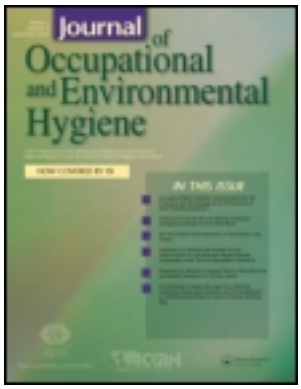

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Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering Facepiece Respirator Fit: Part I – Pilot Study

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The National Institute for Occupational Safety and Health is conducting a first-of-its-kind study that will assess respirator fit and facial dimension changes as a function of time and improve the scientific basis for decisions on the periodicity of fit testing. A representative sample of 220 subjects wearing filtering-facepiece respirators (FFR) will be evaluated to investigate factors that affect changes in respirator fit over time. The objective of this pilot study ($n = 10$) was to investigate the variation in fit test data collected in accordance with the study protocol. Inward leakage (IL) and filter penetration were measured for each donned respirator, permitting the calculation of face seal leakage (FSL) and fit factor (FF). The study included only subjects who (a) passed one of the first three fit tests ($FF \geq 100$), and (b) demonstrated through a series of nine donnings that they achieved adequate fit (90th percentile FSL was ≤ 0.05). Following the respirator fit tests, 3-D scans of subjects were captured, and height, weight, and 13 traditional anthropometric facial dimensions were measured. The same data were collected 2 and 4 weeks after baseline. The mean change in FSL for the 10 subjects was 0.044% between Visits 1 and 2, and was 0.229% between Visits 1 and 3. Technicians achieved at least moderate reliability for all manual measurements except nose protrusion. Filter penetration was generally less than 0.03%. Geometric mean fit factors were not statistically different among the three visits. The large variability was observed with different respirator samples for the same model, between subjects (inter), and within each subject (intra). Although variability was observed, adequate fit was maintained for all 10 subjects. Pilot scans collected show subject faces remained the same over the 4 weeks. The consistent results during the pilot study indicate that the methods and procedures are appropriate for the 3-year main study. In addition, this baseline fit change data will be compared with future fit changes to determine if the changes are meaningful.

Keywords fit change, fit test, frequency of fit test, inter- and intra-subject variability, 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

Millions of industrial and health care workers (HCW)[1] are required to wear respirators to protect themselves from airborne hazards in their workplace. Since the seal of a tight-fitting respirator to the user's face affects the inward leakage into the breathing zone, which can affect the protection provided by the respirator, occupational safety and health professionals recommend fit testing during the initial selection of a respirator model and annually thereafter.

Fit testing is currently the only accepted way to determine if a specific make, model, and size of tight-fitting respirator fits an individual wearer properly. Periodic testing is needed to ensure the fit continues to be acceptable. One philosophy suggests that annual retesting of respirator fit is necessary to detect, at an early stage, the percentage of respirator users whose respirators no longer fit them properly. Another perspective argues that fit testing should be required only when an employee switches to a different make or model of respirator or when a significant change occurs in an individual's physical condition that may interfere with obtaining an adequate face seal (facial trauma, excessive weight gain or loss, dental work, and so on).

In 1998, Occupational Safety and Health Administration (OSHA) adopted new requirements for occupational respiratory protection programs requiring respirator users to receive training and pass a fit test before using a respirator and annually thereafter (29 CFR 1910.134),[2] based on current

American National Standards Institute (ANSI) standards and public comments citing workplace experience.[2] During the public comment period for OSHA's rulemaking, data from four companies were considered in establishing the annual fit test requirement: (1) The Texas Chemical Council indicated that "virtually no individuals fail fit tests a year after initial testing,"[2,p.1228] (2) the Exxon Company reported less than 1% annual fit test failure rate, (3) Lord Corporation conducted fit testing annually and found less than 1–3% of employees switching to different sizes and/or models, and (4) Hoffmann-La Roche conducted fit testing every 2 years and found that 7% of the employees (16 of 233) switched to different sizes and/or models. OSHA considered 7% to be too high and unacceptable.[2] Thus, the annual fit testing was adopted in the 1998 final rule.

Current fit test requirements and their rationale were questioned at the 2004 Centers for Disease Control and Prevention (CDC) Workshop on Respiratory Protection for Airborne Infectious Agents in Atlanta, Georgia, where participants called for the quantification of the benefit and the scientific validity of annual fit testing.[3] Some participants questioned whether annual fit testing must be performed in the same entirety and manner as initial fit testing and asked if annual fit testing could be simplified. The workshop also highlighted the need to quantify the role of weight loss or gain on fit testing.

The National Institute for Occupational Safety and Health (NIOSH) has been called upon to provide support in the effort to address some of these requests. In the 2007 Institute of Medicine (IOM) report *Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users* the IOM recommended that "NIOSH . . . perform research to determine which facial features have the greatest impact on respiratory protection of face masks in the workplace, using quantitative measures."[4,p.71]

Linear distances between landmarks have been associated with respirator fit. Face length and face width in particular have been found to have significant correlation with fit.[5–7] Oestenstad and Perkins[7] also saw correlation with menton-subnasale length and nasal root breadth with fit. Zhuang et al.[6] found significant correlations among fit and two facial dimensions: bigonial breadth and nose protrusion. However, landmark distances are one-dimensional values. Research evaluating three-dimensional facial surfaces and their relationship to the fit of a respirator is minimal. Groce et al.[8] found nose area to be a significant predictor of respirator fit in 10 of 12 regression models; however, only 27 Caucasian test subjects were evaluated.

A first-of-its kind study was conceived to assess how respirator fit and facial dimensions change over time. A representative sample of 220 subjects will be assessed to investigate factors that impact those changes. Because this study will extend over a period of approximately 3.5 years, there was concern that the test environment may, for reasons beyond the control of researchers, change during the course of the study. That is, the test technician or laboratory conditions may change during the 3.5 years, and these changes may adversely impact the study results. To address that concern, this pilot study was initiated to verify consistent data collection methods and ensure that the test results were reproducible. The methods and procedures described for this pilot study in the next section will be used throughout the entire study.

METHODS

Subject Selection/Recruitment

Ten subjects (n = 10) were recruited by asking for volunteers from the pool of experienced N95 FFR users who regularly participate in NIOSH certification testing. To be eligible for inclusion in the pilot study, subjects needed a completed health history, including a yearly physical at Jefferson Regional Medical Center (Pittsburgh, Pa.) and facial measurements that fall within the NIOSH bivariate respirator fit test panel.[9] Exclusion criteria for the study included a history of uncontrolled chronic asthma, pneumonia, and high blood pressure. The diastolic and systolic values had to be less than 95 mmHg and 160 mmHg, respectively.

The pilot subject face size distribution within the NIOSH bivariate panel is shown in parentheses in Figure 1. Individuals who chose to participate signed a consent form and had their height, weight, and blood pressure measured. Height was measured using a Seca 242 Digital Stadiometer (Seca, Hanover, Md). Weight was measured using a Seca 882 Digital Scale (Seca). Blood pressure was measured using an Omron HEM-870 blood pressure monitor (Bannockburn, Ill.). As described below, once eligible for participation, subjects were evaluated for several variables at baseline, and then at 2 weeks and 4 weeks after the initial visit. All volunteers received monetary

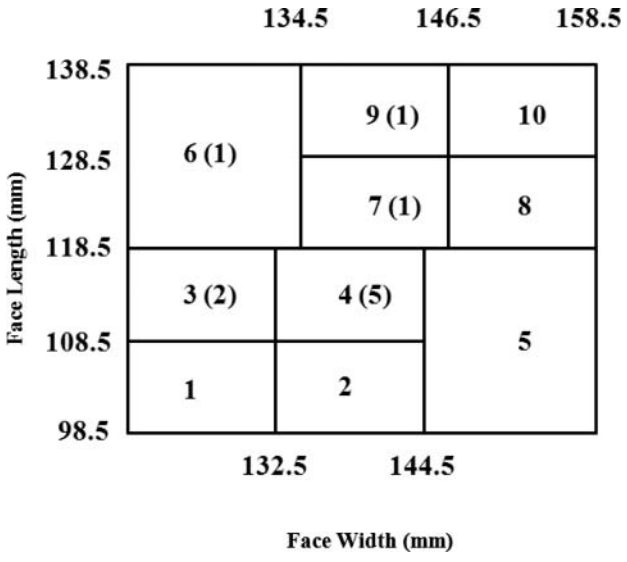

FIGURE 1. NIOSH bivariate respirator fit test panel with cell number and number of subjects participating in the study is indicated in parentheses.

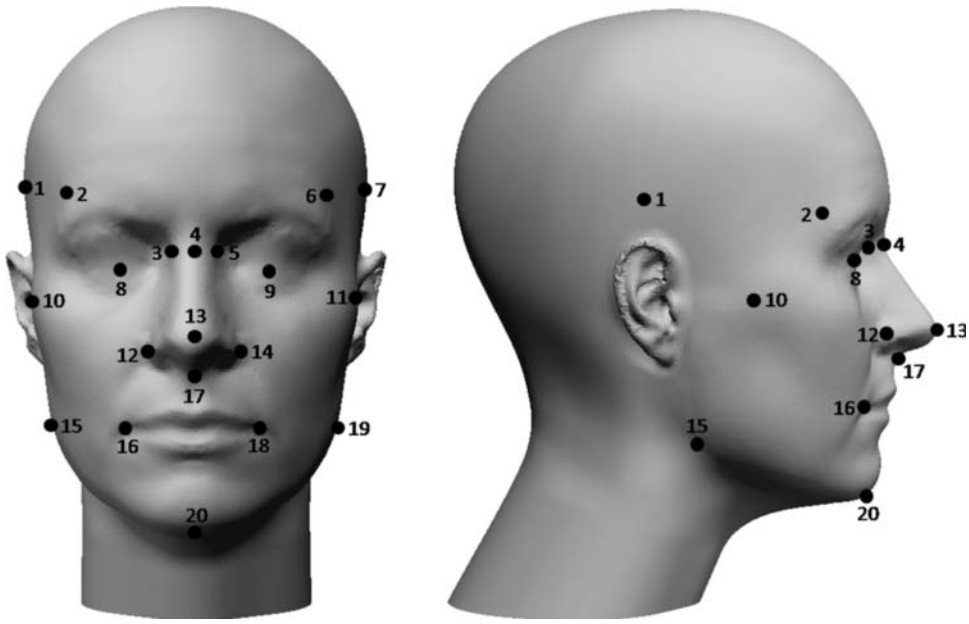

FIGURE 2. The facial dimensions measured are linear lengths between the identified landmarks: head breadth (1–7), minimal frontal breadth (2–6), nasal root breadth (3–5), interpupillary breadth (8–9), face width (10–11), nose breadth (12–14), bigonial breadth (15–19), lip length (16–18), nose length (4–17), nose protrusion (13–17), face length (4–20), menton-subnasale (17–20).

reimbursement for their participation. This study was approved by the NIOSH human subjects review board.

Manual Measurements

Traditional anthropometric measurements of the linear distance between craniofacial landmarks were collected with spreading calipers, sliding calipers (GPM Instruments, Zurich, Switzerland), and Lufkin steel measuring tape (Cooper Tools, Apex, N.C.). Bony and soft tissue landmarks were indicated with black eyeliner, and 13 dimensions of interest were collected: head breadth, minimal frontal breadth, nasal root breadth, interpupillary breadth, face width, nose breadth, bigonial breadth, lip length, nose length, nose protrusion, face length, menton subnasale length (Figure 2), and head circumference. In addition to the manual measurements, 3-D images of the human test subjects were captured using a 3060 Cyberware Rapid 3-D Digitizer (Monterey, Calif.).

Three-Dimensional Scanning

Subjects were asked to don a wig cap and sit on the platform located in the center of the Cyberware 3-D Rapid Digitizer 3060, a scanning device that captures images using the reflection of a thin red laser whose strength is similar to that of a checkout scanner. While seated, the subject was asked to hold the jaw closed with teeth slightly occluded and to remain still during the 40-sec scan. Upon completion of the scan, the surface data were evaluated for artifact caused by movement and, if necessary, additional scans were collected. In addition to the collection of 3-D surface information, the scanner can also capture texture information, permitting the future analysis of the 3-D landmark data.

Respirators

Five models in several sizes of FFR, none of which were fitted with exhalation valves, were incorporated into the pilot study. The reasons for focusing on FFR were as follows: (1) more workers use FFR than elastomeric half-masks; (2) the requirement for annual fit testing has been questioned by the health care industry, which represents the predominant users of FFR; and (3) resources and budget are limited.

All respirator models were chosen due to their inclusion in the pre-pandemic Center for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS). The CDC's SNS has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency (terrorist attack, flu outbreak, earthquake) severe enough to cause local supplies to run out. Respirators available in the stockpile were used since they would be representative of respirator models used by health care workers. Subject facial measurements, specifically their face length and face width, were used to determine their face size according to the NIOSH bivariate panel. A variety of respirators was made available that could fit small-, medium-, and large-sized faces. The respirator for a given subject was then randomly selected. If the subject failed to achieve an adequate fit with that model, another model was randomly selected from the remaining respirators. The study design incorporated time constraints; therefore, the first model that provided an adequate fit for the subject was used and may not have been the model to provide the best possible fit.

Inward Leakage Measurement

The OSHA standard for quantitative fit testing accepts the use of the PortaCount Plus (TSI Inc., Shoreview, Minn.)

attached to the N95-Companion module, which counts the ambient concentration and the respirator concentration of particles between 0.03 to 0.06 μm in diameter. The ratio of the ambient particle sample to the respirator particle sample is used to determine a fit factor with an upper limit of 200. Quantitative fit tests were performed, but the PortaCount Plus alone was used to measure inward leakage (IL) of the ambient particles with a detectable size range of 0.2 to 1 (μm).[10] By evaluating a larger size range of particles, a more conservative estimate of fit is achieved, and the detection limit increases to a maximum fit factor value of 10,000. Due to the highly variable nature of fit testing,[11,12] only a subset of the OSHA fit test exercises were used for this study.

While seated, subjects completed a series of five fit test exercises: normal breathing, deep breathing, breathing while moving their head from side to side, breathing while moving their head up and down, and a return to normal breathing. The movements from moving the head side to side and up and down provide opportunities for the respirators to move in at least two directions if the fit on a given subject is susceptible to such movements. If such susceptibility was present, it would have been reflected in the overall fit factor for that subject, based on the three exercises. These exercises are as challenging as the bending in place and talking that are included in the standard OSHA fit test protocol. These exercises were chosen primarily to save subjects' time (thereby increasing continued participation) while still achieving a reasonable diversity of head movements and leak locations. Subjects were asked to don a respirator, wait 3 min for the respirator concentration of particles to reach a steady-state, and complete the seated fit test. A flow chart of the inward leakage measurement process is shown in Figure 3.

Subjects were trained using standardized videos to don and doff an FFR model they selected from the pool of respirators associated with their face size. If the subject failed the first three fit tests, he or she was asked to select another respirator from the sample and watch the appropriate training video to repeat the fit test and find an adequately fitting respirator. If the subject passed one of the first three fit tests, he or she continued using the respirator of choice to complete six more fit tests. A single respirator was used for three fit tests, resulting in subjects donning three respirators of the same model for a total of nine fit tests. Once a respirator model was fit to an individual, six additional respirators from the same box as the three respirators used for the initial visit were set aside for Visits 2 and 3 to complete the pilot study.

Filter Penetration Measurement and Face Seal Leakage Calculation

Filter penetration for each respirator used during a fit test was measured. A 3.5-cm hole was drilled through a Plexiglas plate. After waxing each respirator to the plate, it was placed into a vacuum line that drew air continuously at a rate of approximately 10.3 L/min to simulate the breathing minute volume of a person while seated.[13] Filter penetration was measured by the PortaCount Plus using the program configuration employed for the subjects and each respirator was tested three times. Mean filter penetration for each respirator sample was subtracted from IL for each donning for the corresponding sample to calculate FSL. The reciprocal of FSL is a fit factor (FF).

The study included only subjects who passed at least one of the first three fit tests (FF $\geq$ 100) and demonstrated, through a series of nine donnings, that they achieved adequate fit. A subject was considered to have achieved adequate fit when, after nine trial donnings, the 90th percentile FSL was 5% or less. The nine FSL values were assumed to follow a lognormal distribution for which a 90th percentile value was estimated using the geometric mean (GM) and geometric standard deviation (GSD). The rationale for this study design was that one donning fit test for respirator selection has been found to have a beta error of 9%.[11,12]

Timeline of the Pilot Study

Two and four weeks after baseline, each subject was re-evaluated and all of the measurements collected at baseline were repeated. A flow chart of the inward leakage measurement process is shown in Figure 4 for Visits 2 and 3. In an effort to assess inter-rater and intra-rater variability in facial dimension measurement, some subjects were measured by the same technician and others were measured by a different technician. Subjects were evaluated in the same laboratory, and variation in the average of the nine penetration values was noted and would be used to interpret the final test results if a change in laboratory conditions or technician occurs during the 3.5-year study. It was expected that only nominal changes in facial dimensions would occur over the 30-day period, so the objective of the pilot study was to determine the inherent variation in the collected data due to the study methodology and instrumentation.

Three-Dimensional Scan Data Analysis

The 3-D scan data captured with the Cyberware Rapid 3-D Digitizer were aligned with Polyworks 10.1.6 and the Visit 1 (v1) scans were compared to the Visit 2 (v2) and Visit 3 (v3) scans. Polyworks can perform a best fit alignment of the entire surface, which includes the wig cap region of the scan, but it also allows for a fine-tuned alignment using a selected region of interest. For this comparison, it was important to see if there were changes in the facial dimensions. Therefore, bony landmarks such as the brow ridge and zygomatic arches were selected for the registration. Once the registration was achieved, all non-facial regions (neck and surface of the head covered by the wig cap) were ignored, and a statistical analysis of the overall distance between the two facial surfaces was determined.

Statistical Analysis

Two technicians measured five subjects independently on two separate occasions separated by at least 2 weeks but not more than 4 weeks. Both technicians measured the same

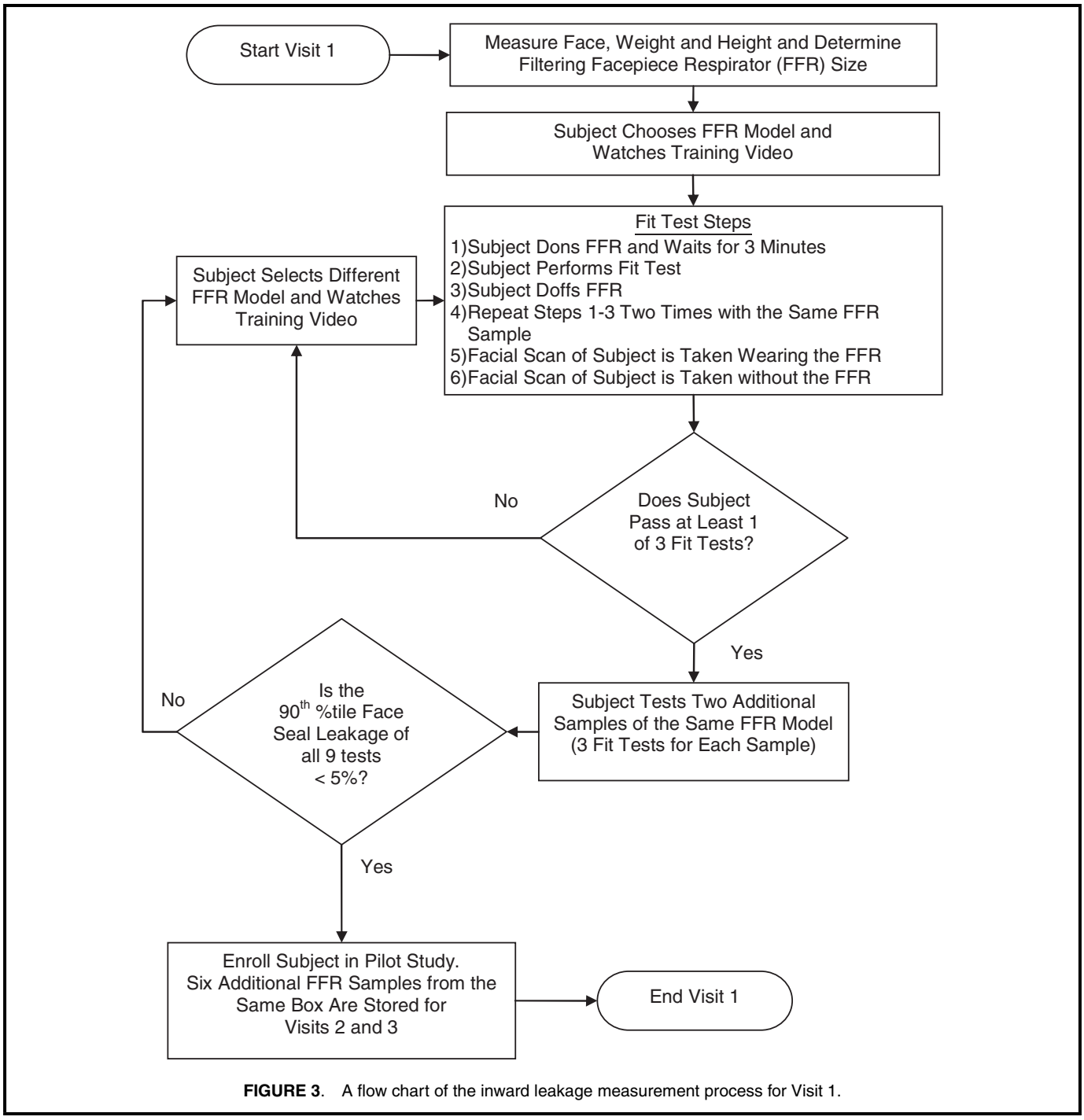

FIGURE 3. A flow chart of the inward leakage measurement process for Visit 1.

four subjects for two sequential visits. Intraclass correlation coefficients were determined from the manual measurements collected by technicians during the pilot study. The intraclass correlation coefficient (ICC) is a measure of reliability that ranges in value from zero (zero reliability) to one (perfect reliability).[14] Geeta et al.[14] further distinguished between the ICC values with values below zero indicating "no reliability," values between 0.0 and 0.2 as "slight reliability," 0.2 to 0.4 "fair reliability," 0.4 to 0.6 as "moderate reliability," 0.6 to 0.8 "substantial reliability," and 1 "almost perfect reliability." Single-factor and two-factor ANOVA were used to calculate intra-reliability and inter-reliability ICC, respectively.[15,16] All ANOVAs were computed with Microsoft Office Excel 2007.

The IL, FSL, and fit factor data were log-transformed and analyzed using professional statistical software (SAS) for Windows 9.2 (SAS Institute Inc., Cary, N.C.). The nine fit tests for each subject were used to calculate the 10th percentile value of fit factors (90% of the fit factors for a given series of donning would be higher than or equal to this number) using the GM and the GSD. The SAS PROC GLM procedure was used to

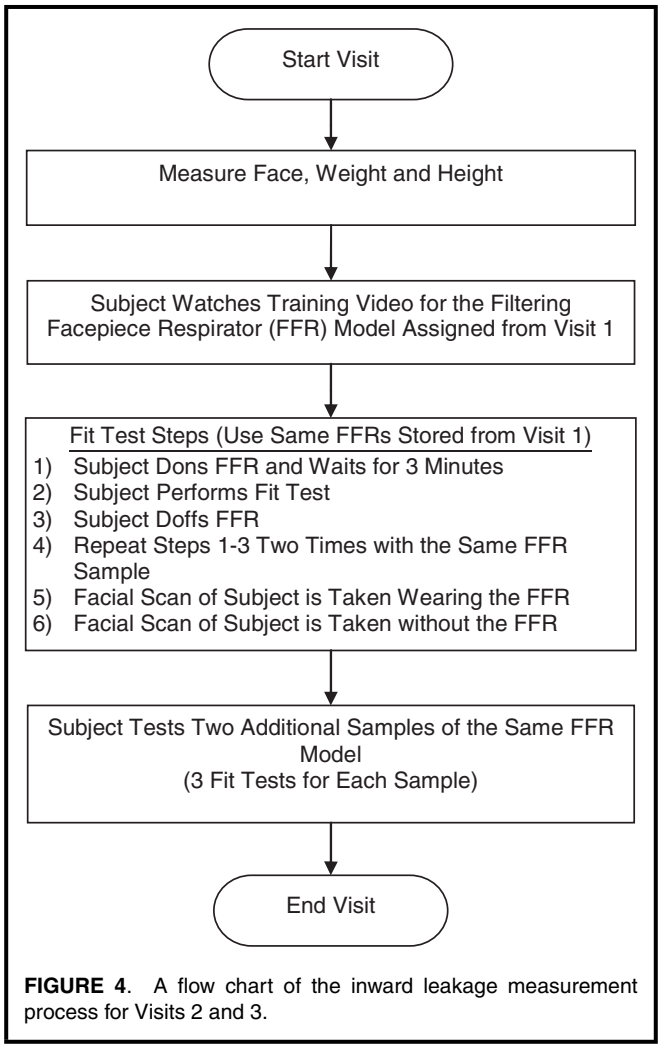

FIGURE 4. A flow chart of the inward leakage measurement process for Visits 2 and 3.

TABLE I. Intraclass Correlation Coefficients Determined from Manual Measurements

Dimension	Intraclass Correlation Between Two Measurements (ICC)		Interclass Correlation Between Two Observers (ICC)
	Observer 1 (n = 5)	Observer 2 (n = 5)	(n = 4)
Bigonial breadth	0.98	0.51	0.77
Bizygomatic breadth	0.66	0.96	0.87
Inter-pupilliary breadth	0.85	0.97	0.98
Lip length	0.96	0.83	0.20
Face length	0.80	0.56	0.59
Menton-subnasale	0.94	0.53	0.82
Nasal root breadth	0.94	0.39	0.72
Nose breadth	0.93	0.72	0.92
Nose protrusion	0.80	−0.52	0.05
Nose length	0.71	−0.33	0.49
Minimal frontal breadth	0.41	0.47	0.84
Head breadth	0.81	0.05	0.17
Head circumference	0.91	0.98	0.98

determine if fit factors between study visits were statistically different. Log-transformed fit factor was the dependent variable. Subject and visit were the independent variables with an interaction term and another term for variation among respirator samples for each model nested within each subject/visit. The overall intra- and inter-individual variation was calculated through a variance component model (PROC VARCOMP).

RESULTS

Manual Measurements

Table I provides the intraclass correlation coefficients for the facial anthropometric dimensions collected over the course of the pilot study. Technician 1 achieved moderate levels of intra-rater reliability for all manual measurements; however, Technician 2 did not achieve reliable intra-rater measurements for nose length and nose protrusion and achieved slight reliability for head breadth. The technicians achieved a moderate level of inter-rater reliability for all measurements except head breadth, nose protrusion, and lip length, which achieved only slight reliability.

All subjects maintained their weight with a maximum range less than 1 kg between all visits, except Subjects 8 and 9, who lost 3.3 and 5.1 kg, respectively, between the first and last pilot study visit.

Three-Dimensional Scan Data

Table II shows the variation between baseline and the subsequent visits. Due to the nature of the scanning process, movement artifacts were captured in the scan. These artifacts resulted in distances from one surface to another having a range between the maximum and minimum error of almost 30 mm. This variability is higher than measurements associated with traditional anthropometric manual measurement techniques.[17] However, that range was associated only with pinpoint regions of the surface.

The root mean square (RMS) error provides an absolute error of the entire facial surface of 2.5 mm or less. This value was determined by using Polyworks to register the facial surfaces for v1 and v2. Polyworks contains an algorithm that determines the perpendicular distance between polygons and generates an RMS value for the comparison of the second visit to the first visit (Figure 5).

TABLE II. Three-Dimensional Surface Comparisons of Scans Collected with the Cyberware Rapid 3-D Digitizer

	Mean (mm)		Standard Deviation		RMS Error (mm)		Max Error + (mm)		Max Error – (mm)	
Subject	v1 to v2	v1 to v3	v1 to v2	v1 to v3	v1 to v2	v1 to v3	v1 to v2	v1 to v3	v1 to v2	v1 to v3
1	−0.15	−0.10	2.17	2.50	2.17	2.50	7.13	8.24	−9.12	−8.61
2	0.67	−0.44	1.05	1.21	1.24	1.29	8.19	8.66	−9.95	−8.31
3	−0.10	0.76	1.05	0.71	1.06	1.04	5.89	4.83	−6.29	−3.29
4	−0.68	−0.23	1.12	1.21	1.31	1.24	4.78	4.86	−5.95	−4.99
5	0.01	0.08	0.83	1.31	0.83	1.31	4.59	8.16	−4.76	−6.62
6	0.82	−0.40	1.24	0.93	1.49	1.01	6.82	7.74	−7.36	−8.25
7	−0.10	0.01	1.19	0.86	1.19	0.86	15.79	12.22	−14.79	−13.52
8	0.58	0.27	1.01	0.92	1.17	0.96	4.80	3.94	−3.70	−4.86
9	0.20	−0.24	1.00	1.02	1.02	1.04	11.13	2.67	−17.87	−4.71
10	0.21	−0.38	1.11	1.08	1.13	1.14	7.87	6.58	−8.90	−9.35

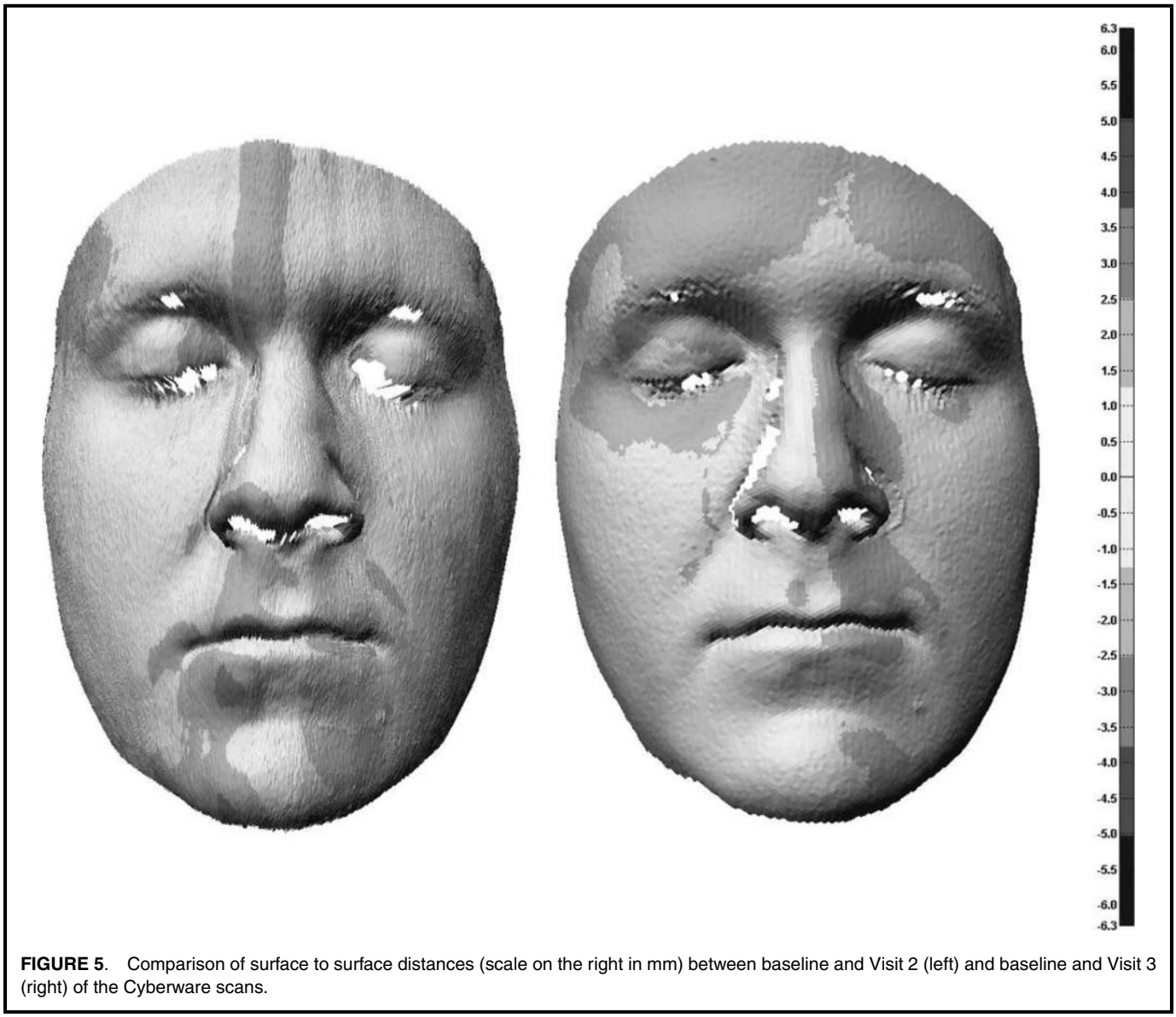

FIGURE 5. Comparison of surface to surface distances (scale on the right in mm) between baseline and Visit 2 (left) and baseline and Visit 3 (right) of the Cyberware scans.

Inward Leakage, Filter Penetration, and Face Seal Leakage

Subjects received training on proper donning and doffing procedures for their respirator at the beginning of every visit and were then asked to perform a set of three fit tests for each of three respirators of the same model. The GM and GSD for IL were calculated for each series of nine donnings by visit and subject (Table III). Sometimes the respirator straps broke and more than three respirator samples were needed resulting in more than nine donnings.

Every respirator donned during the pilot study was tested post-use to determine its filter penetration. The filter penetration is also summarized by visit and subject in Table III. With vacuum flow at approximately 10.5 L/min, filter penetration remained below 0.02% for all respirators except the first set of 3M 1860s used by Subject 10 during the first visit. The discrepancy is likely due to the inability to completely seal the respirator to the wax plate rather than the quality of the respirator filter material.

FSL was also calculated by subtracting the mean filter penetration for each respirator sample from the IL (Table III). With low vacuum flow levels, filter penetration was minimal, resulting in FSL calculations very similar to IL values (Table III). The GM of FSL of nine donnings for individual subjects ranged from 0.22% to 1.00% for the first visit, from 0.21% to 0.96% for the second visit, and from 0.24% to 1.93% for the third visit. The mean change in FSL for the 10 subjects was 0.04% between Visits 1 and 2, and was 0.23% between Visits 1 and 3. All subjects maintained an adequate level of fit as defined by a 90th percentile FSL of less than 5%.

TABLE III. The Geometric Mean Inward Leakage, Mean Filter Penetrations for the Respirators Used, and Geometric Mean Face Seal Leakage for a Series of Nine Donnings by Visit and Study Subject

		Inward Leakage			Filter Penetration			Face Seal Leakage			
Visit	Subject	n	GM (%)	GSD	n	Mean (%)	SD (%)	n	GM (%)	GSD	90th Percentile (%)
1	1	9	0.66	2.1	3	0.01	0.004	9	0.65	2.1	1.69
1	2	9	1.00	1.3	3	0.02	0.013	9	0.97	1.3	1.33
1	3	10	0.29	1.7	4	0.02	0.020	10	0.27	1.7	0.54
1	4	9	0.60	2.1	3	0.02	0.015	9	0.57	2.1	1.52
1	5	11	0.24	2.7	4	0.02	0.005	11	0.22	2.8	0.84
1	6	11	0.45	1.5	4	0.02	0.019	11	0.42	1.5	0.74
1	7	9	0.44	1.3	3	0.01	0.004	9	0.43	1.3	0.61
1	8	9	0.44	1.2	3	0.01	0.008	9	0.43	1.2	0.54
1	9	10	0.60	1.4	4	0.01	0.005	10	0.59	1.4	0.94
1	10	9	0.71	1.2	3	0.09	0.112	9	0.61	1.3	0.88
2	1	9	0.97	1.6	3	0.01	0.003	9	0.96	1.6	1.73
2	2	9	0.85	1.6	3	0.03	0.030	9	0.83	1.6	1.47
2	3	9	0.47	1.2	3	0.02	0.017	9	0.46	1.2	0.59
2	4	9	0.50	2.2	3	0.01	0.003	9	0.49	2.2	1.36
2	5	9	0.23	1.5	3	0.02	0.003	9	0.21	1.6	0.38
2	6	9	0.59	1.8	3	0.01	0.003	9	0.58	1.8	1.24
2	7	9	0.61	1.2	3	0.02	0.008	9	0.60	1.2	0.72
2	8	9	0.62	1.2	3	0.01	0.002	9	0.61	1.2	0.79
2	9	9	0.62	1.3	3	0.01	0.006	9	0.62	1.3	0.83
2	10	9	0.37	1.7	3	0.02	0.017	9	0.35	1.7	0.70
3	1	9	1.94	1.8	3	0.01	0.009	9	1.93	1.8	4.10
3	2	9	0.97	1.4	3	0.02	0.014	9	0.95	1.4	1.42
3	3	9	0.70	1.8	3	0.01	0.008	9	0.69	1.8	1.47
3	4	9	0.46	1.3	3	0.04	0.060	9	0.42	1.2	0.55
3	5	9	0.25	1.3	3	0.01	0.004	9	0.24	1.3	0.34
3	6	9	0.67	1.6	3	0.01	0.005	9	0.66	1.6	1.19
3	7	9	0.69	1.5	3	0.01	0.009	9	0.67	1.5	1.11
3	8	9	0.56	1.2	3	0.01	0.007	9	0.55	1.2	0.71
3	9	9	0.61	1.0	3	0.02	0.011	9	0.59	1.0	0.61
3	10	9	0.50	2.1	3	0.01	0.007	9	0.48	2.2	1.32

TABLE IV. ANOVA Table

Source	Degrees of Freedom	Expected Mean Square	F Value	P-Value
Visit	2	$\sigma^2 + 3\sigma_m{}^2 + 9\sigma_{SV}{}^2 + 90\sigma_V{}^2$	2.49	> 0.05
Subject	9	$\sigma^2 + 3\sigma_m{}^2 + 9\sigma_{SV}{}^2 + 27\sigma_S{}^2$	9.03	< 0.05
Subject*visit	18	$\sigma^2 + 3\sigma_m{}^2 + 9\sigma_{SV}{}^2$	1.14	> 0.05
Respirator(subject*visit)	64	$\sigma^2 + 3\sigma_m{}^2$	3.43	< 0.05
Error	182	σ^2		

Note: *Indicates the interaction between the subject and their visits.

GM fit factors and the 10th percentiles for the series of nine donnings are plotted in Figure 6 by subject and visit. The results demonstrate that the criterion for the 90th percentile of FSL being equal to or less than 5% was met. The analysis of variance (ANOVA) table is summarized in Table IV. There was no significant difference in fit factors among the three visits (p-value > 0.05). The interaction between subject and visit was not statistically significant (p-value > 0.05). There were significant differences in fit factors among subjects and among the three different respirator samples for the same model used for the nine donnings (p-value < 0.05).

The variance component estimates are summarized in Table V. Variance is also expressed as standard deviation, geometric standard deviation, and coefficient of variance. The variance for subject (inter-subject variability) was the largest (GSD = 1.49). The variances for the subject-visit interaction (GSD = 1.11) and visit (GSD = 1.13) were much smaller than the variance for the other components. Intra-subject variability is similar to inter-subject variability, with a GSD of 1.47.

DISCUSSION

The pilot study demonstrated that the incorporated manual measurement techniques provided reliable measurements for the majority of facial dimensions. Minimal inter-rater reliability was obtained for three dimensions: lip length (ICC = 0.20), nose protrusion (ICC = 0.05), and head breadth (0.17). Intra-rater reliability was consistently high for Technician 1; however, Technician 2 demonstrated the need for further training on properly measuring for nose protrusion, nose length, and head breadth. To overcome weakness with consistency in manual measurement, technicians received additional training in how to accurately collect these facial dimensions. In addition, a proper calculation of ICC requires at least 20 subjects. However, the pilot was limited to 10 subjects, so in future calculations, during the full study, more manual measurement comparisons will be achieved.

The initial scans acquired with the Cyberware Rapid 3-D Digitizer contain movement artifact. It proved difficult for subjects to remain perfectly still during the course of a

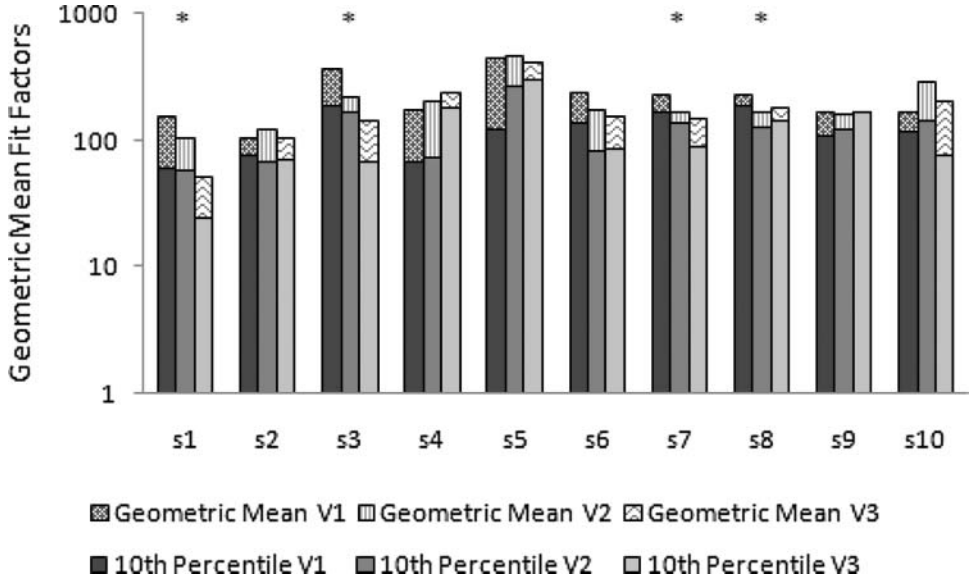

FIGURE 6. The GM and the 10th percentile fit factors for the series of nine donnings conducted during the three visits by each subject. The * indicated statistically significant changes between visits.

TABLE V. Variance Component Estimates

Variance Component	Variance	SD	GSD	Coefficient of Variance (%)
Var(visit), σ_V^2	0.002885	0.0537	1.13	2.4
Var(subject), σ_S^2	0.030310	0.1741	1.49	7.7
Var(subject*visit), σ_{SV}^2	0.002083	0.0456	1.11	2.0
Var(respirator(subject*visit)), σ_m^2	0.022170	0.1489	1.41	6.6
Var(error), σ^2	0.027990	0.1673	1.47	7.4

40–sec scan, resulting in surface discrepancies between visits. Directly after the completion of the pilot study, a new 3-D surface capturing system was acquired. The 3dMDcranial5 System (3dMD LLC, Atlanta, Ga.) uses stereophotogrammetry to capture 3-D data in milliseconds (ms), which removes any artifact due to motion, providing consistent surface capture between visits. The authors believe that with the acquisition of the new imaging capturing equipment, 3-D scans will be more reliable and show less variability compared with the manual measurements. In addition, the scans are expected to be used for future analysis in determining how the three-dimensional surface of the face changes over time.

Fit testing is not error free and is associated with the fitting characteristics of a given respirator as well as the accuracy of the fit testing method.[18] Two studies investigated the alpha (failing a fit test in error) and beta (passing a fit test in error) errors associated with various fit testing methods. A comparison of bitrex, saccharin, and the PortaCount Plus with N95 Companion showed beta errors of 8%, 8% and 9%, respectively, and alpha errors of 71%, 68% and 40%, respectively.[11] A comparison of those same fit testing methods, as well as the ambient aerosol method using the PortaCount Plus and the generated aerosol method with corn oil, found that when the errors are combined, the PortaCount Plus had the lowest percentage of wearers being assigned a poor-fitting respirator.[12]

There was a high level of variability associated with the levels of fit achieved over the course of the pilot study. However, the high variability was due to both inter- and intra-subject variability. Previous studies have also shown that variability is inherent to fit testing research. Oestenstad and Zwissler[19] performed three fit tests per respirator type on 45 subjects wearing natural silicone and rubber half-mask respirators. The GSD ranged from 1.06 to 17.09 for silicone facepieces and 1.06 to 5.68 for natural rubber facepieces.

Similar results have been found in other research associated with reusable half-mask respirators.[20–22] Da Roza et al.[20] found reproducibility is more easily achieved when tests are given on the same day than when fit tests are conducted on different days. There was significant between-subject variability for the pilot study, but the between-visit variability was not significant. This may be due to the characteristics associated with N95 FFRs. They are not designed to be donned multiple times, whereas elastomeric half-mask respirators are designed to be reused and remain unchanged from donning to donning. By using the fit testing method with the lowest associated error, it was demonstrated that all pilot subjects maintained an adequate fit over the course of the first 4 weeks for this study. The fit test method, the exercises, and the three respirator samples (each with three donnings for a total of nine donnings) can adequately measure various variance components to allow accurate comparison of fit between visits. Therefore, the study design was appropriate.

In conjunction with the overall study, a pilot study using elastomeric respirators was also conducted and will be reported in a separate article.

CONCLUSIONS

Technicians achieved at least moderate reliability for all manual measurements except nose protrusion. Filter penetration was generally less than 0.03%. GM fit factors were not statistically different between the three visits. Large variability was observed with different respirator samples for the same model, between subjects (inter) and within each subject (intra). Although variability was observed between subjects and respirator samples for each model, adequate fit was still maintained for all 10 subjects. Pilot scans collected show subject faces remained the same, within the limits of each measurement technique, over the 4 weeks. The consistent results during the pilot study indicate that the methods and procedures are appropriate for the 3-year main study. In addition, this baseline fit change data will be compared with future measurements of fit change to determine if the fit changes are meaningful. Future analysis will focus on the data collected with the 3dMDcranial5 System.

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