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Flat Fold and Cup-Shaped N95 Filtering Facepiece Respirator Face Seal Area and Pressure Determinations: A Stereophotogrammetry Study

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Abstract

Twenty subjects underwent quantitative respirator fit testing with two styles (flat fold, cup-shaped) of N95 filtering facepiece respirators (N95 FFRs). Passing a fit test was followed by stereophotogrammetry to determine the face seal area and computation of seal pressure. There were significantly different seal pressures ($p < 0.01$) between standard size flat fold and cup-shaped N95 FFRs but no significant differences in face seal area. No significant differences were noted in fit factors, but more individuals passed fit testing wearing flat fold respirators. The ability of flat fold N95 FFRs, at lower seal pressures, to obtain similar fit factors as cup-shaped N95 FFR at higher seal pressures offers the possibility of enhanced facial comfort without a loss of protection. Stereophotogrammetry offers a relatively simple, non-invasive technology to evaluate various properties of N95 FFR fit.

Keywords

face seal area; N95 filtering facepiece respirators; seal pressure; stereophotogrammetry

INTRODUCTION

The respiratory protection afforded by a filtering facepiece respirator (FFR) is dependent not only on its filtration capability but also on the face seal leakage that occurs at the face/FFR interface.[(1)] The adequacy of the face seal is reliant on various factors, including the design of the facepiece sealing surface and the pressures generated by the FFR tethering devices (e.g., straps, bands, and so on).[(2,3)] Discontinuities at the face seal area (FSA) are responsible for the greatest portion of inward leakage of contaminants, with face seal leakage averaging 3–5 times that of filter penetration in a recent study.[(4)] Computational fluid dynamics studies have indicated that FSAs with low pressure are more likely to leak,[(5)] whereas high-pressure areas may cause facial discomfort[(6)] that can lead to intolerance and

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negatively impact FFR use compliance.[7] This has prompted suggestions that a priority in improved FFR development should emphasize fit while striking a harmonious balance with comfort.[4] Pressure developed by the tethering devices is distributed over the FSA[8] and is inversely proportional to contact surface area.

The N95 class of FFR (N95 FFR) is the most commonly used FFR in U.S. private industry and health care,[2] but despite decades of its use, little scientific data exist regarding contact area dimensions and pressures of the FSA when worn. Stereophotogrammetry (SPG), the process of obtaining geometric data from photographic images, enables the determination of an object's subcomponent features during real-time use and has been used previously to study N95 FFRs.[2] This study, a part of a larger National Institute for Occupational Safety and Health (NIOSH) investigation examining multiple facets of respiratory protective equipment (portions of which have been previously reported,[2,9–12]) used SPG to determine the FSA of six N95 FFR models and thereby calculate associated pressures. These data may be useful to respiratory protective equipment researchers and manufacturers in developing FFRs that are more comfortable for the wearer while still affording adequate protection.

MATERIALS AND METHODS

Twenty healthy, non-smoking subjects (13 men, 7 women) participated in this study. Demographic mean values (standard deviations) were: age 23.0 years (2.8), height 175.8 cm (9.5), weight 77.6 kg (15.9), and body mass index 25.0 kg/m^{-2} (4.1). The study was approved by the NIOSH Human Subjects Review Board, and all subjects provided oral and written informed consent.

Subjects first underwent Occupational Safety and Health Administration (OSHA) quantitative respirator fit testing[13] with the PortaCount Plus Respirator Fit Tester and N95 Companion (TSI, Shoreview, Minn.) that uses condensation nuclei or particle counting technology to count the number of ambient particles. The ratio of measured ambient particles to within-FFR particles, calculated as geometric means, is termed the fit factor and is one measure of the adequacy of the fit of the FFR to the subject. The fit tester, as configured for the study, reports out a maximum score of 200 irrespective even if higher scores are attained. Passing a fit test required a fit factor of ≥100, equivalent to a passing score on an OSHA quantitative respirator fit test.[13] This score for determining a passed fit test was used because our U.S. government laboratory follows U.S. Code (19 CFR 1910) with regard to the score required to pass quantitative fit testing of respirators.[13]

Subjects donned the individual FFRs as per the manufacturer's instructions, performed a user seal check to evaluate the FFR seal,[14] and fit tested each of four molded, cup-shaped N95 FFR models from one manufacturer (Models A, B, C, D) and each of two flat-fold, "one size fits all" models from a second manufacturer (Models E, F). Two models (A, C) were medium/large size, two (B, D) were small size versions of Models A and C, and three models (C, D, F) were equipped with an exhalation valve. Two models (E, F) feature a pliable nose bar for enhancing the seal of the N95 FFR around the nasal region, whereas the other models (A, B, C, D) have a defined, pre-molded nasal contour. Only respirators that passed fit testing were included in the study data (i.e., Model A = 5 subjects, Model B = 15 subjects, Model C = 5 subjects, Model D = 13 subjects, Model E = 20 subjects, Model F = 20 subjects).

The tethering devices (straps) of the N95 FFRs were marked at 1-cm intervals along their entire length (Figure 1) to determine donning lengths for calculation of stretch and stress values used to compute the generated Z-forces (forces exerted front-to-back of the subject's face), as described previously.[2]

SPG enables the determination of geometric properties from photographic images. This process involves estimating the three-dimensional (3D) coordinates of points on an object. Photographs are taken from multiple locations (lines of sight) and, using the principle of triangulation (mathematical intersection of lines of sight), the X, Y, and Z coordinates of each point of interest are determined. Study subjects underwent SPG with the 3dMD system (3dMD, Atlanta, Ga.) while wearing N95 FFR models that had passed fit testing. Other digital camera systems have been used in respirator research (e.g., Cyberware rapid 3-D digitizer, Monterey, Calif.), but scan times were ~45 sec and increased the possibility of motion artifact.[15] Reverse engineering techniques, using commercial software (i.e., LS-DYNA) have also been used to evaluate respirator surface area characteristics and pressures.[8] The 3dMD SPG unit uses five precisely synchronized digital cameras set at various angles to capture simultaneous 3D images within 2 milliseconds (Figure 2). Proprietary algorithms integrate the multiple images to produce a single 3D image highlighting surface geometry and texture.[16]

It was first necessary to align the 3dMD scan of the subject not wearing an FFR and the scan of the same subject wearing an FFR. This was done by first importing the two scans into IMInspect of PolyWorks software (Innovmetric Software Inc., Quebec, Canada). IMInspect contains a function called "Best-fit Data Object" that automatically creates an alignment of all selected models. Once the two scans were aligned, they were imported into IMEdit of the Polyworks software that allows manipulation of the scans. By changing the view of the scan of the subject not wearing an FFR, the intersection of the two scans can be seen as a change in texture corresponding to the overlay of the skin and respirator frameworks that represents the FSA (Figure 3a). All regions of the scan in which the FFR was not in contact with the face were highlighted and removed, leaving the FSA (Figure 3b), which was measured via a function on IMEdit. The SPG data for three N95 FFRs (B, E, F) from the same subject were of poor quality due to movement artifact and could not be used for the data analysis (Table I).

Following calculation of the FSA, pressure derived from the tethering devices was calculated. The Z-forces and FSA are the subcomponents utilized to determine the seal pressure. Pressure is the distribution of force over a given area, and the force used in this determination is the force normal to the surface area that was calculated as $P=\frac{F_n}{A}$ and reported in Pascal units (Newtons/m^2). The donning lengths of the tethering devices of the N95 FFR were used to calculate the Z-forces (forces exerted front-to-back on the subject's face), as previously described.[2] The direction of the force contained vertical (up and down), horizontal (front-to-back), and side-to-side (left or right) components. The decision was made to use only the horizontal component of the force for several reasons. It is by far the largest component of the overall force generated by the tethering devices, the vertical component would be tangent to the face surface at almost every point (except possibly the underside of the chin), eliminating it from the pressure calculation, and any side-to-side component contributed on average less than 10% of the total force and was therefore considered negligible. The strap length data were unavailable for one subject (Table I).

Statistical analysis was carried out with a one-way analysis of variance to determine differences in the study variables of the FFRs from each of the six respirator models that passed fit testing, followed by Tukey's post-hoc test for a significant F-value. The proportional relationship of seal pressure above or below 1000 Pa with achievement of a fit factor of 200 was evaluated with a Z-test for proportions of dependent groups. A statistical significance was accepted when $p < 0.05$ and analyses were performed using a statistical software package (SPSS v19.0; IBM, Somers, N.Y.)

RESULTS

There were significant differences in the Z-component ($F = 39.565$; $p < 0.001$), FSA ($F = 7.336$; $p < 0.001$) and seal pressure ($F = 32.692$; $p < 0.001$) between the six models of N95 FFRs. Two models (E, F) were significantly different from two other models (B, D) for FSA ($p < 0.01$) and from four models (A, B, C, D) for Z-component ($p < 0.01$) and seal pressure ($p < 0.01$) (Table I). A total of 78/120 (65%) fit tests achieved a passing score and there were no significant differences in geometric mean fit factors achieved by the FFRs of the six models that passed fit testing ($p < 0.126$), but more subjects passed fit testing with models E and F than with models A, B, C and D (Table I, Figure 4). There was no significant difference in the proportion of FFRs achieving a fit factor of 200 with seal pressures above or below 1000 Pa (Table I).

DISCUSSION

Recent studies investigating the FFR/contact surface have used non-human modeling techniques.[3,5,8,17] SPG enables the real-time study of human subjects wearing FFRs and can serve to validate non-human modeling studies. The SPG data from the current study indicate that the only significant differences in FSA ($p < 0.01$) were, understandably, between the regular size models (A, C, E, F) and the small size models (B, D) owing to the lesser dimensions of the latter (Table I). It is interesting to note that, despite the fact that the cup-shaped N95 FFRs (Models A, B, C, D) are more rigid than the flat fold models (E, F)—because they incorporate a mesh plastic support skeleton (non-filtering) over the entire outer surface and between the inner and middle filter layers [2]—there was no significant difference in FSA between the standard size models of these two styles. This is likely due, at least partially, to the significantly greater seal pressures ($p < 0.01$) generated by the tethering devices of Models A, B, C, and D compared with Models E and F (Table I) that overcome some of the rigidity to allow for more FFR surface contact. The tethering devices of the six models consist of single upper and lower non-latex (polyisoprene) elastomeric bands,[10] but Models A, B, C, and D bands are of greater length, thickness, and cross-sectional area and have previously been shown to generate greater forces than the E and F devices.[2] The Z-component, a summation of the horizontal (front-to-back) forces over the entire FSA, was significantly less for Models E and F than for the other models ($p < 0.01$) and is attributable to the lesser forces generated by their tethering devices.

There were no significant differences in fit factors between the different N95 FFR models and no association with seal pressure noted, but the maximum reportable fit factor of 200 with the fit tester configurations used in the study results in skewing of the fit factor data (Table I). Fit factors are not dependent solely on FSA and seal pressures but are impacted by many other features including, but not limited to, facial anthropometry, skin texture, respirator features (e.g., presence of inner flanges, pliable nose bars), and so on. However, more subjects were able to pass fit testing with the two flat fold models than the cup-shaped models, despite lower associated seal pressures for the former. Although there was no significant difference in the proportion of FFRs that attained a fit factor of 200 above or below a seal pressure of 1000 Pa, absolute greater numbers of FFRs achieving a fit factor of 200 were noted above a seal pressure of 1000 Pa (Table I). Therefore, no conclusions of "better fit" can be made beyond acknowledging higher actual attained fit factors for some fit tests of N95 FFR models tested.

A larger study using multiple styles of FFRs would be needed to determine if higher seal pressures are associated with greater fit factors in significant numbers. More subjects passed fit testing with the small size models (B, D) than the same manufacturer's medium/large models (A, C) despite no significant difference in seal pressures (Table I), highlighting the importance of facial anthropometry in respirator fit.[(18)] One prior investigation found that respirator design (4 flat fold vs. 14 cup –shaped N95 FFRs) was not a significant factor in respirator fit,[(18)] whereas another study noted one model of a flat fold respirator was associated with both the highest fit factor pass rate and level of comfort when compared to other N95 FFRs.[(19)]

Facial pressure from N95 FFRs is a common complaint among users that limits their wear over extended periods,[(7)] so if lower pressures equate with equal protection but greater comfort, users may be more inclined to wear N95 FFRs and this could conceivably translate to improved compliance. In addition, it has been reported that flat fold N95 FFRs can be less expensive to manufacture because they do not require molding or multiple manufacturing steps of a cup-shaped respirator, and that they are favored by some wearers because of their portability (e.g., fit easily into a shirt pocket).[(20)]

LIMITATIONS

Limitations of the current study include the low number of subjects who were able to pass fit tests on Models A and C ($n = 5$ for each). We did not evaluate N95 FFRs that failed fit testing and that might have offered information on differences in FSA and seal pressure that correlated with successful passage of a fit test. Only two styles of N95 FFR (flat fold, cup-shaped) from two manufacturers were studied, so that we cannot comment on other styles (e.g., pleated, duck bill) or similar styles from other manufacturers. For the purposes of this study, the reported Z-component forces are presented as a mean for the entire FSA of the N95 FFR when, in fact, the Z-forces may be unequally distributed in different areas of the FSA as has been previously demonstrated by computer modeling.[(17)]

The measurements reported in this study are mean values representing the entire FSA and do not describe the varying FSA widths that occur in real-time due to such issues as differing facial anthropometry and the impact of continually occurring facial movements (e.g., respirations, head turning). Similarly, the reported seal pressures are mean values that likely are not evenly distributed along the N95 FFR periphery. The fit tester used in the current study was configured to report a maximum fit factor of 200, irrespective of whether higher fit factors are achieved, so that it is possible that if actual attained fit factors were reported there might have been significant differences between N95 FFR models, but this is speculative. We did not take into account the contribution of other FFR components (e.g., pliable nose bars) to pressure, but the majority of the pressure occurs via the contribution of the tethering devices.[3] Facial comfort was not subjectively assessed during the study, so that we cannot determine if differences in FSA and seal pressure affected subjective perceptions of comfort. Future studies should evaluate any possible such relationship because if N95 FFRs with the lowest pressures are still capable of passing fit tests, they may also correlate with greater facial comfort and, by extension, improved compliance with use.

CONCLUSION

This study has demonstrated the utility of SPG in the determination of N95 FFR FSA and seal pressures, properties that impact comfort and fit. For the models tested, flat fold N95 FFR with lower seal pressures were able to pass fit testing in greater numbers than molded cup-shaped N95 FFR with similar FSA. Inasmuch as N95 FFR comfort is related to compliance, and facial pressure is one complaint that is frequently voiced by N95 FFR wearers,[7] the ability to determine the minimum FSA contact pressure to achieve an adequate FFR/face seal offers the prospect of equivalent protection at the highest comfort level.[8] Further studies using SPG will be required to more fully elucidate its role in evaluating respiratory protective equipment and to validate the current study's findings. SPG is a technology that is rapid, non-invasive, and relatively easy to perform that may assist in elucidating the role of FSA in optimizing N95 FFR fit.

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FIGURE 1.
N95 filtering facepiece respirator with 1-cm gradations marked on the tethering devices for use in determining stress and strain for pressure calculations.

FIGURE 2.
Stereophotogrammetry unit.

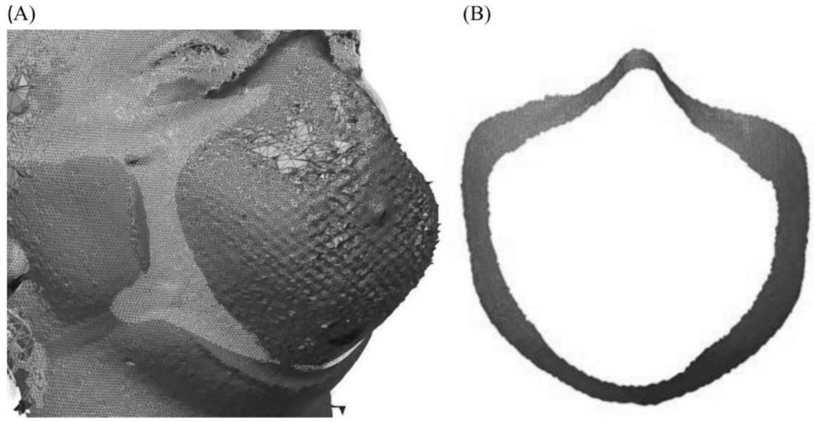

FIGURE 3.

(A) Two overlaping 3D stereophotogrammetry images of a subject with and without wearing a molded, cup-shaped N95 filtering facepiece respirator demonstrating the increased texture at the respirator's sealing surface area that represents the overlay of skin and respirator frameworks, and (B) isolated portion of a molded, cup-shaped N95 filtering facepiece respirator that represents the face seal area.

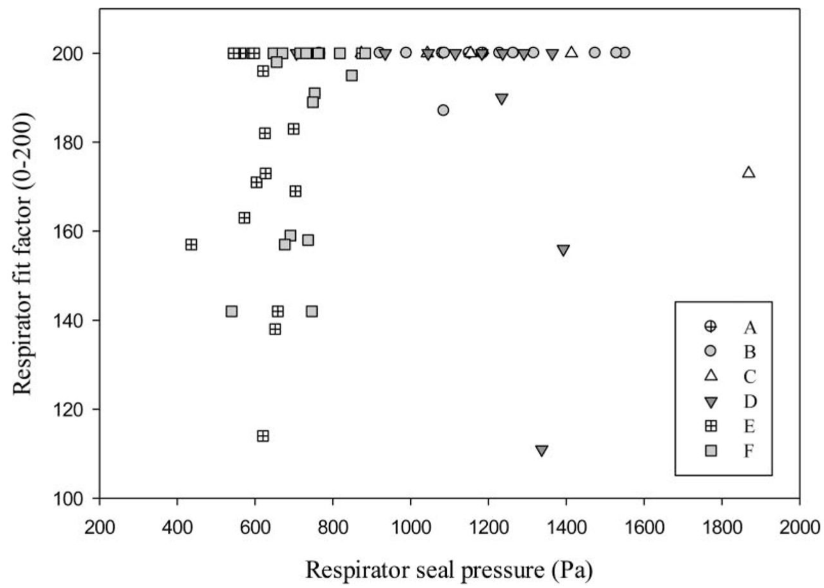

FIGURE 4.
Relationship of fit factors to seal pressure of six models of N95 filtering facepiece respirators.

TABLE I

Mean Values and Standard Deviations for N95 Filtering Facepiece Respirator Study Variables

Variables	N95 Filtering Facepiece Respirator Models					
	Model A	Model B[A]	Model C[B]	Model D[A,B]	Model E	Model F[B]
Fit Factor[C]	200 ± 0.0	198.8 ± 3.9	194.6 ± 12.1	187.0 ± 28.5	178.3 ± 25.9	185.1 ± 22.0
(0–200)	(n = 5)	(n = 15)	(n = 5)	(n = 13)	(n = 20)	(n = 20)
Seal Pressure[D]	1073.9 ± 177.4	1246.7 ± 212.9	1270.4 ± 387.9	1167.2 ± 206.6	630.2 ± 90.8[E]	728.9 ± 78.7[E]
(Pa/cm^2)	(n = 5)	(n = 14)	(n = 5)	(n = 13)	(n = 19)	(n = 18)
Z-Component	7.71 ± 0.94	7.19 ± 1.24	8.05 ± 0.84	6.90 ± 1.09	4.46 ± 0.40[E]	4.97 ± 0.46[E]
(N)	(n = 5)	(n = 14)	(n = 5)	(n = 13)	(n = 20)	(n = 19)
Face Seal	72.9 ± 6.5[E]	59.5 ± 7.6	67.8 ± 16.2[E]	60.1 ± 6.9	71.6 ± 6.4[F]	68.3 ± 4.4[F]
Area (cm^2)	(n = 5)	(n = 15)	(n = 5)	(n = 13)	(n = 20)	(n = 20)

[A] Small size.

[B] Exhalation valve equipped.

[C] Maximum achievable study fit factor = 200 (parentheses indicate subjects who passed fit testing).

[D] Z-component and FSA are utilized to determine seal pressure.

[E] Significantly different from Models A, B, C, D ($p < 0.01$).

[F] Significantly different from Models B, D ($p < 0.01$).