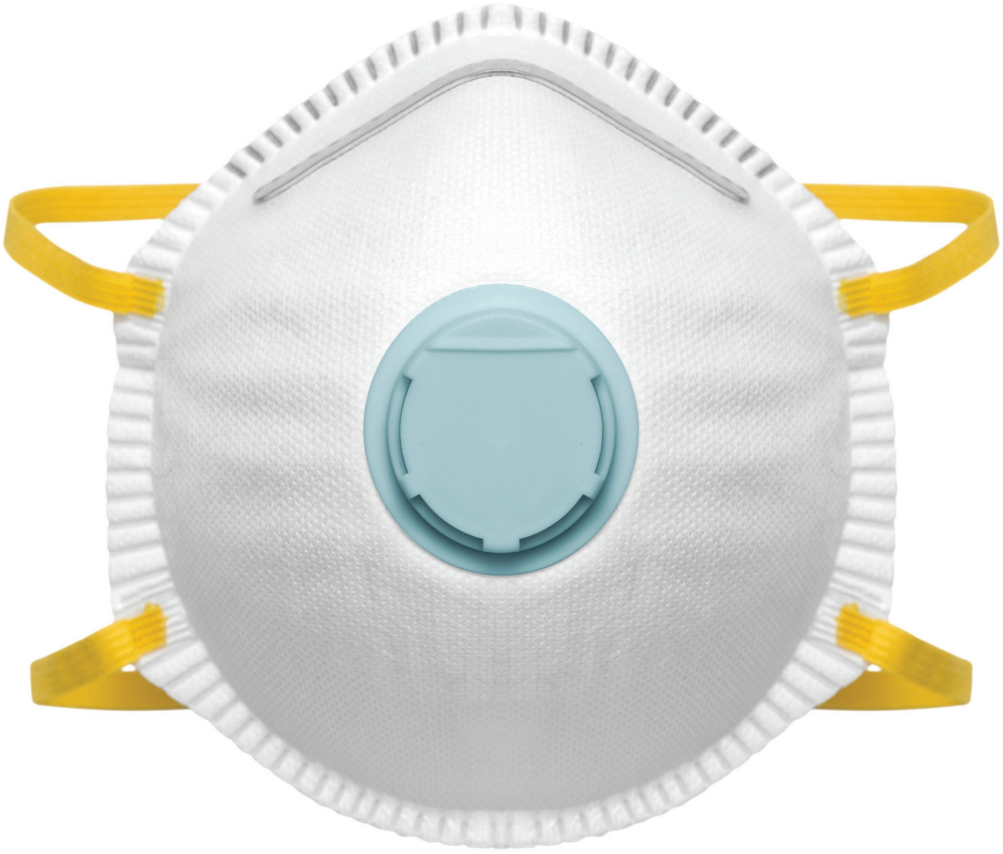
Technical Report

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



Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Technical Report

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory

Disclaimer

Get More Information

Find NIOSH products and get answers to workplace safety and health questions:

1-800-CDC-INFO (1-800-232-4636) | TTY: 1-888-232-6348

CDC/NIOSH INFO: cdc.gov/info | cdc.gov/niosh

Monthly NIOSH eNews: cdc.gov/niosh/eNews

Suggested Citation

NIOSH [2020]. Filtering facepiece respirators with an exhalation valve: measurements of filtration efficiency to evaluate their potential for source control. By Portnoff L, Schall J, Brannen J, Suhon N, Strickland K, Meyers J. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2021-107. https://doi.org/10.26616/NIOSHPUB2021107

DOI: https://doi.org/10.26616/NIOSHPUB2021107

DHHS (NIOSH) Publication No. 2021-107

December 2020

Cover photo by Shutterstock

CONTENTS

LIST OF FIGURES

LIST OF TABLES

ACRONYMS AND ABBREVIATIONS

CDC	Centers for Disease Control and Prevention
CMD	count median diameter
FFR	filtering facepiece respirator
GSD	geometric standard deviation
HCP	healthcare personnel
MMAD	mass median aerodynamic diameter
NaCl	sodium chloride
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
PAPR	powered air-purifying respirator

UNIT OF MEASURE ABBREVIATIONS

cm	centimeter
g	gram
g/cc	grams per cubic centimeter
in	inches
lpm	liters per minute
mg/m^3	milligrams per cubic meter
mm	millimeter
mmH_2O	millimeters of water column
nm	nanometer
µm	micrometer

EXECUTIVE SUMMARY

Filtering facepiece respirators (FFRs) are used extensively by healthcare personnel (HCP) during a pandemic. FFRs are primarily reserved for those personnel who have a greater risk and longer duration of exposure compared with other workers and the general public. Some FFR models contain an exhalation valve, which is a device that closes to allow inhaled breath to be pulled through the filter media and opens in order to allow exhaled breath to be expelled from the respirator through the exhalation valve as well as the filter media. These FFR models provide the wearer with a level of protection similar to that of an FFR without an exhalation valve, and they are thought to increase the wearer's comfort at high work rates and be suitable for longer periods of use. However, respiratory secretions expelled by wearers may exit along with air through the exhalation valve. A concern with FFRs with an exhalation valve is that individuals may spread disease if unfiltered, virus-laden aerosols pass through the valve.

Current guidance from the Centers for Disease Control and Prevention (CDC) does not recommend using an FFR with an exhalation valve for source control (i.e., to filter respiratory secretions to prevent disease transmission to others) and advises that if only this option is available and source control is needed, then the valve should be covered with a surgical mask, procedure mask, or a cloth face covering that does not interfere with the respirator fit. The CDC has requested research in order to provide improved science-based recommendations on the use of exhalation valves. The current study was designed to respond to this request and to evaluate particle penetration in FFRs with an exhalation valve. Further, this research compares mitigation strategies, including investigating the practice of covering the FFR exhalation valve with a mask. Finally, some publications have criticized the use of FFRs with an exhalation valve, and airline industry leaders have banned their use on flights. Given the above, more research is needed to evaluate particle emission through exhalation valves so that a better understanding of risk can be conveyed to the public.

To address these issues, the National Personal Protective Technology Laboratory at the National Institute for Occupational Safety and Health (NIOSH), CDC, developed a study with three aims: (1) to measure the filtration efficiency provided by FFRs with an exhalation valve under conditions of inward airflow (i.e., in the direction of inhalation) and outward airflow (i.e., in the direction of exhalation); (2) to evaluate how particle penetration in FFRs with an exhalation valve compares to particle penetration in surgical masks, procedure masks, cloth face coverings, and fabric from cotton t-shirts; and (3) to determine the filtration efficiency of three modifications to the exhalation valve in FFRs with the goal of mitigating the emission of unfiltered particles.

To accomplish these three aims, thirteen FFR models were each tested in two positions: inward position, which is used by the NIOSH Respirator Approval Program when testing N-type respirators, and outward position, which was used experimentally to channel airflow in the direction of exhalation. For the inward position, three mitigation strategies were used:
(1) covering the valve on the interior of the FFR with commonly available surgical tape,
(2) covering the valve on the interior of the FFR with an electrocardiogram (ECG) pad; and
(3) stretching a surgical mask over the exterior of the FFR.

The purpose of these three strategies was to measure the varying filtration efficiencies to determine their contribution toward source control. Both positions and all mitigation strategies were tested at three airflow rates: 25, 55, and 85 lpm (liters per minute). In addition to the FFR evaluations, researchers evaluated a selection of surgical masks, procedure masks, cloth face coverings, and fabric from cotton t-shirts using the outward position and flowrates detailed above.

Findings for the 13 FFR models were derived from a total of 1,125 tests. In the inward position, particle penetration was less than 5%, which is the target value for NIOSH Respirator Approval Program tests. For all three mitigation strategies in the outward position where air flowed out through the valve, particle penetration ranged from <1% to 55%. The variance in particle penetration for the outward position is likely explained by design differences between FFR models and variances in how the exhalation valve opens. For all models, at all flowrates, the best mitigation strategy was to cover the valve from inside the FFR with an ECG pad. Securing surgical tape over the valve from inside the FFR performed nearly as well. Covering the FFR with a surgical mask was the least effective mitigation strategy.

For the small sample of non-FFR devices (surgical masks, procedure masks, cloth face coverings, and fabric from cotton t-shirts) evaluated using the outward position, results are included to verify that the equipment and test methods employed in the current study produced comparable results to previous NIOSH research that explored the particle penetration of select types of non-FFR devices.

FFRs with an exhalation valve provide respiratory protection to the wearer and—according to the findings from this study—can also reduce particle emissions to levels similar to or better than those provided by surgical masks and unregulated barrier face coverings. This study shows that modifications to these respirators can further reduce particle emissions. The use of an ECG pad or surgical tape secured over the valve from the inside of the FFR can provide source control similar to that of an FFR with no exhalation valve.

These results represent one of the first measurements of particle penetration through FFRs with an exhalation valve that are tested in an outward position, and the findings have important implications for guidance on source control and mitigation.

INTRODUCTION

Masks and respiratory protective devices may protect the wearer to varying degrees from exposure to potentially infectious droplets, and these devices have varying degrees of protection. These devices can be classified into three categories: (1) respirators (e.g., those that are NIOSH-approved respirators or authorized for emergency use); (2) masks intended for medical purposes (e.g., FDA-cleared surgical masks including those labeled as procedure masks); and (3) masks intended for a non-medical purpose.[1]

Respirators are designed to filter the most penetrating particles, which are <1 micrometer (µm), and respirators are fit-tested to try to minimize inward leakage of particles around the face seal. Surgical masks are evaluated to less stringent filtration efficiency requirements [ASTM 2019] than NIOSH-approved respirators [CFR 42 Part 84]. However, some may have filtration efficiency that performs similar to that found in respirators. Importantly, surgical masks do not have a fit requirement and therefore are more susceptible to inward leakage when compared to respirators.

Unregulated barrier face coverings typically lack electrostatically charged fibers, multi-layer filter media, and other properties that provide the ability for respirators to filter submicron particles (<1 µm). Although barrier face coverings are not recommended to filter submicron particles, they have demonstrated the ability to filter large particles and diffuse airflow [Clase et al. 2020]. In addition to providing varying degrees of protection to the wearer, the above protective devices have the potential to filter respiratory secretions from the wearer to help prevent disease transmission to others (i.e., they may provide source control).

Filtering facepiece respirators (FFRs) are a type of respirator that is approved by NIOSH and designed to protect the wearer by filtering the smallest and most penetrating particles—0.35-µm mass median aerodynamic diameter (MMAD). FFRs provide protection from large droplets that are found in coughs and sneezes and also fine droplets that are emitted by talking. Surgical N95 FFRs are a subcategory of NIOSH-approved respirators and have the same level of filtration as N95 respirators. Surgical N95 FFRs do not have exhalation valves. Because they are used extensively by healthcare personnel (HCP) during a pandemic, surgical N95 FFRs and all unvalved NIOSH-approved FFRs are primarily reserved for those personnel with a greater potential for exposure compared with other workers and the general public.

A pandemic strains the availability of respiratory protection. During a pandemic, HCP, emergency responders, and other critical infrastructure workers may struggle to acquire respiratory protection. For this reason, unregulated barrier face coverings are recommended for use by the general public and non-HCP to reduce airborne transmission of virus during a pandemic while preserving critical supplies of respirators and masks needed by HCP.

While HCP primarily rely on FFRs, elastomeric (full facepiece and half-mask) respirators and powered air-purifying respirators (PAPRs) are alternatives. However, some FFRs, elastomeric respirators, and PAPRs allow exhaled breath to be expelled from the respirator without passing through the filter media. Particles are emitted with this exhaled breath, which may impact the level of source control provided by these types of respirators.

[1] Masks that are *not* intended for a medical purpose are *not* medical devices and are not regulated by the FDA.

Some FFRs have a device called an exhalation valve that bypasses the filter media to exhaust exhalation directly to the surroundings. However, the effectiveness of FFRs with exhalation valves as a potential contributor to source control has not been evaluated before now.

Exhalation Valves

Exhalation valves in respirators are devices that close to allow inhaled breath to be pulled through the filter media and open to allow exhaled breath to be expelled from the respirator through the exhalation valve as well as the filter media. In FFRs, an exhalation valve typically has a membrane composed of natural rubber, silicone, or neoprene. The membrane sits atop a support structure and lies beneath a plastic cover. During inhalation, the membrane closes against the support structure and blocks the valve hole, thereby providing maximum air filtration through the filter material. During exhalation, if there is adequate air pressure, the air lifts the membrane and allows a passageway through which unfiltered exhaled breath can escape. These valves are included in some FFR models and are thought to increase the wearer's comfort at high work rates and be suitable for longer periods of use. A respirator with an exhalation valve provides the wearer with a level of protection similar to that of one without an exhalation valve. However, the exhalation valve is likely to affect the level of source control provided by a respirator as some particles expelled by wearers may exit through the exhalation valve.

If an infected individual is wearing a respirator with an exhalation valve, then the amount of viral emissions relates to the individual's respiratory secretions that would be associated with breathing, talking, coughing, and sneezing. These activities result in expelling droplets of different sizes containing varying amounts of virus. Large droplets quickly fall to the ground, but small droplets remain airborne, accumulate, and may be inhaled by others. Once droplets become airborne, their transport and viability depend upon such factors as travel distance, length of time airborne, fresh air exchange, and sunlight [Chin et al. 2020; Ratnesar-Shumate et al. 2020; Augenbraun et al. 2020]. Finally, once virus-laden droplets are inhaled, their ability to infect a person also depends on the droplets making contact with mucosal cells in the respiratory tract, attachment to a virus receptor, and a dose sufficient to cause infection [Perrotta et al. 2020; Schröder 2020].

Respirators are highly effective at filtering fine particulates (i.e. <2.5 µm) and virus to protect the wearer [Zhou et al. 2018; Dau et al. 2020]. However, respirators with an exhalation valve that release respiratory emissions directly to the surroundings may not be suitable when a sterile field must be maintained [DHHS 2015]. On its "Considerations for Wearing Masks" page, the CDC advises the general public about all types of masks and states that the CDC does not recommend using masks with exhalation valves for source control [CDC 2020a]. On its "Personal Protective Equipment: Questions and Answers" page, whose primary audience is healthcare personnel, the CDC provides advice on the use of protective equipment and states that if only a respirator with an exhalation valve is available and source control is needed, then "the exhalation valve should be covered with a surgical mask, procedure mask, or a cloth face covering that does not interfere with the respirator fit" [CDC 2020b].[2]

In recent publications, the above CDC statements have been interpreted to mean that "masks with exhalation valves can do more harm than good" [Jones 2020], that exhalation valves pose

[2] In some sources, "cloth face coverings" are referred to as "cloth masks."

major concerns about outward protection [Ippolito et al. 2020], and that a "mask with a vent is useless in protecting others" and is the equivalent of "wearing nothing" [Pallini 2020].

Some municipalities have banned the use of masks with exhalation valves [Department of Public Health Order of the Health Officer 2020], and airline industry leaders also prohibit their use [Alaska Airlines 2020; American Airlines 2020; Delta Airlines 2020; Southwest Airlines 2020].[3]

Given the above, more research is needed to evaluate particle emission through exhalation valves so that a better understanding of risk can be conveyed to the public. The CDC has requested research in order to provide improved science-based recommendations on the use of exhalation valves. The current study was designed to respond to this request and to evaluate particle penetration in FFRs with an exhalation valve.

Objective

To provide data to address the issue of the extent to which FFRs with an exhalation valve may provide source control, the objective of this study is threefold:

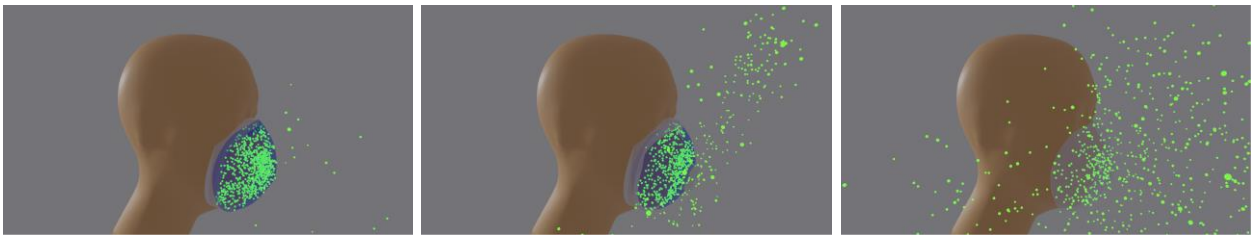
(1) to measure the filtration efficiency provided by FFRs with an exhalation valve under inward and outward airflow conditions (12 N-95 FFRs and 1 N-99 FFR);
(2) to evaluate how particle penetration in FFRs with an exhalation valve compares to particle penetration in surgical masks, procedure masks, cloth face coverings, and fabric from cotton t-shirts; and
(3) to determine the filtration efficiency of three modifications to the exhalation valve in FFRs with the goal of mitigating the emission of unfiltered particles.

BACKGROUND

Visualizations of mannequins emitting a simulated cough and sneeze are helpful tools to demonstrate how different types of masks provide source control. As examples, at Florida Atlantic University, researchers use green laser light to visualize droplet transmission [Verma et al. 2020]. Other studies employ Schlieren imaging, a tool used to photograph the flow of fluids of varying densities, which also helps to visualize movements of aerosols such as those generated by a cough [Tang et al. 2008; Staymates 2020].

The above studies used visualizations of humans emitting respiratory secretions. To help readers visualize particle transport in the context of the current study, models were employed to generate two-dimensional illustrations. Figure 1, left, shows how an FFR without an exhalation valve provides a tight fit and filters particles. Figure 1, center, shows how an FFR with an exhalation valve provides a tight fit, filters particles, and releases particles through the valve. Figure 1, right, shows how a barrier face covering does not provide a tight fit; it filters fewer particles, allows them to be released through the gaps around the covering, and pushes some particles backwards.

[3] In the cited sources, other terminologies used for "exhalation valve" include "one-way vent," "exhaust valve," and "vent."



Illustrations by NIOSH

Figure 1. Simulations of particle exhalation through an FFR without an exhalation valve (left), an FFR with an exhalation valve (center), and a barrier face covering (right). Density of particles near the face represents particles remaining inside the mask.

Illustrations for Figure 1 were created using Blender software, a three-dimensional modelling and rendering package (Stichting Blender Foundation, Amsterdam). Model settings were chosen to represent particle penetration efficiency and the presence or absence of face sealing based on mask type, as follows: *left*—the FFR without an exhalation valve provides a tight seal around the face and permits <5% of particles to escape the respirator; *center*—the FFR permits <5% of particles to escape through the filter media and also has an exhalation valve that provides an opening that allows 20% of the particles to escape through the valve; *right*—the barrier face covering does not have a seal around the face, which causes particles to move behind the head and also releases 50% of particles through the covering.

METHODS

The NIOSH National Personal Protective Technology Laboratory (NPPTL) evaluated 13 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.[4] Six replicates were tested for each model, unless otherwise indicated in Table 1.

[4] 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].

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	2001V	N95	6	No	Yes	Non-NIOSH-approved***
3M Company	9211	N95	5**	Unknown	Yes	84A-2668
3M Company	8511CN	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, 6 specimens were not available.
***This respirator model met NIOSH testing requirements but does not have a NIOSH approval.

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.

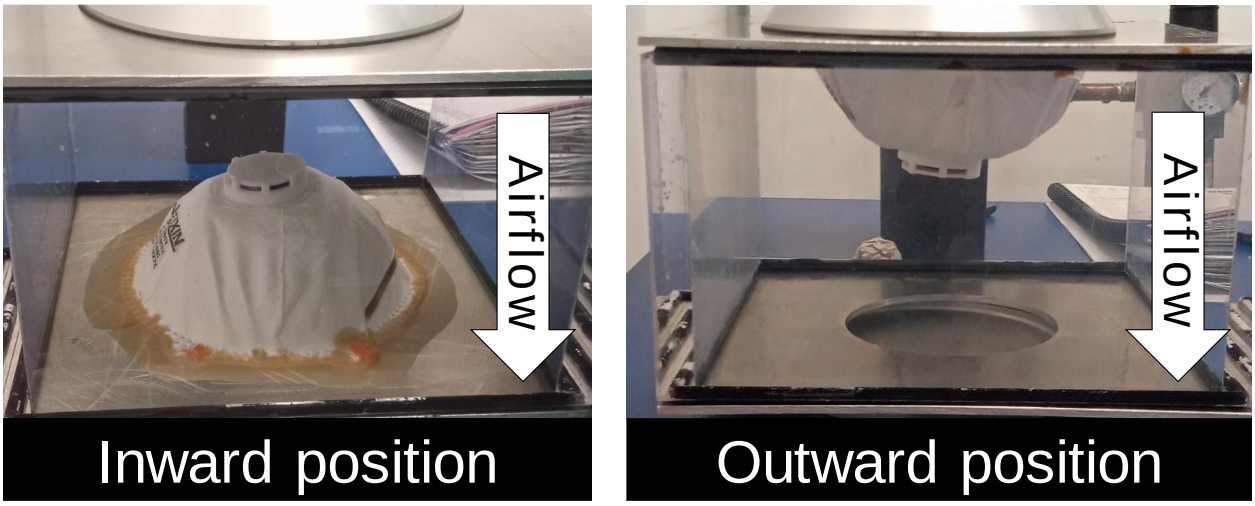
For each FFR, NIOSH researchers examined two positions and three mitigations at three flowrates. The total number of possible tests was 1,170 (13 models × [2 positions + 3 mitigations] × 3 flowrates × 6 replicates); however, six replicates were not available for every model, and therefore the dataset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



Photos by NIOSH

Figure 2. 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

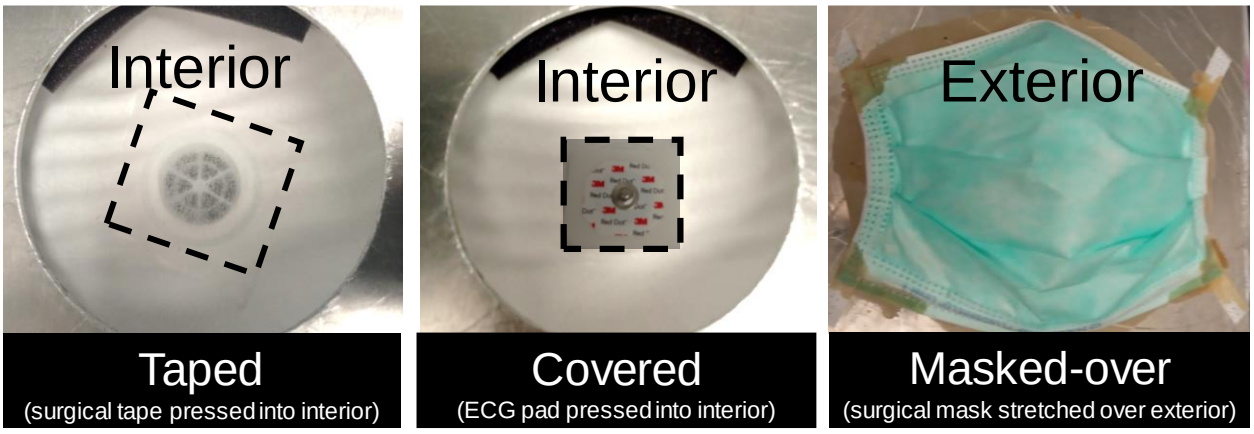
The inward position control measures the inward filtration efficiency of the FFR. This is the same position that the NIOSH Respirator Approval Program uses to approve N-type respirators. For the 12 N95 FFRs tested, the efficiency should be >95%, which is equivalent to <5% penetration (penetration = 1 - filtration). For the one N99 FFR tested, the efficiency should be >99%, which is equivalent to <1% penetration (penetration = 1 - filtration). The respirators were sealed with beeswax, as shown in Figure 2.

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 3) 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 in order to compare particle penetration in relation to the outward position control.



Photos by NIOSH

Figure 3. 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 3, right. For the masked-over mitigation, the test results depend 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. In light of 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 current CDC recommendation [CDC 2020b] if source control is needed and only an FFR with an exhalation valve is 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].

FILTRATION TEST FINDINGS

The findings for the 1,125 tests performed on the 13 FFRs with an exhalation valve are summarized in Figure 4.

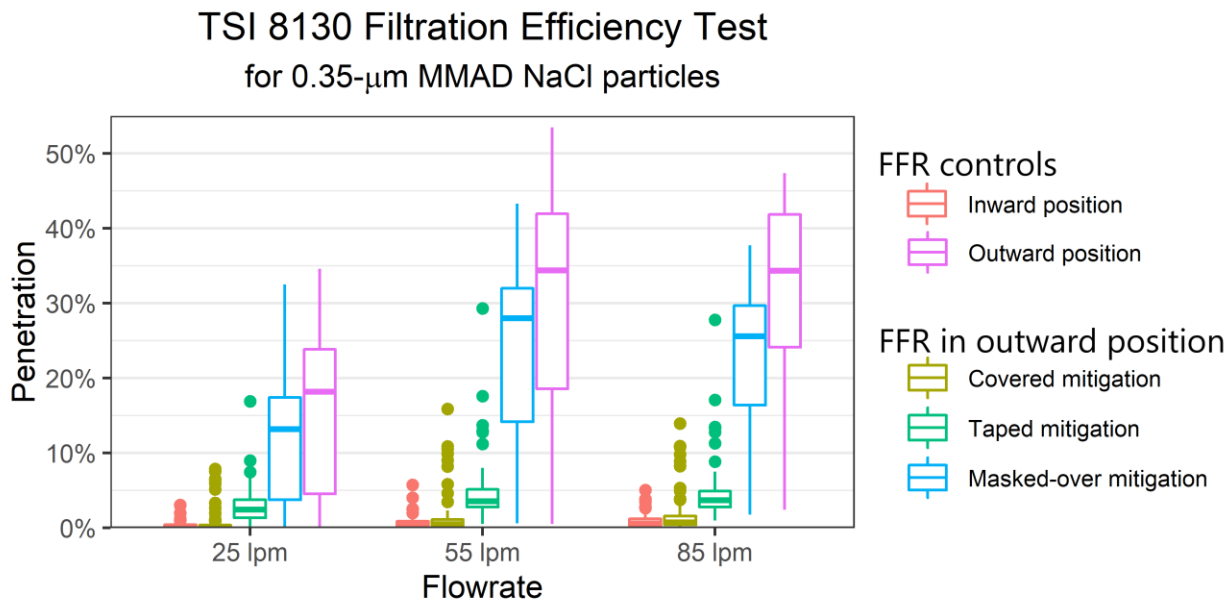


Figure 4. Filtration efficiency by testing position at flowrates of 25, 55, and 85 lpm, reported as percentage of penetration. The boxes show median, 25% quantile, and 75% quantile of all 13 FFRs tested (n=1,125). Three mitigations were performed in the outward position. For related descriptive statistics, see Table A1 in the Appendix.

The penetration with the inward position control was <5% for all but one test. Results for the outward position control (in which the airflow goes the same direction as exhaled breath) ranged from <1% to 55%. The covered mitigation performed nearly as well as the inward position control. Considering the median penetration at 85 lpm, penetration was 31% for the outward position control; penetration was 23% for the masked-over mitigation; penetration was 5% for the taped mitigation; penetration was 2% for the covered mitigation. This high-to-low order (outward position control, masked-over, taped, and covered) was the same for every flowrate. The penetration was lowest at 25 lpm and highest at 55 lpm and 85 lpm.

Figure 5 shows test results of the outward position control for each FFR model. Flowrates of 25, 55, and 85 lpm are indicated by color and shape.

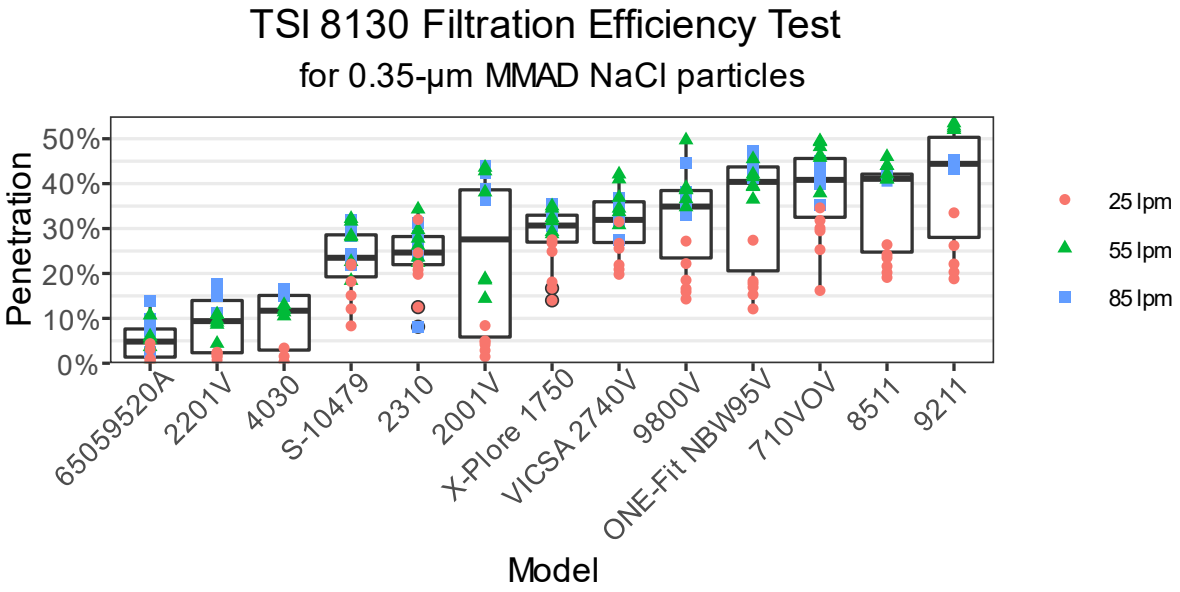


Figure 5. Filtration efficiency of each FFR tested in the outward position control—i.e., with no mitigation measure. Results reported as percentage of penetration (n=1,125). Boxes show median, 25% quantile, and 75% quantile with icons that indicate the range of flowrates (25, 55, and 85 lpm). For related descriptive statistics, see Table A2 in the Appendix.

For the outward position controls, some models (65059520A, 2201V, and 4030) had less than 20% penetration even without any mitigation. Other models (S-10479, 2310, 2001V, X-Plore 1750, VICSA 2740V, 9800V) had much greater penetration with a median penetration above 40%. Some models showed large variability in penetration, with model 2001V ranging from <1% to 44% penetration.

The least particle penetration occurred at 25 lpm across all models with one exception—model 2310, which had a minimum penetration of 8% at 85 lpm. The maximum penetration occurred at 55 lpm for most models. For the models that had less than 20% penetration (65059520A, 2201V, and 4030), the maximum penetration occurred at 85 lpm.

Figure 6 shows results of surgical masks, procedure masks, cloth face coverings, and fabric from cotton t-shirts evaluated for submicron particle penetration using the outward position.

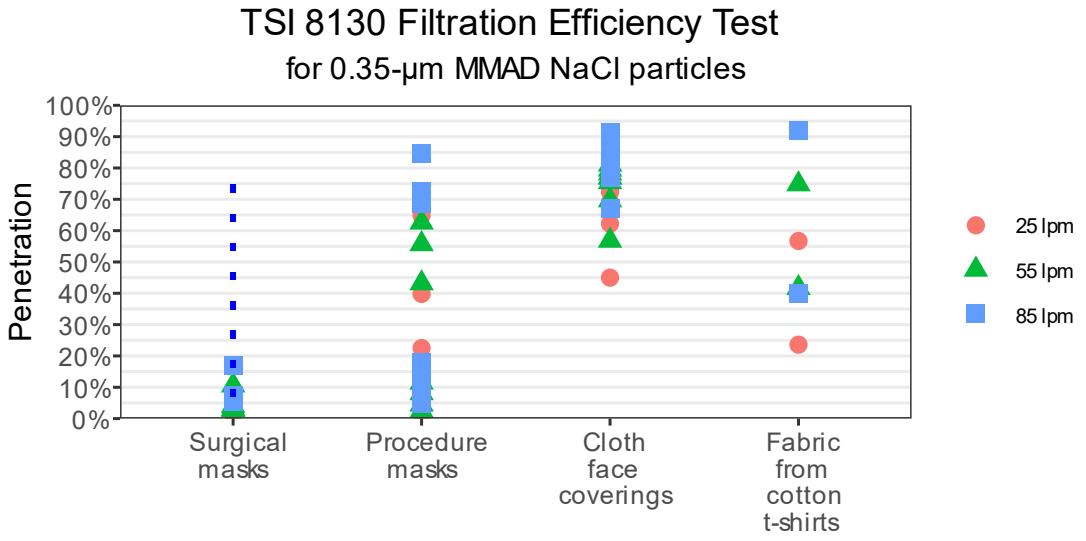


Figure 6. Filtration efficiency of non-FFR protective devices by type, reported as percentage of penetration. The dotted line shows results found by Rengasamy et al. [2009] for surgical masks when fitted over a mannequin. Importantly, when interpreting these findings, note that unregulated devices (procedure masks, cloth face coverings, and fabric from cotton t-shirts) are not expected to efficiently filter submicron particles. The penetration for these devices would be lower as particle size increases. For related descriptive statistics, see Table A3 in the Appendix.

Particle penetration through the surgical mask ranged from 2% to 17%. Procedure masks were most variable and ranged from 1% to 85%. Cloth face coverings ranged from 45% to 91%, and fabric from cotton t-shirts tested ranged from 24% to 92%.

For the two cloth face coverings that had a filter insert, the inserted filter improved performance by 6%, 11%, and 14% at 25 lpm, 55 lpm, and 85 lpm, respectively, in one face covering. In the other face covering, the filter improved performance by 39%, 22%, and 20%, respectively. For the three cloth face coverings with exhalation valves, the outward percent penetration efficiency ranged from 67% to 91%, while for the three cloth face coverings without exhalation valves, the outward percent penetration ranged from 45% to 87%.

DISCUSSION

This study evaluated filtration efficiency of small particles with a 0.35-µm MMAD through FFRs with an exhalation valve. Measurements were obtained with a TSI 8130 filtration efficiency tester by positioning the FFRs in the inward position and also by placing the FFRs in the outward position to reverse the airflow to be the same direction of exhaled breath. NIOSH evaluated three mitigation strategies: covered, taped, and masked-over. Tests were conducted at three flowrates that correspond to low and moderate peak inhalation flowrates: 25, 55, and 85 lpm.

In the inward position, the penetration was less than 5%, which is the target value in the NIOSH Respirator Approval Program tests.

With air flowing out through the exhalation valve, penetration ranged from <1% to 55%. The penetration was mostly dependent upon the FFR model and indicative of models having different exhalation valve designs and materials. Although the functioning of the exhalation valve was not evaluated in this study, NIOSH researchers inferred that the valves on some models may have remained mostly closed; this inference is based on low penetration findings such as measurements of <1% that would not be possible with an open exhalation valve (as demonstrated by model 65059520A in Figure 5). As an explanation, those FFRs whose valves did not open may have been designed to open at higher flowrates. The variability within each FFR model could also be explained by how the exhalation valve opens, with some models consistently opening to the same position and other models having variations with the valve even fluttering in the air currents.

For all models of FFRs, at all flowrates, the best mitigation strategy was to cover the exhalation valve inside the FFR with an ECG pad. With this mitigation, the penetration was below 5% except for one model. Unlike the other FFRs where the tape/ECG pad could make contact with a hard, plastic ring of the valve, the rim of this model was covered with filter media; thereby the adhesive bonded to the fabric and not the plastic, not allowing a complete seal. Securing surgical tape over the exhalation valve inside the FFR performed nearly as well as using the ECG pad.

Covering the FFR with a surgical mask was the least effective mitigation strategy. This may be explained by the principle that contaminants are more easily controlled at their source before they are released, spread, or diluted. A further explanation as to why the covered mitigation strategy was not effective could be that after hitting the exhalation valve, the flow of air travels parallel with the surgical mask covering. A poorly fitting surgical mask with an exhalation valve that protrudes from the FFR provides a clear exhaust channel for the test aerosol.

For the non-FFR protective devices, the surgical mask had the least penetration (2% to 17%); however, the current study methods sealed the mask with beeswax and did not account for fit. When accounting for fit, the outward leakage of submicron particles in surgical masks in a previous NIOSH study was found to be much greater (7% to 76%) [Rengasamy et al. 2009].

Procedure masks showed the greatest range of particle penetration (1% to 85%). This is expected, because the term “procedure mask” may not denote a medical device and would therefore not be regulated by the FDA unless the manufacturer claims the mask to be for medical use. The unregulated barrier face coverings were not expected to perform well with the small particles generated for the filtration efficiency tests [Clase et al. 2020]. However, these study results for unregulated barrier face coverings do not imply that they cannot efficiently filter large particles.

For the six cloth face coverings, the submicron particle penetration ranged from 24% to 92%. For the two types of fabric from cotton t-shirts, submicron particle penetration ranged from 45% to 91%. Although this sample size was small, these penetration percentages for the cloth face coverings and fabric from cotton t-shirts are comparable to the 40% to 90% penetration found by previous NIOSH testing of cloth face coverings and fabrics [Rengasamy et al. 2010]. The results for the six face coverings tested in the current study showed a minimum penetration (24%) that was slightly lower than in the previous NIOSH testing, while the maximum penetration (92%) was nearly the same.

Based on the study results, an important question emerges: Does breathing out through an unmitigated FFR with an exhalation valve provide greater source control than that provided by a

surgical mask? Although penetration depends on which model of FFR with exhalation valve and which model of surgical mask is considered, the maximum particle penetration through the unmitigated FFRs evaluated in this study was 55%, which occurred at 55 lpm, while the maximum penetration for surgical masks was 17% for the filter media and 76% when considering fit [Rengasamy et al. 2009]. Increasing the flowrate did not increase pressure because the airflow through the exhalation valve is finite; the increased pressure at 85 lpm channeled air through the filter media when the exhalation valve approached saturation. This phenomenon could make the contribution towards source control provided by FFRs with an exhalation valve more consistent than that provided by surgical masks, which can have openings on the perimeter of the mask that have more variability in surface area than the opening of an exhalation valve.

This study evaluated the filtration efficiency of FFRs with an exhalation valve to consider their potential for source control. Even without mitigation, every FFR studied here allowed penetration of <55% of the submicron particles, meaning that nearly half of the most penetrating particles were filtered regardless of respirator model. With mitigation measures such as surgical tape or an ECG pad secured inside, the FFRs can perform nearly as well as an FFR with no exhalation valve.

This study, using the most penetrable particle size, indicates that even unmitigated FFRs with an exhalation valve can help to provide some degree of source control. A similar evaluation of PAPR and elastomeric respirator mitigation strategies would be an important continuation of this research, since a surgical mask over the exhalation valve of an elastomeric respirator is a mitigation currently being used by some healthcare institutions to help provide source control.

Limitations

The primary limitation of this study is that only one particle size range was used for all the testing (0.35-µm MMAD with a ≤1.86 GSD). These particles have two routes of escape—through the filter media and through the exhalation valve. For the particles that escape through the filter media, these submicron particles are considered to be the maximum penetrating particle size, and when neutralized these particles are expected to more easily penetrate through the filter media [Eshbaugh et al. 2008]. For those respiratory secretions that escape through the exhalation valve, the larger droplets have more inertial energy and are therefore more likely to impact onto surfaces rather than follow the air currents [Fuchs 1986]. For these reasons, the particles studied here should represent the “worst-case” particle penetration, and larger particle sizes are expected to have less penetration.

Other limitations are as follows:

- The TSI 8130 test requires an airtight seal and does not address FFR fit.
- The study did not account for conditions where an FFR adds outward leakage due to improper fit when comparing these respirators to surgical masks.
- The effect of humidity/wetness, which can cause the exhalation valve to stick, was not evaluated, and this study used machine-generated aerosol that lacks the moisture content
- that would be found in human breath.
- The study did not evaluate the length of time and conditions for adherence of a surgical tape or an ECG pad to the inside of an FFR.

- The TSI 8130 test does not represent particles that are emitted by way of coughing or sneezing.
- The study did not evaluate aerosol concentrations that are typically emitted by humans.
- FFR models and specimen selection were not completely randomized.
- The effects of "use-by" date and "open box" of FFRs listed in Table 1 were not evaluated.
- The study evaluated three flowrates that correspond to moderate worker breathing rates; these were continuous flowrates to represent the instantaneous peak flowrate associated with sinusoidal breathing.
- The 25 lpm flowrate may not have reached equilibrium during the sample time (38 seconds) and this may affect the accuracy and precision of the measurements at this flowrate.
- The conclusions are generalized from the models tested. Researchers assess that 13 models from 10 manufacturers is a good effort to survey the population; however, additional models may exceed the bounds of the models selected for testing.

CONCLUSIONS

Based on a sample size of 13 models, this study found that unmitigated FFRs with an exhalation valve that were tested in an outward position (with particles traveling in the direction of exhalation) have a wide range of penetration, emitting between <1% and 55%. Further testing could measure greater particle penetration.

Even without mitigation, FFRs with exhalation valves can reduce 0.35-µm MMAD particle emissions more consistently than surgical masks, procedure masks, cloth face coverings, or fabric from cotton t-shirts; however, the 0.35-µm MMAD particle emissions are not expected to be lower for every model.

With mitigations that cover the exhalation valve, 0.35-µm MMAD particle emissions can be limited to 5% if the filter media does not interfere with providing a good seal to the exhalation valve. The exhalation valves could be improved by establishing criteria for valve performance. Such criteria may be to maintain a plastic surface that is not obstructed with filter media or to have minimum and maximum outward leakage at given airflow conditions.

Covering an FFR with a surgical mask was not the most effective mitigation strategy evaluated here. The best mitigation strategy evaluated was to cover the exhalation valve inside the FFR with an ECG pad. Securing surgical tape over the exhalation valve inside the FFR performed nearly as well as using the ECG pad. Researchers intentionally selected products with no expected toxicological effects in relation to skin contact, inhalation, and ingestion.

FFRs with an exhalation valve provide respiratory protection to the wearer, and this study demonstrates that they can also reduce 0.35-µm MMAD particle emissions to levels similar to or better than those provided by surgical masks and unregulated barrier face coverings. Based on these study results, modification of FFRs with an exhalation valve can further limit the emission of particles by the wearer, although such modifications should be carefully evaluated to conform to medical protocols and NIOSH Respirator Approval Program standards. During shortages of respiratory protection, FFRs with an exhalation valve provide an additional source of equipment for workers who need respiratory protection and are concerned about source control.

These results represent one of the first measurements of particle penetration through FFRs with an exhalation valve that are tested in an outward position, and the findings have important implications for guidance on source control and mitigation.

For Further Information

For further information on the use of personal protective equipment, please visit NPPTL's "Contact Us" page.

REFERENCES

Alaska Airlines [2020]. Alaska Airlines strengthens face covering policy: No mask, no travel, no exceptions. https://newsroom.alaskaair.com/2020-08-05-Alaska-Airlines-strengthens-face-covering-policy-No-mask-no-travel-no-exceptions

American Airlines [2020]. New face covering guidelines for customer and team member safety: exhaust valves or vents will no longer be allowed on American Airlines. News release. http://s21.q4cdn.com/616071541/files/doc_news/New-Face-Covering-Guidelines-for-Customer-and-Team-Member-Safety-Exhaust-Valves-or-Vents-will-No-Longer-be-Allowed-on-American-Airlin-UKCJM.pdf

ASTM [2019]. ASTM F2100-19e1. Standard specification for performance of materials used in medical face masks. West Conshohocken, PA: ASTM International. https://www.astm.org/Standards/F2100.htm

Augenbraun BJ, Lasner ZD, Mitra D, Prabhu S, Raval S, Sawaoka H, Doyle JM [2020]. Assessment and mitigation of aerosol airborne SARS-CoV-2 transmission in laboratory and office environments, J Occup Environ Hyg *17*(10):447–456. https://oeh.tandfonline.com/doi/full/10.1080/15459624.2020.1805117

CDC [2020a]. Considerations for wearing masks. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Accessed December 12, 2020. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html.

CDC [2020b]. Personal protective equipment: questions and answers. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. Accessed December 12, 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

CFR 42 Part 84. Approval of respiratory protective devices. https://ecfr.io/Title-42/Part-84

Chin AWH, Chu JTS, Perera MRA, Hui KPY, Yen H-L, Chan MCW, Peiris M, Poon LLM [2020]. Stability of SARS-CoV-2 in different environmental conditions. The Lancet Microbe *1*(1):e10. https://doi.org/10.1016/S2666-5247(20)30003-3

Clase CM, Fu EL, Ashur A, Beale RCL, Clase IA, Dolovich MB et al. [2020]. Forgotten technology in the COVID-19 pandemic: filtration properties of cloth and cloth masks—a narrative review. Mayo Clinic Proc *95*(10):2204–2224. https://www.sciencedirect.com/science/article/pii/S0025619620308260

Dau NQ, Peled H, Lau H, Lyou J, Skinner C [2020]. Why N95 should be the standard for all COVID-19 inpatient care. Ann Intern Med. Nov 3. https://www.acpjournals.org/doi/10.7326/M20-2623

Delta Airlines [2020]. Face masks required for everyone's safety. https://www.delta.com/us/en/travel-update-center/ways-we-are-keeping-you-safe/onboard-services#facemask

Department of public health order of the health officer [2020]. Order of the Health Officer of the city and county of San Francisco generally requiring members of the public and workers to wear face coverings. https://www.sfdph.org/dph/alerts/files/Order-C19-12-Face-Coverings.pdf

DHHS [2015]. Hospital respiratory protection program toolkit. U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. DHHS (NIOSH) Publication Number 2015-117. https://www.cdc.gov/niosh/docs/2015-117/default.html

Eninger RM, Honda T, Reponen T, McKay R, Grinshpun SA [2008]. What does respirator certification tell us about filtration of ultrafine particles? J Occup Environ Hyg *5*(5):286–295. doi:10.1080/15459620801960153

Eshbaugh JP, Gardner PD, Richardson AW, Hofacre KC [2008]. N95 and P100 respirator filter efficiency under high constant and cyclic flow. J Occup Environ Hyg *6*(1):52–61. doi: 10.1080/15459620802558196

Fuchs NA [1986]. Methods for determining aerosol concentration. Aer Sci Tech *5*(2):123–143. doi: 10.1080/02786828608959084

Ippolito M, Iozzo P, Gregoretti C, Grasselli G, Cortegiani A [2020]. Facepiece filtering respirators with exhalation valve should not be used in the community to limit SARS-CoV-2 diffusion. Infect Control Hosp Epidem *15*:1–2. https://pubmed.ncbi.nlm.nih.gov/32408923/

Jones [2020]. Why health experts say masks with exhalation valves can do more harm than good. KVUE ABC news. https://www.kvue.com/article/news/health/coronavirus/why-health-experts-say-masks-with-exhalation-valves-can-do-more-harm-than-good/85-804a13cc-7619-41ce-8207-b52698842663

Pallini T [2020]. Most people are wearing N95s incorrectly when they fly. Business Insider. https://www.businessinsider.com/why-you-shouldnt-wear-n95-mask-when-traveling-2020-11

Perrotta F, Matera MG, Cazzola M, Bianco A [2020]. Severe respiratory SARS-CoV2 infection: does ACE2 receptor matter? Resp Med, *168*:105996. https://doi.org/10.1016/j.rmed.2020.105996

Ratnesar-Shumate S, Williams G, Green B, Krause M, Holland B, et al. [2020]. Simulated sunlight rapidly inactivates SARS-CoV-2 on surfaces J Inf Dis *222*(2):214–222. https://doi.org/10.1093/infdis/jiaa274

Rengasamy S, Miller A, Eimer BC, Shaffer RE [2009]. Filtration performance of FDA-cleared surgical masks. J Int Soc Respir Prot *26*(3):54–70. https://www.isrp.com/the-isrp-journal/journal-public-abstracts/1150-vol-26-no-3-2009-pp-54-70-rengasamy-open-access

Rengasamy S, Eimer B, Shaffer RE [2010]. Simple respiratory protection—evaluation of the filtration performance of cloth masks and common fabric materials against 20–1000 nm size particles. Ann Occup Hyg *54*(7):789–798. doi:10.1093/annhyg/meq044

Schröder I [2020]. COVID-19: a risk assessment perspective. ACS Chem Health Saf *27*(3):160–169. doi:10.1021/acs.chas.0c00035

Southwest Airlines [2020] Southwest Airlines further bolsters the Southwest promise with updated face covering policy. https://www.swamedia.com/releases/release-b7be572470a097dea61e12368f05e97d-southwest-airlines-further-bolsters-the-southwest-promise-with-updated-face-covering-policy

Staymates M [2020]. Flow visualization of an N95 respirator with and without an exhalation valve using schlieren imaging and light scattering. Phys of Fluids *32*(11):111703. https://aip.scitation.org/doi/10.1063/5.0031996

Tang JW, Path FRC, Settles GS [2008]. Coughing and aerosols. New Eng J Med *359*(15). https://www.nejm.org/doi/full/10.1056/NEJMicm072576

Verma S, Dhanak M, Frankenfield J [2020]. Visualizing droplet dispersal for face shields and masks with exhalation valves. Phys of Fluids *32*(09). https://doi.org/10.1063/5.0022968

Zhou SS, Lukula S, Chiossone C, Nims RW, Suchmann DB, Ijaz MK [2018]. Assessment of a respiratory face mask for capturing air pollutants and pathogens including human influenza and rhinoviruses. J Thorac Dis *10*(3):2059–2069. http://jtd.amegroups.com/article/view/20136/html

APPENDIX

Table A1. Particle penetration descriptive statistics by mitigation and flowrate among the 13 FFR models

Mitigations	Flowrate	Mean Particle Penetration (%)	Standard Deviation	N	Minimum Mean Penetration Variability Among the 13 Models	Maximum Mean Penetration Variability Among the 13 Models
Outward position	25 lpm	16.03	10.22	75	1.36	27.92
	55 lpm	31.03	14.77	75	5.33	53.16
	85 lpm	31.45	12.05	75	8.43	44.68
Covered	25 lpm	0.83	1.80	75	0.03	6.54
	55 lpm	1.58	2.96	75	0.06	10.73
	85 lpm	1.80	2.82	75	0.11	10.43
Taped	25 lpm	2.98	2.58	75	0.26	9.13
	55 lpm	4.69	4.18	75	0.88	16.25
	85 lpm	4.74	4.03	75	1.10	15.96
Masked-over	25 lpm	11.91	8.00	75	0.85	25.48
	55 lpm	24.21	11.18	75	4.85	40.53
	85 lpm	23.42	8.54	75	7.07	34.74

Table A2. Particle penetration descriptive statistics by model for the outward and inward position controls

Model	Position	N	Mean Particle Penetration	Standard Deviation	p-value difference
2001V	Outward	18	0.26	0.24	<0.001
	Inward	18	24.39	16.93	
2201V	Outward	18	0.06	0.05	<0.001
	Inward	18	8.67	5.96	
2310	Outward	18	0.27	0.14	<0.001
	Inward	18	24.39	6.52	
4030	Outward	12	0.08	0.07	<0.001
	Inward	12	9.56	6.36	
65059520A	Outward	18	1.27	1.17	0.09
	Inward	18	5.14	4.04	
710VOV	Outward	18	0.37	0.31	<0.001
	Inward	18	38.58	9.25	
8511	Outward	18	0.70	0.43	<0.001
	Inward	18	35.75	9.83	
9211	Outward	15	0.23	0.05	<0.001
	Inward	15	40.60	12.98	
9800V	Outward	18	1.95	1.44	<0.001
	Inward	18	31.87	10.35	
ONE-Fit NBW95V	Outward	18	1.53	1.13	<0.001
	Inward	18	34.46	12.62	
S-10479	Outward	18	0.70	0.44	<0.001
	Inward	18	23.60	7.09	
VICSA 2740V	Outward	18	0.56	0.19	<0.001
	Inward	18	31.34	6.52	
X-Plore 1750	Outward	18	0.63	0.78	<0.001
	Inward	18	28.73	6.49	

Table A3. Particle penetration descriptive statistics by flowrate among each of the four non-FFR protective devices

Type	Flowrate	N	Mean Penetration	Standard Deviation	Minimum	Maximum
Surgical mask	25 lpm	4	2.83	1.70	1.50	5.30
	55 lpm	4	5.18	3.66	2.80	10.60
	85 lpm	4	8.98	5.41	5.50	17.00
Procedure mask	25 lpm	7	19.86	24.45	1.00	64.90
	55 lpm	7	26.87	26.00	2.50	62.60
	85 lpm	7	38.40	35.05	4.80	84.80
Cloth face covering	25 lpm	8	69.25	12.20	45.00	84.10
	55 lpm	8	74.36	7.86	56.80	81.10
	85 lpm	8	83.15	7.83	67.10	91.30
Fabric from cotton t-shirts	25 lpm	2	40.15	23.41	23.60	56.70
	55 lpm	2	58.25	23.41	41.70	74.80
	85 lpm	2	65.90	36.77	39.90	91.90

Promoting productive workplaces through safety and health research
DHHS (NIOSH) Publication No. 2021-107
DOI: https://doi.org/10.26616/NIOSHPUB2021107