ORIGINAL ARTICLE

Adequacy of a Novel Qualitative Fit Test Kit and Protocol during the COVID-19 Pandemic

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ABSTRACT

Objectives. To develop our own qualitative fit test kit and protocol for respirators and validate this against the manufacturer-issued kit.

Methods. This is a crossover study of 50 healthcare workers in a tertiary government hospital. Some healthcare workers were tested multiple times according to the number of respirators they want tested. Qualitative fit testing was done according to manufacturer protocol for the commercial kits or according to our own protocol for the novel kits.

Results. A total of 63 fit tests were analyzed. This novel kit was determined to be noninferior to manufacturer-issued kits in detecting leaks among worn respirators (p=0.005).

Conclusion. A fit test kit can be successfully created from readily available household and hospital materials. Fit tests with these novel kits using our validated protocol are shown to be noninferior to commercial test kits. This can greatly aid in qualitative fit testing of respirators in a logistically constrained pandemic setting.

Keywords: healthcare workers, respirators, SARS-CoV-2

INTRODUCTION

The global shortage of personal protective equipment during the early months of the COVID-19 pandemic has prompted the extensive proliferation of substandard or untested gear. Particulate respirators, especially, have been counterfeited because of increased demand from both healthcare workers and laypeople. Even if respirators are legitimate and approved by regulatory bodies, they may not provide the desired protection as they may not be fit tested by the healthcare worker (HCW) using them. Fit testing gives HCWs the assurance that a respirator is working as intended and is adequately fitted to the shape of their face.

Ideally, all HCWs must undergo a respiratory fit test with a specific type and size of mask. Fit testing can be done qualitatively or quantitatively. Quantitative testing requires specialized equipment and a trained operator and is thus not useful in the field. Qualitative testing, on the other hand, is a pass or fail test that can be quickly done in the hospital setting. These kits are commercially sourced and include a hood, pump nebulizer and fit test solutions.[1] Unfortunately, these kits are difficult to source either due to absence of local manufacturers or dwindling supply. In the absence of a commercial fit test kit, most HCWs just do a cursory "fit check" by looking for air escape on exhalation and mask collapse on inspiration.

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Because of the difficulty in procurement of commercially available fit test kits, we sought to develop our own fit test kit, with an accompanying protocol, to guide HCWs in choosing a good-fit respirator. This will be compared against a commercially available fit test kit to determine if they are comparable in performance.

MATERIALS AND METHODS

Philippine General Hospital HCWs under the age of 60 voluntarily undergoing fit testing of respirators were invited to participate in the study. Excluded from this study are HCWs who experience significant difficulty of breathing after donning the respirator. Similarly, subjects who have trouble breathing anytime during the test are withdrawn from the study.

A sample size of 59 tests was computed to achieve 80.572% power at a significance level of 0.050 using a one-sided non-inferiority test of correlated proportions. Standard proportion is 0.130 and the actual difference of the proportions is 0.200 based on pre-tests. The maximum allowable difference between these proportions that still results in non-inferiority (the range of non-inferiority) is 0.010.

To allow for 10% potential dropouts when subjects were unable to appreciate either one of the test solutions, the sample size was increased to 65.

For the novel tests, a homemade test kit was fabricated. This includes a makeshift hood constructed from a used powered respirator hood, a regular hospital nebulizer and a homemade saccharin solution prepared according to the method described by Mitchell et al.[1] Making the test solution involves dissolving 830 mg of sodium saccharin (equivalent to 26 1-g sachets of Equal® Saccharin) in a 100 mL distilled water solution. From the test solution, the sensitivity solution can be made by diluting 1 mL of test solution at a 1:100 proportion.[1] The test was conducted following a special protocol made by the investigators using these materials (Figure 1).

For the commercial tests, a 3M FT-30 fit test kit was provided. This kit included a test hood, a pump nebulizer and a bitter solution called Bitrex® (FT-31 sensitivity solution and FT-32 test solution). The commercial fit test followed the protocol prescribed by the manufacturer (Figure 2).

The type, brand, and model of respirator that the subject used was noted. Prior to fit testing, a fit check was first performed by cupping the hands around the respirator and exhaling, watching for air escape. During sensitivity testing, if a subject failed to perceive the taste of Bitrex® or saccharin, they only underwent testing with the solution they are sensitive to. Ultimately, however, these subjects were excluded from the study as dropouts.

Participants who were able to perceive both Bitrex® and saccharin on sensitivity testing were subject to both novel and commercial fit test methodologies. The first half underwent fit testing using the commercial kit first, followed by the novel kit. The latter half of subjects underwent fit testing with the novel kit first followed by the commercial kit. A series of exercises were performed by the subject. Any instance of perception of the bitter (Bitrex®) or sweet (saccharin) taste solutions were marked as a "fail" test. Successful completion of all exercises with no perception of bitter or sweet taste were marked as a "pass" test. Whether the participant passed or failed the test, they were still crossed over for the other method of testing.

Table 1. Pass/fail results of commercial and novel fit tests.

Novel	Commercial		Total
	Pass	Fail	
Pass	24	6	30
Fail	8	25	33
Total	32	31	63

Noninferiority of the novel kit and protocol will be analyzed by computing for the 95% confidence interval of the sensitivity differences for the two tests using Nam's restricted maximum likelihood estimate and comparing them against predetermined equivalence bounds.

RESULTS

A total of 65 fit tests were conducted among 50 unique subjects as some subjects tested more than one type of respirator. Among the 50 subjects tested, one subject was unable to taste the bitter solution, and another was unable to taste the sweet solution. They are ultimately excluded from analysis.

The results of the tests are shown in a 2x2 table (Table 1). Both kits are being evaluated on their ability to detect an air leak which is essentially a "fail" test.

In 77.8% of tests, both novel and commercial test kits are in concordance (both are "pass" or both are "fail"). When they differed in results, the novel test kit detected a leak 57% of the time. When a leak was detected, 64% of them were discovered even without the additional maneuvers performed during testing (subject was only quietly breathing and stationary).

Testing for non-inferiority, the difference between the sensitivities of the novel test and commercial test is computed at -0.0317 with a confidence interval of [-0.1344, 0.0697] (equivalence tests use twice the alpha). Since the lower confidence limit is larger than the predetermined lower equivalence bound (-0.2), the null hypothesis is rejected and the sensitivity of the novel kit in detecting a leak is concluded to be non-inferior to the commercial one (p value=0.005).

DISCUSSION

Our understanding of COVID-19 transmission is continuously changing. Most studies will maintain that the main mode of viral transmission is via respiratory droplets ranging from 5-10 μm in size.[2] Depending on airflow, these

Modified Fit Test Protocol

1. The subject dons the hood without any respirator on.
2. The diluted threshold test solution is loaded into the nebulizer.
3. Instruct the subject to breathe through the mouth with the tongue slightly extended.
4. One end of the nebulizer T-piece is occluded and the other is placed inside the hole of the clear acetate portion of the hood. The nebulizer is turned on for 10 seconds.
5. The subject is asked if she/he can appreciate a sharp sweet taste when inhaling through the mouth. Threshold testing is concluded if the subject can appreciate the taste and the time it takes for them to appreciate the taste is noted. If a subject is unable to taste the solution after 5 seconds, the nebulizer is turned on for another 10 seconds. This is done in 10 second increments until a maximum of 30 seconds is reached. Inability to perceive the test solution means that a different solution, or a quantitative fit test, must be done for that subject.
6. The hood is removed, and the patient is asked to clear the taste from the mouth by swallowing saliva or drinking sips of water.
7. The subject dons the respirator and performs a fit check.
8. The hood is placed and the subject is instructed to again breathe normally through the mouth with the tongue slightly extended.
9. The solution inside the nebulization kit is replaced with the stronger test solution.
10. The T-piece is placed inside the hole and the nebulizer is turned on for the number of seconds it took the subject to appreciate the threshold test. The subject is asked if she/he perceives the taste. Thirty seconds are allowed to elapse before the nebulizer is turned on for half the amount of time of the threshold solution. Perception of the test solution means that the fit test has failed. Readjustment or a different respirator must be used.
11. The fit test is conducted with the subject doing several activities as listed below. Each activity must be completed after 1 minute. Detection of the test solution at any activity means that the fit test has failed and readjustment or a different respirator must be used.
    a. Breathing deeply
    b. Turn head left to right, pausing to breathe at each side
    c. Move head up and down, pausing to breathe at each angle
    d. Reading aloud the Rainbow Passage
    e. Bending forward at the waist
    f. Breathing normally

Figure 1. Fit test protocol modified for the novel test kit.

Commercial Fit Test Protocol

1. The subject dons the hood without any respirator on.
2. The sensitivity test solution is loaded into the nebulizer.
3. Instruct the subject to breathe through the mouth with the tongue slightly extended.
4. The pump nebulizer is placed inside the hole of the clear acetate portion of the hood. Ten pumps of sensitivity solution are given
5. The subject is asked if she/he can appreciate a bitter taste when inhaling through the mouth. Threshold testing is concluded if the subject can appreciate the taste and the time it takes for them to appreciate the taste is noted. If a subject is unable to taste the solution after 5 seconds, another 10 pumps of solution is given. This is done in 10 pump increments until a maximum of 30 pumps are reached. Inability to perceive the test solution means that a different solution, or a quantitative fit test, must be done for that subject.
6. The hood is removed, and the patient is asked to clear the taste from the mouth by swallowing saliva or drinking sips of water.
7. The subject dons the respirator and performs a fit check.
8. The hood is placed and the subject is instructed to again breathe normally through the mouth with the tongue slightly extended.
9. The solution inside the nebulizer is replaced with the stronger test solution.
10. The test solution is delivered through the hole in increments of 10 corresponding to the number of pumps it took for the subject to perceive the sensitivity solution (10, 20 or 30). The subject is asked if she/he perceives the taste. Thirty seconds are allowed to elapse before a top-up dose is given which is half the amount of pumps of the threshold solution. Perception of the test solution means that the fit test has failed. Readjustment or a different respirator must be used.
11. The fit test is conducted with the subject doing several activities as listed below. Each activity must be completed after 1 minute. Detection of the test solution at any activity means that the fit test has failed and readjustment or a different respirator must be used
    a. Breathing deeply
    b. Turn head left to right, pausing to breathe at each side
    c. Move head up and down, pausing to breathe at each angle
    d. Reading aloud the Rainbow Passage
    e. Bending forward at the waist
    f. Breathing normally

Figure 2. Fit test protocol lifted from manufacturer instructions.

microbe-containing droplets are generally not airborne and fall to the ground or come in contact with different objects in the vicinity of the infected patient. Airborne transmission has been demonstrated when the virus is carried in droplet nuclei (<5 μm) generated during aerosolizing procedures such as nebulization, endotracheal intubation, bronchoscopy, tracheostomy, manual ventilation, and open suctioning.[3]

Due to limited knowledge surrounding the virus' airborne capabilities, it has been recommended that HCWs wear N95 respirators, when working in high-risk areas.[2-4] Filtered facepiece respirators are recommended in the direct care of COVID positive patients or when performing aerosol-generating procedures.[5,6] CDC-certified and authentic N95 masks can filter 0.3-0.5 μm of particulate with 95% efficiency. The performance of these respirators is highly dependent on its fit which is specific to the face of the wearer.[7]

Respiratory fit tests are essential to the proper use of respirators to ensure that the seal is optimal and adequate protection is afforded. According to Occupational Safety and Health Administration (OSHA) guidelines of the US Department of Labor, fit testing can be done quantitatively or qualitatively. Since quantitative fit testing is a cumbersome procedure and is not readily available in most settings, qualitative testing is done more often.[8]

OSHA does qualitative fit testing using one of 4 established methods: 1) isoamyl acetate, 2) saccharin, 3) denatonium benzoate (Bitrex®) and 4) stannic chloride (smoke). Testing is done by following a series of maneuvers as indicated in

an established protocol. The perception of the smell and taste of these substances when wearing a respirator generally means a poor fit for that wearer and respirator combination.[8]

Unfortunately, these kits and the compounds used therein may not be readily available in all institutions. Cost is prohibitive and the supply of consumables is uncertain. Saccharin presents an attractive alternative to Bitrex® because of two reasons. First, it is more readily available and can thus be concocted in abundant amounts. Second, it provides a more pleasant taste during sensitivity testing. In our study, more subjects reported a persistent unpleasant bitter taste after Bitrex® sensitivity testing. Using a homemade saccharin test solution is not a novel idea. Previous authors have already validated a homemade test solution made from artificial sweeteners which showed comparable efficacy against a commercially prepared saccharin solution.[1]

We also wanted to create a delivery method that will no longer require the pump nebulizers used in commercial fit test kits. We replaced them with a regular hospital jet nebulizer and created a protocol that will determine threshold doses akin to what is done for commercial kits. Instead of determining the number of pumps, the delivery of aerosolized solution was determined by the amount of time the nebulizer is turned on in seconds. Jet nebulizers typically generate particles ranging from 1.9–5.3 μm which is still much larger than the filtration efficiency of an authentic N95 respirator.[9] The possibility, therefore, of diffusion through the filter of an authentic respirator is negligible and effectively removes that as a possible confounder.

Overall, the combination of novel kit and protocol has been found to be non-inferior to the commercially available kit in detecting an air leak. The results of the study could be of great benefit among institutions or care facilities with no fit test kits of their own or struggling with limited resources. It is much cheaper and is made from more readily available materials and equipment.

Inadvertently, this study also exposed the substandard quality of some respirators especially those sourced from donations. For example, many donated KN95 respirators were not working as intended and failed frequently regardless of wearer face type. Whether this is due to inefficient seal mechanisms, or an inherent filter problem remains to be determined. Respirators sourced from donations should be scrutinized for adequacy before use by any HCW.

Lastly, we acknowledge that the control used in this study is not the gold standard for determining an adequate fit. That distinction belongs to quantitative fit testing, which would also still be the test of choice for healthcare workers unable to taste any test solution.

CONCLUSION

In this study, we were able to successfully create our own qualitative fit test kit using readily obtainable household and hospital materials. Using our own testing protocol, fit tests using these novel kits were found to be noninferior to commercially available tests. This could be of great benefit to improve readiness and protection of healthcare workers in more resource-constrained settings.

Statement of Authorship

CVLG contributed in the conceptualization, review of literature, data acquisition and analysis, and drafting and revising of manuscript; PAUS and APCD contributed in the drafting and revising of manuscript, and final approval of the version to be published.

Author Disclosure

All authors declared no conflicts of interest.

Funding Source

This study was funded by the authors.

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