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Comparison of Fit for Sealed and Loose-Fitting Surgical Masks and N95 Filtering Facepiece Respirators

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Abstract

Objectives: N95 filtering facepiece respirators (N95 FFRs) and surgical masks are comprised of multiple layers of nonwoven polypropylene. Tight-fitting N95 FFRs are respiratory protective devices (RPDs) designed to efficiently filter aerosols. During the COVID-19 pandemic, health care workers (HCWs) throughout the world continue to face shortages of disposable N95 FFRs. Existing version of widely available FDA cleared loose-fitting surgical masks with straps do not provide reliable protection against aerosols. We tested the faceseal of a modified strapless form-fitting sealed version of surgical mask using quantitative fit testing (QNFT) and compared the performance of this mask with that of N95 FFRs and unmodified loose-fitting surgical masks.

Methods: Twenty HCWs participated in the study (10 women; 10 men; age 23–59 years). To create the sealed surgical masks, we removed the straps from loose-fitting surgical masks, made new folds, and used adhesive medical tape to secure the new design. All participants underwent QNFT with a loose-fitting surgical mask, the sealed surgical mask, and an N95 FFR; fit factors were recorded. Each QNFT was performed using a protocol of four exercises: (i) bending over, (ii) talking, (iii) moving head side to side, and (iv) moving head up and down. When the overall fit factor for the sealed surgical mask or N95 FFR was <100, the participant retook the test. Participants scored the breathability and comfort of the sealed surgical mask and N95 FFR on a visual analog scale (VAS) ranging from 0 (unfavorable) to 10 (favorable).

Results: The median fit factor for the sealed surgical mask (53.8) was significantly higher than that of the loose-fitting surgical mask (3.0) but lower than that of the N95 FFR (177.0) ($P < 0.001$), equating to significantly lower inward leakage of ambient aerosols (measuring 0.04–0.06 μm) with the sealed surgical mask (geometric mean 1.79%; geometric standard deviation 1.45%; range 0.97–4.03%) than with the loose-fitting surgical mask (29.5%; 2.01%; 25–100.0%) but still higher than with the N95 FFR (0.66%; 1.46%; 0.50–1.97%) ($P < 0.001$). Sealed surgical masks led to a marked reduction (range 60–98%) in inward leakage of aerosols in all the participants, compared to loose-fitting surgical masks. Among the exercises, talking had a greater effect on reducing overall fit factor for the sealed surgical mask than for the

What's important about this paper?

Loose-fitting surgical masks allow profound inward leakage of aerosolized particles, mostly due to lack of a face seal. Our study suggests that face seal can be achieved in FDA-cleared loose-fitting surgical masks using simple modifications and adhesives, leading to marked reduction in inward leakage of aerosols, though leakage remain higher than with N95 filtering facepiece respirators. Sealed versions of surgical masks may offer useful levels of respiratory protection during an extreme shortage of N95 filtering face piece respirators.

N95 FFR; when talking was excluded, the fit factor for the sealed surgical mask improved significantly (median 53.8 to 81.5; $P < 0.001$). The sealed surgical mask, when compared with the N95 FFR, offered better reported breathability (median VAS 9 versus 5; $P < 0.001$) and comfort (9 versus 5; $P < 0.001$).
Conclusions: Widely available loose-fitting surgical masks can be easily modified to achieve faceseal with adhesives. Unlike loose-fitting surgical masks, sealed surgical masks can markedly reduce inward leakage of aerosols and may therefore offer useful levels of respiratory protection during an extreme shortage of N95 FFRs and could benefit HCWs who cannot comply with N95 FFRs due to intolerance. However, because a wide range of surgical masks is commercially available, individual evaluation of such masks is highly recommended before sealed versions are used as RPDs.

Keywords: breathability; fit test; inward leakage; N95 filtering facepiece respirator; respiratory protectionsurgical mask

Introduction

The World Health Organization has recommended that surgical masks should be worn by healthcare workers (HCWs) in the same room as a patient with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), whereas devices such as US National Institute for Occupational Safety and Health (NIOSH)–approved filtering facepiece respirators (FFR) with N95 filters (N95 FFRs) are reserved for high-risk settings such as aerosol-generating procedures (World Health Organization, 2020). However, research has shown that rates of respiratory illness among HCWs wearing surgical masks is higher than among those wearing N95 FFRs (MacIntyre *et al.*, 2011; Chu *et al.*, 2020). Of note, some countries and jurisdictions have more stringent requirements than the WHO. For instance, the Centers for Disease Control and Prevention (CDC) in the USA has recommended the use of N95 FFRs when caring for a patient with suspected or confirmed COVID-19, as well as when performing or present for an aerosol-generating procedure (Centers for Disease Control and Prevention, 2020).

Surgical masks cleared by the Food and Drug Administration (FDA) (product code FXX [US Food and Drug Administration, 2019]) are loose-fitting devices that create a physical barrier, blocking droplets`, or splashes that may carry pathogens from a source (a person or surgical field) and preventing spillage of saliva and respiratory secretions from HCWs. The loose-fitting design of these masks allows profound inward leakage along the edges; thus, the FDA does not consider them effective against pathogens within aerosolized particles. As such, users of surgical masks are not required to undergo fit testing, and surgical masks are not part of the written respiratory protection program (RPP) under the Occupational Safety and Health Administration's (OSHA) Respiratory Protection Standard (29 CFR 1910·134) (Occupational Safety and Health Administration, 1998). Additionally, most surgical masks used in many healthcare settings do not undergo FDA clearance or standardized testing. In contrast, FDA-cleared surgical N95 FFRs (product code MSH [US Food and Drug Administration, 2019]) are certified by NIOSH and are included in the RPP. They are expected to form a tight seal around the nose and mouth, eliminating leaks along the edges. HCWs must therefore undergo fit testing before using N95 FFRs.

Penetration of aerosols through a device can occur via two pathways: through the filter medium and through faceseal leakage. The filter medium in sealed N95 FFRs undergo tests in NIOSH laboratory and demonstrate at least 95% particle filtration efficiency (PFE) when charge-neutralized polydisperse sodium chloride is used as a challenge aerosol (count median diameter, 0.075 ± 0.02 μm) at a flow rate of 85 l/min (Rengasamy *et al.*, 2017). The filter medium in surgical masks, in contrast, undergo tests under ASTM

(formerly known as American Society for Testing and Materials) F1215-89 standard and demonstrate PFE of at least 95% when unneutralized 0.1-μm polystyrene latex particles are used as challenge aerosols at a face velocity ranging from 0.5 to 25 cm/s (US Food and Drug Administration, 2004; Rengasamy *et al.*, 2017); however, this does not include the effect of unfiltered air leakage through gaps in the faceseal. It is important to note that ASTM testing standard is not equivalent to NIOSH standard, and the standards are therefore not comparable. In addition, most masks used in healthcare settings are not required to be cleared by FDA and hence do not meet FDA clearance requirements.

Loose-fitting surgical masks with straps allow profound inward leakage through gaps along the mask edges. Research has shown that surgical masks allow 8–12 times more penetration than N95 FFRs, with 86% of this penetration caused by lack of faceseal (Grinshpun *et al.*, 2009). One study using infectious influenza virus—containing aerosols found that a poorly fitted N95 FFR performed similarly to a loose-fitting surgical mask; however, when the surgical mask was sealed over the mouth of the manikin with silicone caulk, the filtration efficiency increased from 56 to 95%, comparable to the minimum efficiency seen with a sealed N95 FFR (Noti *et al.*, 2012). This suggests that eliminating faceseal leakage in high quality surgical masks could substantially increase their aerosol filtration efficiency; however, this cannot be generalized to all surgical masks. Grinshpun *et al.* (2009) suggested that priority in the development of respiratory protection devices should be shifted from improving the efficiency of the filter medium to establishing a better fit that would eliminate or minimize faceseal leakage.

Before the COVID-19 pandemic, the demand for N95 FFRs was low. Manufacturers therefore had limited manufacturing capacity and have since been unable to scale up production quickly enough to meet the worldwide demand. OSHA issued interim enforcement flexibility on 24 April 2020 that includes the use of disposable N95 FFRs beyond their manufacturer's recommended shelf life, extended use and reuse after decontamination (Occupational Safety and Health Administration, 2020). Unlike N95 FFRs, surgical masks remain more readily available. To meet the need for improved respiratory protection during this N95 FFR shortage, we have developed a technique for achieving faceseal by modifying loose-fitting surgical masks with straps into strapless form-fitting sealed surgical masks. The study presented here was conducted to compare the impact of faceseal in these sealed surgical masks with that of loose-fitting surgical masks and N95 FFRs using quantitative fit testing (QNFT). The primary objective was to determine whether the fit factor of a sealed surgical mask is higher than that of a loose-fitting surgical mask and whether the inward leakage of submicron particles measured is comparable to that seen with an N95 FFR. We also evaluated the breathability and comfort of the sealed surgical mask versus those of an N95 FFR and assessed whether particular face measurements affect the overall fit factors.

Methods

Participants

This study was approved by the Institutional Review Board, with all participants providing written informed consent. Twenty HCWs (10 women, 10 men; 3 Asian participants, 1 Black participant, and 16 White participants; mean age, 43.4 years; range, 23–59 years) from the radiology department at a single institution volunteered to participate in this study. The participants included four computed tomography technologists, six magnetic resonance imaging technologists, three nuclear medicine technologists, five ultrasound technologists, one nurse, and one radiology assistant. All participants completed an OSHA respirator medical clearance questionnaire, were medically cleared and previously approved for use of an N95 FFR. Individuals with known intolerance to skin adhesives or with facial hair that could interfere with the faceseal were not included in the study. When donned, the sealed surgical masks extended vertically from just below the sellion to the menton and horizontally to the outer canthi of the eyes (Fig. 1, bottom panels). Hence, the outer canthal distance [OCD] and menton–sellion length [MSL] for each study participant were recorded in this study. Although NIOSH has not established a bivariate panel to conduct tests on surgical masks, the OCD and MSL provide relevant facial dimensions of the participants in this study.

Devices tested

All participants underwent fit testing with a loose-fitting surgical mask with straps, the strapless form-fitting sealed surgical mask, and an N95 FFR. Details about the FDA-cleared loose-fitting surgical mask (Model 15525; Precept, Arden, NC, USA) (Fig. 1, top left panel) and N95 FFR (Model 1860; 3M, St Paul, MN, USA) used in the study are provided in Table 1. To create sealed surgical masks, we removed the straps from another set of loose-fitting surgical masks. New folds were made along the

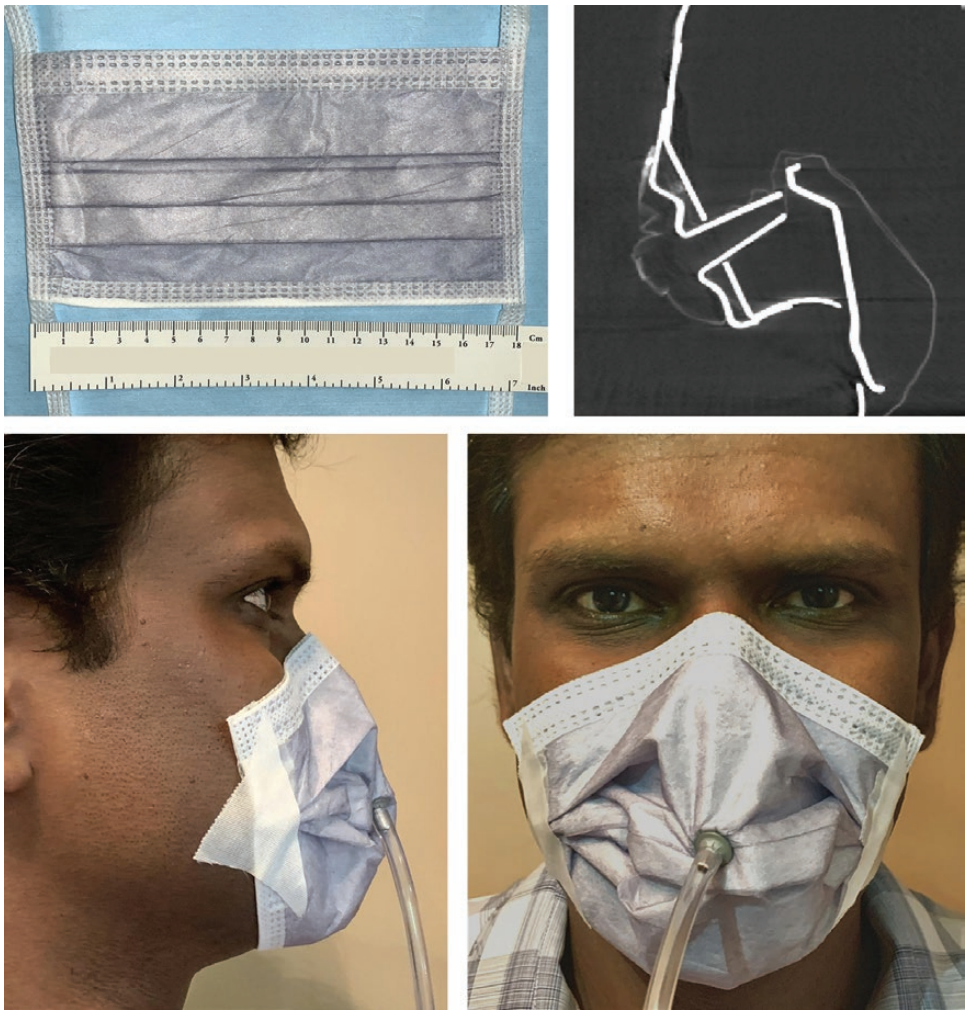

Figure 1. Sealed surgical masks used in this study. Top left panel: photograph of surgical mask used in the study. Top right panel: illustration of sealed surgical mask donned on a manikin using a sagittal reconstruction computed tomography image. Bottom panels: sealed surgical mask with sampling probe and hose during a fit test.

sides of each mask; these folds were secured with single-coated adhesive medical tape (Model 1538; 3M, St Paul, MN, USA). Double-coated adhesive medical tape (Model 5733; Avery Dennison, Glendale, CA, USA) was then fixed along the inner edges, and the side corners were reinforced with a single-coated adhesive medical tape (Model 1538; 3M, St Paul, MN, USA). Participants removed the paper liner covering the adhesives before donning this device and then applied pressure to the edges to achieve faceseal. A sampling probe was attached to each device before fit testing (Fig. 1, bottom panels).

Fit testing

The temperature and humidity of the testing area were recorded. Fit testing was conducted separately for each device. After donning the sealed surgical mask or the N95 FFR, participants completed a 5-min comfort assessment and confirmed a positive pressure user seal check before undergoing fit testing. Fit testing comprised four exercises (bending over, talking, turning head side to side, and turning head up and down) as per the modified ambient aerosol condensation nuclei counter QNFT protocol for FFRs (Occupational Safety and Health Administration, 2019) (trial 1). Based on a prior annual fit test, 10 participants used 3M model 1860 regular N95 FFRs and 10 participants used 3M model 1860S small N95 FFRs for this study. When the overall fit factor for the sealed surgical mask or N95 FFR was <100, the participant performed another user seal check, waited for 3–5 min, and then retook the

Table 1. Surgical mask and N95 FFR used in the study.

	Surgical mask	N95 FFR
Model	15525; Precept, Arden, NC, USA	1860; 3M, St. Paul, MN, USA
Straps	4 ties	2 elastic loop bands
FDA cleared	Yes	Yes
PFE testing standard	ASTM F 1215–89: ≥98% (for 0.1-μm latex particles)	NIOSH: ≥95% (for polydisperse NaCl aerosols; count medium diameter 0.075 ± 0.02 μm)
Shape	Flat and flexible with 3 pleats	Rigid cup
Layers	4: 2 layers of polypropylene filter with inner and outer layers of a cellulose/polyester blend	3: polypropylene/polyester filter with a polypropylene shell and polypropylene coverweb
Differential pressure (ΔP)	<3.3 H_2O/cm^2	~6 mm H_2O/cm^2

test (trial 2). For the N95 FFRs, five participants required a second trial; for the sealed surgical mask, all 20 participants required a second trial. When two fit trials were performed, the mean fit factor of two trials was used for analysis. Because faceseal was not expected with the loose-fitting surgical mask, a second trial was not performed.

The quantitative fit test (QNFT) was conducted using PortaCount Pro+ Respirator Fit Tester 8038 (TSI Incorporated, St Paul, MN, USA) with the built-in N95-Companion enabled. The N95-Companion is an electrostatic classifier that isolates and transports negatively charged 0.04- to 0.06-μm particles to the tester to measure ambient particle concentration outside and inside the device (Fit factor = count [out]/count [in]). Fit factor values up to 200 are then calculated. In our study, values reported as 200+ were rounded to 200 for our calculations.

The overall fit factor for the exercises mandated by OSHA standards was calculated using the harmonic mean of individual exercise fit factors. This is described in the following equation:

$$\text{Overall fit factor} = \frac{\text{Number of exercises}}{(1/ff_1) + (1/ff_2) + (1/ff_3) + (1/ff_4)}$$

where ff_1, ff_2, ff_3, and ff_4 are the fit factors for exercises 1, 2, 3, and 4.

Statistical analysis

The primary objective of this study was to determine whether the fit factor improves when a surgical mask is sealed and whether the inward leakage of a sealed surgical mask is comparable to that of an N95 FFR; the null hypothesis was that they are the same. In order to detect a 25% difference in fit factor between respiratory protection devices, we estimated that 19 subjects were needed for a study with 80% power. Because the fit factors were not normally distributed, nonparametric methods were used. Friedman's test was used to compare fit factors between the three devices and Wilcoxon signed rank test within a device type. A significance level of 0.05 was applied and Holm's method was used for pairwise comparison of devices. The inward leakage (%) was calculated as (1/fit factor) × 100. Two-way ANOVA was used to test for differences in inward leakage.

We had two secondary objectives. First, we sought to assess the breathability and comfort of the sealed surgical mask versus those of an N95 FFR. To this end, participants scored the breathability and comfort of each device on a visual analog scale ranging from 0 (very difficult to breathe; extremely uncomfortable) to 10 (very easy to breathe; very comfortable); Friedman's test was used to compare these results. Second, we sought to determine whether the face triangle area ([OCD × MSL]/2) affects the overall fit factor. Spearman's rank correlation was computed to identify a linear relationship and a regression model for the log scores and a quadratic term for the face triangle area was fit to identify nonlinear relationships.

Role of the funding source

There were no study sponsors. The corresponding author has full access to all of the data in the study and the final responsibility for the decision to submit for publication.

Results

In study participants, the mean MSL was 116.5 mm (range, 79–131 mm), and the mean OCD was 96.3 mm (range, 87–110 mm). The mean face triangle area was

5607 mm² (range, 3990–7150 mm²). During testing, the mean room humidity was 48·3% (range, 44–51%), and the mean room temperature was 22.1°C (range, 20.7–24.1°C).

The sealed surgical mask demonstrated a significantly higher overall fit factor than the loose-fitting surgical mask (median 53.8 versus 3.0) ($P < 0.001$) but a significantly lower overall fit factor than the N95 FFR (median 177.0) ($P < 0.001$) (Table 2). Among the exercises, talking had a greater effect on reducing overall fit factor for the sealed surgical mask than for the N95 FFR; when talking was excluded, the overall fit factor for the sealed surgical mask improved significantly (median 53.8 to 81.5) ($P < 0.001$).

A significant difference in inward leakage of measured aerosols was seen among the mask types, with the sealed surgical mask demonstrating significantly lower inward leakage than the loose-fitting surgical mask [geometric mean (GM) 1.79% versus 29.50%] ($P < 0.001$) and significantly higher inward leakage than the N95 FFR (GM 0.66%) ($P = 0.001$) (Table 3). Sealed surgical masks led to a reduction in inward leakage ranging from 60 to 98%, compared to loose-fitting surgical masks (Fig. 2).

Breathability (median VAS 5.0 versus 9.0) and comfort (5.0 versus 9.0) were significantly higher with sealed surgical masks than with N95 FFRs ($P < 0.001$) (Fig. 3). The breathability score reported by participants on a VAS ranged from 2 to 9 for N95 FFRs and 6 to 10 for sealed surgical masks. Similarly, the comfort score ranged from 1 to 8 for N95 FFRs and 6 to 10 for sealed surgical masks. Among the participants, 19 of 20 reported better breathability and 18 of 20 reported better comfort with sealed surgical masks than with N95 FFRs.

Table 2. Fit factor for N95 FFRs, sealed surgical masks, and loose-fitting surgical masks.

	Type of device			*P**	*P*†	*P*‡
	N95 FFR	Sealed surgical mask	Loose-fitting surgical mask			
Overall harmonic mean fit factor—based on 4 exercises	177.0 [69.0]	53.8 [30.5]	3.0 [3.5]	<0.001	<0.001	<0.001
Fit factor for each exercise						
Bending over	192.5 [54.3]	118.5 [72.8]	3.0 [3.0]	<0.001	<0.001	0.002
Talking	171.5 [90.5]	31.5 [15.0]	4.0 [3.5]	<0.001	<0.001	<0.001
Head side to side	198.5 [74.3]	60.8 [26.3]	3.5 [4.5]	<0.001	<0.001	<0.001
Head up and down	171.5 [54.8]	104.0 [58.3]	3.0 [2.0]	<0.001	<0.001	<0.001
Harmonic mean fit factor—based on 3 exercises (talking excluded)	178.0 [58.5]	81.5 [40.8]	3.0 [4.0]	<0.001	<0.001	<0.001
P#	0.061	<0.001	0.008			

Data are median [IQR].

**P* value from Friedman's test of differences among three devices.

†Adjusted *P* value from Friedman's test of differences between sealed and loose-fitting surgical masks.

‡Adjusted *P* value from Friedman's test of differences between sealed surgical masks and N95 FFRs.

Adjusted *P* value from Wilcoxon signed rank test of differences between harmonic mean fit factor that includes and excludes talking exercise within each device group.

Table 3. Inward leakage of ambient aerosols (ranging from 0.04- to 0.06-μm in size) with N95 FFRs, sealed surgical masks, and loose-fitting surgical masks.

Inward leakage	Type of device			*P**
	N95 FFR	Sealed surgical mask	Loose-fitting surgical mask	
	0.6623 (1.46) {0.3906} [0.5552, 0.7900]	1.7880 (1.45) {0.3861} [1.5017, 2.1288]	29.5002 (2.01) {0.7940} [21.27, 40.92]	<0.001

Data are geometric mean (geometric standard deviation) {coefficient of variation} [95% confidence interval].

**P* value from Friedman's test of differences between any two devices.

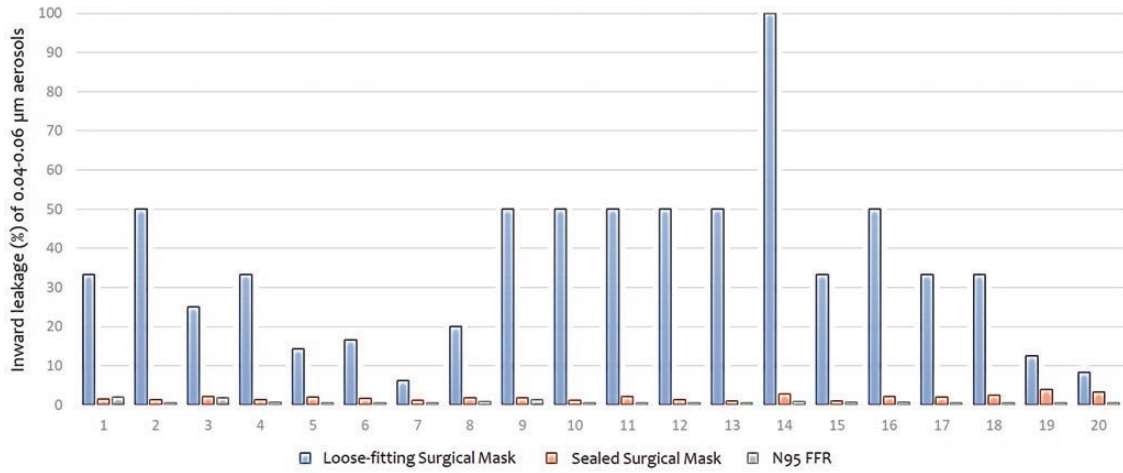

Figure 2. Inward leakage of ambient aerosols (ranging from 0.04- to 0.06-µm in size) estimated from fit factors for each participant. Inward leakage is shown for each participant when wearing a loose-fitting surgical mask, a sealed surgical mask, and an N95 FFR.

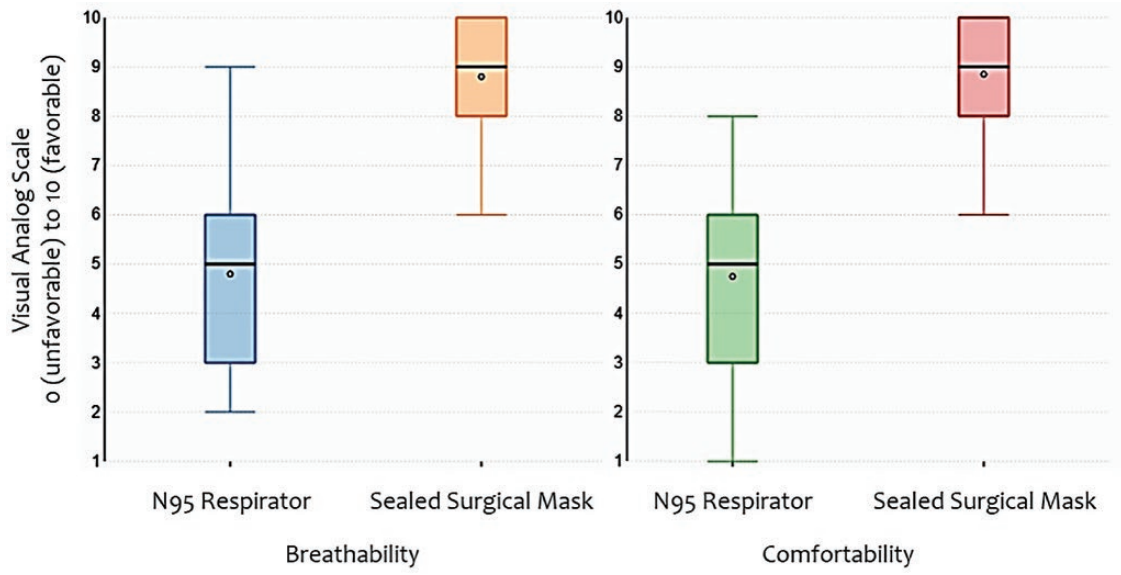

Figure 3. Breathability and comfort assessed using a visual analog scale. Participants rated the breathability and comfort of N95 FFRs and sealed surgical masks using a visual analog scale ranging from 0 (unfavorable) to 10 (favorable).

There was no evidence of an association between face triangle area and the overall fit factor for any of the mask types.

Discussion

In this study, we demonstrated that unlike loose-fitting surgical masks, surgical masks modified to achieve faceseal could substantially reduce inward leakage of aerosols and remain breathable and comfortable while providing reliable and meaningful levels of respiratory protection against submicron aerosols. When compared with loose-fitting surgical masks, inward leakage of aerosols reduced significantly in all participants wearing sealed surgical masks.

To prevent airborne diseases, it is important to understand the size and behavior of the particles that carry pathogens. Exhaled particles range from 0.01 to 1000 µm

in size, depending on the generation mechanism and site of origin (Bake *et al.*, 2019). 'Infectious aerosols' refers to those particles small enough that they remain suspended in air (airborne) for prolonged periods and carry pathogens. Larger particles that travel only short distances and settle down rapidly are referred to as 'droplets'. Some droplets, initially expelled by coughing or sneezing, can rapidly shrink by evaporation, become small droplet nuclei, and behave as aerosols (Centers for Disease Control and Prevention, 2019). SARS-CoV-2 viruses range from ~0.06 to 0.14 µm in size with 0.01-µm spikes (Zhu *et al.*, 2020), whereas influenza viruses range from 0.08 to 0.12 µm (Noda, 2012). Filter media in a device designed to prevent airborne transmission of these viruses should demonstrate high filtration efficiency for those aerosols that can carry them; such a device should also achieve faceseal.

Unlike N95 FFRs (inward leakage measured in our study range, 0.5–1.7%), surgical masks do not provide a predictable level of protection against aerosols. The purpose of a surgical mask is to prevent outward emissions of large particles from the wearer onto a surgical field and to protect the wearer from splashes; the purpose is not to prevent the wearer from inhaling aerosols. As such, loose-fitting surgical masks are neither designed nor expected to achieve the faceseal necessary to prevent inward leakage of aerosols. This is reflected in our study, where the inward leakage with loose-fitting surgical masks was 29.5% (range, 6.25–100%), similar to the penetration (30–40%) reported in a previous study (Grinshpun *et al.*, 2009). However, when these masks were modified to achieve faceseal in our study, the inward leakage reduced significantly (GM 1.79%, range 1.0–4%). This reduction is similar to that reported in a study of infectious influenza aerosols (43% with surgical mask attached using straps versus 5% with surgical mask attached using silicone sealant on a manikin) (Noti *et al.*, 2012) and to the penetration reported when a surgical mask was sealed to a breathing manikin (3–4%) (Rengasamy *et al.*, 2014). Taken together, these results suggest that even high-quality loose-fitting surgical masks (with a manufacturer reported PFE of ≥98% for 0.1 µm particles) create paths for unfiltered air to leak inward along the edges of the mask, whereas a sealed version of the mask forces air to enter only through the filter medium, thus maximizing the filtration. It should be noted, however, that most surgical masks used by HCWs are not tested or cleared by FDA and may have filters that perform with much lower efficiency than the one used in this study. Additionally, even surgical masks with FDA clearance are not predictable in their filter efficiency, as the tests required by FDA are not as stringent as those required by NIOSH.

In our study, the fit factor of sealed surgical masks (53.8) was substantially higher than that of loose-fitting surgical masks (3.0). However, sealed surgical masks such as the one tested in our study are not commercially available and are not approved as respirators. Additionally, an appropriate fit factor has not been defined for these devices, and so the fit factor measured in our study cannot be considered a protection factor. It is important to understand that workplace protection factor, assigned protection factor (APF), and fit factor are not interchangeable. Workplace protection factor is derived by measuring the penetration of aerosols of a wide range of sizes throughout an employee's actual work shift while wearing a respirator. APFs are assigned to respirators by OSHA after the agency conducts a thorough review of the available literature, including chamber-simulation studies and workplace protection factor studies and hears testimony (Occupational Safety and Health Administration, 2006). QNFT, in contrast, is conducted annually and is used to calculate fit factor during simulated workplace exercises before an employee is authorized to use a respirator.

Determining a permissible exposure limit (PEL) for pathogens is not feasible. The health effects of different pathogens on HCWs can vary greatly. N95 FFRs with an APF of 10, based on PEL of hazardous chemicals, are chosen for HCWs, and a safety factor of 10 is used to calculate the desired fit factor of 100 (APF × safety factor). A safety factor is arbitrarily used because the actual protection that employees receive at work sites tends to be much lower than the fit factors achieved during fit testing (Occupational Safety and Health Administration, 2011). Compared to N95 FFRs, a device with a lower APF or fit factor could still provide a reduced but useful level of protection to HCWs during a public health emergency. While APF for sealed surgical masks do not exist and hence, cannot be considered as respirators, our study suggests that such devices could substantially reduce the inward leakage of aerosols and achieve a fit factor that indicates improved faceseal in HCWs than loose-fitting surgical masks. Without a designated APF for sealed surgical masks, however, a desired fit factor cannot be chosen for this device.

In this study, for loose-fitting surgical masks with ASTM level 3 filter media that were not expected to achieve faceseal, the median overall fit factor was 3.0, similar to values reported previously (Lee *et al.*, 2016). With sealed surgical masks, a fit factor of at least 100 was achieved in 51 out of 160 exercises. Although the overall fit factor (for four exercises) was substantially higher with sealed surgical masks (median 53.8), in spite of user-confirmed faceseal, a value of at least

100 was achieved in only one of the 40 trials in our study. However, when the maximum desired overall fit factor was reduced to at least 50 for sealed surgical masks (equivalent to ≤2% inward leakage of 0.01-µm particles expected for this filter media), 75% of users achieved an overall fit factor of at least 50 in at least one of the two trials, and 55% achieved this in both trials. In 37 of 40 trials (92.5%) with sealed surgical masks, an overall fit factor ≥34 was seen (equivalent to <3.0% inward leakage of 0.04- to 0.06-µm particles measured).

The design of facepiece respirators affects the APF assigned by OSHA; the APF is 5 for quarter-mask and 10 for half-mask respirators (Occupational Safety and Health Administration, 1998). Design also affects fit factor. For instance, among flat fold and cup-shaped N95 FFRs available, the latter requires higher seal pressures to achieve high fit factor Niezgoda *et al.*, 2013). Likewise, differences in the design of the sealed surgical mask with pleats and folds and the N95 FFR used in our study likely influenced the differences we observed.

High-quality filter media restrict the free flow of air, resulting in a pressure drop across the media [differential pressure (ΔP)]. For devices that achieve faceseal, this can be perceived as discomfort, resistance to breathing, and increased thermal sensations (Roberge *et al.*, 2012), which can negatively affect compliance. At least 50% compliance with the proper use of N95 FFRs is required before meaningful protection can be received by HCWs (Chen *et al.*, 2017), with wear time of at least 75% (Gosch *et al.*, 2013). However, when continuous use of the device is expected, less than two-thirds of HCWs report compliance, while nearly two-thirds report discomfort (MacIntyre *et al.*, 2013). Additionally, among HCWs using N95 FFRs and managing COVID-19, a high prevalence (97%) of skin injury has been reported (Lan *et al.*, 2020). The sealed surgical masks used in our study are lighter (~6 versus 12 g with a sampling probe) and more flexible than N95 FFRs, with pleats that can be stretched to conform around the nose and mouth of the wearer and form a conical tent that keeps the mask away from the lips (Fig. 1, top right panel). Additionally, these sealed surgical masks do not require elastic straps to maintain faceseal, whereas N95 FFRs require strong elasticity in the straps. These features likely explain why 18 of 20 HCWs in this study reported significantly higher comfort scores with the sealed surgical masks than with the N95 FFRs. In a previous survey of HCWs, two-thirds reported difficulty breathing with N95 FFRs, and 9 out of 10 believed that they would not be able to tolerate wearing the device for 8 hours (Baig *et al.*, 2010). In our study, 40% of participants reported difficulty breathing with N95 FFRs (breathability score ≤4), but everyone reported ease of breathing with sealed surgical masks (breathability score ≥6). Among the participants, 95% reported that breathability was better with the sealed surgical masks. These findings likely reflect the lower differential pressure (ΔP <3.3 versus ~6 mm H_2O/cm^2) in the filter media within the sealed surgical mask. If filter media within the sealed surgical masks are replaced with media from N95 FFRs to achieve similar filtration efficiencies, this could result in higher differential pressure and reduction in breathability scores in such masks. Future research should focus on identifying materials and designs that can achieve high filtration efficiencies while maintaining ease of breathing to ensure compliance among users, especially when these devices have to be donned for long hours.

It is worth noting that N95 FFRs and other similar FFR were primarily designed to protect industrial workers, not HCWs against pathogens. Additionally, type of pathogen and its risk to HCWs varies with time, and the access to protective devices impact morale among HCWs. A new class of respirator specifically designed to protect HCWs against bioaerosols has been proposed (Gosch *et al.*, 2013); however, no such device yet exists, and N95 FFRs remain in short supply during pandemics. While previous research focused on new designs of respirators, and new methods of achieving faceseal, including through the use of adhesive on manikins (Lantos *et al.*, 2009), our work focused on the use of readily available surgical masks and evaluated the benefit when faceseal is achieved in these masks using folds and adhesive medical tape in HCWs. Solutions similar to the one evaluated in this study could therefore offer HCWs protection in the interim.

This feasibility study had several limitations, including its small sample size. Facial measurements of the volunteers in this study may not reflect the measurements of HCWs worldwide, and testing room conditions may not be generalizable to other settings. Results with different models of FDA-cleared surgical masks from the same and different manufacturers may differ from the findings we observed due to the dissimilarities in the composition of the layers between the masks; hence, each model should be subjected to tests to better understand performance. It should also be noted that surgical masks that did not undergo tests under ASTM standards would likely have significantly different inward leakage compared with those that did when challenged with similar aerosols. Thus, results from this study using surgical masks with ASTM level 3 filter media cannot be used to make far-reaching conclusions. Tiny holes in surgical masks have previously been shown to negatively affect filtration

efficiency (Rengasamy *et al.*, 2012, 2014), but we did not assess for damage caused by inserting the sampling probes required to conduct QNFT. Previous research has demonstrated that N95 FFRs do not result in harmful changes in physiological parameters (Roberge *et al.*, 2010, 2013); similar studies are needed to assess the physiological effects of sealed surgical masks on HCWs. The inward leakage of the 0.04- to 0.06-μm particles used to estimate fit factor in this study cannot be assumed to be the same for particles of other sizes (Rengasamy *et al.*, 2009; He *et al.*, 2013). Finally, although none of the participants in this study reported an adverse reaction to the adhesive medical tape used to achieve faceseal, the participants wore the sealed surgical masks for only 13–15 min. Medical adhesive-related skin injury is an often mild but widely reported problem (Farris *et al.*, 2015); thus, prospective studies are needed to evaluate the safety of using adhesives to achieve faceseal.

In this study, we demonstrated that faceseal can be achieved in FDA-cleared disposable surgical masks and that when these masks are donned by HCWs, inward leakage of submicron ambient aerosols is substantially reduced during simulated workplace exercises. Although the filtration performance of these sealed masks is lower than that of N95 FFRs, our results suggest that selected models of surgical masks modified in this fashion can provide significantly improved respiratory protection over loose-fitting surgical masks against aerosols relevant to HCWs, and these masks may therefore offer useful levels of protection during an extreme shortage of disposable N95 FFRs and could benefit HCWs who cannot comply with tight-fitting N95 FFRs due to intolerance. Workplace protection factor studies at healthcare facilities will be required to determine the appropriate APF and the desired fit factor for such masks. Further research is also required to refine the design of these masks, study the durability of the faceseal, and assess user tolerance.

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Conflicts of interest

K.K. has a provisional patent application filed.
N.O. has nothing to disclose.

Data sharing statement

All data relevant to the study are included in the article. Deidentified participant data is available upon reasonable request.

Authors' contributions: K.K. conceived the presented idea, performed literature search, designed, and conducted the study. Data analytical methods were designed by N.O. Analysis and interpretation of data was conducted by N.O. and K.K. Figures and tables were created and reviewed by K.K. and N.O. K.K. drafted and finalized the manuscript. Manuscript was revised by N.O.

Name of the guarantor. K.K.

Transparency declaration

K.K. affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Ethics committee approval

This study was approved by the Institutional Review Board.

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References

Baig AS, Knapp C, Eagan AE *et al.* (2010) Health care workers' views about respirator use and features that should be included in the next generation of respirators. *Am J Infect Control*; **38**: 18–25.

Bake B, Larsson P, Ljungkvist G *et al.* (2019) Exhaled particles and small airways. *Respir Res*; **20**: 8.

Centers for Disease Control and Prevention. (2019) 2007 guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings. Available at https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf. Accessed 3 November 2020.

Centers for Disease Control and Prevention. (2020) Interim infection prevention and control recommendations for healthcare personnel during the coronavirus disease 2019 (COVID-19) pandemic. Available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html. Accessed 3 November 2020.

Chen X, Chughtai AA, MacIntyre CR. (2017) Herd protection effect of N95 respirators in healthcare workers. *J Int Med Res*; **45**: 1760–7.

Chu DK, Akl EA, Duda S *et al*; COVID-19 Systematic Urgent Review Group Effort (SURGE) study authors. (2020) Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. *Lancet*; **395**: 1973–87.

Farris MK, Petty M, Hamilton J *et al*. (2015) Medical adhesive-related skin injury prevalence among adult acute care patients: a single-center observational study. *J Wound Ostomy Continence Nurs*; **42**: 589–98.

Gosch ME, Shaffer RE, Eagan AE *et al*. (2013) B95: a new respirator for health care personnel. *Am J Infect Control*; **41**: 1224–30.

Grinshpun SA, Haruta H, Eninger RM *et al*. (2009) Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: two pathways for particle penetration. *J Occup Environ Hyg*; **6**: 593–603.

He X, Reponen T, McKay RT *et al*. (2013) Effect of particle size on the performance of an N95 filtering facepiece respirator and a surgical mask at various breathing conditions. *Aerosol Sci Technol*; **47**: 1180–87.

Lan J, Song Z, Miao X *et al*. (2020) Skin damage among health care workers managing coronavirus disease-2019. *J Am Acad Dermatol*; **82**: 1215–6.

Lantos G, Vadas P, Grinshpun SA. (2009) A novel design of FFPR's to minimize TIL: results of adhesion technology. In Abstracts of the American Industrial Hygiene Conference and Exposition. Toronto, Canada; #307.

Lee SA, Hwang DC, Li HY *et al*. (2016) Particle size-selective assessment of protection of European standard FFP respirators and surgical masks against particles-tested with human subjects. *J Healthc Eng* **2016**: 8572493.

MacIntyre CR, Wang Q, Cauchemez S *et al*. (2011) A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in health care workers. *Influenza Other Respir Viruses*; **5**: 170–9.

MacIntyre CR, Wang Q, Seale H *et al*. (2013) A randomized clinical trial of three options for N95 respirators and medical masks in health workers. *Am J Respir Crit Care Med*; **187**: 960–6.

Niezgoda G, Kim JH, Roberge RJ *et al*. (2013) Flat fold and cup-shaped N95 filtering facepiece respirator face seal area and pressure determinations: a sterophtogrammetry study. *J Occup Environ Hyg*; **10**: 419–24.

Noda T. (2012) Native morphology of influenza virions. *Front Microbiol*; **2**: 269.

Noti JD, Lindsley WG, Blachere FM *et al*. (2012) Detection of infectious influenza virus in cough aerosols generated in a simulated patient examination room. *Clin Infect Dis*; **54**: 1569–77.

Occupational Safety and Health Administration. (1998) Standard number 1919.134: respiratory protection. Available at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134. Accessed 3 November 2020.

Occupational Safety and Health Administration. (2006) 29 CFR parts 1910, 1915, and 1926: assigned protection factors; final rule. Available at https://www.govinfo.gov/content/pkg/FR-2006-08-24/pdf/06-6942.pdf. Accessed 3 November 2020.

Occupational Safety and Health Administration. (2011) Small entity compliance guide for the respiratory protection standard. Available at https://www.osha.gov/Publications/3384small-entity-for-respiratory-protection-standard-rev.pdf. Accessed 3 November 2020.

Occupational Safety and Health Administration. (2019) Additional ambient aerosol CNC quantitative fit testing protocols: respiratory protection standard. Available at https://www.osha.gov/laws-regs/federalregister/2019-09-26. Accessed 3 November 2020.

Occupational Safety and Health Administration. (2020) Enforcement memos/enforcement guidance on decontamination of filtering facepiece respirators in healthcare during the coronavirus disease 2019 (COVID-19) pandemic. Available at https://www.osha.gov/memos/2020-04-24/enforcement-guidance-decontamination-filtering-facepiece-respirators-healthcare. Accessed 3 November 2020.

Rengasamy S, Eimer BC, Shaffer RE. (2012) Evaluation of the performance of the N95-companion: effects of filter penetration and comparison with other aerosol instruments. *J Occup Environ Hyg*; **9**: 417–26.

Rengasamy S, Eimer BC, Szalajda J. (2014) A quantitative assessment of the total inward leakage of NaCl aerosol representing submicron-size bioaerosol through N95 filtering facepiece respirators and surgical masks. *J Occup Environ Hyg*; **11**: 388–96.

Rengasamy S, Miller A, Eimer BC *et al*. (2009) Filtration performance of FDA-cleared surgical masks. *J Int Soc Res Prot*; **26**: 54–70.

Rengasamy S, Shaffer R, Williams B *et al*. (2017) A comparison of facemask and respirator filtration test methods. *J Occup Environ Hyg*; **14**: 92–103.

Roberge R, Benson S, Kim JH. (2012) Thermal burden of N95 filtering facepiece respirators. *Ann Occup Hyg*; **56**: 808–14.

Roberge RJ, Coca A, Williams WJ *et al*. (2010) Physiological impact of the N95 filtering facepiece respirator on healthcare workers. *Respir Care*; **55**: 569–77.

Roberge RJ, Kim JY, Powell JB *et al*. (2013) Impact of low filter resistances on subjective and physiological responses to filtering facepiece respirators. *PLoS One*; **8**: e84901.

US Food and Drug Administration. (2004) Surgical masks—premarket notification [510(k)] submissions. 8. Filtration

efficiency. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions#8. Accessed 3 November 2020.

US Food and Drug Administration. (2019) Recognized Consensus Standards. ASTM F2100-19: standard specification for performance of materials used in medical face masks. Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=39911. Accessed 3 November 2020.

World Health Organization. (2020) Advice on the use of masks in the context of COVID-19. Available at https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak. Accessed 3 November 2020.

Zhu N, Zhang D, Wang W *et al*; China Novel Coronavirus Investigating and Research Team. (2020) A novel coronavirus from patients with pneumonia in China, 2019. *N Engl J Med*; **382**: 727–33.