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REPORT

Total outward leakage of half-mask respirators and surgical masks used for source control

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ABSTRACT

Both respirators and surgical masks (SM) are used as source control devices. During the COVID-19 pandemic, there was much interest in understanding the extent of particle total outward leakage (TOL) from these devices. The objective of this study was to quantify the TOL for five categories of devices: SMs, National Institute for Occupational Safety and Health (NIOSH) Approved N95 filtering facepiece respirators (FFRs) without exhalation valves, NIOSH Approved N95 FFRs with exhalation valves (N95 FFRV), NIOSH Approved elastomeric half-mask respirators (EHMRs) with exhalation valves, and NIOSH Approved EHMRs with an SM covering the exhalation valve (EHMRSM). A benchtop test system was designed to test two models of each device category. Each device was mounted on a headform at three faceseal levels (0% faceseal, 50% faceseal, and 100% faceseal). At each faceseal level, the TOL was assessed at three flow rates of minute ventilations of 17, 28, and 39 L/min. The experimental design was a split-split-plot configuration. Device type, faceseal level, flow rate, and the interaction of device type and faceseal level were found to have a significant effect ($p-$value < 0.05) on the TOL. This study found that the N95 FFRs without exhalation valves had the lowest mean TOL. The SMs had about three times higher TOL than the N95 FFRs without exhalation valves. The TOL of the N95 FFRV was comparable to that of the SM at 0% and 50% faceseal on average overall conditions, but the N95 FFRV had a significantly higher TOL than the SM at a 100% faceseal. The EHMRs had the highest TOL because of the exhalation valve. Using an SM to cover the exhalation valve did not improve the EHMRs' efficiency in mitigating the TOL. Caution should be exercised when using N95 FFRVs as a source control measure against respiratory activities with heavy work rates, such as performing CPR. Results of this study showed that reduced faceseal leakage for N95 FFRs and SMs improves source control.

KEYWORDS

COVID-19; healthcare; N95 filtering facepiece respirator; respirator; respiratory protection

Introduction

The COVID-19 pandemic caused an estimated 88 million infections and 1 million deaths in the United States according to the Centers for Disease Control and Prevention (CDC) (2020a). The virus that causes COVID-19, SARS-CoV-2, can spread by droplet and aerosol transmission (Jayaweera et al. 2020). Source control has been defined to "include removal or reduction of exposure at the source (infected person), such as precluding those who are ill from attendance at social gatherings, equipping ill individuals with facemasks (face-worn products) to block exhaled particles or expelled secretions, administering vaccinations to those who may become sources, and cohorting or isolating symptomatic people in separate locations" (Sietsema et al. 2019). Surgical masks (SM) and respirators are both employed as source control devices. During the COVID-19 pandemic, the CDC recommended that healthcare personnel (HCP) wear respirators, well-fitting facemasks, or well-fitting cloth masks as source control to prevent the spread of respiratory secretions when breathing, talking, sneezing, or coughing (CDC 2020b).

Various studies have evaluated the effectiveness of SM and respirators to reduce airborne exposures. The

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National Institute for Occupational Safety and Health (NIOSH) Approved N95 filtering facepiece respirators (FFRs) were found to have at least 95% filtration efficiency against aerosols of bacteria, NaCl, and polystyrene latex particles in the size range of 0.1 to 0.3 μm (Qian et al. 1998). Harnish et al. (2013) tested the filtration efficiency of five NIOSH-approved N95 FFRs against an H1N1 influenza aerosol under continuous flow conditions and observed >95% filtration efficiency for all models. Lee et al. (2008) evaluated protection factors of N95 FFRs worn by 12 subjects performing an OSHA-accepted fit-testing protocol and observed that protection factors against bacteria and virus aerosols were lowest in the size range of 0.04 to 0.2 µm; furthermore, no significant difference was found in fit factors provided by N95 FFRs equipped with and without an exhalation valve (Lee et al. 2008).

A headform study found that when an aerosol-producing-source headform wore either an SM or N95 FFR as a source control device, aerosol transmission to a receiver headform was reduced by a factor of 170–320 compared to the source headform not wearing any device (Diaz and Smaldone 2010). Another headform study has corroborated these findings and emphasized the critical role of fit of N95 FFRs in providing source control (Mansour and Smaldone 2013). A recent study quantified the outward leakage of an N95 FFR and an ASTM F2100-11 Level 3 surgical mask mounted on a pliable skin headform against an aerosol produced by simulated coughing. The study found that the N95 FFR blocked about 99% of the simulated coughing aerosol while the procedure mask could only block about 59% of the aerosol (Lindsley et al. 2021). Portnoff et al. (2021) performed a laboratory study to evaluate the outward leakage of a submicrometer sodium chloride test aerosol for 13 FFRs equipped with an exhalation valve (FFRV) with FFRVs faceseal peripheries sealed to a test plate. For the first two test conditions, exhalation valves were blocked on the inside of the FFRV either by using surgical tape or an electrocardiogram (ECG) pad. The third test condition was stretching a surgical mask over the exterior of the FFRV and not blocking the valve from the FFRV's interior. Including the control condition of an FFRV with no particle mitigation strategy, a wide range of outward leakage from <1% to 55% was observed. Covering the FFRV with a surgical mask was the least effective mitigation strategy.

The public health crisis caused by the COVID-19 pandemic produced an increase in demand for SMs and respirators by HCP and first responders, which resulted in major supply shortages of N95 FFRs and SMs. As a result, elastomeric respirators, especially elastomeric half-mask respirators (EHMRs), were considered as a potential alternative to disposable N95 FFRs because they are reusable, can be decontaminated, and have good faceseal characteristics (Chiang et al. 2020; Pompeii and Hines 2021). During the COVID-19 pandemic, some NIOSH approval holders obtained approval for EHMRs without an exhalation valve or with filtered exhalation to reduce outward particle leakage (Fernando et al. 2021). Before these advancements, it had been suggested to cover the exhalation valve with an SM to reduce outward leakage through the exhalation valve (Howard 2020). A NIOSH laboratory study was initiated during the COVID-19 pandemic to investigate inspired carbon dioxide levels (CO_2) and exhalation resistance of EHMRs modified by blocking the exhalation valve and removing the inhalation valve membranes (CDC 2022); the study observed that EHMRs with these modifications still met the NIOSH minimum performance requirement for exhalation resistance and that inspired CO_2 levels increased. The report concludes that the modifications may increase user discomfort but are unlikely to cause serious physiological symptoms in healthy users (CDC 2022).

This study compares the outward leakage performance of various SMs and respirators using a breathing manikin system. This study is unique in that the total outward leakage (TOL) (defined as the summation of outward particle leakage through the faceseal, filter, and exhalation valve—if so equipped) of SMs, NIOSH Approved N95 FFRs, NIOSH-approved N95 FFRVs, NIOSH Approved EHMRs with exhalation valve, and NIOSH Approved EHMRs with exhalation valve covered by an SM (EHMRSM) were compared under different conditions of facepiece sealing levels and flow rates using a manikin headform performing cyclic breathing.

Materials and methods

Test system

A schematic diagram of a benchtop test system to quantify TOL is shown in Figure 1. The TOL of the SMs and the NIOSH-approved respirators were evaluated by donning the devices on a hard-surface headform. For testing, the headform was placed in a 0.26-m^3 (0.75 m × 0.59 m × 0.59 m) chamber, denoted as the leakage test chamber, which was connected via a three-way valve to a breathing simulator (Model 1101; Hans Rudolph, Inc., Shawnee, KS) and a second 1.728-m^3 (1.2 m × 1.2 m × 1.2 m) chamber, denoted as

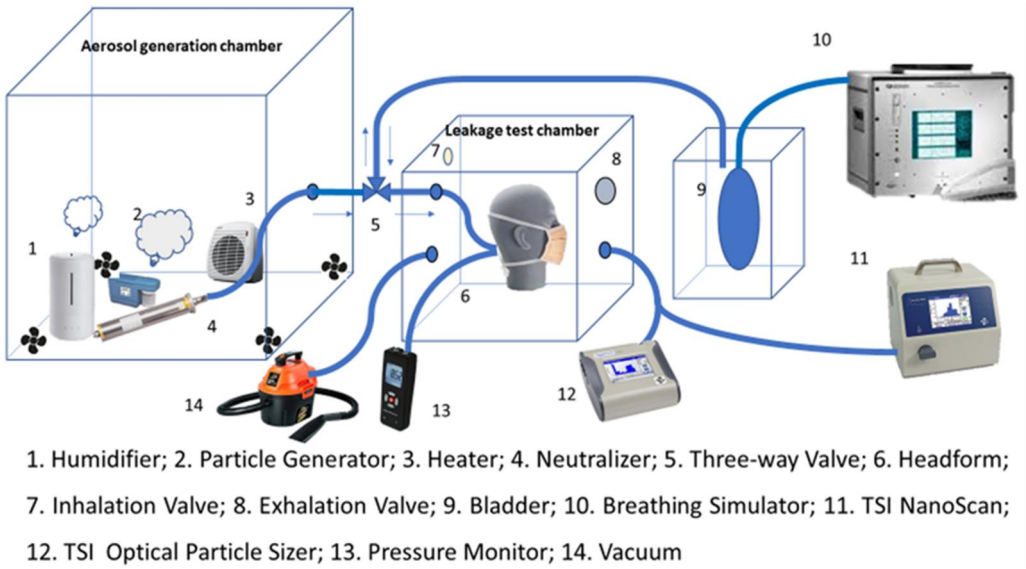


Figure 1. The schematic diagram of the test system.

the aerosol generation chamber. One horizontal port of a three-way valve was connected to the aerosol generation chamber into which the NaCl aerosol was introduced while the other horizontal port was connected to the leakage test chamber into which the headform was placed. The vertical port of the three-way valve was connected to the breathing simulator, which drew the NaCl aerosol from the aerosol generation chamber and exhaled the air through the SMs and respirators mounted on the headform.

A particle generator (Model 8026; TSI, Inc., Shoreview, MN) was used to generate the NaCl test aerosol in the aerosol generation chamber. Four fans were deployed in the aerosol generation chamber to thoroughly mix the aerosols, ensuring their uniform distribution within the chamber. A humidifier and a heater in the aerosol generation chamber were used to maintain the relative humidity (RH) to $60 \pm 2\%$ and a temperature of $32 \pm 2\,^{\circ}C$ to minimize the effects of these parameters on particle size. To minimize the aerosol loss during the transmission from the aerosol generation chamber to the headform's mouth, the length of the connecting tube was made as short as possible. An aerosol neutralizer (Model: 3054; TSI, Inc., Shoreview, MN, USA) was used to bring the NaCl aerosol to Boltzmann charge equilibrium.

During the breathing simulator's inhalation cycle, aerosol was drawn out of the aerosol generation chamber via the three-way valve. During the simulator's exhalation cycle, aerosol was exhaled through the headform wearing an SM or respirator sample. Both the particle concentrations and size distributions inside the cavity of the SM or respirator and in the leakage test chamber were measured using a NanoScan SMPS (Model: 3910, TSI Inc., Shoreview, MN, USA) and an Optical Particle Sizer (Model: 3330, TSI Inc., Shoreview, MN, USA). The combined particle-size range of these instruments is 0.01–10 μm. All of the equipment in the system was calibrated before testing.

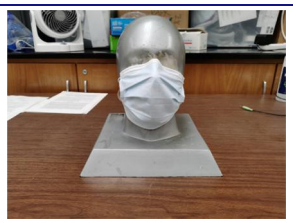
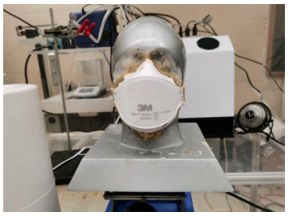
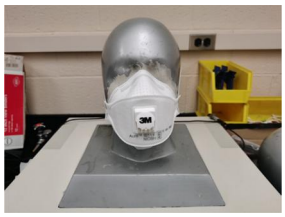
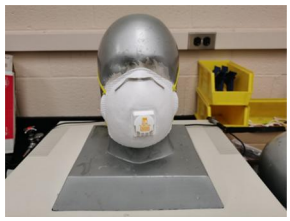
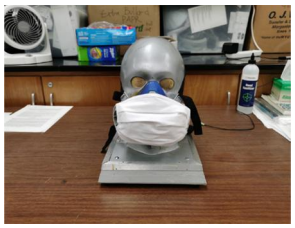
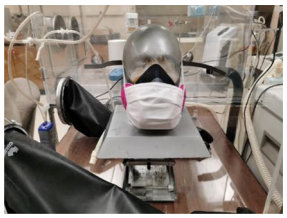
Tested devices

The devices evaluated in this study include two SMs, two NIOSH Approved N95 FFRs without an exhalation valve, two NIOSH Approved N95FFRVs, two NIOSH Approved EHMRs with an exhalation valve, and two NIOSH Approved EHMRs with an exhalation valve covered by an SM. The device models are provided in Table 1.

Faceseal levels for the devices tested

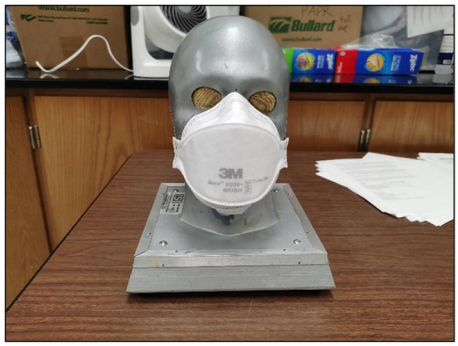
All devices, including SMs and respirators, tested in this study were mounted to a hard-surface headform with different faceseal conditions that simulated faceseal levels to evaluate the impacts of fit on the TOL. Three faceseal conditions were defined as 100% faceseal, 50% faceseal, and 0% faceseal. The 50% and 100% faceseal levels were achieved by sealing the edge of the SMs and respirators to the headform with beeswax. For the 100% faceseal condition, the entire sealing surface of the SMs and respirators was sealed with beeswax. For the 50% faceseal condition, after placing the respirator on the headform, pinching the nose piece, and adjusting to approximate the best fit using personal judgment, one-half of the SMs and respirators sealing surface was left unsealed from the bridge

Table 1. Information on the devices tested.

Type code	Manufacturer	Model	Picture	Manufacturer	Model	Picture
SM	Cardinal Health	–		Aleen	–	
N95 FFR	3M TC-84A-8590	Aura9205		Fangtian TC-84A-7863	N058	
N95 FFRV	3M TC-84A-5669	Aura9211		3M TC-84A-1299	8511	
EHMR	MSA TC-84A-6764	200LS		3M TC-84A-0022	7503	
EHMRSM	MSA + Cardinal Health	200LS		3M + Cardinal Health	7503	

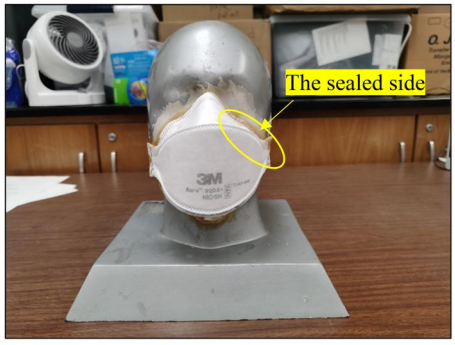
of the nose to the middle of the chin. The 0% faceseal level was achieved by placing the device on the headform, pinching the nose piece, and adjusting to approximate the best fit using personal judgment, then using only the device's straps to keep the sample in place. An example of the three faceseal levels with an N95 FFR mounted on a test headform is shown in Figure 2. Testing of the different faceseal levels was performed on all the devices in the study using this methodology.

The fit factor of each device at each faceseal level was measured by a PortaCount Pro + Respirator Fit Tester (model: 8038, TSI Inc., MN, USA). The "N95-mode" (which limits the reported overall fit factors to a maximum of 200+) was used for the SMs and N95 FFRs. Because the EHMRs were equipped with P100® filters, the "N95-mode" was not used for these devices, and overall fit factors were not limited. For the 100% faceseal level, we set a benchmark for the NIOSH Approved N95 FFR, FFRV, and EHMR to achieve a fit factor of $\geq$100. We did require that the surgical mask achieve a benchmark fit factor level for the 100% faceseal level. For the 50% and 0% faceseal levels, we did not require any device to meet a benchmark fit factor level, but the fit factor was measured to confirm the difference between these two seal levels for each device type.



(a) 0% faceseal

(b) 50% faceseal



(c) 100% faceseal

Figure 2. Example of three faceseal levels of an N95 FFR on the headform.

Breathing pattern and challenge aerosol

A breathing machine was used to provide tidal breathing to the headform. According to "ISO/TS 16976-1; Respiratory protective devices—Human factors—Part 1: Metabolic rates and respiratory flow rates" (ISO 2015), the minute ventilation flow rates V_E (L/min) are calculated by Equation (1):

$$V_E = 31.85 \times \overline{V_{O_2}} \tag{1}$$

where $\overline{V_{O_2}}$ is the oxygen consumption (L/min) and is calculated by Equation (2):

$$\overline{V_{O_2}} = \frac{M \times A_{Du}}{349} \tag{2}$$

where M is the metabolic rate (W/m^2) which is 100, 165, and 230 W/m^2 corresponding to a light, moderate, and heavy work rate, respectively. A_{Du} is Dubois body surface area (m^2) and is calculated by Equation (3):

$$A_{\mathrm{Du}} = 0.202 \times W_b^{0.425} \times H_b^{0.725} \tag{3}$$

where the body weight (W_{b}) and body height (H_b) were calculated from data from 18 HCP from previous studies (Zhu et al. 2019; Williamson 2020). The resulting flow rates calculated using Equations (1)–(3) are 17 L/min (20 BPM × 0.85 L/breath) to mimic a light work rate (e.g., blood pressure measurement, typing nursing notes), 28 L/min (25 BPM × 1.12 L/breath) to mimic a moderate work rate (e.g., pushing computer cart, helping patients sit up), and 39 L/min (30 BPM × 1.30 L/breath) to mimic a heavy work rate (e.g., performing CPR).

The particle size distribution of the NaCl aerosol upstream was continually measured in the cavity of SMs and respirators until it reached a stable concentration level. The challenge particles had an average geometric mean diameter (GMD) of 0.10 μm. This study used the same particle generator throughout the study and controlled the temperature and RH to minimize the particle size variation.

Test procedure

At the beginning of each test, NaCl particles were aerosolized in the aerosol generation chamber and were allowed to reach a stable aerosol concentration level. The headform with the mounted devices was placed in the leakage test chamber. The background particle concentration at the start of each test inside the leakage test chamber was controlled to less than 500 particles/cm^3 by flushing the chamber with HEPA-filtered air between each test. For device testing, the breathing simulator was turned on and set to the target breathing parameters while the three-way valve was opened to allow the NaCl test aerosol to be exhaled through the headform. To perform the TOL measurements, the number concentration of aerosol inside the cavity of the SMs and respirators was measured continuously until it reached a stable aerosol concentration level. Similarly, the number concentration of aerosol outside the headform in the leakage test chamber was also measured in succession until it reached a stable concentration level.

The TOL was calculated by Equation (4):

$$\text{Total outward leakage} = \frac{C_{\mathrm{out}} - C_{\mathrm{bg}}}{C_{\mathrm{in}}} \times 100\% \tag{4}$$

where C_{bg} is the average background concentration of 3 data points inside the leakage test chamber when it reached the stable concentration level, C_{in} is the

average concentration of three samplings inside the cavity of the SMs and respirators during exhalation when it reached the stable concentration level, and C_{out} is the average concentration of three samplings outside the SMs and respirators in the leakage test chamber when it reached the stable concentration level.

Experimental design and statistics

The restriction on randomization of the device type and faceseal was handled by a split-split-plot design in which the device type was considered as whole plots, the faceseals as subplots, and the flow rates as the sub-subplots (Montgomery 2017). A simplified linear statistical model for this split-split-plot design is:

$$y_{ijkl} = \mu + \tau_i + \beta_j + (\tau\beta)_{ij} + \gamma_k + (\beta\gamma)_{jk} + \delta_l + (\beta\delta)_{jl} + (r\delta)_{kl} + (\beta\gamma\delta)_{jkl} + \epsilon_{ijkl} \begin{cases} i = 1, 2 \\ j = 1, 2, 3, 4, 5 \\ k = 1, 2, 3 \\ l = 1, 2, 3 \end{cases} \quad (5)$$

where τ_i represents the error of replicates; $(\tau\beta)_{ij}$ represents the whole plot error; β_j represents the effects of device type; γ_k represents the effects of faceseals; δ_l represents the effects of flow rates; $(\beta\gamma)_{jk}$, $(\beta\delta)_{jl}$, $(r\delta)_{kl}$, and $(\beta\gamma\delta)_{jkl}$ represent the interaction of these three factors, respectively; and ϵ_{ijkl} is the random error.

The dependent variable was TOL, and the independent variables were device type, the level of faceseal, and flow rate. The testing order of three faceseal levels of a specific device was randomized and then at that faceseal level, the testing at three flow rate levels was conducted in random order. All the device types were tested with two replications which were randomly selected. A total of 90 tests (5 types of device $\times$ 2 models $\times$ 3 faceseal levels $\times$ 3 flow rate levels) were completed.

The group data were compared using a three-way ANOVA with the significance level of $\alpha = 0.05$. To analyze the factor with notable effects, the Fischer Least Significant Difference (LSD) test was employed to conduct paired comparisons between each level within the factor. The statistical analysis was conducted using JMP software (Sall et al. 2017). The assumptions of normality, independence, and constant variance for the ANOVA F-test were examined by residuals. Homogeneous variance and normally distributed residuals were examined and were found to be satisfied. All analyses were checked to ensure that the assumptions of the analysis were being met, and all differences were considered significant if the $p-\text{value} < 0.05$.

Results

TOL for different types of devices

Table 2 summarizes the TOL of aerosol exhaled through the different types of devices at three faceseal levels and three flow rate levels.

The ANOVA results in Table 3 show that device type ($p-\text{value} = 0.0022$), faceseal level ($p-\text{value} < 0.0001$), flow rate ($p-\text{value} < 0.0001$), and the interaction of device type and faceseal level ($p-\text{value} = 0.0001$) have a significant effect on the TOL.

An additional paired comparison was conducted using the Fisher LSD Method to evaluate individual mean differences; those results are shown in Table 4. Among the five types of devices tested, the TOL of the EHMR and the EHMR covered by an SM have the highest TOL with an average of 69.6% (95% CI: 58.8%–80.5%) and 67.9% (95% CI: 56.4%–79.5%), respectively. There was no significant difference in

Table 2. The TOL (%) of aerosols exhaled through different types of devices by faceseal and flow rate ($n = 1$).

			Flow rate (L/min)		
Device type	Model	Faceseal	17	28	39
SM	Cardinal Health	100%	7.2%	10.6%	13.9%
		50%	30.7%	31.2%	34.0%
		0%	61.0%	64.6%	61.3%
	Aleen	100%	18.0%	27.9%	26.1%
		50%	43.3%	50.0%	51.0%
		0%	39.6%	45.5%	47.3%
N95 FFR	3M Aura9205	100%	1.4%	1.4%	1.5%
		50%	1.9%	2.3%	2.4%
		0%	5.1%	6.7%	7.8%
	FT N058	100%	0.3%	0.6%	1.1%
		50%	19.8%	21.6%	22.9%
		0%	41.4%	45.4%	45.8%
N95 FFRV	3M Aura9211	100%	31.4%	42.9%	48.6%
		50%	30.7%	51.3%	52.8%
		0%	37.9%	51.1%	55.2%
	3M 8511	100%	26.6%	37.6%	42.2%
		50%	30.2%	51.5%	47.4%
		0%	38.3%	53.8%	62.2%
EHMR	MSA 200LS	100%	53.3%	67.5%	74.6%
		50%	53.3%	72.4%	74.7%
		0%	55.6%	72.2%	74.8%
	3M 7503	100%	56.9%	77.0%	80.2%
		50%	58.9%	83.9%	88.7%
		0%	55.3%	72.8%	81.5%
EHMRSM	MSA 200LS	100%	56.1%	71.8%	75.0%
		50%	58.2%	73.1%	69.0%
		0%	62.4%	70.2%	73.2%
	3M 7503	100%	54.1%	70.2%	79.2%
		50%	56.0%	66.8%	76.7%
		0%	63.6%	73.9%	*

*Data set removed due to data collection error.

Table 3. Analysis of variance for TOL of different types of devices.

Source of variation	SS	DF	MS	*F*	*p*−value
Replicates	0.069	1	0.069	2.5065	0.1885
Device type	3.925	4	0.981	35.458	0.0022*
Whole plot error	0.106	4	0.027	4.157	0.0053*
Faceseal	0.320	2	0.160	25.168	<.0001*
Device type*faceseal	0.286	8	0.036	5.617	0.0001*
Flow rate	0.288	2	0.144	22.658	<.0001*
Device type*flow rate	0.111	8	0.014	2.178	0.0509
Faceseal*flow rate	0.002	4	0.001	0.088	0.9856
Device type*faceseal*flow rate	0.013	16	0.001	0.128	1

The *p*−value marked with "*" means there is a significant difference.
In the "Sources of Variation" column, the "*" is used to indicate interaction of the listed variables.

Table 4. The Fisher LSD comparison results of TOL between different device types

Level	*n*	Mean TOL	Std Error	Lower 95%	Upper 95%
EHMR	18	69.6%^{A}	3.9%	58.8%	80.5%
EHMRSM	17	67.9%^{A}	4.2%	56.4%	79.5%
N95FFRV	18	44.0%^{B}	3.9%	33.1%	54.9%
SM	18	36.8%^{B}	3.9%	25.9%	47.7%
N95FFR	18	12.8%^{C}	3.9%	1.9%	23.6%

Levels not connected by the same letter are significantly different.

TOL between the EHMR with or without the exhalation valve being covered by an SM. The N95 FFRV and the SM had TOL averaging 44.0% (95% CI: 33.1%–54.9%) and 36.8% (95% CI: 25.9%–47.7%), respectively. There was no significant difference between the TOL measured on the N95 FFRV and the SM. The N95 FFR devices had the lowest TOL values among the devices with an average of 12.8% (95% CI: 1.9%–23.6%).

The effect of faceseal level on TOL

The inverse relationship between faceseal level and TOL was expected and was anticipated to hurt TOL. The average TOL with 95% confidence intervals at each faceseal level for each device is given in Table 5. No significant difference in TOL for different faceseal levels was observed between the EHMR with or without the exhalation valve covered by an SM. Faceseal level had a significant effect on the TOL measured on the N95 FFR, N95 FFRV, and SM devices. The SM and N95 FFR devices had significantly different TOL as a function of faceseal level. There was no significant difference in TOL measured on the N95 FFRV device with 0% faceseal level, a mean of 49.7% (95% CI: 43.2%–56.3%), and with 50% faceseal level, a mean of 44.0% (95% CI: 37.4%–50.6%); however, the N95 FFRV TOL with a 100% faceseal level was significantly lower, mean of 38.2% (95% CI: 31.6%–44.8%), as compared to the 0% faceseal level or 50% faceseal level condition. No significant difference was found between TOL measured on the SM and the N95 FFRV for the 0% or 50% faceseal level conditions, while the N95 FFRV had a significantly higher TOL than the SM at the 100% faceseal level.

Table 5. The Fisher LSD comparison results of TOL between different faceseal levels and that between interactions of device type and faceseal levels

Factor	Level	*n*	Mean TOL	Std Error	Lower 95%	Upper 95%
Faceseal	0%	29	53.3%^{A}	1.5%	50.3%	56.4%
	50%	30	46.9%^{B}	1.5%	43.9%	49.8%
	100%	30	38.5%^{C}	1.5%	35.6%	41.4%
Device Type *Faceseal	EHMR-50%	6	72.0%^{A}	3.3%	65.4%	78.6%
	EHMRSM-0%	5	69.5%^{A}	3.8%	61.8%	77.2%
	EHMR-0%	6	68.7%^{A}	3.3%	62.1%	75.3%
	EHMR-100%	6	68.3%^{A}	3.3%	61.7%	74.8%
	EHMRSM-100%	6	67.7%^{A}	3.3%	61.1%	74.3%
	EHMRSM-50%	6	66.6%^{A}	3.3%	60.0%	73.2%
	SM-0%	6	53.2%^{B}	3.3%	46.6%	59.8%
	N95FFRV-0%	6	49.7%^{B}	3.3%	43.2%	56.3%
	N95FFRV-50%	6	44.0%^{BC}	3.3%	37.4%	50.6%
	SM-50%	6	40.0%^{C}	3.3%	33.4%	46.6%
	N95FFRV-100%	6	38.2%^{C}	3.3%	31.6%	44.8%
	N95FFR-0%	6	25.4%^{D}	3.3%	18.8%	32.0%
	SM-100%	6	17.3%^{DE}	3.3%	10.7%	23.9%
	N95FFR-50%	6	11.8%^{E}	3.3%	5.2%	18.4%
	N95FFR-100%	6	1.1%^{F}	3.3%	−5.5%	7.6%

Levels not connected by the same letter are significantly different.
In the "Factor" column, the "*" is used to indicate an interaction of the listed variables.

The effect of flow rate on TOL

The TOL measured across all the test devices, at a 17 L/min flow rate level, had a mean of 38.3% (95% CI: 35.3%–41.2%). At flow rate levels of 28 L/min and 39 L/min, the mean TOL measured across all the test devices was 48.9% (95% CI: 46.0%–51.9%) and 51.5% (95% CI: 48.4%–54.5%), respectively. The mean TOLs measured at flow rate levels of 28 L/min and 39 L/min were not significantly different but were significantly higher than the TOL measured at the 17 L/min flow rate level. Table 6 presents the mean TOL as a function of flow rate and the interaction of device type and flow rate, respectively. The flow rate was not found to have a significant effect on the mean TOL measured on SMs and N95 FFRs; however, flow rate clearly had significant effects on the TOL measured on the N95 FFRV and the EHMR, with or without the exhalation valve covered by an SM. The N95 FFRV had a mean TOL of 48.0% (95% CI: 41.4%–54.6%) at 28 L/min and a mean of 51.4% (95% CI: 44.8%–58.0%) at 39 L/min. These mean TOLs were significantly higher than the TOL mean of 32.5% (95% CI: 25.9%–39.1%) measured at 17 L/min. The mean TOLs measured on the EHMR at 28 L/min and 39 L/min were 74.3% (95% CI: 67.7%–80.9%) and 79.1% (95% CI: 72.5%–85.6%), respectively. These

Table 6. Fisher LSD comparison results of TOL between flow rate levels and that between interactions of device type and flow rate.

Factor	Level (L/min)	*n*	Mean TOL	Std Error	Lower 95%	Upper 95%
Flow rate	39	29	51.5%^{A}	1.5%	48.4%	54.5%
	28	30	48.9%^{A}	1.5%	46.0%	51.9%
	17	30	38.3%^{B}	1.5%	35.3%	41.2%
Device Type *Flow rate	EHMR-39	6	79.1%^{A}	3.3%	72.5%	85.7%
	EHMRSM-39	5	74.5%^{A}	3.8%	66.7%	82.2%
	EHMR-28	6	74.3%^{A}	3.3%	67.7%	80.9%
	EHMRSM-28	6	71.0%^{A}	3.3%	64.4%	77.6%
	EHMRSM-17	6	58.4%^{B}	3.3%	51.8%	65.0%
	EHMR-17	6	55.6%^{BC}	3.3%	49.0%	62.2%
	N95FFRV-39	6	51.4%^{BC}	3.3%	44.8%	58.0%
	N95FFRV-28	6	48.0%^{CD}	3.3%	41.4%	54.6%
	SM-39	6	38.9%^{DE}	3.3%	32.3%	45.5%
	SM-28	6	38.3%^{E}	3.3%	31.7%	44.9%
	SM-17	6	33.3%^{E}	3.3%	26.7%	39.9%
	N95FFRV-17	6	32.5%^{E}	3.3%	25.9%	39.1%
	N95FFR-39	6	13.6%^{F}	3.3%	7.0%	20.2%
	N95FFR-28	6	13.0%^{F}	3.3%	6.4%	19.6%
	N95FFR-17	6	11.7%^{F}	3.3%	5.1%	18.3%

Levels not connected by the same letter are significantly different.
In the "Factor" column, the "*" is used to indicate interaction of the listed variables.

TOLs were not significantly different. Again, the TOLs at 28 L/min and 39 L/min were significantly higher than the mean TOL of 55.6% (95% CI: 49.0%–62.2%) measured at 17 L/min. Even though an SM was used to cover the exhalation valve on the EHMR, it had no significant effect on the TOL for each device. The EHMRSM with the flow rate levels of 28 L/min and 39 L/min had a mean TOL of 71.0% (95% CI: 64.4%–77.6%) and 74.5% (95% CI: 66.7%–82.2%), respectively. These TOL values were significantly higher than the mean TOL of 58.4% (95% CI: 51.8%–65.0%) measured at 17 L/min.

Discussion

This study quantified and compared the TOL performance of different device types used by healthcare personnel. Respirators or well-fitting face-worn products such as procedure and surgical masks act as source control of infectious particles emitted by the wearer when they are breathing, talking, sneezing, or coughing. Outward leakage pathways of these devices can be around the faceseal area, through the filter, and through exhalation valves (if equipped). This study used aerosolized NaCl to quantify TOL of various devices and was the first to achieve this using a cyclically breathing headform test system. The effects of the faceseal level and flow rate on the TOL of these devices were also evaluated.

The device types evaluated were two SMs from different manufacturers, two configurations of N95 FFR equipped with or without an exhalation valve, and two configurations of EHMR with the exhalation valve covered or uncovered by an SM. Among the devices tested, the N95 FFR without an exhalation valve had the lowest TOL, averaging 12.8% overall faceseal levels and flow rate levels used in the study. The SM achieved an overall average TOL of 36.8%. The EHMRs equipped with an exhalation valve with or without an SM covering had higher TOL than the SMs and other respirators. There was no statistical difference between TOL for the EHMR and EHMRSM conditions (Table 4). Intuitively, the higher TOL observed with the valved EHMRs is due to exhaled air flowing through the exhalation valve without being filtered. The test data on the valved respirators also indicate that for all faceseal levels (Table 5), and all flow rate levels (Table 6) the N95 FFRV configurations had significantly lower TOL than the EHMR configurations. Further investigation is needed to understand the reason for the differences in valved respirators.

The N95 FFRV had an average TOL of 44.0% compared to the 12.8% found with the N95 FFR. The average TOL of 38.2% for the N95 FFRVs at 100% faceseal falls within the range of values, <1% to 55%, reported for other N95 FFRVs (Portnoff et al. 2021). The average TOL of 44.0% for the N95 FFRV was not significantly different from the 36.8% TOL measured on the SM. The EHMR had a TOL of 69.6%, which is about six times the TOL observed with the N95 FFR. The TOL of the EHMR was about two times higher than that of the SM.

Device faceseal level was shown to be a critical factor in reducing the TOL of the N95 FFR and SM in this study. The TOLs of 25.4% and 11.8% for the N95 FFR at 0% and 50% faceseal levels, respectively, were reduced to 1.1% at the faceseal level of 100%. SMs are not respirators and do not require fit testing per the OSHA respiratory protection standard (OSHA 1998). Our study showed that improving the faceseal of an SM substantially reduces the TOL. The 100% faceseal level of the SM on the headform reduced the TOL to 17.3%, which is not significantly different from the TOL of N95 FFR at 0% faceseal level. Although the N95 FFRV had a comparable TOL to the SM on average overall conditions, it is worth noting that the SM demonstrated a significantly lower TOL of 17.3% compared to the N95 FFRV, which had a TOL of 32.8%, when both were 100% sealed on the headform. Thus, fit-tested N95 FFRs and well-fitting facemasks can facilitate a reduction in TOL. In a headform study where several device types were evaluated for outward leakage of aerosols, (Lindsley et al. 2021) similarly

observed that the fit of the device is an important factor in reducing outward particle leakage.

Exhalation flow rate was found to have a significant effect on the TOL of both N95 FFRV and EHMR. The TOL observed with the N95 FFRV and EHMR devices increased with increasing flow rate but without a linear pattern. The TOLs at 28 L/min and 39 L/min for both the N95 FFRV and EHMR device types were found to be not significantly different from each flow rate within each device type. However, within each device type, the TOLs at 28 L/min and 39 L/min were both significantly higher than the TOL measured at 17 L/min (Table 6). Portnoff et al. (2021) also made a similar observation testing FFRs with exhalation valves and attributed this to the leakage reaching a maximum through the exhalation valve and the extra flow then flowing through the filtration media. It is worth noting that at the flow rate of 39 L/min, the N95 FFRV had a significantly higher TOL of 51.4% than the SM, which exhibited a TOL of 38.9%. These results suggest that N95 FFRVs may not be suitable for source control during respiratory activities with heavy work rates, such as performing CPR.

Limitations

This study has several limitations. Firstly, it was difficult to randomize faceseal levels due to the time needed to perform the sealing; therefore, once a faceseal level was established, all test conditions were evaluated at that faceseal level. This restriction on randomization for the SM, N95 FFR, and the valved N95 FFR may lead to TOL measurement errors due to aerosol loading of the filter over time (Mahdavi 2013). To evaluate this potential aerosol loading effect, an N95 FFR was 100% sealed on the test headform with beeswax and tested at each flow rate over three repeat measurements. The average TOL increased slightly over the three repeat measurements at three flow rates, but the change was not statistically significant. The authors concluded that under the experimental conditions, aerosol loading would not have a critical effect on our study results.

A second limitation is that the breathing simulator used in the experimental setup was not able to duplicate coughing or sneezing functions, so the TOL occurring during these conditions was not assessed. Another limitation of this study is the restricted testing of respirators and surgical masks SMs at only three faceseal levels of 0%, 50%, and 100% due to constraints in both budget and time. Further studies with more faceseal levels, such as 25% and 75%, could be conducted. An additional limitation is that the close proximity between the headform and outer particle concentration measurement (<1 m) may not represent situations experienced in healthcare settings.

Conclusions

In this study, the TOL of eight NIOSH-approved respirators and two SMs were evaluated on a headform test system exhaling a charge-neutralized NaCl aerosol of the size range of 0.1 μm to 10 μm. The N95 FFR had the lowest TOL among all the devices evaluated in the study. The TOL offered by SMs and the N95 FFRVs were not significantly different at 0% and 50% faceseal levels, but the N95 FFRVs had a significantly higher TOL than the SMs at 100% faceseal level. However, when considering the difference at 100% faceseal, practical use in the workplace must be understood—SMs are not required fit testing by OSHA regulations because they are not expected to have a high level of faceseal; for FFRs, OSHA regulations do require fit testing to specifically ensure that high levels of faceseal are achieved (OSHA 1998). The EHMR had the highest TOL of all the devices and covering the exhalation valve with an SM provided no significant improvement in the reduction of TOL. Although not evaluated in this study, models of NIOSH-approved EHMRs are now available either with filtered exhalation or having no exhalation valve; these models are expected to greatly reduce TOL (Fernando et al. 2021).

This study showed that leakage across the faceseal significantly affects the TOL of N95 FFRs. While this finding is not particularly unexpected, it clearly emphasizes the need for healthcare personnel and first responders to use and be trained on a fit-tested N95 FFR, which will likely minimize TOL during use in the workplace and emergency settings. Even though there is no current requirement to test the fit of SMs, a well-fitting SM fit could substantially reduce the TOL. This study's findings support the recommendation by the CDC for the use of well-fitting respirators and face-worn products as source control with the important stipulation that EHMRs with unfiltered exhalation valves not be used as source control in surgical and other healthcare settings due to concerns that air coming out of the exhalation valve may contaminate the sterile field (CDC 2020c). In the context of respiratory activities with heavy work rates, it is important to exercise caution when using N95 FFRVs as a source control, as they may not be effective.

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Disclosure statement

The authors report this study has no conflicting interests to declare.

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Data availability statement

The data will be available on the NIOSH Data and Statistics Gateway once cleared by NIOSH.

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