Novel Faceseal Technology Improves Outcomes of N95 Respirator Quantitative Fit Testing for Hard-to-Fit Individuals

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ABSTRACT

Background: The COVID-19 pandemic has highlighted the importance of respiratory protection for healthcare workers (HCWs) and patients alike. Presently, respiratory protective devices are worn in hospitals and healthcare settings globally. HCWs are generally required to wear N95 filtering facepieces respirators (FFRs) in high-risk settings and during certain high-risk procedures. According to OSHA, HCWs who are assigned NIOSH-approved N95 FFRs must be fit tested using either qualitative or quantitative testing protocols (QLFT and QNFT, respectively). However, HCWs often fail the initial fit test on the first N95 model chosen. A novel Faceseal technology was recently developed and successfully applied to commercial N95 FFRs. In this pilot study, we assessed how this technology affects the QNFT outcomes for subjects who had failed their initial N95 fit test.

Methods: Ten subjects who failed the QNFT with N95 FFRs on the first fitting were recruited to perform a QNFT study in which each subject was tested in triplicate on the same N95 model and with that same model modified with the novel Faceseal of a unique configuration, which is made of a thermoplastic copolymer, enhancing the respirator fit to the user's face. The fit factors (FFs) and passing rates were determined, and the results were compared.

Results: The Faceseal technology increased the overall FF for the entire cohort from 59.8±18.3 to 163.2±27.3 (threshold=100) and the test passing rate from 10% to 90%. This improvement was achieved for the hard-to-fit subjects due to reduction of the faceseal leakage, as the filter and respirator body were left unchanged.

Conclusions: The novel Faceseal technology significantly improved the QNFT outcomes for individuals who had previously failed OSHA fit testing on the same N95 FFR.

Keywords: N95 filtering facepiece, faceseal, fit test

INTRODUCTION

Respiratory protection has always been recognized as one of the main infection control strategies against viral and bacterial aerosol pathogens. The COVID-19 pandemic has greatly elevated the public's awareness and appreciation of adequate respiratory protection for HCWs, patients, and for society at large. It is now a requirement to wear respiratory protective devices in any hospital or healthcare setting. Subject to availability, HCWs often use N95 filtering facepieces (FFRs) approved by the US National Institute for Occupational Safety and Health (NIOSH). The US Occupational Safety and Health Administration (OSHA) mandates that all employees wearing respirators be subjected to OSHA's fit testing (OSHA 29 CFR. 1910.134). The HCWs who are assigned N95 respirators must be tested annually using a qualitative fit testing (QLFT) or the quantitative fit testing (QNFT) method. However, HCWs frequently fail the test on the first donning. Reports reveal that anywhere from 12.5% to about 100% of individuals fail the fit test on the first choice of N95 FFR while some experienced wearers showed relatively high fit factors (FFs) (Coffey et al., 2004; Lee et al., 2004; Derrick et al., 2005; Lee et al., 2008; Danyluk et al., 2011; Wong and Lee, 2011; Hauge et al., 2012; Kim et al., 2016; Zhuang et al., 2016).

Passing the QNFT, which for N95 FFRs requires achieving or exceeding FF=100, has been a particular challenge, which necessitates re-testing and thus prolongs the fit testing process. This delay may significantly disrupt the deployment of medical, nursing, and allied health staff into healthcare units engaging in direct care of the most seriously ill patients. It also creates yet another logistic hurdle for healthcare institutions, as they must acquire an additional stockpiling of alternative N95 FFRs for further fit testing. Otherwise, wearers would not be able to select from several models of FFR to find the one that fits them best. The negative effect associated with these issues has been amplified by the enormous shortages of N95 FFRs across the nation, and globally during the COVID pandemic.

In order to reduce the particle penetration through faceseal inward leakage, and thus enhance the protection offered by commercially available N95 FFRs, we developed a new concept (Koehler et al., 2015) based on facial anatomic zones which we identified in human facial anatomy that were associated with the leakage. These areas were accommodated by introducing a faceseal with a unique configuration, which is made of a thermoplastic copolymer, enhancing the respirator fit to the user's face. Figure 1 presents a Faceseal-equipped and unmodified N95 FFRs. The concept was further developed and improved, and the prototypes of respirators equipped with the novel Faceseal were evaluated (Gao et. Al., 2016; Elmashae et al., 2018). By adding the newly-designed Faceseal, applied to a leading manufacturer's N95 FFR (Model 1860, 3M Co., St. Paul, MN, marketed as Surgical N95 Respirator) without changing any other aspect of the FFR itself, a superior protection was achieved as compared to the stock version of the same N95 FFR. For instance, an approximately 5-fold increase in the average Simulated Workplace Protection Factor (SWPF) against surgical smoke was demonstrated (Elmashae et al., 2018). We noticed that several subjects who had failed the initial QNFT with the unmodified FFR (serving as the control), had then passed after applying the new Faceseal, and in some occasions achieved higher FF-values than subjects who had initially passed with the unmodified FFR.

This investigation was designed to directly quantify the effect of the Faceseal technology on the outcomes of the QNFT performed on ten subjects who failed a QNFT on the first fitting with conventional N95 FFRs. The recruited subjects were fit tested with the same FFR as well as with the version modified by applying the novel Faceseal (three donnings per subject, per respirator). The objective was to determine FF-values and passing rates with both devices for this hard-to-fit cohort. We also sought to examine whether the new Faceseal technology would allow achieving a higher percentage of successful fit tests on the first donning for the same subjects. We suggested that, if a significant improvement is found, it would signify that the Faceseal technology could help expedite fit testing of critically needed HCWs.

A.

B.

Figure 1. Faceseal **prototype: FFR assembly (A); Unmodified and Faceseal-equipped N95 FFRs side-by-side along with a ready-to-be-sealed ¼-inch thick thermoplastic copolymer element (B).**

MATERIALS AND METHODS

Human Subjects and Respirator Chosen for Testing

Ten human subjects representing healthcare workers were recruited for this study. The cohort included four adult males and six adult females; among them there were seven Caucasians, two Asians, and one African American. These were selected from a larger cohort, and the inclusion criterion was a failed QNFT on the first donning with three commercial N95 FFR of different designs. We selected the hard-to-fit population for this study to make a conservative case for examining whether the novel Faceseal technology significantly improves the FF and passing rates for the individuals who often fail an QNFT. The recruited ten subjects represented a broad variety of facial dimensions that fell within the ranges of the NIOSH bivariate panel (one of the fit test panels established to reflect the anthropometric head/face size characteristics of the US working population) (Zhuang et al., 2007). The subjects featured small, medium and large faces.

The human study protocol was approved by the University of Cincinnati Institutional Review Board (IRB). Prior to the testing, each subject completed the OSHA respirator medical clearance questionnaire administered by the University Occupational Pulmonary Program.

The Model 1860 Surgical N95 Respirator chosen for this study is widely used in healthcare settings. Half of the respirators acquired for testing were modified by sealing the novel Faceseal (a ¼-inch thick thermoplastic copolymer element) to the inner peripheral edge of the N95 FFR, without changing any other aspect of the device itself.

Fit Testing

The QNFT was conducted in accordance with the standard OSHA fit testing protocol (OSHA 29 CFR 1910.134) **[1]**, which includes eight exercises: normal breathing, deep breathing, turning head side to side, moving head up and down, talking, grimace, bending over, and – again – normal breathing. Sodium chloride (NaCl) particles were generated with a particle generator (Model 8026, TSI Inc., Shoreview, MN). The overall FF was measured and recorded for each subject on each donning by a PortaCount Respirator Fit Tester (Model 8048 TSI Inc., Shoreview, MN) operating with an N95 Companion™. A passing criterion of FF=100 was applied as specified by OSHA for filtering facepieces (OSHA 29 CFR. 1910.134).

Study Design

Each subject was fit tested in triplicate with each of the two N95 FFRs – unmodified and modified with the Faceseal. Thus, a total of 10x3x2=60 fit tests were conducted generating 60 FF-values. The PortaCount software does not display values in excess of 200. In these cases, FF= 201 was recorded which represents a conservative approach. For each subject and each respirator, an FF arithmetic average and a standard deviation were calculated. Further, an average value with a standard deviation was determined across the entire cohort, separately for each respirator. The pass/fail rates were also quantified. It was verified whether the Faceseal-equipped respirators were more likely to pass the fit test on the first donning for a given subject. Paired t-test was conducted to examine the difference between the FF-values averaged from three replicates per subject, which were obtained with the unmodified and modified devices. Additionally, a two-way ANOVA (FFR at 2 levels and Subject at 10 levels) with n = 3 repetitions per treatment combination was deployed as an alternative analysis. A p-value below 0.05 represented a significant difference.

RESULTS

For the unmodified N95 FFR, the single-donning FF-values ranged from 5 to 174 (with an average per subject ranging from 13.7±3.1 to 117.7±45.8). For the Faceseal-equipped respirator, the single-donning FFs ranged from 62 to 201 (with a subject-averaged values between 76.0±13.5 and 201.0±0.0). Only one subject wearing the Faceseal-equipped respirator showed an average FF below the pass/fail threshold of 100.

The overall FF across the entire cohort increased from 59.8±18.3 for the unmodified respirator to 163.2±27.3 for the Faceseal-equipped version. The data are presented in Figure 2. Regardless of the analytical method deployed (see Materials and Methods), the difference in FF between unmodified and Faceseal-equipped respirators was highly significant ($p<0.01$).

The passing rate increased from 10% (3 out of 30) to 90% (27 out of 30) due to the Faceseal. Furthermore, all three failures recorded for the Faceseal-equipped FFR occurred with the same subject. All remaining subjects passed the fit test on the first donning and demonstrated FF>100 in all three donnings per subject.

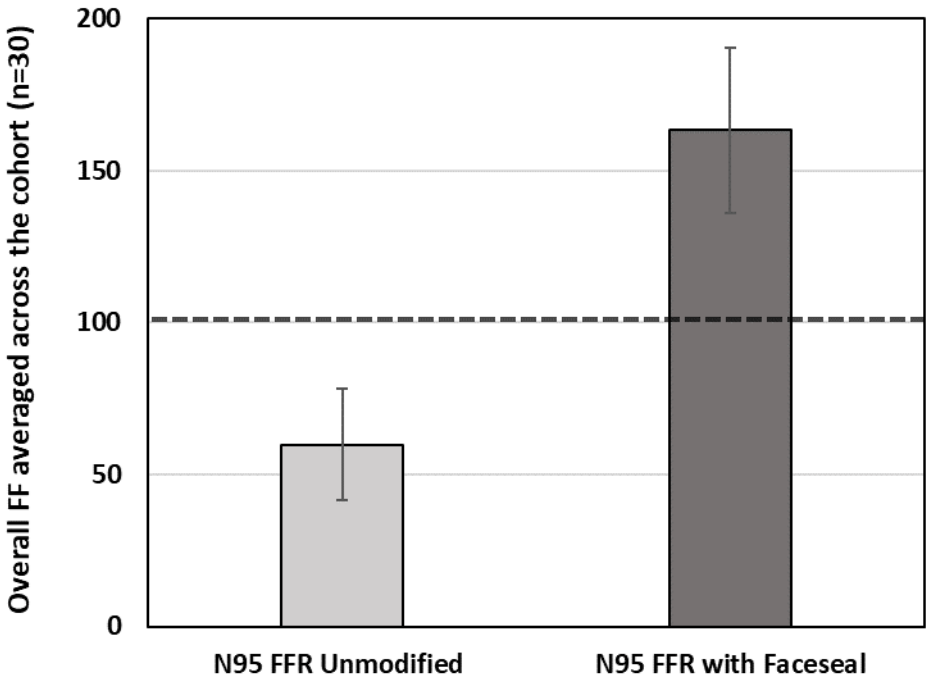

Figure 2. The overall fit factors averaged across the hard-to-fit cohort fit tested with 3M 1860 N95 FFRs – unmodified and modified with the Faceseal. The arithmetic average and standard deviation values are calculated from the data collected with ten test subjects in triplicate (n=30).

DISCUSSION

The above findings are attributed to the ability of the new technology to reduce the faceseal leakage and thus decrease the aerosol particle penetration into an FFR being fit tested. The findings are consistent with the results reported on the SWPF for different FFRs which utilized the Faceseal concept (Gao et al., 2016; Elmashae et al., 2018),

It is important to emphasize that the faceseal modification does not alter the filter or the structure of the FFR itself, and yet provides for the facepiece to achieve a 90% fit test passing rate for the hard-to-fit individuals who had previously failed on the stock version of the same FFR. We note that this was found for an N95 FFR which is not only commonly used in many US healthcare institutions, but also is one of the principal respirators in the Strategic National Stockpile (National Academy of Sciences, 2016).

It is acknowledged that the relatively small number of participants being tested, and the use of a single model of N95 FFR, are both limitations of this pilot study. While our findings on the improvement of the QNFT outcomes (FF-value and passing rate) obtained for this hard-to-fit cohort appears consistent and definitive, future studies should be performed with a larger subject pool and respirators representing various models and manufacturers. Additionally, we believe that it would be useful to conduct a similar study to examine whether, and how, the Faceseal technology improves the outcomes of the QLFT. Ultimately, one may consider seeking a NIOSH approval for the Faceseal technology as part of the respirator to be used in the workplace.

CONCLUSION

The study results showed that the novel Faceseal technology significantly improves the outcomes of a QNFT for N95 wearers who had previously failed an OSHA fit testing on the same FFR model. The findings demonstrate a major potential of this technology for implementation with various types of filtering facepieces.

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