Title: Filtering Facepiece Respirators with an Exhalation Valve: Measurements of Filtration Efficiency to Evaluate Their Potential for Source Control

Materials and Methods

The NIOSH National Personal Protective Technology Laboratory (NPPTL) evaluated 13 filtering-facepiece respirators (FFRs) from 10 manufacturers to determine the inward and outward filtration efficiency of particles through the exhalation valves. A convenience sample of models was composed from all available excess NPPTL stock of FFRs with exhalation valves that had four or more specimens. Because of a limited supply of product, researchers tested FFRs that were beyond their "use-by" date and were taken from an open box; however, researchers did not expect that this would affect the study results. The above constraints are identified in Table 1 and acknowledged as a limitation of the study.

Each model was evaluated using a TSI 8130 filtration efficiency tester with a sodium chloride (NaCl) 2% solution in distilled water.[1] Six replicates were tested for each model, unless otherwise indicated in Table 1.

Table 1. FFRs with an exhalation valve tested for this study. The table includes two classes of respirators, variable sample sizes, and non-NIOSH-approved respirators, due to a limited supply of product.

Supplier Manufacturer	Model Number	Class	Sample Size	Beyond "Use-by" Date	Open Box	Approval Number
Dräger Safety AG & Company, KGaA	X-plore 1750	N95®	6	No	Yes	84A-4396
Jinhua Meixin Protective Equipment Factory	2100V	N95	6	No	Yes	Non-NIOSH Approved®***
3M Company	9211	N95	5**	Unknown	Yes	84A-2668
3M Company	85111CN	N95	6	No	Yes	84A-5402
Visca Safety Comercial Limitada	Visca 2740V	N95	6	No	Yes	84A-4486
AirGas Inc., Radnor	65059520A	N95	6	No	Yes	84A-6250
Willson Dalloz Safety Products	NBW95V	N95	6	Yes—2017	Yes	84A-4378
Makrite Industries, Inc.	710VOV	N95	6	No	Yes	84A-9219
Makrite Industries, Inc.	9800V	N95	6	No	Yes	84A-9055
ATEM Company, Ltd.	4030	N95	4**	No	Yes	84A-7720
Moldex-Metric, Inc.	2310	N99®*	6	Yes—2012	No	84A-1459
Uline	S-10479	N95	6	Unknown	Yes	84A-3714
Makrite Industries, Inc.	2201V	N95	6	No	Yes	84A-9231

*The N99 FFR is designed to have greater filtration than an N95 FFR.

**For these two models, six specimens were not available.

***This respirator model met NIOSH testing requirements but does not have a NIOSH approval.

[1] The sodium chloride (NaCl) aerosol has a count median diameter (CMD) of 75 ± 20 nanometer (nm) and a geometric standard deviation (GSD) of ≤1.86. With a density of 2.13, the MMAD is 0.347 µm [Eninger et al. 2008].

Test Equipment

The following test equipment was used for these evaluations:

- A TSI Model 8130 filtration efficiency tester.
- A microbalance accurate to 0.0001 g.
- Type A/E glass filters, 102-mm-diameter, with a 1-µm pore size.
- Sodium chloride (NaCl), a 2% solution in distilled water.
- A temperature and humidity chamber.
- A test fixture (rectangular tube of 6.4-mm polycarbonate [20.3 x 20.3 x 11.4 cm]).
- Aluminum plates with a centered 7.6-cm-diameter hole on the top and bottom of the test fixture.

Pressure drop across the respirator—which is an indicator of breathing resistance—was measured by the TSI 8130.

For each FFR, NIOSH researchers examined two positions and three mitigations at three flowrates. The total number of possible tests was 1,170 (13 models × [2 positions + 3 mitigations] × 3 flowrates × 6 replicates); however, six replicates were not available for every model, and therefore the dataset includes 1,125 tests.

Effect of Flowrate

With the NIOSH Respirator Approval Program standard test procedure, a flowrate of 85 lpm is specified for FFRs. This flowrate is intended to correspond to breathing that would occur during moderate exercise. When following this test procedure, airflow travels in one direction and with a velocity that corresponds to the maximum flow in the breathing cycle (i.e., instantaneous peak flowrate). Lower airflow rates of 25 lpm and 55 lpm were also evaluated to compare the effect that lower breathing rates may have on filtration efficiency.

Control Group

The control group evaluated FFRs in two positions (see Figure 1). The inward position corresponds to the direction of inhalation; the outward position corresponds to the direction of exhalation. For both positions, the valve in the FFR was not altered in any way. The inward position is a control to validate the filtration efficiency of the FFRs. The outward position is a control that measures the filtration efficiency without any mitigation strategy.

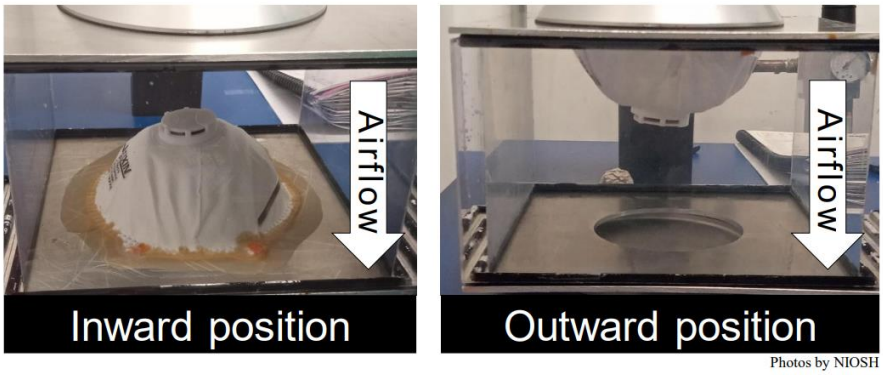

Figure 1. The two positions used for the 13 FFR models tested. The inward position (left) is used by the NIOSH Respirator Approval Program when testing N-type respirators. The outward position (right) was used experimentally to channel airflow in the direction of exhalation.

Inward Position

The inward position control measures the inward filtration efficiency of the FFR. This is the same position that the NIOSH Respirator Approval Program uses to approve N-type respirators. To be approved, the 12 N95 FFRs used in this study had to meet the required minimum efficiency of 95%, which is equivalent to a maximum penetration of 5% (penetration = 1 - filtration). For the one N99 FFR tested, the required minimum efficiency was 99%, which is equivalent to a maximum penetration of 1% penetration (penetration = 1 - filtration). The respirators were sealed with beeswax, as shown in Figure 1.

Outward Position

The outward position control measures the outward filtration efficiency through the filter media and includes additional unfiltered particles passing through the exhalation valve, if open. This position is not used by the NIOSH Respirator Approval Program to approve N-type respirators. For the 13 FFRs tested, the efficiency should be a combination of particles that pass through the filter media and the exhalation valve. The respirators were sealed with beeswax.

Experimental Group

Three mitigations to inhibit particle penetration by covering the exhalation valve (see Figure 2) were chosen as the experimental group: taped (with surgical tape), covered (with an electrocardiogram [ECG] pad), and masked-over (with a surgical mask). The mitigations were tested in the outward position to compare particle penetration in relation to the outward position control.

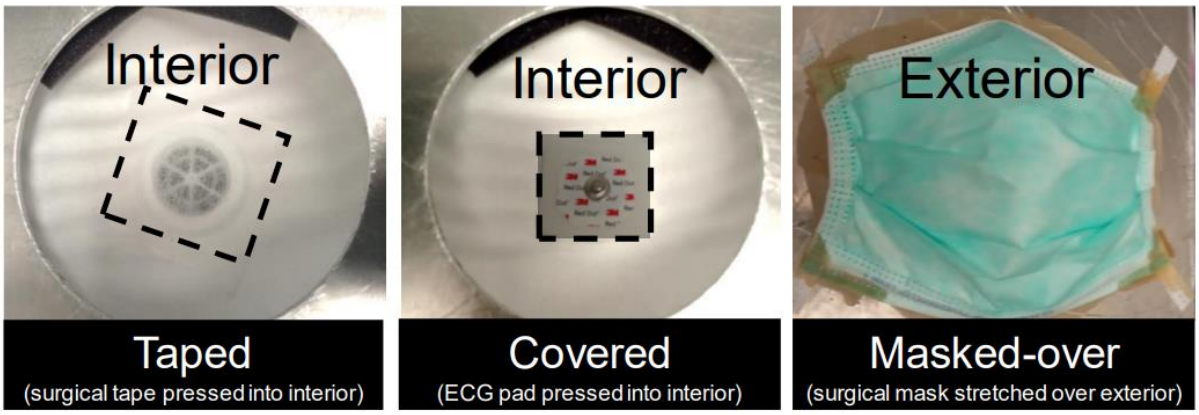

Figure 2. Three mitigations used on FFRs to measure the reduction of particle penetration. Dotted lines represent tape edges (left) and ECG pad edges (center).

Mitigation Strategies

Taped Mitigation

The taped testing mitigation had a 2" x 2" swatch gently pressed onto the interior of the FFR. As with the inward position sealing approach, the respirator was sealed with beeswax. A Nexcare gentle paper tape, with medium hold, was used (hospital name: 3M Micropore surgical tape). The taped test used the outward position but with the surgical tape covering the exhalation valve.

Covered Mitigation

The covered testing mitigation had an ECG pad (3M Red Dot) gently pressed onto the interior of the respirator. As with the inward position sealing approach, the respirator was sealed with beeswax. The covered test used the outward position, but with the ECG pad covering the exhalation valve.

Masked-over Mitigation

The masked-over testing mitigation used a surgical mask stretched over the exterior of the respirator. As with the inward position sealing approach, the respirator was sealed with beeswax. The surgical mask was then stretched over the FFR to simulate a reasonably tight fit and was secured with hot glue. The nose wire of the surgical mask was pinched around the respirator, and the four corners where the elastic band attaches were sealed with beeswax, as shown in Figure 2, right. For the masked-over mitigation, the test results depended upon the FFR/surgical mask interface, so great care was taken to simulate a realistic, snug fit.

Mitigation Strategy Selection

Taped and covered mitigations were selected because the materials are available in a hospital, are nontoxic, and provide good adherence to moist surfaces. Two concerns are that the adhesive could pull away from the surface, thereby not blocking airflow to the same degree over time, and that these adhesives could contain chemicals that have toxicological effects. Considering these concerns, the surgical tape and ECG pads used in this study both have no expected toxicological effects in relation to skin contact, inhalation, and ingestion, and they provide greater adherence in moist conditions. The masked-over mitigation was selected because this aligns with the CDC recommendation at the time of this study [CDC 2020] if source control was needed and only an FFR with an exhalation valve was available.

Non-FFR Protective Devices

In addition to the FFR evaluations, researchers also evaluated a small selection of masks intended for medical purposes and unregulated barrier face coverings made up of four models of surgical masks, seven models of procedure masks, six models of cloth face coverings, and two types of fabric from cotton t-shirts. For the surgical masks, two models were used for the masked-over mitigation strategy. For the cloth face coverings, two had filter inserts and three had exhalation valves. The sample size of the non-FFR devices evaluated in this current study was too small to represent the population of those devices but is included to provide confidence that the equipment and test methods employed in the current study produced results comparable to previous NIOSH research that explored the particle penetration of select types of non-FFR devices [Rengasamy et al. 2009; Rengasamy et al. 2010].

Attribution

N99 is a certification mark of the U.S. Department of Health and Human Services (HHS) registered in the United States. N95 and NIOSH Approved are certification marks of the U.S. Department of Health and Human Services (HHS) registered in the United States and several international jurisdictions.

References

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