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Original Article

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Assessing the Fit of N95 Filtering Facepiece Respirators Fitted with an Ear Loop Strap System: A Pilot Study

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Abstract

Throughout the COVID-19 pandemic, hundreds of millions of people worldwide have become new users of respiratory protective devices. Facemasks and KN95 respirators utilizing an ear loop straps system (ELSS) have recently become popular among occupational and non-occupational populations. Part of this popularity is due to the ease of wearability as compared with traditional devices utilizing two headbands, one worn over the head and the other behind the neck—a universal strap system used in NIOSH-certified N95 filtering facepiece respirators (FFRs). Some users convert the two-strap configuration to an adjustable ELSS. The first objective of this pilot study was to quantitatively characterize how such a conversion impacts the respirator fit. Additionally, a novel faceseal (NFS) technology, which has been previously demonstrated to enhance the fit of N95 FFRs, was deployed to modify the ELSS-converted N95 FFRs. The second objective of this study was to quantify the fit improvement that results from adding the NFS to the ELSS. The study was conducted by performing the Occupational Safety and Health Administration (OSHA)-approved quantitative fit testing (QNFT) on 16 human subjects featuring different facial shapes and dimensions. Three models of cup-shaped N95 FFRs were tested in three versions: the standard version with manufacturer's strap system, the ELSS-converted, and the ELSS-converted version modified by adding the NFS. QNFT demonstrated that the fit of an N95 FFR featuring the traditional/standard headbands strap system is negatively impacted when this system is converted to an ELSS. The fit of an ELSS-converted respirator can be significantly improved by the addition of the NFS. We found that the FFR model and the strap system version are significant factors affecting the QNFT-determined respirator fit factor (FF), as well as the OSHA QNFT pass rate (FF ≥100). The findings suggest that the current NFS, if further improved, has a potential for developing a 'universally fitting' ELSS-equipped N95 FFR that can be used by the general public, the vast majority of whom do not have access to OSHA fit requirements.

Keywords: ear loop; faceseal; fit test; N95 respirator

What's important about this paper

Increased use of facemarks and respirators during the COVID-19 pandemic led to the exploration of alternative designs by the public, including changing the two head straps into ear loop straps. This study found that the modification to ear loop straps decreases the fit of N95 filtering facepiece respirators, but that the addition of a novel faceseal technology can improve the fit factor of the modified respirators. Further development is needed, but the designs tested in this study suggest a path towards a 'universally fitting' device for public use.

Introduction

As a result of respiratory protection protocols adopted worldwide during the COVID-19 pandemic, hundreds of millions of people—many of whom had not used respiratory protection routinely—began wearing a wide variety of respiratory devices on a daily basis. Many of these were low-efficiency cloth masks or face coverings, while others, such as NIOSH-approved filtering facepiece respirators (FFRs) offered a significantly higher level of protection for a wearer (Grinshpun *et al.*, 2009; Reutman *et al.*, 2021; CDC, 2022). NIOSH-certified N95 FFRs were in severely short supply during the early phases of the pandemic, and as such it was advised that they be restricted to occupations in the highest risk categories, being primarily in healthcare. In a number of occupational settings, OSHA fit testing was required, and available, to employees.

In the January of 2022, the CDC updated their standards for respiratory protection for the general public, recommending the use of N95 FFRs as the highest level of protection against virus aerosol pathogens—including COVID-19 (CDC, 2022). Simultaneously, the US government dispensed 400 million N95 respirators to be available to the public, without charge, at pharmacies and community health centers. These latest efforts present challenges associated with differences in the public awareness and compliance. N95 FFRs require fit testing to ensure that the wearer has an expected level of protection. In the US, these tests follow OSHA's 29CFR1910.134 protocol.

However, it is unlikely that the general public—the vast majority of whom are not employed in an occupation requiring employer-provided respiratory protection—will have knowledge of an OSHA fit test, nor where to seek an OSHA fit testing facility. The general public may not fully understand how the individual choices of the models and sizes of respiratory protective devices relate to the face dimensions of a specific wearer. Most internet-based purchasing sites offer the 'regular' size first, with a smaller size offered only through further searching. On-site retail stores seldom offer anything but the 'regular' size, or 'Medium/Large' versions. Finally, a significant number of manufacturers offer only 'one size fits all' masks.

Another issue is ease of donning and doffing of the facemasks/respirators. Essentially, all NIOSH-approved FFRs marketed in the US are designed with two headbands, one worn over the head and the other behind the neck. In contrast, virtually all facemasks, and K95-style respirators, utilize an ear loop strap system (ELSS) to secure the mask to the user's face. However, headband-designed respirators present challenges for the wearers. As an example, female healthcare workers often find the traditional two-strap design problematic as the strap over their head can disrupt, or be disrupted by their hair configuration, which can then cause changes in the head strap's tension and thereby potentially in the respirator fit. It has been reported by the Centers for Disease Control and Prevention (CDC, 2021) that masks and respirators using an ELSS, e.g. KN95, are becoming popular among occupational and non-occupational populations because they are more comfortable to wear. Therefore, users sometimes convert the traditional two-strap headband design to an adjustable ELSS.

Recent studies looking at compliance with wearing facemasks/respirators, has substantiated that if given the choice, the public would still be more inclined to buy a cloth mask or K95 FFR with ELSS, rather than an N95 (Ritter and Brenan, 2020; The Economist, 2020; Morning Consult, 2022).

There is a lack of data regarding the effect of this conversion on the respirator fit. As the fit is conventionally quantified by performing the OSHA-approved quantitative fit testing (QNFT) on human subjects, the first objective of this pilot study was to quantitatively characterize how the ELSS configuration impacts the fit factor (FF) and the QNFT pass rate (FF ≥100) of an N95 respirator.

Additionally, the University of Cincinnatis bjects subjectsectsuantitative fit tefaceseal (NFS) technology developed and patented by one of the authors of this paper (RK). The application of this technology to N95 FFRs has been demonstrated to significantly increase

the FF of an N95 FFR (Koehler *et al.*, 2014; Grinshpun *et al.*, 2020). The NFS design is based upon critical zones in human facial anatomy where leakage has been shown to be most likely to occur (Oestenstad *et al.*, 1990; Roberge *et al.*, 2011; Lei *et al.*, 2013). The key element of this technology is an ethylene vinyl acetate (EVA) foam that is secured to the inner perimeter of the respirator, enhancing its fit to the user's face. In this effort, we applied the new faceseal to the ELSS-configured N95 FFRs and evaluated the modified respirators through the above-mentioned QNFT. Thus, the second objective of this study was to quantify how the respirator fit is affected by adding the faceseal to the ELSS-configured N95 FFRs.

Methods

Experimental design

This pilot study was conducted in a 24-m^3 aerosol exposure chamber. Sixteen human subjects were recruited and medically cleared for wearing N95 FFRs. Participants included students and staff members of the Department of Environmental and Public Health Sciences and other departments of the University of Cincinnati, as well as the local community members. The participants were contacted by email and in person. Each participant received a $60 gift card as an incentive. The cohort included seven adult males and nine adult females; among them there were nine Caucasians, three Asians, two African Americans, and two Hispanics. Prior to the testing, each subject completed the OSHA's respirator medical clearance questionnaire administered by the University of Cincinnati Occupational Pulmonary Program, and provided an informed consent approved by the Institutional Review Board (IRB), Study ID 2013-6014. The face dimensions, specifically the width and length, were initially collected from 30 subjects as a prescreening effort aiming at selecting the final study cohort with a broad variety of facial dimensions that fit the latest NIOSH-approved bivariate panel (Zhuang *et al.*, 2007; NIOSH, 2018). The face width and length were measured with spreading calipers (Fabrication Enterprises Inc., White Plains, NY, USA). Among the sixteen selected participants, two had facial dimensions outside the panel's 10-zone area, and the remaining participants had facial dimensions representing 7 of the 10 zones (no. 2, 3, 4, 5, 6, 7, and 9). The distribution of the 16 subjects in the NIOSH bivariate panel is shown in Fig. 1.

Three different models of N95 FFRs were tested: DC365 Surgical N95 Respirator (Honeywell International Inc., Charlotte, NC, USA), 9500-N95 Disposable Particulate Respirator (Makrite, Taipei, Taiwan), and 3M™ Health Care Particulate Respirator and Surgical Mask 1860 (3M Corp., Saint Paul, MN, USA). The photos are presented in Fig. 2. All tested respirators feature a cup-shaped style with 'Regular' size only. The tests were conducted with three versions of each N95 FFR model: the standard version with manufacturer's strap system (Standard), the

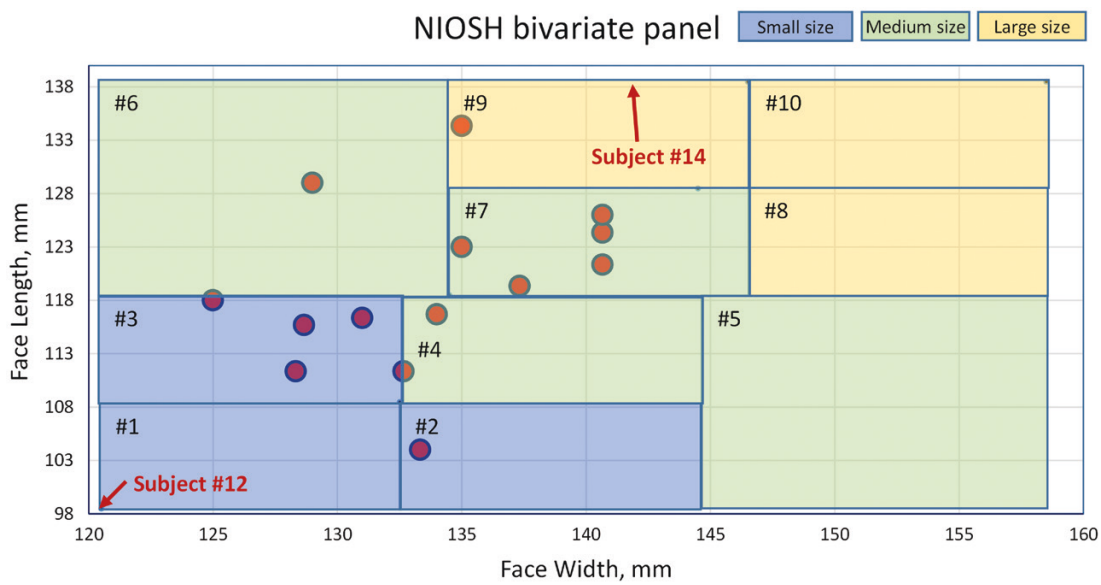

Figure 1. Face dimensions of the 16 study subjects shown in the NIOSH bivariate panel plot.

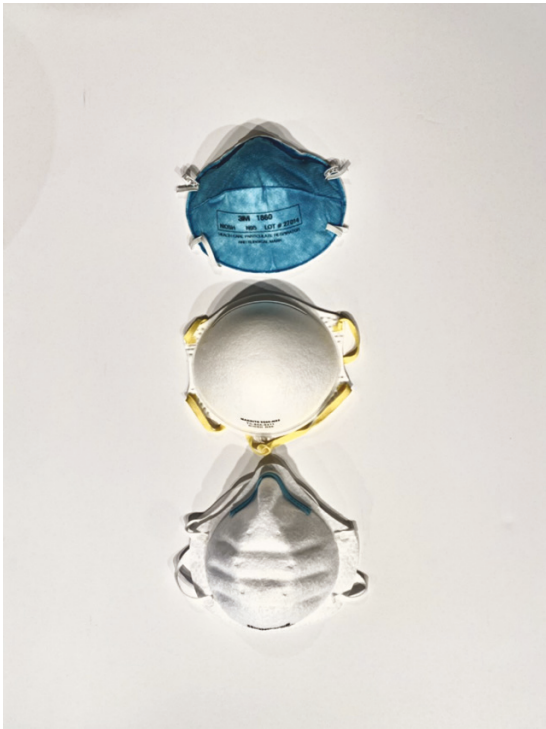

Figure 2. Three respirator models tested in the study. The top one is the 3M™ Health Care Particulate Respirator and Surgical Mask 1860; the middle one is the Makrite 9500-N95 Disposable Particulate Respirator; and the bottom one is the Honeywell DC365 Surgical N95 Respirator.

Figure 3. Three steps of creating ELSS-configured respirator: The top picture shows the standard N95 FFR with two headband straps. The middle one shows each of the straps cut at the midpoint and brought around the respective sides of the respirator. The bottom one shows the straps placed through the plastic toggle spring clasps.

ELSS-converted version (ELSS), and the ELSS-converted version modified by adding the NFS (ELSS + NFS). The upper and lower straps of the standard N95 FFRs were cut in the midpoint and the cut straps were then joined together using the plastic toggle spring clasps (1.1″ × 0.6″), as shown in Fig. 3. Two ear loop straps were formed on the left and right sides of the respirator. The strap adjustments were made to assure that the best possible fit can be achieved. Half of the ELSS-configured FFRs acquired for testing were modified with the NFS in the inner peripheral edge, as shown in Fig. 4.

The NSF prototype used in this study utilized a 3/8″ ethylene vinyl acetate, which FDA approved for such applications, as well as for intraoral use. One side had an FDA-approved adhesive backing with a backing sheet. The backing sheet was removed, and the NFS was aligned with the receiving mask perimeter; subsequently, it press-secured to the mask perimeter via the adhesive backing (see Fig. 4).

The quantitative fit testing was performed using a PortaCount Respirator Fit Tester (Model 8048, TSI Inc., Shoreview, MN, USA) equipped with an N95 Companion software (FitPro Ultra 4.12.1, TSI Inc.). An N95 Fit Test Probe Kit (Model 8025-N95, TSI Inc.) was utilized to sample air inside of the respirator. The probe was installed in the center of the tested N95 FFR, between the subject's nose and the upper lip. The sodium chloride (NaCl) polydisperse aerosol was generated in the exposure chamber with a particle generator (Model 8026, TSI Inc.). The background aerosol particle concentration was maintained within a range of 8000–12 000 particles per cm^3 during the tests.

The OSHA QNFT protocol includes eight sequentially performed exercises: (i) normal breathing, (ii) deep breathing, (iii) moving head side to side, (iv) moving head up and down, (v) talking, (vi) grimace, (vii) bending over, and (viii) normal breathing in the fit testing. For each exercise, the FF is determined as a ratio of the aerosol concentration outside and inside the respirator (OSHA, 1998). The overall FF value is calculated using

Figure 4. The ELSS-configured respirators enhanced with novel faceseal technology. The left side shows the adhesive surface with part of the backing removed. The right side shows the faceseal in place viewed from the back side of respirator.

the exercise-specific FFs and recorded for each set of conditions according to the OSHA protocol (OSHA, 1998). Each subject was fit tested with each of the three versions of FFRs—standard N95 FFR, ELSS-configured FFR, and ELSS-configured FFR enhanced with NFS in random order. Therefore, a total of 144 tests were carried out. This accounts for 3 FFR models, 3 versions, and 16 subjects.

Additionally, the pass (FF ≥100) rate was determined for each combination of the N95 respirator model, in each of the three versions, as the percent of subjects who did not fail the fit test (OSHA, 1998). Comparisons were performed between FF values obtained with the standard strap version and the ELSS-converted configuration, as well as between the two ELSS-converted configurations—one with the faceseal enhancement, and one without it.

Data analysis

Data analysis was performed using IBM SPSS Statistics version 23 (IBM Inc., Armonk, NY, USA). The overall FF values obtained under different conditions were found to be normally distributed and compared using a paired sample *t*-test. Two-way analysis of variance (ANOVA) was conducted to study the effects of FFR model and the strap/faceseal design on the FF value, and $P < 0.05$ was designated to denote significant differences.

Results

Fit factor

The overall FF values averaged over 16 subjects for each tested respirator model and version are presented in Fig. 5. The overall FF values varied widely for each individual model, and each FFR test version. The average overall FF values of 16 subjects obtained for the standard headband two-strap version were 105.2 ± 62.2 for Honeywell DC365; 22.4 ± 15.5 for Makrite 9500; and 161.6 ± 46.9 for 3M 1860.

When the standard headband two-strap system was converted to the ELSS configuration, there was a strongly significant ($P < 0.01$) decrease of FF on two FFR models (Honeywell DC365 and 3M 1860) and a significant ($P = 0.04$) decrease for the Makrite 9500. At the same time, adding the faceseal technology to the ELSS configuration generated a significant ($P < 0.01$) increase for two FFR models (Makrite 9500 and 3M 1860) and a border-line significant ($P = 0.05$) increase for the Honeywell DC365, as compared with ELSS-converted version without the faceseal. The Makrite 9500 FFR model with the ELSS-configured and faceseal-enhanced version also showed a strongly significant ($P < 0.01$) increase in the overall FF compared with the standard version. For the other two tested respirator models, these differences—standard alone versus ELSS-configured with the added faceseal—were found to lack statistical significance ($P = 0.62$ for Honeywell DC365, while $P = 0.39$ for 3M 1860).

The data analyzed by ANOVA was used to examine the main effect of the FFR version (Standard, ELSS, and ELSS with added faceseal), the main effect of the FFR model, and their two-way interaction. It was found that both main effects on the overall FF are significant ($P < 0.01$). Additionally, their interaction was also significant ($P < 0.01$), indicating that the FF is affected by the combined effects of FFR test version and model. Different combinations of these two factors affected the

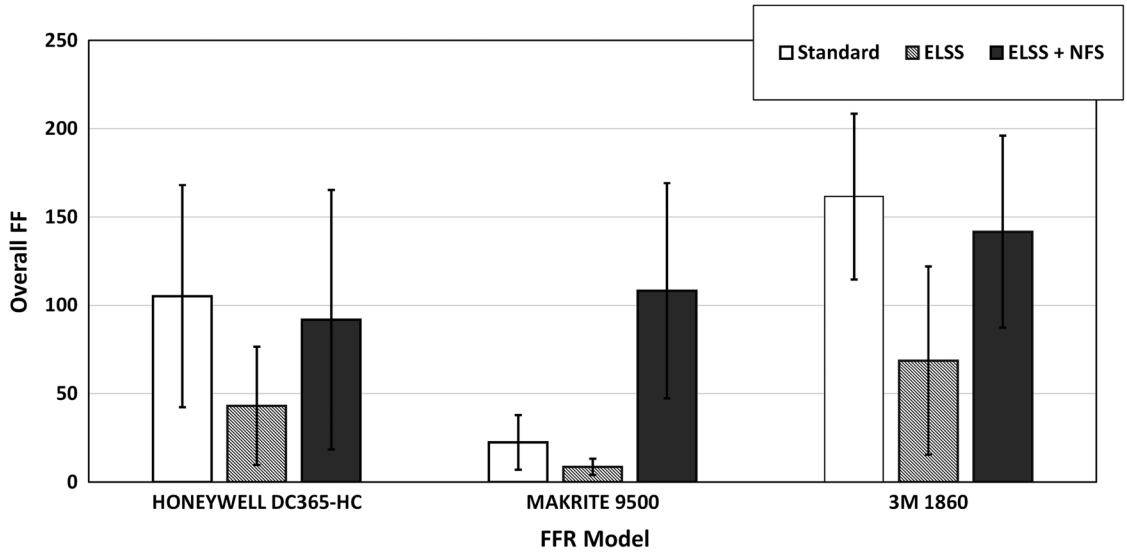

Figure 5. The overall FFs for three N95 FFR models with three versions each, averaged over 16 human subjects. The bars represent the mean and standard deviation.

FF values in different ways, causing either its increase or decrease. If the combination of the standard respirator version and the Honeywell DC365 model was postulated to be the reference in the two-factor model, the interaction between any of the FFR test versions and any of the FFR models tested in this study, significantly ($P < 0.01$) affected the overall FF.

Pass rate

The pass rate data are presented in Table 1. Firstly, for the Honeywell DC365 and 3M 1860 respirator models, the pass rate of the ELSS-configured version was lower than that of the standard version. Adding the NFS increased the pass rate of the ELSS-converted respirator. The findings for the Makrite 9500 respirator were different; here both the ELSS and ELSS + NFS configurations generated the pass rates above that of the standard version. Among the three models, the Makrite 9500 was shown to have the greatest benefit for the pass rate from the faceseal addition to the ELSS-converted version: the pass rate increased from 6.3 to 50%. Secondly, the 3M 1860 respirator consistently showed the highest pass rates across three different FFR test versions. For example, the 3M 1860 pass rate of 31.3% recorded for the ELSS configuration exceeded by far the rates obtained for the other two models modified with the ELSS: 12.5% for the Honeywell DC365 and 6.3% for the Makrite 9500. In addition, we observed that for two respirators, the Honeywell DC365 and the Makrite 9500, the pass rate obtained for the ELSS + NFS version exceeded the pass rate obtained for the standard version. This difference was not observed for the 3M 1860, possibly, due to the pass rate of the standard version being so high.

Discussion

The results of this pilot study suggest that the conversion from the standard two-strap respirator version to the ELSS configuration, which aims at improving wearability and comfort, may negatively impact the performance of an N95 FFR (two of three models showed such a trend for the pass rate). This may be attributed to the fact that the two ear loop straps, which comprise the ELSS used herein, are less capable of assuring sufficient tightness (as compared with the standard version). Although the ELSS was made adjustable in this study, this strap configuration did not achieve a sufficiently tight seal between the respirator's facepiece and the wearer's face resulting in lower FF values. This finding is consistent with the results reported on the fit of masks, virtually all of which feature ear loop straps (Mottay *et al.*, 2021; Yung *et al.*, 2021). Among them, Mottay *et al.* (2021) evaluated the seal, fit and filtration efficiency of several KN95 masks with ear loop designs, and found that the tested masks failed the stipulated safety thresholds. Yung *et al.* (2021) also found that masks with ear loops had much lower efficiency than those with headbands. Additionally, our data are in agreement with the results reported by Caoili *et al.* (2020), who found a high failure rate (39 failures

Table 1. Pass rate per OSHA QNFT threshold (FF≥100) by respirator models and version.

Respirator model	Design version	Number of pass/fail tests		Pass rate (%)
Honeywell DC365-HC	Standard	Pass	6	37.5
		Fail	10	
	ELSS	Pass	2	12.5
		Fail	14	
	ELSS + NFS	Pass	7	43.8
		Fail	9	
Makrite 9500	Standard	Pass	0	0.0
		Fail	16	
	ELSS	Pass	1	6.3
		Fail	15	
	ELSS + NFS	Pass	8	50.0
		Fail	8	
3M 1860	Standard	Pass	13	81.3
		Fail	3	
	ELSS	Pass	5	31.3
		Fail	11	
	ELSS + NFS	Pass	10	62.5
		Fail	6	

Standard = the NIOSH-approved FFRs with two-strap headbands, one worn over the head and the other behind the neck. ELSS = the FFRs with ear loop strap system configuration. ELSS + NFS = the ELSS-configured FFRs enhanced with the novel faceseal.

out of 42 fit tests) of KN95 vertical-fold shaped masks with the ear loop design.

It is noted that FFs measured for the standard and the ELSS + NFS versions were not significantly different for Honeywell DC365 and 3M 1860 models. However, this study was designed to address only on two comparisons: Standard versus ELSS and ELSS versus ELSS + NFS.

The outcome of this study—a documented improvement of the performance of ELSS-configured N95 FFRs due to the faceseal technology—is in line with our earlier findings (Koehler *et al.*, 2014; Grinshpun *et al.*, 2020). While all the tested subjects wearing the standard Makrite 9500 and almost all tested subjects wearing the ELSS version (15 of 16) failed the fit test, yet, with the faceseal added to the ELSS version, half of the subjects passed the fit test. The face dimensions of the test subjects who passed the fit testing were concentrated in zones 4, 5, 6, 7, and 9 of the NIOSH bivariate panel. A similar trend was observed for the other two respirator models. This finding corroborates that the QNFT pass rate is influenced by the face dimensions. The tested subjects whose facial dimensions represent zones 2 and 3 of the NIOSH panel achieved lower pass rates, even when the faceseal was applied. This reflects limitations that obviously exist for subjects with small faces in achieving a tight fit with the regular size respirators even in the presence of the faceseal enhancement. Since in this pilot study we did not perform fit testing on respirators with small size, a follow-up investigation covering subjects with small faces and respirators of different sizes is called for.

In 2020, the American Society for Testing and Materials (ASTM) developed the ASTM F3407-20 voluntary standard for respirator manufacturers, which proposed a minimum QNFT pass rate for 25 subjects wearing N95 FFRs being 13 out of 25, i.e. slightly in excess of 50% (ASTM, 2020). Our data show that by applying the faceseal technology to the ELSS versions of the three N95 FFRs that we tested, two of three models would produce a pass rate of 50% or greater and the third model would be close to that. Therefore, we believe that this technology, if further improved, has a potential for developing a 'universally fitting' N95 FFR with ELSS that can be used in various occupational environments as well as by the general public. In the event of a major pandemic, potential users in the general public will likely be selecting a N95 FFR at random with limited knowledge of judging an adequate fit. Furthermore, the universal availability of OSHA fit testing equipment for hundreds of millions of users appears highly unrealistic. Therefore, the findings of this study are significant for getting FFRs meeting the ASTM-proposed standard to the general public.

We acknowledge that the NFS used herein represents a first stage design, which was tested for a concept

evaluation only. At this point, it is in no way suggested that the new respirators be submitted for NIOSH certification. Likewise, it is in no way proposed that the modifications made in the study protocol be construed as suggesting that the respirator wearers should try to modify an existing NIOSH-approved N95 FFR with the NFS or alter it with the ELSS.

Limitations

There are several limitations in this pilot study. The three N95 respirators which we tested feature the same cup-shaped style and the same size ('Regular'). The cup-shaped respirators were selected because the faceseal prototype was originally developed and validated for the cup-shaped FFRs (Koehler *et al.*, 2014). Some other styles of N95 FFRs, such as 'Flat-V' and 'Flat Fold' are becoming popular now, and it remains to be seen whether the faceseal technology is applicable to other N95 respirators designs. In addition, the 3M respirators with the 'small' size were not tested in this pilot study, and thus the data were not representative of the fit of the 1860 FFR models to the subjects with smaller face dimensions.

The other limitation is a relatively small size of the cohort. A follow-up investigation should be performed with a greater number of subjects that would more closely represent specific workplace groups as well as the general population. Additionally, the fit tested subjects did not occupy all 10-zone areas of the NIOSH bivariate panel. A greater number of subjects with different face dimensions should be considered in follow-up research.

Further, the ELSS which was implemented in this effort features a simplistic design with the upper and lower straps of the N95 FFRs being cut in the middle and then brought together, using a plastic toggle spring clasps, on the sides of the respirator. This was done to minimize any changes to the FFR other than the strap system itself. An ELSS with a more sophisticated strap adjustment should perhaps be considered in the future.

Although this study has limitations, it is the only study that proposed the application of faceseal technology to ELSS-configured respirators. As ELSS-configured respirators become more popular with the public, further studies should be advocated to apply faceseal technology to various respirator shapes and designs.

Conclusions

The fit of an N95 FFR featuring the standard strap system may be negatively impacted when this system is converted to the ELSS format. At the same time, the fit of an ELSS-converted respirator can be significantly improved by the addition of the novel faceseal technology. The FFR model and design were found to be significant factors in affecting the fit as quantified by the outcomes such as the FF value and the QNFT pass rate. We believe that the faceseal concept provides the foundation for the development of a 'universally fitting' ELSS-configured N95 FFR, which can be used by workers as well as by the general public. This is an important benefit considering that it would be immensely difficult, if not impossible, to implement and administer a mandatory respirator fit testing program for the general public, who will be choosing an N95 largely by random selection.

As a follow-up on this pilot research, a more extensive testing of the faceseal technology will be performed to address a greater and more diverse study population, involve different shapes and sizes of respirators and, possibly, examine other variables.

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Conflict of interest

The authors declare no conflicts of interest relating to the material presented in this article. It is disclosed that one of the authors (R.H.K.) holds a US Patent on the faceseal technology used in this study; however, his invention has not been either licensed or commercialized. The paper contents, including any opinions and/or conclusions expressed, are solely those of the authors.

Data availability

The original data that support the findings of this study are available from the corresponding authors [sergey.grinshpun@uc.edu] upon request.

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