Does a Modified Adhesive Respirator Improve the Face Seal for Health Care Workers Who Previously Failed a Fit Test?: A Pilot Study During the Coronavirus Disease 2019 Pandemic

Richa Wardhan, MD, Meghan M. Brennan, MD, Holden L. Brown, MD, and Trey B. Creech, MD

Approximately 30% of health care workers (HCWs) fail the respirator fit test. Evidence suggests that addressing face leaks in the 3M respirator enhances its fit and improves its efficacy. Between March 31 and April 9, 2020, HCWs who failed fit tests for 3M 1860 and 1860S respirators were invited to retest with an adhesive modification of the 3M respirator. Sixty-eight percent of HCWs who failed the fit test with their first-choice respirator passed with a modified adhesive respirator. To increase the efficacy and safety of 3M respirators, ineffective face seals need substantial improvement in design. (A&A Practice. 2020;14:e01264.)

GLOSSARY

BMI = body mass index; **CONSORT** = Consolidated Standards of Reporting Trials; **COVID-19** = coronavirus disease 2019; **HCW** = health care worker; **MAR** = modified adhesive respirator; **QLFT** = qualitative fit test; **SD** = standard deviation

During the coronavirus disease 2019 (COVID-19) pandemic, the availability of personal protective equipment for health care workers (HCWs) is critical for their safety. Medical masks may be effective in preventing the spread of droplet-type infections in the community, but HCWs need respiratory protection against aerosol-borne diseases like mycobacterium, influenza, Middle East respiratory syndrome, and COVID-19. N95 respirators certified by the National Institute for Occupational Safety and Health are available for that purpose. However, every year, many HCWs fail the qualitative fit test (QLFT), leaving them with no options. For respirators, most particles enter through breaks in the face seal, suggesting that achieving a better face seal is just as important as improving the efficacy of the filter medium.[1–3]

Over the past decade, several new technologies have been used to overcome the face seal leak problem. Novel FitSeal adhesion technology by Wein Products (Los Angeles, CA), FaceSeal Technologies (Toronto, Canada), TechNova Imaging Systems (Maharashtra, India), and others have used some form of adhesive along the perimeter of the respirator.[4] Unfortunately, none of these respirators are ready for use during this current pandemic, and, to our knowledge, no studies have tested these prototypes.

From the Department of Anesthesiology, University of Florida College of Medicine, Gainesville, Florida.

Accepted for publication June 5, 2020.

Funding: None.

The authors declare no conflicts of interest.

Address correspondence to Richa Wardhan, MD, Department of Anesthesiology, University of Florida College of Medicine, 1600 SW Archer Rd, PO Box 100254, Gainesville, FL 32610. Address e-mail to richa.wardhan@ufl.edu.

DOI: 10.1213/XAA.0000000000001264

Recent QLFT of the 3M respirators (St Paul, MN) at the University of Florida performed during the COVID-19 pandemic resulted in several failed tests. Evidence suggests that even a passing fit test does not guarantee that every time an HCW puts on a respirator, an adequate fit will be achieved. It only indicates that a certain respirator has the potential to provide an adequate fit.[5] It is critical that the respirator function as intended and not jeopardize the health of the wearer. We hypothesized that an adhesive seal along the edges of a 3M (1860 and 1860S) respirator will improve its effectiveness. The study was initiated as a quality improvement project with review from the institutional review board determining that the study did not require approval; the requirement for informed consent was waived as well.

METHODS

We performed a pilot study to test a modification we made to 3M N95 1860 and 1860S respirators that we named a modified adhesive respirator (MAR) on HCWs who previously failed respirator fit tests. Ninety-two HCWs who failed the 3M 1860 and 1860 S respirator fit testing between March 31 and April 9, 2020, were invited via email to participate in the study (a list of HCWs who failed the test was provided by the occupational health department). Because the MAR testing study was conducted in the same location as the fit testing, we approached those HCWs (n = 13) who failed the fit test on site and recruited them to the study if they were willing (n = 13). We screened potential study participants via email or in person. Those with facial hair, fear of closed-in places, tape allergy, and symptomatic lung or cardiac disease were excluded. Sixteen HCWs responded and agreed to participate (Figure 1).

Each participant was retested with the same model of the respirator they had previously failed with, but after modification with adhesive tape. To conserve resources, we

used resterilized respirators. Medical-grade, soft, waterproof apparel tape (Flash Tape; Brazabra Corp, Lee, MA) was applied and molded along the edges of the respirator (Figure 2). We also added extra adhesive along the metal clip that has been identified in previous studies as an area that commonly allows leaks. We collected deidentified sex, height, and weight data.

For QLFT, we used the saccharin solution aerosol protocol as described by the Occupational Safety and Health Administration.[6] After the initial injection of aerosol, participants were asked to perform the following exercises: normal breathing, deep breathing, counting aloud to 10, turning the head side to side, moving the head up and down, and bending over to touch their toes. Participants passed if they did not detect an artificial sugar taste at any time during the test. If at any point the participants detected the sugar taste, the fit of the respirator was judged inadequate.

In addition, we explored if there were any sex-related differences in fit testing and whether HCWs from the cohort who failed fit testing, but did not participate in our study, were able to find a respirator that fit.

Statistical Analysis

Demographic data were summarized using mean and standard deviation (SD) for continuous data. Percentages were listed for categorical data. Given the small sample size, Fisher exact test was used to evaluate the association between body mass index (BMI) and gender and QLFT results.

RESULTS

Of the 92 HCWs screened (79 via email and 13 in person), 29 HCWs (24 women, 5 men) agreed to participate (Figure 1; Table 1). Three participants were excluded from the study, 2 because of abnormal facial anatomy and the other due to claustrophobia. Twenty-six participants (23 women, 3 men) were retested (Table 2). Mean BMI was 24 (women = 24, SD = 5.2; men = 25, SD = 4.38) (Table 1).

Sixteen women and 2 men, 68% of the participants, passed with an MAR. There were 9 failures (35%) despite the modification (Tables 2 and 3). Of the 9 HCWs who failed the MAR fit test, 5 later passed with a Safelite respirator (Columbus, OH) and 3 passed with a 3M 8210 respirator. One failed with each of the respirator models available to

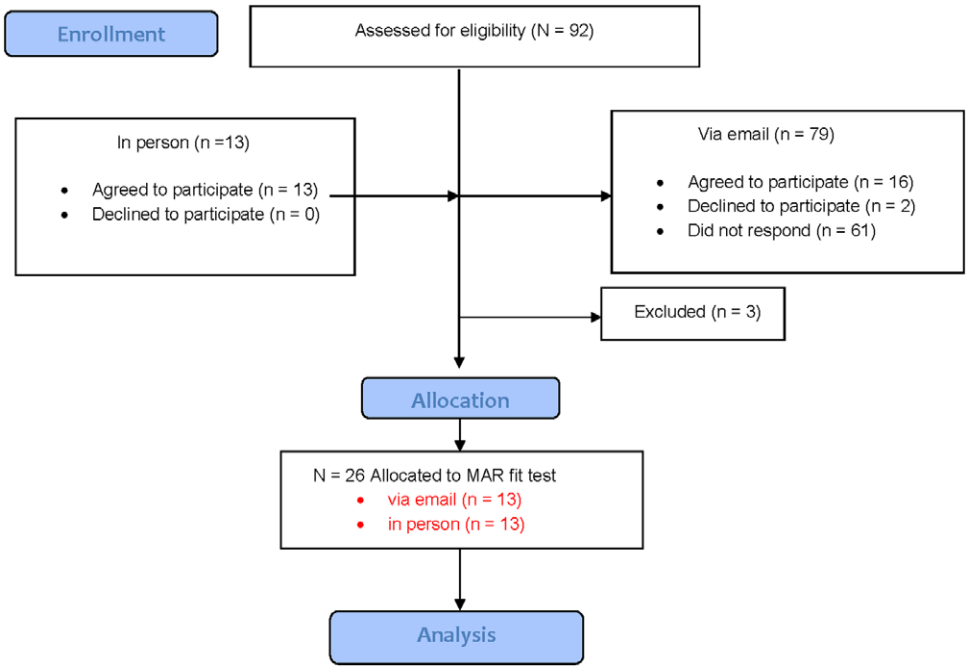

Figure 1. CONSORT flow diagram. CONSORT indicates Consolidated Standards of Reporting Trials; MAR, modified adhesive respirator.

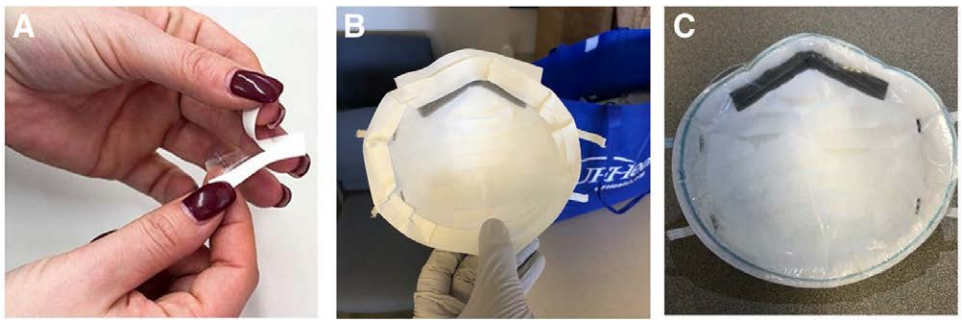

Figure 2. Modification to an N95 respirator. A, Double-sided adhesive tape; (B) inside view of the respirator after application of the adhesive tape; and (C) after removal of the paper backing.

Table 1. Descriptive Statistics of the Participant Group

Demographics	Value
Female (%)	89
Age, y (mean, SD)	33 (7.6)
Body mass index (mean, SD)	24 (5.06)
Passed fit testing[a] (%)	65

Abbreviation: SD, standard deviation.
[a]With modified adhesive respirator after previous fit test failure.

Table 2. Correlation of Modified Adhesive Respirator Fit Test With Body Mass Index and Sex

Variable	Fit Test Results		Correlation
Body Mass Index	Pass	Fail	χ^2 test: $P = .3364$
<25	8	6	
≥25	9	3	
Sex			χ^2 test: $P = .2147$
Male	1	2	
Female	16	7	

Table 3. Modified Adhesive Respirator Fit Test Result in Relation to Sex

Modified Adhesive Respirator Fit Test	Female (N = 23)		Male (N = 3)	
Fit test result (saccharin solution aerosol)	Pass	Fail	Pass	Fail
Number	16	7	1	2

us (3M, Safelite, and Kimberly-Clark respirators [Kimberly-Clark, Irving, TX]).

Of the 26 personnel who participated in the study, 14 participants had a BMI between 18 and 25 and 12 had a BMI >25. Mean BMI was 24 (women = 24, SD = 5.2; men = 25, SD = 4.38) (Table 1). Although the BMI of those who failed fit testing with an MAR was slightly lower than those who did not fail (mean, 24 vs 25), no significant relationship of fit to an MAR and BMI was observed ($P = .59$) (Table 2).

We also looked back at the original cohort (N = 63) of HCWs who failed their fit tests but did not participate in our study. In that group, 73% of HCWs (46 women, 17 men) who failed were women. However, we found no relationship between fit with an MAR and sex, likely due to the small participant group ($P = .227$) (Table 2).

Of the 63 HCWs in the original cohort, 16 (46%) passed with a 3M 8210 respirator, 14 (40%) passed with a Safelite SM respirator, and 5 (14%) passed with a Kimberly-Clark SM/R respirator. Twenty-eight HCWS did not follow-up with occupational health.

Discussion

The results of this study are in accordance with data suggesting that for high-efficacy respirators, the greatest contributing factor to inward leakage is the face seal.[5] An MAR eliminated face seal leakage in 68% of the participants who had previously failed. During manufacturing, total inward leakage can be tested using sulfur hexafluoride gas, but this testing is not a part of National Institute for Occupational Safety and Health standards. Also, even if the respirator originally fit well, the face seal may be breached during use.[7] Factors including physical activity, ventilatory rate, and head and body movements influence particle entry through face seal leaks.[2] Some studies have also suggested that N95 respirators fail to protect HCWs during strenuous activities such as performing chest compressions.[8,9]

In line with studies by Lee et al[10] and McMahon et al,[11] women had higher fit failure rates compared with men. We observed a similar pattern with fit testing of standard respirators. Due to small sample size, we were unable to test for sex differences with the MAR.

Consistent with studies by Harber et al[12] and Roberge et al,[13] our study participants reported that the leaks were most prominent at the nasal bridge. We observed that the metal nose clip on the 3M respirator hindered the adhesive tape from conforming to the nasal bridge.

This study had limitations. First, the overall response rate was low because 55% (35 of the 63 in the original cohort) of HCWs were offered other respirator models and passed the fit test with those. Our results may be biased in that those who responded were those who had been unable to find a respirator that passed the fit test. Second, the modification we applied to the respirator was nonstandard and has not been tested or validated before. This modification can be inadequate because the MAR did not undergo vigorous quality tests as a commercial respirator would. Third, we only tested a small number of HCWs due to scarcity of resources. More studies are needed to test the efficacy of adhesive-sealed respirators.

Conclusions

A successful respirator fit test is important for the safety of HCWs and should be an essential component of a respirator program. Achieving a high success rate with 3M models 1860 and 1860 S is possible by modifying the design and enhancing the fit. Sex is an important consideration because the failure rate is much higher in women than in men. Respirator manufacturers should consider fit characteristics and focus on minimizing face seal leakage. We further recommend that an adhesive modification be considered to protect HCWs during strenuous work activities, even if a passing fit is initially achieved.

DISCLOSURES

Name: Richa Wardhan, MD.
Contribution: This author helped with study design, literature search, manuscript preparation, and tables.
Name: Meghan M. Brennan, MD.
Contribution: This author helped with data analysis, data analysis interpretation, and manuscript preparation.
Name: Holden L. Brown, MD.
Contribution: This author helped with data collection, study design, and manuscript preparation.
Name: Trey B. Creech, MD.
Contribution: This author helped with data collection, study design, and manuscript preparation.
This manuscript was handled by: BobbieJean Sweitzer, MD, FACP.

REFERENCES

1. Grinshpun SA, Haruta H, Eninger RM, Reponen T, McKay RT, Lee SA. Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing:

two pathways for particle penetration. *J Occup Environ Hyg*. 2009;6:593–603.
2. Rengasamy S, Eimer BC. Nanoparticle penetration through filter media and leakage through face seal interface of N95 filtering facepiece respirators. *Ann Occup Hyg*. 2012;56:568–580.
3. Reponen T, Lee SA, Grinshpun SA, Johnson E, McKay R. Effect of fit testing on the protection offered by n95 filtering facepiece respirators against fine particles in a laboratory setting. *Ann Occup Hyg*. 2011;55:264–271.
4. Racz LA, Yamamoto DP, Eninger RM. *Handbook of Respiratory Protection: Safeguarding Against Current and Emerging Hazards*. Boca Raton, FL: CRC Press; 2017.
5. Clayton M, Vaughan N. Fit for purpose? The role of fit testing in respiratory protection. *Ann Occup Hyg*. 2005;49:545–548.
6. Occupational Safety and Health Administration. Respiratory protection. Available at: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134. Accessed April 30, 2020.
7. Leppänen M, Wu B, Corey J, Yermakov M, Grinshpun SA. Performance of a novel real-time respirator seal integrity monitor on firefighters: Simulated workplace pilot study. *J Occup Environ Hyg*. 2018;15:607–615.
8. Hwang SY, Yoon H, Yoon A, et al. N95 filtering facepiece respirators do not reliably afford respiratory protection during chest compression: a simulation study. *Am J Emerg Med*. 2020;38:12–17.
9. Shin H, Oh J, Lim TH, Kang H, Song Y, Lee S. Comparing the protective performances of 3 types of N95 filtering facepiece respirators during chest compressions: a randomized simulation study. *Medicine (Baltimore)*. 2017;96:e8308.
10. Lee K, Slavcev A, Nicas M. Respiratory protection against Mycobacterium tuberculosis: quantitative fit test outcomes for five type N95 filtering-facepiece respirators. *J Occup Environ Hyg*. 2004;1:22–28.
11. McMahon E, Wada K, Dufresne A. Implementing fit testing for N95 filtering facepiece respirators: practical information from a large cohort of hospital workers. *Am J Infect Control*. 2008;36:298–300.
12. Harber P, Su J, Badilla AD, Rahimian R, Lansey KR. Potential role of infrared imaging for detecting facial seal leaks in filtering facepiece respirator users. *J Occup Environ Hyg*. 2015;12:369–375.
13. Roberge RJ, Monaghan WD, Palmiero AJ, Shaffer R, Bergman MS. Infrared imaging for leak detection of N95 filtering facepiece respirators: a pilot study. *Am J Ind Med*. 2011;54:628–636.