtained from a set of 10 facial dimensions. Respirators designed to fit these panels are expected to accommodate more than 95% of current U.S. civilian workers. Both panels more accurately represent the population than the LANL panel used today and may be appropriate for testing both half-masks and full-facepiece respirators.

Respirator manufacturers, standards development organizations, and government respirator certification bodies need to select the appropriate fit test panel for their particular needs. The bivariate panel is simpler to use than the PCA panel and is most similar to the LANL panel currently used. The inclusion of the eight additional facial measurements allows the PCA panel to provide better criteria for excluding extreme face sizes from being used. Because the boundaries of the two new panels are significantly different from the LANL panel, it may be necessary to develop new respirator sizing systems.

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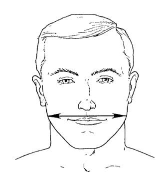
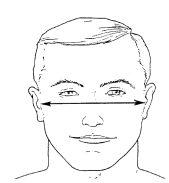
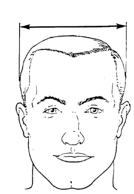
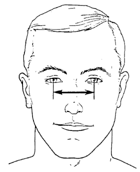
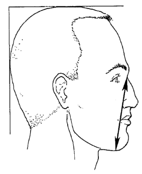
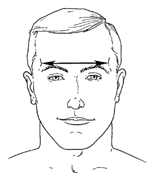
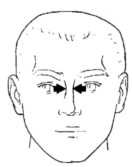
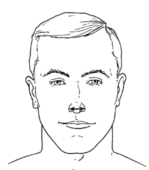
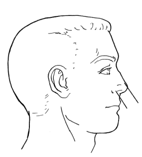
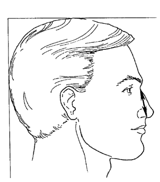
APPENDIX A

Description, Definition, and Diagram of Measurements

Description	Definition	Diagram
Bigonial Breadth	Straight-line distance measured with a spreading caliper between the right and left gonion landmarks on the corners of the jaw	
Bizygomatic Breadth	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches	
Head Breadth	Maximum horizontal breadth of the head as measured with a spreading caliper above the level of the ears	

Dimension	Description	Diagram
Interpupillary Distance	Distance as measured with a pupillometer at the center of the right and the center of the left pupil	
Menton-Sellion Length	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark	
Minimum Frontal Breadth	Straight-line distance as measured with a spreading caliper between the right and left frontotemporale landmarks	
Nasal Root Breadth	Horizontal breadth of nose as measured with a sliding caliper at the sellion landmark and a depth equal to one-half the distance from the bridge of the nose to the eyes	
Nose Breadth	Straight-line distance as measured with a sliding caliper between the right and left alare landmarks	
Nose Protrusion	Straight-line distance as measured with a sliding caliper between the pronasale landmark and the subnasale landmark	
Subnasale-Sellion Length	Straight-line distance as measured with a sliding caliper between the subnasale landmark and the sellion landmark	

APPENDIX B

Algorithm for Classifying Test Subjects into the PCA Panel Cells

x	=	PC1 - 281.6217618
y	=	PC2 - 28.9865054
slope	=	5.5847930/13.6991108 = 0.4076756
a	=	2.54 * 13.6991108
b	=	2.54 * 5.5847930
c	=	1.21 * 13.6991108
d	=	1.21 * 5.5847930
r1	=	sqrt $((x^2)/(a^2)+(y^2)/(b^2))$
r2	=	sqrt $((x^2)/(c^2)+(y^2)/(d^2))$

where

x and y are new coordinates for translating the origin of PC1 and PC2 from their mean values (281.6217618 for PC1 and 28.9865054 for PC2) to zero

slope is the slope value for the two lines dividing the ellipse into 8 cells

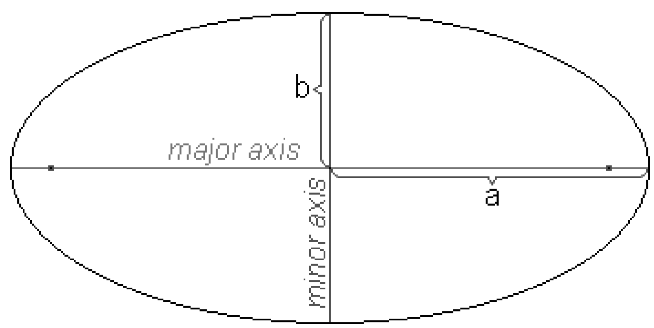
a is a constant for the length of the semimajor axis for the outer ellipse (see the illustration below)

b is the constant for the length of the semiminor axis for the outer ellipse (see the illustration below)

c is a constant for the length of the semimajor axis for the inner ellipse

d is the constant for the length of the semiminor axis for the inner ellipse

r1 and r2 are calculated values to determine where a particular data point or a subject is, e.g., the data point is outside the outer ellipse when r1 > 1 or on the outer ellipse when r1 = 1 or inside the outer ellipse when r1 < 1.



Use the x, y, and r1 values and the algorithm below to determine if the subject is in ells 1, 3, 6, and 8:

if x >= 0 and y >= 0 and r1 <= 1 and abs(y)/abs(x) <= slope then cell = 8

if x >= 0 and y < 0 and r1 <= 1 and abs(y)/abs(x) < slope then cell = 8

if x >= 0 and y< 0 and r1 <= 1 and abs(y)/abs(x) >= slope then cell = 3

if x < 0 and y < 0 and r1 <= 1 and abs(y)/abs(x) > slope
then cell = 3
if x < 0 and y < 0 and r1 <= 1 and abs(y)/abs(x) <= slope
then cell = 1
if x < 0 and y >= 0 and r1 <= 1 and abs(y)/abs(x) < slope
then cell = 1
if x < 0 and y >= 0 and r1 <= 1 and abs(y)/abs(x) >= slope
then cell = 6
if x >= 0 and y >= 0 and r1 <= 1 and abs(y)/abs(x) > slope
then cell = 6

If the r2 value is less than or equal to 1, use the following algorithm to adjust the cell number:

if cell = 8 and r2 <= 1 then cell = 7
if cell = 3 and r2 <= 1 then cell = 4
if cell = 1 and r2 <= 1 then cell = 2
if cell = 6 and r2 <= 1 then cell = 5