

Frame to Improve the Fit of N95 Filtering Face Mask Respirators

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Objective: Test a device that can improve upon the seal of filtering face mask respirators (FFRs). **Methods:** A 3-D prototype for a fit improvement frame (FIF) was created and quantitative fit testing was performed for FFRs with and without the FIF. **Results:** Thirty eight volunteers underwent fit testing. The overall fit pass rate was 100% for the 3M model 1860 masks, 50% for the 3M model 8511 masks, 13% for the BYD CARE model DE2322, and 7% for the Honeywell DC300N95. When using the FIF the overall passing rate increase to 87% for the DE2322 + FIF ($P < 0.01$) and for the DC300N95 + FIF the passing rate increase to 73% ($P < 0.01$). **Conclusion:** The FIF is effective in improving the mask fit of a common flat fold N95 masks and potentially other N95 masks.

Keywords: filtering face mask respirators, frame, N95, personal protective equipment, quantitative fit testing

The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that caused the coronavirus disease 2019 (COVID-19) pandemic has significantly increased the risks associated with providing patient care. Common transmission routes of the novel coronavirus include direct transmission via droplet or airborne mode inhalation and indirect transmission through contact with oral, nasal, or eye mucus membranes.¹ Frontline healthcare workers (HCW) and first responders are particularly vulnerable to infection by the novel coronavirus, with 4% to 29% of worker cohorts reporting positive COVID-19 tests.^{2–11} Frontline HCWs have an increased risk (hazard ratio 3.4) of testing positive for COVID-19 compared with the general population, even after adjusting for increased testing eligibility among these workers.⁵

Unsurprisingly personal protective equipment (PPE) plays a critical role in preventing transmission of SARS-CoV-2. Consequently, there has been an unprecedented demand for PPE, particularly N95 filtering face mask respirators (N95, FFR), and severe shortages have been reported at healthcare facilities nationwide throughout the pandemic. Due to the drastic need for N95 masks in these circumstances, strategies for prolonging the usability of these

masks became tantamount to safety at healthcare institutions. State governments nationwide urgently needed to aid in securing new supplies of N95 masks, and quickly signed contracts with providers of N95 or equivalent masks.^{12,13} Due to the rush to procure N95s, there have been concerns regarding deficient quality and unverified certification processes for some respirators being introduced to US healthcare facilities.¹⁴

In the United States, N95 respirators must meet standards described in US 42 CFR part 84 and are regulated by the National Institute of Occupational Safety and Health (NIOSH) and the Food and Drug Administration (FDA). Analogous standards can be found in other countries, with the KN95 mask conforming to GB2626–2006 in China and the FFP2 mask following EN149:2001 across Europe. The NIOSH standard testing procedure (STP-0059) for certifying N95s only investigates the filtration efficiency of the filter material and does not include any testing for facial fit, seal, or leak (NIOSH STP-0059). Instead, NIOSH provides standardized headforms to guide the design of mask contours that are based on anthropomorphic measurements of a panel of civilian workers.¹⁵ Other countries have similar headforms made from representative cohorts of civilian workers.^{15,16}

The goal of this study is to develop a device that can improve upon the seal of FFRs, particularly the N95 flat fold mask. In California, millions of BYD CARE DE2322 N95s are being distributed to hospitals and first responders to supplement the depleted N95 standard equipment. The flat fold masks have garnered reports of poor fit, especially when compared with stalwarts such as the 3M FFR line and the “duckbill” N95 (Kimberly, Halyard).¹⁴ The ideal fit improvement frame (FIF) should be easily replicated, manufactured from readily available materials, and rapidly scalable for distribution to address the acute need for better fitting FFRs.

METHODS

Novel Mask Frame Design and Fabrication

Cai et al¹⁷ outlined a method of producing custom face seal devices using 3D scans of individual user’s facial features, however this process requires significant time and costs to execute. The authors of this study set out to determine a face seal device design that could be relatively universal in providing proper face seal to a large population, specifically for use with a respirator that had been identified as nearly consistent with failing quantitative fit tests (TSI PortaCount 8048).¹⁸ The NIOSH headforms created by (Zhuang et al,¹⁹) have been a staple in previous studies for respirator face fit and face fit testing, which is why they were selected for our purposes.

The shape of the FIF created for this study was constructed to mimic the surface contact area of existing regulation conforming respirators. Using the Centers for Disease Control and Prevention/NIOSH index of approved N95 FFRs, an assortment of compliant FFR shapes were referenced to establish the initial design.²⁰ The resulting FIF design reflects the results found by Lei et al²⁰ on the evaluation of contact area for six filtering facepiece respirators (FFRs) against the NIOSH headforms and computed average contact areas of the headforms and FFRs. Niezgoda et al²¹ used stereophotogrammetry to determine the face seal area (FSA) by overlaying scans of users with and without donned FFRs, and their findings also informed the FIF design.

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Clinical Significance: Some filtering face mask respirators widely available during the COVID pandemic have poor quantitative fit test results. However, when an additional frame was placed over the poorly fitting respirators, the fit improved and was comparable to the better fitting designs. These frames are easy to 3D print.

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Beginning with the NIOSH large 3D headform, our initial FIF design was created on a 2D plane using a B-spline for the inner profile, relative to the headform not using any explicit geometric relations. The spline positioning and shape was adjusted to mimic the coverage of existing FFRs. A copy of the profile was then projected 4 mm radially outward in the same plane to create the outer profile. These two B-splines were joined with vertical lines at either end to create a closed contour. The contour was projected from the 2D plane onto the 3D surface of the Large NIOSH Headform from the Principal Component Analysis Study,²² creating a set of non-uniform rational B-splines (NURBS). These NURBS were used to generate a surface from the NIOSH headform, which became the basis of the 3D frame. Four basic hooks were created to serve as attachment points; their placement was selected again referencing existing respirator designs.

Physical prototypes of the FIF devices were created using the FormLabs Form 3B printer with Grey v4 resin at a 100 μm layer height, following manufacturer recommended cleaning and curing procedures. The prototypes were used for quantitative face fit testing protocol found in 29 CFR 1910.134 with a known failing FFR. After the preliminary testing results (11 passing where previously failed, $N=13$), the 2D spline was converted into a Bézier curve using a minimal number (six) of spline control points, as shown in Fig. 1. Using a Bézier curve should allow for easier parametric control of the design and could be used in developing a more rigorous method in determining the geometry and dimensions of the 2D splines based on facial landmarks. The parametric design allows for mathematically driven 3D models in the case of multiple headform versions/sizes.

Mask Selection

Four different types of N95 FFRs were chosen for testing: the 3M 1860 and 8511 masks, the BYD CARE DE2322 mask, and the Honeywell DC300N95 (Fig. 2). The 3M 1860 comes in two sizes, small and regular, and is a dome shaped respirator. Only the Regular was utilized in this study based on a participant's prior qualitative

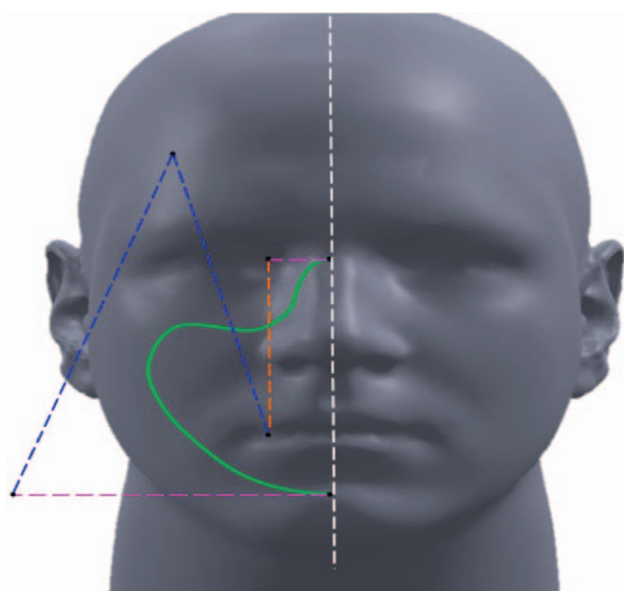


FIGURE 1. Overlay of Bézier curve with six control points on Large NIOSH headform, which create the spline profile for the face fit device. The white line is the axis of symmetry used, the pink lines are horizontal, the orange line is vertical, and the blue lines are at arbitrary angles that produce the initial design shape.

mask fit testing result to optimize quantitative fit testing results. The BYD DE2322 is a single size, sagittal axis flat fold mask that was NIOSH approved on June 9, 2020. The flat fold design is significantly different from the dome design in terms of shape and likely fit. The Honeywell DC300N95 is a NIOSH approved cup style N95 and has been on the market for years for non-healthcare use. Due to increased demand, production was increased and this mask is widely distributed in the southern California region.

Quantitative Fit Testing Protocol

Volunteers underwent the Occupational Safety and Health Administration quantitative fit testing protocol using the ambient particle counting method on a Portacount (TSI Incorporated, Shoreview, MN). The mask being tested was fitted with a testing port using the metal probe and hole punch/setting tool provided by TSI. Plastic tubing was used to create an airtight seal with the adaptor and was connected to the Portacount respiratory fit tester. The Portacount compares the concentration of aerosolized particles sized 0.4 to 0.7 μm in the ambient air and within the mask space to generate a fit factor. The fit factor is a ratio of the concentration of particles in the ambient air to the concentration in the mask space. Each participant had this score measured under various conditions, including normal breathing, deep breathing, head turning side to side, head nodding up and down, talking, bending over, and normal breathing again (normal breathing 2).²² The Portacount Fit Protocol is compliant with the Ambient Aerosol Condensation Nuclei Counter (CNC) Quantitative Fit Test (QNFT) Protocols in 29 CFR 1910.14, Appendix A.²³

Statistical Analysis

Fit factor score was recorded for each quantitative fit test and were grouped together by mask or mask plus accessory. A fit factor score of 100 is considered passing per TSI Portacount documentation. Significant differences in mean score were determined by *t* test. Significant differences in passing frequency were calculated by Fisher exact test. Analyses were performed using R 3.6.3 for Windows.

RESULTS

A total of 38 volunteers consisting of attending physicians, respiratory therapists, medical assistants, clinic staff, and faculty were enrolled in this study. Twenty (51.3%) of participants were women.

Of the 38 volunteers, 8 were quantitatively fit tested with 3M model 1860 masks, 8 were tested with 3M 8511 a valved emergency authorized mask, 15 with BYD CARE model DE2322 with and without the FIF, and finally 15 with the Honeywell DC300N95 with and without the FIF. A score of 100 is passing out of a total possible 200. The mean overall fit factor score for the 1860 mask was 161.38, with no test exercise scoring below the passing threshold on average (Fig. 3). The 8511 had an overall fit factor score mean of 101.25, exercises recorded scores above and below the passing threshold on average (Fig. 3). The DE2322 had a mean overall score of 39.07, with each test exercise scoring below the passing threshold on average (Fig. 3). The DC300N95 had an overall fit factor score of 24.73, with each test exercise also scoring below the passing threshold on average (Fig. 3). However, when the DE2322 was fit tested with the FIF, the mean overall score increased to 167.87 and each exercise also increased above the passing threshold ($P < 0.01$ overall and across all exercises). For the Honeywell DC300N95 being tested with the FIF the mean overall score increased to 150.53 and each exercise also increased above the passing threshold ($P < 0.01$ overall and across all exercises). These improvements in mean fit factor score were statistically significant and gave both the DC300N95 + FIF and DE2322 + FIF a similar fit result compared with the 1860 mask with mean and overall passing scores above the emergency use 3M 8511 (Fig. 2).



FIGURE 2. One of the authors wearing the DE2322 39.07 without (A and B) and with (E and F) the fit improving frame (FIF) and the DC300N95 without (C and D) and with (G and H) the FIF.

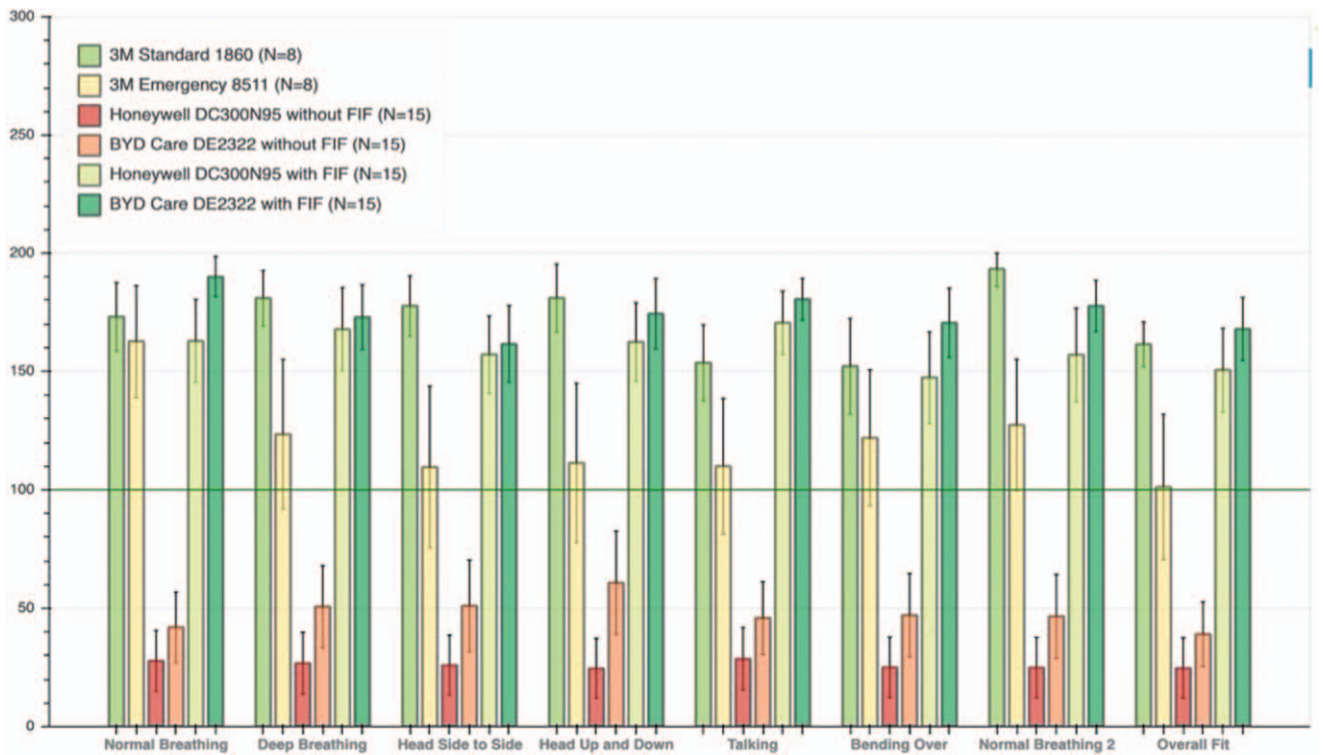


FIGURE 3. Fit factor score by quantitative fit testing by mask model.

TABLE 1. Pass Rate by Mask and Fit Testing Exercise

| | Overall | Normal Breathing | Deep Breathing | Head Side to Side | Head Up and Down | Talking | Bending Over | Normal Breathing 2 |
|-------------------------|---------|------------------|----------------|-------------------|------------------|---------|--------------|--------------------|
| 1860 (n = 8) | 100% | 100% | 100% | 100% | 87.5% | 87.5% | 87.5% | 100% |
| 8511 (n = 8) | 50% | 87.5% | 62.5% | 50% | 50% | 50% | 62.5% | 62.5% |
| DE2322 (n = 15) | 13% | 13% | 13% | 20% | 27% | 20% | 13% | 20% |
| DE2322 + FIF (n = 15) | 87% | 93% | 87% | 73% | 87% | 100% | 80% | 87% |
| DC300N95 (n = 15) | 7% | 7% | 7% | 7% | 7% | 7% | 7% | 7% |
| DC300N95 + FIF (n = 15) | 73% | 73% | 80% | 73% | 73% | 87% | 67% | 73% |

FIF, fit improving frame.

The pass rates for the mask types revealed a similar trend (Table 1). The overall fit pass rate was 100% for the 1860 mask, 50% for the 8511, 13% for the DE2322, and 7% for the DC300N95. When using the FIF, the overall passing rate increase to 87% for the DE2322 + FIF ($P=0.002$) and for the DC300N95 + FIF the passing rate increase to 73%. The increase in overall passing rate for the DE2322 and for the DC300N95 when used with the frame accessory were statistically significant ($P < 0.01$).

Concurrent use of the FIF also significantly increased the pass rate of the DE2322 and the DC300N95 for all test exercises (for all comparisons, $P < 0.01$). However, the 1860 demonstrated a higher pass rate than the DE2322 + FIF and the DC300N95 among all exercises except talking.

DISCUSSION

The basic principles of FFR design include the efficient filtration of small particles, adequate air flow with respirations, and a snug fit to the face of a user to prevent the passage of air around the filtration material on breathing.²⁴ The large differences in facial and nasal size and shape clearly has made designing a universally fit mask difficult, with varying brands of N95s more suited to particular face shapes.²⁵ As a result, healthcare facilities generally stock multiple FFR types when performing fit testing to accommodate differences in fit. However due to the pandemic, reserves of conventional N95s have been depleted and many facilities and first responder departments are limited to emergency use approved folding style N95s such as the BYD CARE N95 mask being used in California. However, the BYD CARE flat fold mask passed the QNFT for only 13% of participants in our cohort of civilian hospital workers.

Occupational Safety and Health Administration allows for two methods of fit testing, the qualitative (QLFT) and quantitative fit test (QNFT). The vast majority of fit testing performed in the United State is qualitative testing due to the simplicity and the low cost. Historically, qualitative testing was considered equivalent to a score of at least 100 on the quantitative test and this was the threshold for indicating adequate fit. However, two studies have demonstrated that QNFT is superior to QLFT.^{26,27} Up to 12% of respirators which passed the QLFT had failed the QNFT, corresponding to a sensitivity and specificity of QLFT to correctly identify a leak of 53% and 99%, respectively.²⁷⁻²⁹ QLFT is typically performed using an aerosolized aromatic or gustatory molecule that is filtered by the N95 mask. Since QNFT compares particulate concentrations, it is an objective measurement and it therefore bypasses the subjective nature of taste or smell. Additionally, quantitative testing does not require preparation of a nebulized chemical and testing for user sensitivity, so it may be performed more rapidly than QLFT. Since the introduction of the first Porta-count tester in the 1980s, the testing units have dramatically decreased in price.³⁰ Given the improvements in speed and cost,

QNFT has increasing cost effectiveness considering its greater accuracy in detecting leaks. It is also worth mentioning that the loss of taste and/or smell are common symptoms of the SARS-CoV-2 infection.

Using the quantitative method, we demonstrate that the sagittal axis flat fold N95 and another common cup style N95 approved for use due to COVID does not fit well on a wide range of volunteer faces. In comparison, the 3M 1860 masks maintains an adequate seal throughout the testing protocol in 100% of participants. The 8511 valve mask had an adequate seal in 50% of participants. However, when used in conjunction with FIF, the fit factor scores of the flat fold N95 and the cup style DC300N95 improved significantly with a corresponding increase in the fit test pass rate. While the mask frame did not produce a passing score for all participants, this finding is consistent with the fact that there are large variations in facial and nasal shape. Nevertheless, concurrent use of the FIF resulted in an increase in pass rate to 87% for the sagittal flat fold and 73% for the cup design. We anticipate that a limited series of such devices in different sizes will be sufficient to cover the wide range of facial geometry present in the United States.

Another advantage of this device is that production of it can be scaled up rapidly. By using a standard frame shape and minimal requirements for the construction material, these devices can be mass produced immediately with a consumer grade 3-D printer or commercially manufactured. Since these devices are not custom molded to an individual’s face, they are easily replaceable if lost or discarded. Given that these devices are likely to be exposed to SARS-CoV-2, having the option to dispose of the device when doffing PPE can be useful. However, they can also be cleaned and reused depending on the resin used for printing. While universities such as Stanford have created personalized respirators and a smartphone application exists for a personalized frame for a respirator, these projects are difficult to scale to rapid deployment due to problems with scanning an entire workforce and with providing replacement personalized respirators or frames if lost, broken, or soiled.^{31,32}

There are several limitations to this study mostly involving the small sample size of both participants and mask models. These limitations are due to the continued shortage of FFRs within our healthcare facilities the inability to use more than a small number of masks for non-patient care related activities. The results would be more generalizable to the greater population of healthcare workers and first responders if enough masks were available for a greater number of volunteers to be fit tested. Additionally, it would allow us to develop and test different sized FIF devices. Ultimately, the FIF is a prototype and with more data we would be able to fine tune the shape of the frame to improve its fit on a greater range of facial shapes. We hope to do this soon as more masks become available for research studies. It is not possible based on the current data to determine user comfort after prolonged use, which will be critical

for the products uptake. We have not tested whether the frame continues to improve fit if a single use mask is used for multiple days or if the frame itself is used for multiple days after cleaning. Also, currently there is no formal regulatory pathway for approval of a frame which improves the fit of NIOSH regulated respirators.

CONCLUSION

The 3-D printed mask fit improvement frame is effective in improving the mask fit of common sagittal flat fold N95 masks and there is a signal that other shapes may benefit as well. The features of a single design and unibody construction are beneficial for mass production to meet the current demand for well-fitting FFRs. Fabrication of an additional, smaller sized frame can potentially broaden the range of face types that will achieve passing scores with the flat fold N95 on quantitative fit testing. In this study, the gold standard quantitative fit testing was used to test FFRs with relative speed and ease. Given the virulence and severity of COVID-19 infections, quantitative fit testing should be utilized more than qualitative fit testing for high-risk individuals including HCWs and first responders.

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