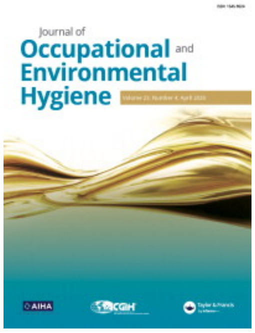

Taylor & Francis
Taylor & Francis Group

Journal of Occupational and Environmental Hygiene

ISSN: 1545-9624 (Print) 1545-9632 (Online) Journal homepage: www.tandfonline.com/journals/uoeh20

Fit testing of N95 respirators: A pilot study on respirator design and demographic factors

Xinyi Niu, Michael Yermakov, Sergey Grinshpun & Jun Wang

JOURNAL OF OCCUPATIONAL AND ENVIRONMENTAL HYGIENE
https://doi.org/10.1080/15459624.2026.2650644

Fit testing of N95 respirators: A pilot study on respirator design and demographic factors

Xinyi Niu, Michael Yermakov, Sergey Grinshpun, and Jun Wang

Department of Environmental and Public Health Science, College of Medicine, University of Cincinnati, Cincinnati, Ohio

ABSTRACT

N95 filtering facepiece respirators (FFRs) approved by the National Institute for Occupational Safety and Health are widely used by healthcare workers to prevent the inhalation of hazardous airborne contaminants. Various nose-clip shapes and respirator styles in N95 FFRs are designed to eliminate gaps between the respirator and the wearer's facial skin, ensuring adequate protection for the wearer. However, variations in facial dimensions across sexes and races may affect the fit and, consequently, the performance of these respirators. The primary objective of this study was to assess the effect of N95 FFR design, specifically the nose-clip shape and respirator style, on the fit factor (FF). The second aim was to assess how subject characteristics, specifically sex and race, affect the respirator fit. Additionally, the efficacy of N95 FFRs may degrade over prolonged use. The authors recently developed a portable device called the Exposure Protection Integrated Communicator (EPIC) that uses dual optical sensors to measure particle concentrations inside and outside the workplace and provide real-time monitoring of the workplace protection factor for FFRs. The EPIC's performance was evaluated by comparing its results with the reference PortaCount fit tester. Two cup-shaped FFRs with different noseclip shapes and six N95 FFRs with various styles were tested. Twenty human subjects were recruited to perform the Occupational Safety and Health Administration approved quantitative fit test (QNFT) protocol by running both PortaCount and EPIC devices in triplicate with each respirator. Results indicated that respirator FF was significantly affected by respirator design and subject facial characteristics. Caucasian males generally achieved the best fit, while Hispanic or Latino females had the poorest fit, highlighting the need for design improvements that account for differences in sex and race. Additionally, the comparison between EPIC and PortaCount demonstrated a strong proportional bias, with EPIC tending to report higher fit factor values, particularly under conditions where the respirator achieved higher fit factors. These findings underscore the need for cautious interpretation and potential calibration before EPIC can be reliably used in occupational settings.

KEYWORDS

N95 FFRs; respiratory protection; occupational exposure; low-cost sensor

Introduction

Airborne contaminants in the workplace, including vapors, dust, particles, smoke, fumes, gases, or combinations of these, can pose serious health risks to workers (Ramachandran 2005). Occupational exposure to these hazardous airborne contaminants may cause or exacerbate serious respiratory diseases, such as asthma and bronchitis, as well as other short-term acute symptoms (Randem et al. 2004; Matheson et al. 2005). It may also produce long-term chronic irritation and inflammation of the respiratory tract, which can potentially lead to cancer. Effective respiratory protection can prevent or reduce exposure to airborne contaminants in the workplace when effective engineering controls are infeasible or have not yet been implemented (OSHA 1999). To ensure adequate protection for wearers, the US National Institute for Occupational Safety and Health (NIOSH) certifies respirators as required by the US Occupational Safety and Health Administration (OSHA).

N95 filtering facepiece respirators (FFRs) approved by NIOSH can offer protection against exposure to hazardous airborne particulate matter, particularly for healthcare workers and the public during outbreaks of emerging infectious diseases. However, the performance of a respirator depends on the leakage of contaminants through the filter media, faceseal, and exhalation valve (CDC 2019). Although N95 FFRs are

CONTACT Jun Wang jun.wang@uc.edu Department of Environmental and Public Health Science, College of Medicine, University of Cincinnati, Cincinnati, OH 45267-0056.

designed to filter at least 95% of airborne particles, studies report that particle penetration through faceseal leakage may exceed penetration through the filter media (Coffey et al. 1998; Zhuang et al. 1998; Grinshpun et al. 2009; Rengasamy and Eimer 2012; He et al. 2013). Therefore, the filtration efficiency of a respirator largely depends on how well it fits on the wearer's face.

To ensure adequate protection for the wearer, NIOSH-approved N95 FFRs feature specific design elements, including nose-clip-shaped designs, various respirator styles, and two headband straps. Previous studies have evaluated the effect of respirator straps on respirator seal by measuring the contact pressure of different models of N95 FFR restraints on both human heads and manikin head forms (Lei et al. 2012; Roberge et al. 2012). However, there is a lack of data on the impact of respirator design (including shape styles and nose-shaped designs) on respirator performance. The primary objective of this study was to investigate the impact of respirator design (nose-clip shape and respirator style/type) on the fit factor of N95 FFRs.

Respirator fit is influenced by user characteristics, including facial anthropometry, facial structure variations, nose and cheekbone proportions, and soft tissue characteristics, which vary by sex and race (Chapman et al. 2023; Hernandez et al. 2006). Facial shape plays a critical role in determining respirator fit, and demographic patterns in facial features may inform the development of more inclusive respirator design (Zhuang et al. 2005; Yang et al. 2007; Chen et al. 2009; Zhuang et al. 2010; Chopra et al. 2021; Caggiari et al. 2022; Chapman et al. 2023). Many existing respirator studies did not include diverse ethnic groups, limiting the understanding of how individual variability in facial dimensions may impact respirator performance (Chen et al. 2009; Wilkinson et al. 2010; Caggiari et al. 2022). Therefore, the second aim of this study was to explore the relationships between subjects' demographics (sex and race (Asian, Black or African American, Caucasian) or ethnicity (Hispanic or Latino)) and respirator fit.

Ill-fitted respirators may compromise the protection offered to wearers (Zhuang et al. 2005). OSHA mandates that all employees required by the employer to wear respirators be subject to fit testing in accordance with OSHA 29 CFR. 1910.134 Respiratory Protection to protect the wearer (OSHA 1999). The ambient aerosol quantitative fit testing (QNFT) protocol is conducted primarily using a PortaCount Fit Tester (TSI Inc., Shoreview, MN), which utilizes a condensation nuclei counter (CNC)/condensation particle counting (CPC) technique. The test outcome is a fit factor (FF) calculated as the ratio of aerosol concentrations measured outside and inside the respirator. However, the PortaCount has several limitations: its single CPC sensor makes it challenging to monitor aerosol concentrations simultaneously inside and outside the respirator, and the requirement for alcohol on the condensational particle sensor restricts its applications to laboratory environments. However, in actual workplace settings, time pressure and work-related constraints may lead to the incorrect use of N95 respirators, resulting in ill-fitting respirator use and reduced protection. To address these limitations, a novel device, the Exposure Protection Integrated Communicator (EPIC), was developed by the authors. The EPIC was a low-cost, wearable, field-portable device designed with dual optical particle counting (OPC) sensors, which simultaneously enabled aerosol concentration measurement both inside and outside the respirator. This capability allows EPIC to continuously monitor the performance of FFRs and alert wearers to performance compromises. The EPIC could be used for both lab-based fit testing and the assessment of real-time fit in the workplace. This study also aimed to conduct a preliminary comparison of the EPIC's performance against the existing CPC method to explore its potential as a practical alternative for field-based fit evaluation.

Methods

Subject recruitment

Twenty human subjects were recruited to participate in the testing. The cohort included 10 adult males and 10 adult females, of which eight were Caucasian, four were Asian, four were Black or African American, and four were of Hispanic or Latino heritage. Participants included students and staff members of the University of Cincinnati and local community members in the Cincinnati area. Participants were recruited through email and in-person outreach, and each was assigned a unique identification (ID) to serve as their study identifier. Before testing, each subject completed OSHA's respirator medical clearance questionnaire administered by the University of Cincinnati Occupational Pulmonary Program, and provided informed consent approved by the Institutional Review Board (IRB) with protocol #2023-0561. A $75 gift card was sent to each participant as compensation for their participation. Facial dimensions, specifically the width and length of each participant, were measured using a spreading caliper (Fabrication Enterprises Inc., White Plains, NY, USA). These measured facial dimensions were then plotted onto the NIOSH-approved bivariate panel to achieve the distribution of the 20 subjects within the panel (Zhuang et al. 2007; NIOSH 2018).

Respirator selection

Noseclip design and modification of the N95 respirator

The study evaluated N95 FFRs with three noseclip designs: FFRs with a conventional adjustable metal noseclip, FFRs with an M-shaped adjustable metal noseclip, and FFRs without a noseclip, which served as the control, as shown in Figure 1. The M-shaped adjustable metal noseclip, originally designed for the 3M Particulate Respirator 8511 FFRs (3M Corp.), was engineered to conform to the nose and minimize the gap between the respirator and facial skin, thereby providing a custom and secure seal (3M Particulate Respirator 8511 n.d.). Both conventional nose clips and M-shaped nose clips were compatible with cup-shaped respirators. To assess the influence of noseclip shape on respirator fit, two cup-shaped respirator models were selected: the 3M Particulate Matter Respirator (Model 8210, 3M Corp., St. Paul, MN, USA) and the Moldex 2200 N95 Respirator (Model S-15312, Moldex-Metric, Culver City, CA, USA). Both respirator models were cup-shaped; the Moldex 2200 features a self-supported, molded nose area without a nose clip, and the 3M 8210 includes a conventional metal nose clip.

The conventional noseclips were carefully removed from the 3M 8210 respirators using a flat-edged precision tool to avoid damaging the respirator body. The M-shaped nose clips were harvested from new, unused 3M 8511 respirators and manually affixed to the 3M 8210 respirators using medical-grade pressure-sensitive adhesive tape. This method ensured stable attachment without compromising the respirator structure. The respirators were then gently pressed along the clip area to replicate standard donning conditions and facilitate seal formation. Both noseclip types (conventional and M-shaped) sourced from 3M respirators were applied to the Moldex 2200 model to create two modified versions: one with a conventional nose clip and one with an M-shaped nose clip. The same attachment method was used for consistency across all modifications. This modification process enabled the creation of four configurations:

- 3M 8210 without a noseclip;
- 3M 8210 with an M-shaped noseclip;
- Moldex 2200 with a conventional noseclip;
- Moldex 2200 with an M-shaped noseclip.

In addition to these modified configurations, two non-modified respirators were included:

- 3M 8210 with its original conventional noseclip;
- original Moldex 2200 without a noseclip.

N95 respirators with different design styles

Six different design styles of respirators were tested, as shown in Table 1. These particulate respirators were approved by NIOSH for use in environments containing certain non-oil-based particles and provide at least 95% filter efficiency for the most penetrating particle size (0.1 to 0.3 µm) (Qian et al. 1998; CDC 2022). They were designed to help reduce exposure to airborne particulates such as silica, as well as biological and liquid or non-oil-based particles from sprays that do not also emit oil aerosols or vapors (Malhotra et al. 2022; Osman et al. 2022). A statistically significant difference has been shown to exist between the respirator size and the respirator fit (Zhuang et al. 2005). Therefore, two sizes, "Small/Medium" and "Medium/Large" of AOSafety 1050 N95 disposable particulate respirators (AOSafety, Indianapolis, IN, USA) were provided for subject participants. The duckbill design of respirators manufactured by Kimberly-Clark Corp. (Irving, TX, USA) included two models with two sizes: 46727 (Regular size) and

Figure 1. N95 FFRs illustrate three noseclip conditions: (left) without a noseclip, (middle) with a conventional adjustable metal noseclip, and (right) with an M-shaped adjustable metal noseclip.

Table 1. Six design styles of N95 respirators.

Respirators	Model	Manufacture	Styles	Size
3M particulate matter respirator	8210	3M (Saint Paul, MN)	Cup-shaped	Regular
3M AURA health care particulate respirator and surgical mask	1870+	3M	3-Panel flat-fold	Regular
3M particulate respirator	9502+	3M	Vertical flat-fold	Regular
3M VFlex particulate respirator	9105	3M	V-flex	Regular
Kimberly-Clark N95 particulate filter respirator mask	48767;46727	Kimberly-Clark (Irving, TX)	Duckbill	Small; Regular
AOSafety pleats plus N95 particulate respirator	1050	AOSafety (Indianapolis, IN)	Flexible pleats	Small/Medium; Medium/Large

48767 (Small size). There was only one "Regular" size for the rest of the respirators.

The respirator was probed to perform QNFT, so an N95 Fit Test Probe Kit (Model 8025) was used to sample the air inside the respirator. The probe was installed in the center of the tested N95 FFR between the subject's nose and the upper lip.

Experiment setup

The testing was conducted in a 24 m^3 chamber room and sodium chloride (NaCl) served as the challenge aerosol, which was generated by a 6-Jet Collison nebulizer (MRE, 6-Jet Vertical, CH Technologies Inc., Westwood, NJ, USA). To ensure an adequate aerosol concentration during fit testing, the nebulizer was operated before testing to establish an initial aerosol concentration in the range of 8,000–12,000 particles/cm^3 with a particle size distribution spanning from the nanometer to micrometer scale. The aerosol concentrations gradually declined due to subject movement and breathing during fit testing, resulting in lower particle levels during the actual fit test. Each recruited subject was randomly assigned a tested respirator to start the modified aerosol CNC QNFT protocol using four exercises: (1) bending over, (2) talking, (3) turning the head side to side, and (4) moving the head up and down (OSHA 2004). For each exercise, the respirator fit factor (FF) value was determined as a ratio of the aerosol concentration outside and inside the respirator:

$$FF = \frac{C_{outside}}{C_{inside}} \quad (1)$$

The overall FF value was calculated using the exercise-specific FFs and recorded for each set of conditions according to the OSHA protocol (OSHA 2004):

$$Overall\ \ FF = \frac{N}{\left[\frac{1}{FF_1} + \frac{1}{FF_2} + \dots + \frac{1}{FF_N}\right]} \quad (2)$$

where N = the number of exercises; FF_1 = the fit factor for the first exercise; FF_2 = the fit factor for the second exercise; and FF_N = the fit factor for the n^{th} exercise.

The aerosol concentrations outside and inside the respirator were measured using the PortaCount Respirator Fit Tester (Model 8048, TSI Inc., Shoreview, MN, USA) as a reference device with the N95 Companion mode disabled. The PortaCount Fit Tester was checked daily before the testing session. The N95 Companion mode was not employed because it targets smaller particles (40–60 nm) that are more likely to penetrate N95 respirators. Since the EPIC utilizes optical particle counting and primarily detects particles in the micrometer range, disabling the N95 Companion enabled a more comparable particle size detection range between the EPIC and PortaCount. The novel prototype EPIC operated in parallel using a Y-splitter tubing connection, enabling simultaneous sampling while the subject performed the modified QNFT exercises. Thus, two FFs were generated, with each donning: one by the reference PortaCount ($FF_{PortaCount}$) and the other by the EPIC (FF_{EPIC}). The PortaCount sampled at a flow rate of 1 L/min while the EPIC operated at 1.1 L/min. Both instruments sampled the in-respirator aerosol concentration concurrently, and consideration was given to the potential influence of dual sampling on airflow dynamics within the respirator. The combined sampling flow rates may have slightly altered the pressure inside the respirator, potentially affecting particle infiltration or seal integrity, especially given the limited volume of the respirator's dead space. However, the relatively low combined flow rate (~2.1 L/min) is still substantially lower than typical human breathing flow rates during light activity, which can range from 10 to 30 L/min. Thus, while the additional sampling burden may have introduced minor perturbations, it is unlikely to have significantly influenced the fit factor measurements. Identical sampling lines with respect to the material, length, and internal diameter were used for both instruments. Each subject was fit tested in triplicate with each N95 respirator.

Data analysis

Data analysis was performed using IBM SPSS Statistics version 23 (IBM Inc., Armonk, NY, USA). Two separate linear mixed-effects models (LMMs) were developed to evaluate the effects of (1) noseclip shape and (2) respirator style, along with race and sex, on the overall FF of the respirators. In both models, Subject ID was included as a random intercept to account for within-subject clustering due to repeated measurements. Fixed effects included the primary design variable (noseclip shape or respirator style), race, sex, and their interactions, which allowed for the evaluation of both main and interaction effects while controlling for individual-level variability in fit performance. A multiple regression analysis was performed to examine the association between overall FF and subjects' facial dimensions following a stepwise procedure to identify the predictive subset of variables for each respirator style. A regression-based Bland-Altman analysis was conducted to evaluate the agreement between EPIC and PortaCount measurements, which accounted for proportional bias by modeling the difference between devices as a function of mean fit factor, allowing for bias and limits of agreement to vary across the measurement range. A *p*-value of less than 0.05 was considered indicative of statistical significance.

Results

Statistical summary of face dimensions

Measurements of the 20 recruited subjects within the NIOSH bivariate panel are illustrated in Figure 2. Among the selected participants, five had facial dimensions outside the panel's designated 10-zone area, while the remaining individuals had facial dimensions representing six of the 10 zones (no 1, 3, 4, 6, 7, and 9). Four female and one male participant had facial dimensions outside the panel's range. Participants whose facial dimensions aligned with the NIOSH panel were predominantly Caucasian, whereas some participants from other racial groups had dimensions falling outside the specified range. Most Caucasian participants had facial dimensions clustered in zones 4, 6, and 7, indicative of medium respirator sizes.

Male participants exhibited face lengths ranging from 116 to 134 mm with face widths between 117 and 138 mm. Female subjects had face lengths ranging from 105 to 147 mm and face widths from 105 to 144 mm. Female face dimensions were generally smaller than male faces, but no statistically significant differences in face length or width were found between genders. Moreover, Asian and Hispanic or Latino participants had smaller facial dimensions compared to Caucasian and African American participants. African American participants exhibited the longest face lengths, whereas Caucasian participants had the widest faces. Asian participants demonstrated relatively wider faces but shorter face lengths than Hispanic or Latino participants, though these differences were not statistically significant. Statistical analysis revealed that face width was significantly influenced by race, while no significant differences were found for gender or for the combined effects of race and gender. Additionally, no significant differences in face length were observed based on either sex or race.

Respirator FF across noseclip shapes

The geometric mean of overall FF values for male and female subjects across the different noseclip-shaped respirators is illustrated in Figure 3. Significant decreases in overall FF ($p < 0.01$) were observed when

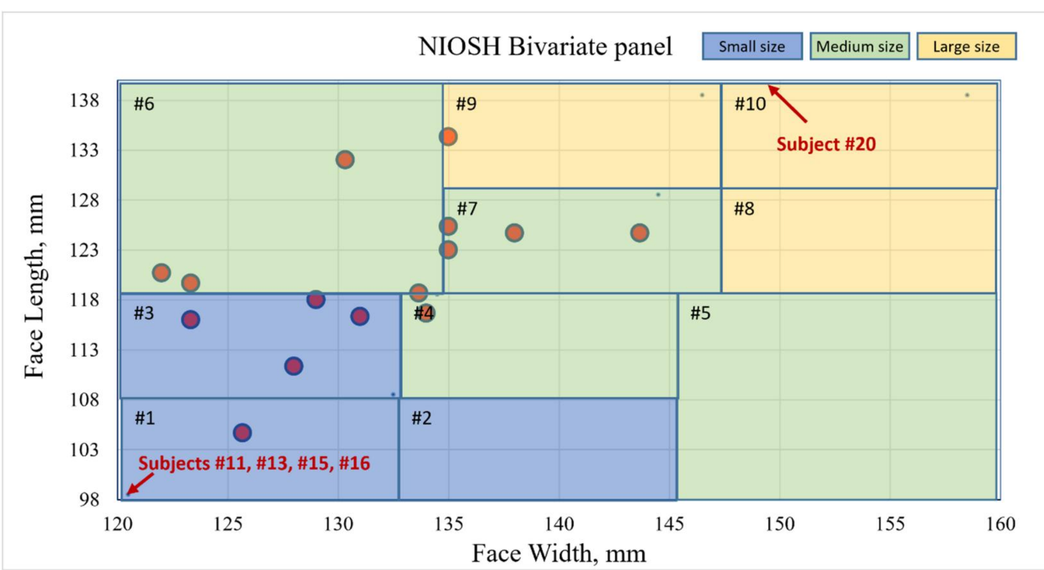

Figure 2. Face dimensions of the 20 study subjects as shown in the NIOSH bivariate panel plot.

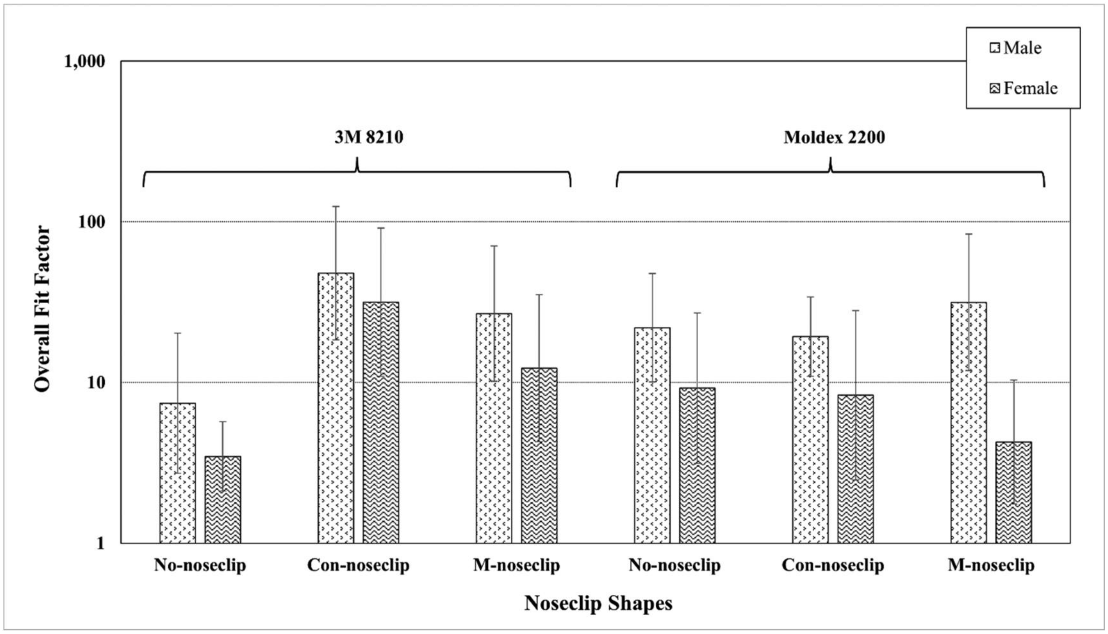

Figure 3. Respirator overall fit factors (FFs) for male and female subjects measured with PortaCount for two N95 respirator models of 3M 8210 and Moldex 2200 with three noseclip shapes. The bars represent the geometric mean of FF values, and the error bars represent the geometric standard deviations of FF values on a log scale.

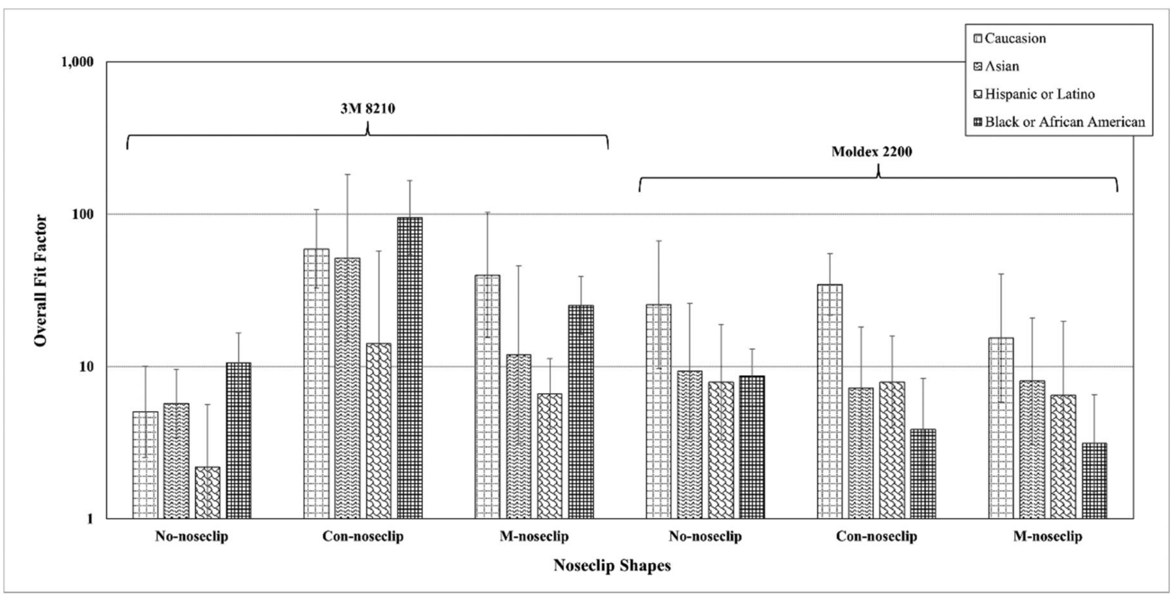

Figure 4. Respirator overall fit factors (FFs) for Caucasian, Asian, Hispanic or Latino, and Black or African American subjects measured with PortaCount for two N95 respirator models of 3M 8210 and Moldex 2200 with three noseclip shapes. The bars represent the geometric mean of FF values, and the error bars represent the geometric standard deviations of FF values on a log scale.

the conventional noseclip of 3M 8210 FFR was either removed or replaced with the M-shaped noseclip. In contrast, for the Moldex 2200 FFR, adding the conventional nose clip resulted in a non-significant reduction ($p > 0.05$) in overall FF values for both male and female subjects, although the M-shaped nose clip significantly ($p < 0.05$) improved FF values for female subjects. Female subjects exhibited lower FF values than the male subjects, but this difference was not statistically significant, except for a borderline significant difference in FF values for the Moldex M-shaped noseclip respirator ($p = 0.05$). The smaller facial dimensions of female participants likely contributed to these lower FF values, as both tested respirators were regular-sized models.

Figure 4 presents the geometric mean of overall FF values categorized by race for each tested noseclip-shaped respirator. Removal or conversion of the conventional noseclip on the 3M 8210 FFR did not lead to significant decreases in FF values across most racial groups, except for a significant decrease ($p < 0.05$) in FF for Caucasian subjects upon noseclip removal. For the Moldex 2200 respirator, adding the conventional noseclip increased FF for Caucasian subjects, though this increase was not statistically significant ($p > 0.05$). In contrast, adding either noseclip shape to the Moldex 2200 reduced FF values for Hispanic or Latino and African subjects, although the differences were not statistically significant. A significant decrease in overall FF was observed with the addition of an M-shaped noseclip on the Moldex respirator for Asian subjects.

The LMM evaluating the impact of noseclip shape, race, and gender on overall fit factor (FF) showed that the fixed effects accounted for 55.3% of the variance in FF (marginal R^2), while the full model, which included a subject-level random intercept, explained 66.5% of the variance (conditional R^2). The inclusion of a random intercept was supported by an intra-class correlation coefficient (ICC) of 0.25, indicating that 25% of the total variance was attributable to between-subject differences. A significant main effect of noseclip shape was observed (F (5, 300.036) = 62.999, $p < 0.001$), indicating that noseclip shape significantly influences the overall FF, as shown in Table 2. While gender ($p = 0.066$) and race ($p = 0.078$) were not statistically significant as individual predictors, significant interaction effects were observed. A race-by-noseclip interaction (F (15, 300.036) = 6.439, $p < 0.001$) and a three-way interaction among gender, race, and noseclip shape (F (15, 300.036) = 2.477, $p = 0.002$) indicated that the effect of noseclip shapes on respirator fit varied across demographic groups. Additionally, female participants generally exhibited lower overall FF values compared to males for the same noseclip configuration, but this trend was not consistent across all racial subgroups.

Respirator FF across respirator styles

An LMM was constructed to examine the effects of respirator style, gender, race, and their interactions on overall FF. Subject ID was included as a random intercept to account for repeated measurements within individuals, contributing an additional 9.4% to the explained variance beyond the fixed effects. The fixed effects alone explained 57.2% of the variance in FF (marginal R^2), while the full model explained 66.6% (conditional R^2), supporting the inclusion of participant-specific random effects (ICC = 0.219). As shown in Table 3, respirator style had a significant main effect on overall FF (F (5, 300) = 29.437, $p < 0.001$), indicating that respirator fit varied substantially across different respirator designs. Race was also a significant predictor (F (3, 12) = 8.263, $p = 0.003$), while sex alone was not statistically significant ($p = 0.119$). However, significant interaction effects were observed between gender and respirator style ($p = 0.004$), race

Table 2. Results from linear mixed-effects model (LMM) assessing the effects of noseclip shape, gender, race, and their interactions on respirator's overall fit factor (FF).

Source	Numerator df	Denominator df	F-value	*p*-value
Noseclip shape	5	300.036	62.999	< 0.001
Gender	1	12.009	4.099	0.066
Race	3	12.009	2.918	0.078
Gender * Race	3	12.009	0.583	0.637
Gender * Noseclip shape	5	300.036	1.642	0.149
Race * Noseclip shape	15	300.036	6.439	< 0.001
Gender * Race * Noseclip shape	15	300.036	2.477	0.002

Numerator df = number of independent comparisons made for the corresponding fixed effect or interaction.
Denominator df = estimated degrees of freedom associated with the model's residual variance, reflecting within-subject clustering and model complexity.

Table 3. Results from linear mixed-effects model (LMM) assessing the effects of respirator style, gender, race and their interactions on respirator overall fit factor (FF).

Source	Numerator df	Denominator df	F-value	*p*-value
Respirator style	5	300.000	29.437	< 0.001
Gender	1	12.000	2.823	0.119
Race	3	12.000	8.263	0.003
Gender * Race	3	12.000	1.480	0.270
Gender * Respirator style	5	300.000	3.551	0.004
Race * Respirator style	15	300	9.618	< 0.001
Gender * Race * Respirator style	15	300	3.964	< 0.001

Numerator df = number of independent comparisons made for the corresponding fixed effect or interaction.
Denominator df = estimated degrees of freedom associated with the model's residual variance, reflecting within-subject clustering and model complexity.

and respirator style ($p < 0.001$), and among sex, race, and respirator style ($p < 0.001$). These interactions suggest that the effect of respirator style on overall FF is not consistent across demographic subgroups, highlighting the importance of evaluating respirator performance across diverse user populations.

Figure 5 presents the geometric mean of overall FF values for each tested respirator across male and female subjects. No significant differences in overall FF were observed between male and female subjects across all respirator styles. Male participants achieved relatively higher overall FF values than female subjects for all respirator styles except for the duckbill design. It is observed that the cup-shaped respirator yielded the highest overall FF values for both male and female participants across all respirator styles. The duckbill style generated the lowest overall FF for male subjects, whereas female participants produced the lowest overall FF when wearing the vertical flat-fold respirator.

Figure 6 shows the geometric mean of overall FF values for each respirator style across different racial groups. Caucasian subjects achieved the highest

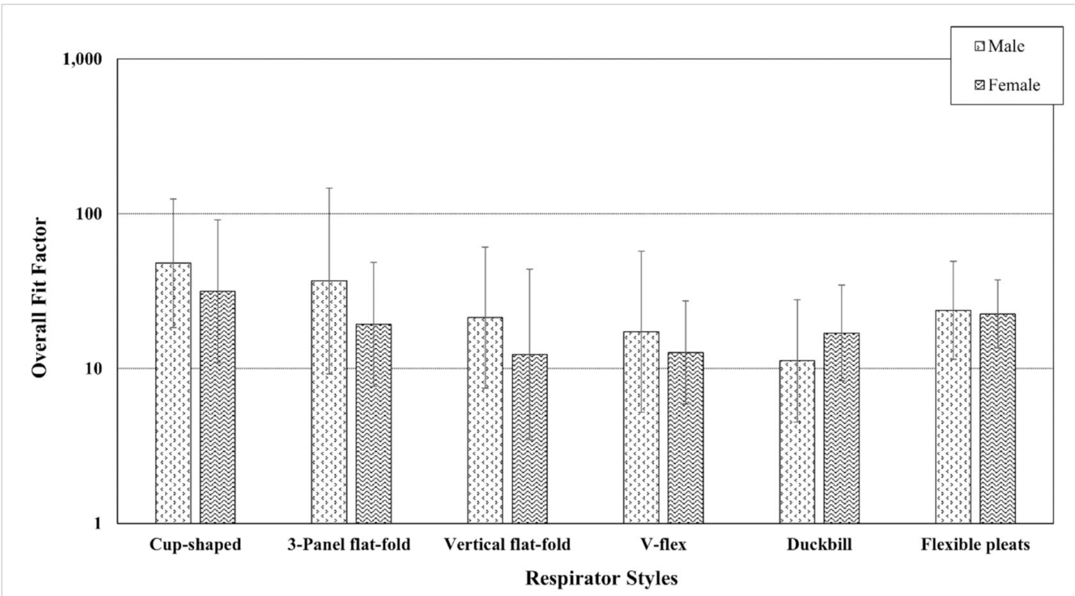

Figure 5. Respirator overall fit factors (FFs) for male and female subjects measured with PortaCount for six styles of N95 respirators. The bars represent the geometric mean of FF values, and the error bars represent the geometric standard deviations of FF values on a log scale.

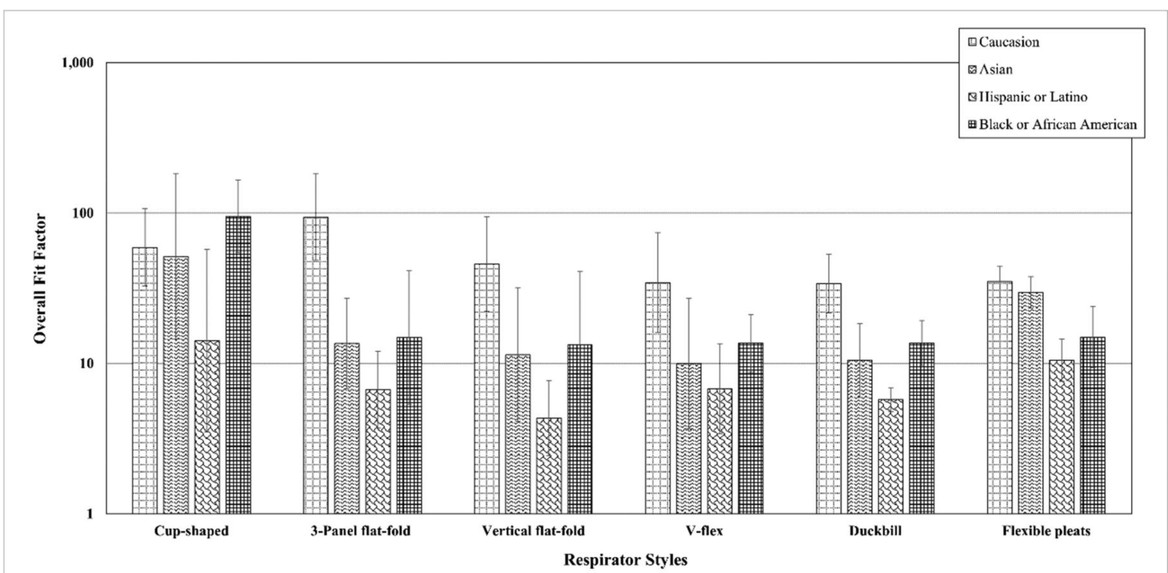

Figure 6. Respirator overall fit factors (FFs) for Caucasian, Asian, Hispanic or Latino, and Black or African American subjects measured with PortaCount for six styles of N95 respirators. The bars represent geometric mean of FF values, and the error bars represent the geometric standard deviations of FF values on a log scale.

overall FF when wearing the 3-panel flat-fold respirator and the lowest FF with the duckbill-style respirator. The highest overall FF values were observed for Asian, Hispanic or Latino, and Blank or African American participants using the cup-shaped respirator. The lowest overall FF values were observed in Asian subjects with the V-Flex style, while both Hispanic or Latino and Black or African American subjects experienced their lowest FF values with the vertical flat-fold respirator. Furthermore, the flexible pleats respirator style demonstrated the lowest variability in FF, as indicated by the error bars shown in Figure 6, compared to other respirator styles.

Relationship of facial dimensions to respirator fit correlation

The relationship between overall FF and face dimensions was analyzed using multiple regression analysis. A stepwise procedure was employed to identify the optimal subset of facial dimensions that could explain the variation in respirator FF for each respirator style. Specifically, face length and face width were included in the analysis to assess their impact on fit factors across six respirator styles. Among these six multiple linear regression models, a statistically significant correlation was found only between face width and respirator fit of the vertical flat-fold style ($p < 0.01$), with an R^2 of 0.398 and an adjusted R^2 of 0.364. However, the analysis revealed that face length did not correlate with FF for any respirator styles tested. Additionally, further analysis indicated that face width was significantly correlated with the vertical flat-fold respirator for male participants ($R^2 = 0.508$, adjusted $R^2 = 0.447$, $p < 0.02$). No significant correlation was found between face width and respirator fit for female participants or across racial categories.

EPIC vs. PortaCount

A regression-based Bland-Altman plot comparing the overall FF values measured by the EPIC and PortaCount devices is presented in Figure 7. The x-axis represents the mean FF between the two devices, while the y-axis shows the difference in FF (EPIC - PortaCount) for each paired measurement. A clear proportional bias was observed, with the difference increasing as the mean FF increased. This trend suggests that the EPIC device consistently reported higher FF values than the PortaCount, particularly under conditions where the respirator achieved higher fit factors. The regression line demonstrated that the bias was not constant across the range of measurements. Approximately 78% of the variability in the differences ($R^2 = 0.7809$) was explained by the mean FF, which confirmed the presence of strong proportional

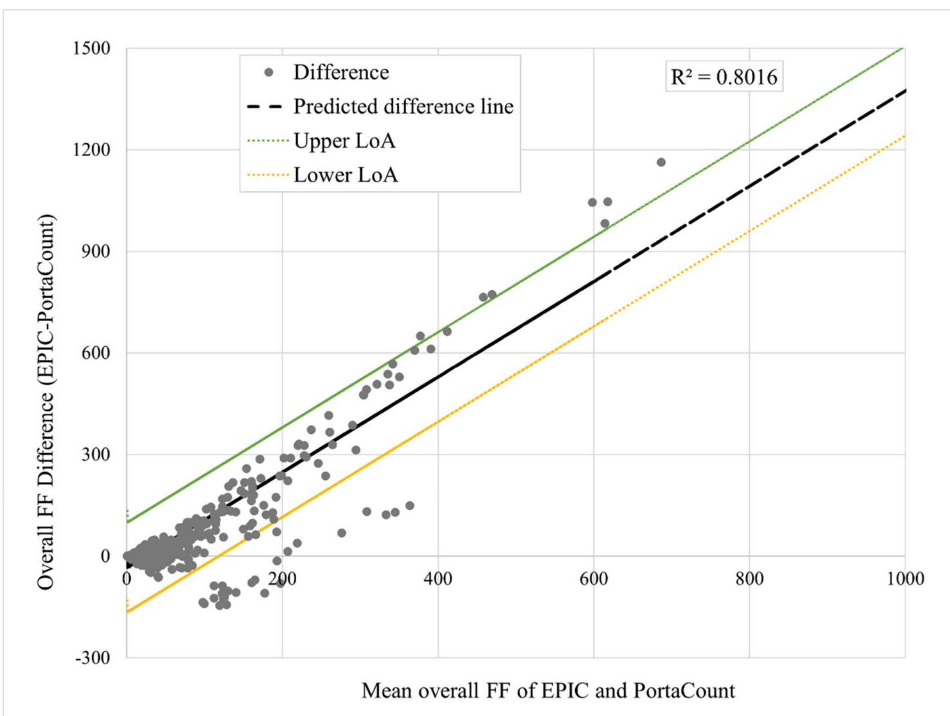

Figure 7. Regression-based Bland-Altman plot comparing the agreement of overall respirator fit factor (FF) measurements between EPIC and PortaCount (reference).

bias. The upper and lower limits of agreement also increased with the magnitude of the measurement, reflecting dynamic agreement limits.

Discussion

Human characteristics on respirator fit

The greater overall FF values observed in 3M respirators with a conventional noseclip shape highlighted the importance of the noseclip in the cup-shaped FFRs. Although the M-shaped noseclip developed by 3M Corp. was designed to better conform to the nose and avoid gaps between the respirator and facial skin, it was less effective in minimizing leakage compared to the conventional noseclip. However, adding an M-shaped noseclip to Moldex FFRs showed a non-significant ($p > 0.05$) increase in overall FF for male participants. There was no statistically significant difference in respirator fit between male and female participants across all noseclip designs. This may be explained by the lack of significant differences in nasal root breadth between genders (Zhuang et al. 2010). Both nose protrusion and nasal root breadth have been shown to influence respirator fit (Oestenstad et al. 1990; Zhuang et al. 2010). However, this study did not specifically assess the relationship between nose dimensions and noseclip shapes with respect to respirator fit. Further investigation into this area is necessary to understand these relationships better. Overall, although the differences were not statistically significant, the addition of a noseclip on Moldex FFRs for Caucasian males showed a trend toward higher FF, indicating a potential alternative design approach.

Male participants generally exhibited better fit across most FFR styles compared to female participants, likely because most commercially available NIOSH-approved respirators are designed for the facial dimensions of the Caucasian male population. (Chen et al. 2009; Zhuang et al. 2010; Caggiari et al. 2022). This observation helps explain why Caucasian males achieved relatively high FF values across most tested FFRs, as illustrated in Figure 5. These results underscore the importance of designing or modifying FFRs through a more extensive dataset of human subjects (Zhuang et al. 2010).

In addition, a significant difference ($p < 0.05$) in the geometric mean of overall FF values between cup-shaped respirators and vertical flat-folding styles was found in this study. This finding contrasts with previous research by Zhuang et al. (2005), which reported no significant difference in the geometric mean of simulated workplace protection factors between cup-style and folding-style respirators. However, it is essential to note that Zhuang et al. employed a significantly larger and more diverse subject pool based on the NIOSH bivariate panel, which makes direct comparisons between the two studies challenging. The difference in study design, sample size, and human variability among the recruited subjects in the QNFT may explain the observed discrepancy.

Face width significantly affected respirator fit, with significant differences ($p < 0.05$) observed between Hispanic or Latino and Caucasian populations. This finding supports the results of Zhuang et al. (2010), who investigated facial anthropometric differences across sexes and identified significant disparities in face width between Caucasians and Hispanics or Latinos. Zhuang et al. (2010) also reported significant differences ($p < 0.05$) in face length between Caucasian and African American subjects, which contrasts with our findings. In addition, a significant ($p < 0.05$) correlation was found between face width and the fit factor of vertical flat-fold respirators in males, with a correlation coefficient of 0.5. This suggests a potential interaction between respirator styles and facial characteristics within fit testing, which could not be thoroughly evaluated due to the limitations of our study design. Furthermore, previous research by Oestenstad (1994) indicated that both face width and face length correlated with respirator fit in females, which differed from the results of this study. The relatively small sample size in the current study may contribute to the variability observed in the quoted studies, and this variability, along with the inherent differences among human subjects, may be attributed to the discrepancies in analytical outcomes.

The current study did not identify a significant correlation between facial dimensions and respirator fit across different racial groups. A prior study examined the influence of facial dimensions on respirator fit across racial differences and concluded that among all the measured face dimensions, only nose protrusion significantly correlated with respirator fit ($R^2 = 0.1596$, $p = 0.0296$) (Brazile et al. 1998). In Brazile et al.'s (1998) study, no significant differences ($p > 0.05$) in respirator fit were observed between male and female subjects (Caucasian, African, and Mexican) when analyzing 14 facial anthropometric dimensions among a total of 186 participants (Brazile et al. 1998). Conversely, Kim et al. (2003) reported significant differences in facial anthropometric dimensions that affected respirator fit between Koreans and Caucasians, based on a study involving 110 university students. In summary, the current study's results partially support the research conducted by Brazile et al. (1998) but differ from the findings of Kim et al. (2003). These differences may be attributed to sample size and demographic grouping differences, which may affect the observed results. The differences in results among these studies highlight the need for further research using multiple respirator models, various sizes, and larger sample groups. Future studies should consider these influencing factors to improve the fit and effectiveness of respirators in different populations.

Additionally, substantial variability was observed in overall fit factor (FF) values, even when using the standardized instrument PortaCount, as shown in Figures 3–6. This variability can be attributed to multiple factors, including inter-subject differences in facial dimensions and morphology, respirator positioning and donning technique, facial movements during testing, and environmental influences. Human factors such as facial hair, perspiration, and facial asymmetry can also affect the respirator seal and, consequently, the FF values. Additionally, FF measurements inherently reflect transient fluctuations in particle concentrations both inside and outside the respirator, which may not fully stabilize during short-duration tests. These sources of biological and procedural variability are especially impactful in studies with relatively small sample sizes, where the influence of outliers or individual differences becomes more pronounced. To address this, the current study employed linear mixed-effects models that accounted for random effects associated with individual subjects, thereby mitigating the impact of inter-subject variability and enhancing the reliability of statistical inferences. Nevertheless, the high degree of variability in FF emphasizes the need for cautious interpretation of device comparisons and supports the importance of larger, more diverse cohorts in future validation studies.

EPIC vs. PortaCount comparison

The presence of a strong proportional bias between the EPIC and PortaCount devices, as revealed by the regression-based Bland-Altman analysis, has significant implications for the interpretation and application of respirator flow rate measurements. The observed trend suggests that the EPIC device may systematically overestimate the protection offered by respirator use, particularly in scenarios in which large concentrations of particles are filtered by the respirator. This overestimation could impact the accuracy of fit testing or workplace protection factor evaluations if EPIC is used as a standalone tool in certain occupational settings. The increasing spread in agreement limits with higher FF values further highlights that discrepancies between devices are not uniform across the measurement range.

Additionally, the EPIC system and PortaCount device were based on different particle counting principles. Human participants introduce confounding factors, such as sweating and the supersaturation of exhaled air, which can lead to condensation within the breathing line, resulting in particle counting errors at the respirator inlet of OPC-based measuring instruments (Brockmann 2011). In contrast, the CPC-principled PortaCount is less influenced by moisture because it relies on a condensation technique to count particles. Furthermore, penetrating particles do not mix uniformly within the cavity of a respirator, a phenomenon that is influenced by the individual's facial structure (Myers et al. 1998). This variation in in-respirator particle concentration may, in turn, affect EPIC's responses among subjects. Future studies should incorporate manikin-based validation under controlled conditions to better assess the performance of EPIC. Moreover, the OPC counters used in the EPIC were factory-calibrated, but no additional calibration against a reference aerosol standard was performed in this study. This may introduce measurement bias or increase variability. Such findings underscore the need for careful calibration, validation, and possible correction factors when integrating newer devices, such as EPIC, into routine assessments.

Limitations

This study has several limitations. First, unlike OSHA-approved fit testing, the current study's protocol does not require users to shave or clean their faces before testing. The absence of these requirements may have compromised the face seal in some cases, potentially contributing to lower or more variable fit factor values. Second, participants were not required to achieve a passing fit factor (FF $\geq$ 100) before inclusion in the analysis. As a result, the data reflect a broader range of fit outcomes, including inadequate fits, which may limit the ability to draw definitive conclusions about respirator performance or protective adequacy. However, this approach also provided insight into the variability in fit that may occur in real-world settings, where not all users achieve optimal fit. Third, the cohort size in this study is relatively small, which may limit the generalizability of the findings. The limited number of participants and the small sample sizes within specific demographic subgroups constrain the ability to draw definitive conclusions regarding the effects of sex and race on fit factor. While linear mixed-effects models were used to account for repeated measures and improve estimation efficiency, the relatively small sample size within certain subgroups may reduce the ability to detect statistically significant interaction effects. While a larger cohort would strengthen the statistical power and enable more robust subgroup analyses, these results provide preliminary insights into respirator performance under real-world conditions. Additionally, the fit-tested subjects did not occupy all 10-zone cells of the NIOSH bivariate panel, which may limit the applicability of the findings across diverse facial dimensions. Subsequent research should include a broader range of participants with varied facial dimensions. However, the observed trends highlight important differences between respirator styles and underscore the need for fit testing protocols that account for individual variability, making the findings relevant despite these constraints. Further studies should involve a larger sample size to more closely represent specific workplace groups as well as the general population.

Conclusions

This study's findings highlight the critical effects of respirator design, sex, and race on N95 fit factor. The results suggest that standard N95 respirators may not provide adequate protection for all users, particularly those with smaller facial dimensions. Although the associations between respirator fit and anthropometric interpretations based on small-sized samples are limited, they underscore the importance of integrating anthropometric diversity into respirator design and fit testing protocols. It is crucial to have more adaptable and inclusive designs that can accommodate a broader range of facial structures. Ensuring a proper fit for all individuals is crucial to optimizing respiratory protection, particularly for workers in high-risk environments such as healthcare and emergency response.

Ethics approval

This research was approved by the University of Cincinnati IRB with protocol #2023-0561. All participants provided informed consent.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

The N95 design and demographic study was supported by the National Institute for Occupational Safety and Health through the Pilot Research Project Training Program of the University of Cincinnati Education and Research Center (#T42OH008432). The authors also acknowledge the Ohio Bureau of Workers' Compensation for supporting the development of EPIC through the Workforce Safety Innovation Center Grants (#WISC23-220513-001 & #WISC24-230331-027).

ORCID

Xinyi Niu http://orcid.org/0000-0002-3261-6382
Michael Yermakov http://orcid.org/0009-0009-5407-2695
Sergey Grinshpun http://orcid.org/0000-0003-4339-927X
Jun Wang http://orcid.org/0000-0003-1690-0460

Data availability statement

The authors confirm that data supporting the findings of this study are available within the article. Raw data supporting the findings of this study are available upon reasonable request from the corresponding author.

References

3M Particulate Respirator 8511. n.d. N95 (Part Number 54343, 3M Product Number 8511, 3M ID 7000002056, UPC 50051138543438). 3M Center. [accessed 29 September 2024] https://www.3m.com/3M/en_US/p/d/v000057511/

Brazile WJ et al. 1998. Respirator fit and facial dimensions of two minority groups. Appl Occup Environ Hyg. 13(4): 233–237. https://doi.org/10.1080/1047322X.1998.10390073

Brockmann JE. 2011. Aerosol transport in sampling lines and inlets. In: Kulkarni P, Baron PA, Willeke K, editors. Aerosol measurement: principles, techniques, and applications. Wiley. p. 68–105. https://doi.org/10.1002/9781118001684.ch6

Caggiari S et al. 2022. Biomechanical and physiological evaluation of respiratory protective equipment application. Med Devices (Auckl). 15:241–252. https://doi.org/10.2147/MDER.S370142

[CDC] Centers for Disease Control and Prevention. 2019. Total inward leakage (TIL) for respiratory protective devices. Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases; [accessed 2024 Sep 23]. https://www.cdc.gov/niosh/data/datasets/rd-1011-2019-1/

[CDC] Centers for Diseases Control and Prevention. 2022. Types of masks and respirators: summary of recent changes. [accessed 2024 Sep 23]. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html

Chapman D, Strong C, Ullah S, Richards L, Ganesan AN. 2023. Personalized 3D-printed frames to reduce leak from N95 filtering facepiece respirators: a prospective crossover trial in health care workers. J Occup Environ Hyg. 20(7):304–314. https://doi.org/10.1080/15459624.2023.2205471

Chen W et al. 2009. New respirator fit test panels representing the current Chinese civilian workers. Ann Occup Hyg. 53(3):297–305. https://doi.org/10.1093/annhyg/men089

Chopra J et al. 2021. The influence of gender and ethnicity on facemasks and respiratory protective equipment fit: a systematic review and meta-analysis. BMJ Glob Health. 6(11):e005537. https://doi.org/10.1136/bmjgh-2021-005537

Clayton M, Vaughan N. 2005. Fit for purpose? The role of fit testing in respiratory protection. Ann Occup Hyg. 49(7):545–548. https://doi.org/10.1093/annhyg/mei046

Coffey CC, Zhuang Z, Campbell DL, Myers WR. 1998. Quantitative fit-testing of N95 respirators: part II-results, effect of filter penetration, fit-test, and pass/fail criteria on respirator performance. J Int Soc Respir Prot. 16(1/4):25–36.

Grinshpun SA et al. 2009. Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: two pathways for particle penetration. J Occup Environ Hyg. 6(10):593–603. https://doi.org/10.1080/15459620903120086

Grinshpun SA et al. 2020. New respirator performance monitor (RePM) for powered air-purifying respirators. J Occup Environ Hyg. 17(11-12):538–545. https://doi.org/10.1080/15459624.2020.1814491

He X et al. 2013. Manikin-based performance evaluation of elastomeric respirators against combustion particles. J Occup Environ Hyg. 10(4):203–212. https://doi.org/10.1080/15459624.2012.760063

Hernandez LM, Blazer DG, Institute of Medicine (US) Committee on Assessing Interactions Among Social, Behavioral, and Genetic Factors in Health, editors. 2006. Genes, behavior, and the social environment: Moving beyond the nature/nurture debate. National Academies Press (US). https://doi.org/10.17226/11693

Kim H, Han DH, Roh YM, Kim K, Park YG. 2003. Facial anthropometric dimensions of Koreans and their associations with fit of quarter-mask respirators. Ind Health. 41(1):8–18. https://doi.org/10.2486/indhealth.41.8

Lei Z, Yang J, Zhuang Z. 2012. Headform and N95 filtering facepiece respirator interaction: contact pressure simulation and validation. J Occup Environ Hyg. 9(1):46–58. https://doi.org/10.1080/15459624.2011.635130

Leppänen M, Wu B, Corey J, Yermakov M, Grinshpun SA. 2018. Performance of a novel real-time respirator seal integrity monitor on firefighters: simulated workplace pilot study. J Occup Environ Hyg. 15(8):607–615. https://doi.org/10.1080/15459624.2018.1479065

Liu Y, Corey J, Yermakov M, Wu B, Grinshpun SA. 2018. Preliminary development of a real-time respirator seal integrity monitor with low-cost particle sensor. IEEE Trans Ind Applicat. 54(4):3928–3933. https://doi.org/10.1109/TIA.2018.2816907

Malhotra V, Kakaria R, Singh N. 2022. An overview of the attributes of face masks in the new normal. Int J Home Sci. 8(2): 42–52. https://doi.org/10.22271/23957476.2022.v8.i2a.1307

Matheson MC et al. 2005. Biological dust exposure in the workplace is a risk factor for chronic obstructive pulmonary disease. Thorax. 60(8):645–651. https://doi.org/10.1136/thx.2004.035170

Myers WR, Allender JR, Iskander W, Stanley C. 1998. Causes of in-facepiece sampling bias—I. Half-facepiece respirators. Ann Occup Hyg. 32(3):345–359. https://doi.org/10.1093/annhyg/32.3.345

[NIOSH] National Institute for Occupational Safety and Health. 2018. Determination of qualitative isoamyl acetate (IAA) facepiece fit test air-purifying respirators standard testing procedure (STP). Procedure No. RCT-APR-STP-0005-05a-06; [accessed 2024 Oct 6] https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0005-05a-06-508.pdf

Oestenstad RK. 1994. Factors affecting respirator leak sites and shapes. Unpublished grant report (NIOSH Grant 1K010H00085). School of Public Health, University of Alabama at Birmingham.

Oestenstad RK, Perkins JL, Rose VE. 1990. Identification of faceseal leak sites on a half-mask respirator. Am Ind Hyg Assoc J. 51(5):280–284. https://doi.org/10.1080/15298669091369655

[OSHA] Occupational Safety and Health Administration. 1999. Respiratory protection: code of federal regulation title 29, part 1910.134.

[OSHA] Occupational Safety and Health Administration. 2004. Personal protective equipment, 1910.134App A—fit testing procedures (mandatory), Part I. OSHA-Accepted fit test protocols.

Osman B et al. 2022. Respiratory protective equipment (RPE) standard–disposable filtering half mask on N95, FFP2 and KN95. J Adv Ind Technol Appl. 3(1):50–54. https://doi.org/10.30880/jaita.2022.03.01.007

Qian Y, Willeke K, Grinshpun SA, Donnelly J, Coffey CC. 1998. Performance of N95 respirators: filtration efficiency for airborne microbial and inert particles. Am Ind Hyg Assoc J. 59(2):128–132. https://doi.org/10.1080/15428119891010389

Ramachandran G. 2005. Occupational exposure assessment for air contaminants. CRC Press.

Randem BG, Ulvestad B, Burstyn I, Kongerud J. 2004. Respiratory symptoms and airflow limitation in asphalt workers. Occup Environ Med. 61(4):367–369. https://doi.org/10.1136/oem.2002.006114

Rengasamy S, Eimer BC. 2012. Nanoparticle penetration through filter media and leakage through face seal interface of N95 filtering facepiece respirators. Ann Occup Hyg. 56(5):568–580. https://doi.org/10.1093/annhyg/mer122

Roberge R, Niezgoda G, Benson S. 2012. Analysis of forces generated by N95 filtering facepiece respirator tethering devices: a pilot study. J Occup Environ Hyg. 9(8):517–523. https://doi.org/10.1080/15459624.2012.695962

Wilkinson IJ, Pisaniello D, Ahmad J, Edwards S. 2010. Evaluation of a large-scale quantitative respirator-fit testing program for healthcare workers: survey results. Infect Control Hosp Epidemiol. 31(9):918–925. https://doi.org/10.1086/655460

Wu B, Corey J, Yermakov M, Liu Y, Grinshpun SA. 2018. Laboratory evaluation of a novel real-time respirator seal integrity monitor. Ann Work Expo Health. 62(6):742–753. https://doi.org/10.1093/annweh/wxy026

Yang L, Shen H, Wu G. 2007. Racial differences in respirator fit testing: a pilot study of whether American fit panels are representative of Chinese faces. Ann Occup Hyg. 51(4):415–421. https://doi.org/10.1093/annhyg/mem005

Zhuang Z, Bradtmiller B, Shaffer RE. 2007. New respirator fit test panels representing the current U.S. civilian work force. J Occup Environ Hyg. 4(9):647–659. https://doi.org/10.1080/15459620701497538

Zhuang Z, Coffey CC, Ann RB. 2005. The effect of subject characteristics and respirator features on respirator fit. J Occup Environ Hyg. 2(12):641–649. https://doi.org/10.1080/15459620500391668

Zhuang Z, Coffey CC, Myers WR, Yang J, Campbell DL. 1998. Quantitative fit-testing of N95 respirators: part I-method development. J Int Soc Respir Prot. 16(1/4):11–24.

Zhuang Z, Landsittel D, Benson S, Roberge R, Shaffer R. 2010. Facial anthropometric differences among gender, ethnicity, and age groups. Ann Occup Hyg. 54(4):391–402. https://doi.org/10.1093/annhyg/meq007