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Project BREATHE – Prototype Respirator Evaluation Utilizing Newly Proposed Respirator Test Criteria

Jung-Hyun Kim,

Raymond J. Roberge*,

Ronald E. Shaffer,

Ziqing Zhuang,

Jeffrey B. Powell,

Michael Bergman,

Andrew J. Palmiero

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania 15236

Abstract

Machine and human subject testing of four prototype filtering facepiece respirators (FFR) and two commercial FFR was carried out utilizing recently proposed respirator test criteria that address healthcare worker-identified comfort and tolerance issues. Overall, two FFR (one prototype, one commercial model) were able to pass all eight criteria and three FFR (two prototypes, one commercial model) were able to pass seven of eight criteria. One prototype FFR was not tested against the criteria due to an inability to obtain satisfactory results on human subject quantitative respirator fit testing. Future studies, testing different models and styles of FFR against the proposed criteria, will be required to gauge the overall utility and effectiveness of the criteria in determining FFR comfort and tolerance issues that may impact user compliance and, by extension, protection.

Keywords

filtering facepiece respirators; prototypes; proposed respirator test criteria

INTRODUCTION

Project BREATHE (Better Respiratory Equipment utilizing Advanced Technology for Healthcare Employees) was a joint undertaking of the National Personal Protective Technology Laboratory (NPPTL) of the National Institute for Occupational Safety and Health (NIOSH) and the Veterans Health Administration (VHA) that sought to develop

*Corresponding author dtn0@cdc.gov.

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a respirator(s) designed specifically for healthcare workers (HCW) and provisionally termed the “B95 Respirator” (Radonovich et al, 2009; Gosch et al, 2013). Seeking outside collaborators, this undertaking was announced by Department of Veterans Affairs in the Federal Register (Federal Register, 2009) with the result that two U.S. respirator manufacturers (Company A, Company B) responded and agreed to participate in this endeavor. Manufacturer-supplied prototype respirators were evaluated with human subject testing (physiological, subjective) and machine testing (filter penetration, breathing resistance) and graded on a pass / fail basis against recently-established metrics for respirator evaluation (Shaffer et al, 2014). While previous publications communicated the vision for Project BREATHE (Gosch et al, 2013), establishing pass-fail criteria and test methods (Shaffer et al, 2014), the purpose of this study was to apply these concepts to actual products and possible future products. This report summarizes the findings of this testing.

MATERIALS AND METHODS

Prototype Respirators

Each manufacturer supplied two models of prototype respirators, each with filters of the N95 class and none of which was equipped with an exhalation valve. The prototypes provided were concept level working prototypes and did not represent final design lockdown of a product nor the refinement that would be expected of a mass production sample.

Company A Prototype Respirator 1 (A-1) - a disposable rigid, cup-shaped filtering facepiece respirator model available in small and standard sizes with two non-adjustable elasticized straps and a pliable plastic nose bar.

Company A Prototype Respirator 2 (A-2) - a disposable pliable, V-shaped, pleated filtering facepiece respirator model available in small and standard sizes with two non-adjustable elasticized straps and a pliable plastic nose bar.

Company B Prototype Respirator 1 (B-1) – a reusable filtering facepiece respirator/ elastomeric respirator hybrid available in small, medium and large sizes, comprised of a pliable, opaque silicone facemask with a centrally located, vertically-positioned, parabolic-shaped, replaceable filter and filter housing with a single piece elasticized harness.

Company B Prototype Respirator 2 (B-2) – a filtering facepiece respirator, available in small and medium / large sizes, with a curved, horizontally-positioned, oblong-shaped, plastic frame that houses a central filter panel, to which is attached a chin panel and a less permeable nasal panel with adjustable aluminum nasal bar, and an adjustable single piece strap.

Other Respirator Testing – two commercially-available surgical N95 filtering facepiece respirator models (3M 1860, 3M 1870; 3M Company, St. Paul, MN), that have received the most previous research attention for this class of respirators (Shaffer et al, 2014; Shaffer and Jansen, 2015) and are commonly available in healthcare facilities (Wizner et al, 2016), were tested with the same test criteria. Both models were tested with the subjects used

in Company A prototype trials (n=21). In addition, model 3M 1870 was tested with the subjects used in Company B prototype trials (n=20).

Machine Testing

Each model of the four prototype respirators was tested individually five times for breathing resistance and for filter penetration of nebulized sodium chloride solution with the Certi Test 8130 filter tester (TSI, Shoreview, MN). NIOSH pass criteria for N95 category respirator filters requires filter penetration ≤5% and inhalation resistance ≤35 mm H_20 pressure tested at a continuous flow rate of 85 L/min (NPPTL, 2012). Filter penetration is not included in the currently proposed respirator test criteria, but was performed in the current study to ensure the requisite protective qualities of the prototype respirators filters. Five respirator samples of each prototype underwent 10 donnings followed by quantitative respirator fit testing (n=50 fit tests for each prototype respirator model) on the Static Advanced Headform (Hanson Robotics, Inc., Plano, Texas) that utilizes Frubber™, a fluid-filled cellular matrix composed of an elastomer that simulates the physics of human facial living soft tissues as the simulant skin covering. Respirator fit testing on the Static Advanced Headform has previously been shown to correlate with human results (Bergman et al, 2015). Passage of a NIOSH respirator quantitative fit test for N95 class respirators is based on a minimum required fit factor of 100 that is calculated as the ratio of measured ambient particles to respirator deadspace particles (OSHA, Appendix A, 2003).

Human Subject Quantitative Respirator Fit Testing

Eighteen men (anthropometrics, 32.3±14.4 yrs, height 179.4±8.9 cm, weight 81.5±17.5 kg, BMI 25.5±5.0 kg/m^2) and 17 women (anthropometrics, 32.9±12.4 yrs, height 165.3±6.2 cm, weight 77.2±21.4 kg, BMI 28.4±8.2 kg/m^2), representative of the cells in the NIOSH respirator fit test panel (Zhuang and Bradtmiller, 2007), underwent quantitative fit testing (OSHA, Appendix A, 2003) on each of the four prototypes. Passage of an OSHA respirator quantitative fit test for N95 class respirators is based on a minimum required fit factor of 100 that is calculated as the ratio of measured ambient particles to particles within the deadspace of the respirator (OSHA, Appendix A, 2003). Respirators were tested as a “family” and up to 2 donnings per size were permitted as indicated in the proposed criteria (Shaffer et al, 2014). A researcher selected a sample of the size most likely to provide a good fit. If the subject failed 2 donnings, another size was selected and tested. Upon passage of a fit test, no further sizes of the respirator were tested. Similar methods were employed elsewhere (Zhuang et al, 2017) in development of proposed respirator fit capability (RFC) test criteria.

Human Physiological/Comfort Studies – Subject Anthropometrics

Subject Test Group 1 (Company A trials) - Twenty-one healthy, non-smoking subjects (12 men, 9 women) participated in the study exercise trials. Subject anthropometrics for men were age 22.6±2.7 yrs, height 180.8±7.9 cm, weight 84.1±16.5 kg, and Body Mass Index (BMI) 25.7±4.8 kg/m^2. Anthropometric values for women were age 23.7±3.3 yrs, height 166.4±4.0 cm, weight 65.6±6.5 kg, and BMI 23.7±2.6 kg/m^2. Each of these subjects also underwent testing with the 3M 1860 and 1870 models.

Subject Test Group 2 (Company B trials) - Twenty healthy, non-smoking subjects (10 men, 10 women) participated in the study. Subject anthropometrics for men were age 23.1±1.6 yrs, height 181.7±7.2 cm, weight 78.9±8.6 kg, and BMI 23.9±2.9 kg/m^2. For women, anthropometrics were age 22.0±2.5 yrs, height 165.5±3.0 kg, weight 62.5±5.2 kg, and BMI 22.8±2.0 kg/m^2. Each of these subjects also underwent testing with the 3M 1870 model.

The exercise trials were conducted in a physiology laboratory with mean ambient temperature 20.3±1.2°C, relative humidity 32.6±14.4%, and barometric pressure 739.1±2.5 mm Hg during the study period. These ambient conditions are similar to those encountered by HCW, the single largest group of respirator users (Smith and Rea, 1977). On the initial day of testing, subjects underwent a screening history and physical examination by a licensed physician. Subjects were dressed in athletic shorts or pants, tee shirt and athletic shoes during exercise testing. The study was approved by the NIOSH Human Subjects Review Board, and all subjects provided oral and written informed consent.

Subject Instrumentation

Subjects were instrumented for continuous physiological monitoring during the exercise trials. The heart rate (HR), oxygen saturation (SpO_2) and transcutaneous carbon dioxide ($tcpCO_2$) were continuously monitored with the Tosca 500™ (Radiometer, Copenhagen, DM), an earlobe-mounted combination pulse oximeter and heated, Severinghaus-type CO_2 sensor that was adhesively attached to the left earlobe (Roberge et al, 2010). The respiratory rate (RR) was monitored with the Zephyr Bioharness™ (Medtronics, Minneapolis, MN, US), an elasticized chest strap utilizing a proprietary embedded capacitive sensor to evaluate chest expansion and contraction (Kim et al, 2012). Tympanic membrane temperatures (T_{tymp}) were measured by a single investigator (research physician) at baseline and pre-and-post exercise trials from the right ear with a Welch/Allyn Pro 4000 infrared tympanic thermometer (Braun GmbH, Kronberg, FRG). Respirator microclimate (deadspace) temperature and relative humidity were continuously monitored with the iButton (Maxim, San Jose, CA, US), a small (16 mm x 6 mm) wireless sensor that was adhesively attached to the inner surface of the N95 FFRs midway between the respirator center and the edge of its right upper quadrant (Roberge et al, 2012a). The temperature of the facial skin covered by the respirators was measured with the VitalSense (Philips Respironics, Bend, OR, US) wireless dermal sensor patch (Roberge et al, 2012b).

Exercise Protocol

The study trials consisted of walking on a treadmill at 5.6 km/h (0° incline) wearing one of five respirators (A-1, A-2, B-1, 3M 1860, 3M 1870) for 1 hr each. Respirator B-2 was not tested because it did not pass fit testing in sufficient numbers to meet the respirator testing criteria (Shaffer et al, 2014). No more than two trials were conducted in a single day with a minimum one-half hour respite between any trials. For trials, the subjects donned a randomized respirator and performed a user seal check (OSHA, Appendix B-1, 2003) immediately prior to the treadmill session. Subjective ratings of exertion and thermal comfort during the trial sessions were assessed at timed intervals (0, 15, 30, 45 and 60 minutes) with the Borg Perceived Exertion Scale (a 15-grade scale ranging from “no exertion at all” to “maximal exertion) (Borg G, 1990) and the Frank Comfort Scale (a

10-point scale ranging from “the coldest you have ever been” to “the hottest you have ever been”) (Frank et al, 1999). Additionally, during the trials, two 7-point respiratory scales for perceived inspiratory effort and perceived expiratory effort (ranging from “not noticeable” to “intolerable”), and one 7-point respiratory scale for overall breathing discomfort (ranging from “no discomfort” to “intolerable discomfort”) were administered (Antunano et al, 1993). Between sessions, subjects were seated and allowed to drink bottled water or a sports drink *ad lib*.

Data Analysis

Study data values for physiological and subjective variables during exercise trials were calculated by differences between mean baseline (0min) and mean 60min values. Prototype respirators and the two commercially available respirator models were not compared to one another for the study, but were individually evaluated by comparison with eight previously-cited proposed respirator test criteria (Shaffer et al, 2014) on a pass/fail basis (see Table I for criteria). Machine test study data for filter penetration were evaluated against NIOSH established testing norms (NPPTL, 2012; Shaffer et al, 2014).

RESULTS

The mean physiological and subjective measurement data during exercise trials for each of the three prototype respirators and the 3M model 1860 and 1870 respirators tested are dichotomized by subject group (Test Groups 1 and 2) and presented in Table 2. As presented in Table 1, Respirator A-2 and 3M model 1870 were able to pass 8/8 criteria, whereas A-1, 3M model 1860 and B-1 were able to pass 7/8 respirator test criteria (Shaffer et al, 2014). Respirator A-1and 3M model 1860 each failed to achieve a Geometric Mean Manikin Fit Factor of ≥100 on 100% of the five samples (n=50 donnings per respirator model) tested with the Advanced Static Headform testing. Respirator B-1 failed the breathing resistance criteria with a mean filter resistance of 13 mm H_2O pressure. Respirators A-1, A-2, B-2, 3M 1860, and 3M 1870 had filter resistances (mm H_2O) of 8.5, 3.7, 5.6, 8.9, and 6.3 respectively. Respirator B-2 achieved a pass rate of 30% on quantitative respirator fit testing (Table 1). All tested respirators were able to achieve NIOSH passing results on filter penetration testing. The four prototype respirators all had filter penetration values less than 1%.

DISCUSSION

Respiratory protective devices were initially developed for industrial workers, not with HCW in mind (Gosch et al, 2013). There are a number of features of industrial work (dusty environments, heavy physical workloads, extreme ambient conditions, etc.) that are not generally present in the typical healthcare setting, suggesting that the respiratory protection needs of HCW may be different and better served with respiratory protective devices tailored to their environment. Project BREATHE (Radonovich et al, 2009) was an effort to partner the U.S. federal government with manufacturers in developing a HCW-specific respirator(s) that could be tested against metrics that have been identified from previously-completed respirator research projects (Shaffer et al, 2014).

The current study is a first attempt at testing prototype respirators, developed with the HCW market in mind, utilizing pass/fail criteria from recently established respirator test criteria (Shaffer et al, 2014). The study data suggest that current respirator manufacturing technology is able to develop respiratory protective devices that can meet the proposed criteria for a HCW-specific respirator(s). This is important in that the recently proposed criteria were developed to evaluate parameters thought to influence user comfort and thereby compliance, while not sacrificing protection. Among the three prototypes undergoing human subject testing, the A-2, A-1 and B-1 prototypes were able to achieve a passing score on 8/8, 7/8 and 7/8 respirator test criteria, respectively, and A-2 ultimately went on to be commercialized. These three prototype models passed the criteria for fit testing with human quantitative fit test results equal to, or better than, those noted for respiratory protective devices currently used in the healthcare setting (Wilkinson et al, 2010). Respirators A-1 and A-2 had pass rates of 83%, while all 35 subjects (100%) passed with the B-1. The similar higher HRs and associated lower RRs noted for B-1 and 3M 1870 at 60 min, compared with the other respirators tested, suggest a greater effort at the work of breathing that could be related to filter resistance. However, with the exception of B-1, all the tested respirators had filter resistances that were <10 mm H_2O resistance, a level that has previously been shown to result in HRs and RRs that are not significantly different from controls without a respirator (Roberge et al, 2013). Therefore, these differences in RR and HR responses may represent nonrespirator related variables such as physical conditioning differences between the two study groups given that, at low and moderate work rates, workload intensity has a greater physiological impact on HR and RR than the magnitude of inspiratory resistance (Antunano et al, 1993).

Respirator prototype testing using the newly proposed criteria may allow for refinement of some respirator features such as improved fit and decreased facial respirator microenvironment temperature elevations, whereas other endeavors, such as attempting further decreases in filter respirator resistance, may not be beneficial or noticeable as evidenced by the similar physiological (e.g., RR) and subjective responses (e.g., inspiratory effort, expiratory effort, overall breathing difficulty) shared by the three prototypes that underwent human testing (Table II). One limitation of the current study is that all of the machine and human subject testing was conducted in a laboratory setting. Confirmation of study findings is still needed in large clinical trials. Field testing of the current study's three prototype respirators in VHA healthcare settings has recently been accomplished and the forthcoming results of that testing should provide further important information (Radonovich et al, 2009). Another limitation of this study is that data from only 8 of the 10 proposed B95 tests could be used. Two of the criteria related to "air exchange" (i.e., average inhaled carbon dioxide and oxygen) relied upon NIOSH's Automated Breathing and Metabolic Simulator (ABMS). Unfortunately, problems occurred during testing that resulted in the data being unusable. However, human subject test data also addressing "air exchange", namely transcutaneous CO_2 and O_2 saturation, were found to be consistent when comparing the repeat 3M 1870 testing (Table 2), suggesting that ABMS testing may not be needed going forward. The newly proposed, metrics-based respirator test criteria may allow for a more robust evaluation of future respirator feature modifications and improvements. Future studies are warranted to improve and further validate the test criteria.

CONCLUSIONS

In the current study, the recently proposed respirator test criteria (Shaffer et al, 2014) have been utilized for the first time to evaluate individual features of prototype and commercial filtering facepiece respirators associated with comfort and tolerance issues that are thought to impact user compliance. This study will serve as a baseline endeavor at criteria utilization in the hope of spawning future laboratory and work site studies that are needed to determine the performance of other filtering facepiece models against the proposed criteria.

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Table I.

Pass (P) / Fail (F) Results of Prototype Respirator Testing Utilizing Recently Proposed Respirator Test Criteria (Shaffer et al, 2014)

Variables Tested	RESPIRATORS TESTED					
	A-1	3M 1860	A-2	3M 1870	B-1	B-2
Breathing Resistance ≤10 mm H_2O	P	P	P	P	F	N/A
tcPCO_2 level increase < 4 mm Hg *	P	P	P	P	P	N/A
SpO_2 decrease ≤ 1% *	P	P	P	P	P	N/A
Moisture retention ≤ 4% *	P	P	P	P	P	N/A
Facial skin microclimate heat ≤ 2.5°C increase over baseline *	P	P	P	P	P	N/A
Respirator microclimate heat ≤ 2.5°C increase over baseline *	P	P	P	P	P	N/A
Reuse/Gauging Fit; manikin geometric mean fit factor ≥100 on 5/5 samples §	F	F	P	P	P	F
Pass rate of ≥74% on OSHA quantitative fit testing	P	P	P	P	P	F

* Over 1 hr.

§ Tested with the Advanced Static Headform.

Table II.

Subjects' Mean Physiological and Subjective Measurement Data (± standard deviation) during Exercise Trials Wearing Three Prototype Respirators and Two Models of Commercially-Available Respirators

Study Variable		Subject Test Group 1				Subject Test Group 2	
		A-1	3M 1860	A-2	3M 1870	B-1	3M 1870
SpO_2 %	0min	98.4±1.0	96.8±6.2	98.3±0.9	98.1±1.0	98.8±0.8	98.4±0.8
	60min	98.4±1.0	97.8±2.2	98.2±0.8	98.3±0.9	98.4±0.8	98.4±0.9
$tcpCO_2$ mm Hg	0min	40.2±4.8	38.0±4.5	38.9±4.3	38.6±4.2	38.0±3.0	37.9±3.2
	60min	40.3±4.8	40.3±4.8	39.2±4.7	39.3±4.4	40.4±3.4	40.1±3.8
HR	0min	100.3±17.6	96.9±18.0	93.5±19.8	94.9±19.2	79.6±15.9	83.4±13.8
	60min	111.1±20.4	109.3±21.7	107.9±21.9	106.2±23.3	115.7±19.7	113.2±20.0
RR	0min	20.9±5.1	21.0±4.9	21.0±4.7	21.1±4.4	17.7±4.6	16.1±3.6
	60min	32.0±9.8	29.1±11.9	28.3±5.7	30.5±6.5	26.9±4.5	25.7±5.3
$T_{tympanic}$ °C	0min	36.4±1.0	36.4±0.6	36.7±0.2	36.5±0.3	36.6±0.3	36.4±0.3
	60min	36.6±0.5	36.6±0.4	36.7±0.3	36.6±0.3	36.9±0.4	36.9±0.4
Inspiratory Effort	0min	1.7±0.4	1.6±0.4	1.4±0.6	1.5±0.5	1.2±0.4	1.1±0.2
	60min	2.3±0.9	2.2±0.8	2.3±1.0	2.1±0.9	2.3±0.8	2.4±0.7
Expiratory Effort	0min	1.7±0.5	1.6±0.4	1.5±0.5	1.7±0.5	1.2±0.5	1.0±0.0
	60min	2.4±0.8	2.2±0.7	2.3±0.9	2.2±0.7	2.4±0.8	2.4±0.7
Overall Breathing Difficulty	0min	1.5±0.5	1.5±0.5	1.4±0.5	1.4±0.5	1.2±0.5	1.1±0.2
	60min	2.3±0.9	2.4±0.8	2.5±1.3	2.1±0.8	2.3±0.8	2.3±0.6
Borg Scale	0min	8.5±1.8	9.2±2.3	8.5±1.8	9.0±2.1	5.9±1.2	6.2±0.4
	60min	11.0±2.9	11.0±2.8	11.0±2.5	10.9±2.7	9.5±2.6	10.4±2.0
Frank Scale	0min	4.5±0.7	4.8±0.7	4.7±0.8	4.8±0.6	4.3±1.0	4.3±0.7
	60min	6.3±0.8	6.4±0.8	8.6±0.5	6.2±0.7	6.2±1.2	6.5±0.7