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Original Article

How Effective Is the Filtration of 'KN95' Filtering Facepiece Respirators During the COVID-19 Pandemic?

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Abstract

Objectives: The high demand of filtering facepiece respirators (FFRs) worldwide during the period of the COVID-19 pandemic has led to a critical situation for decision-makers regarding their supply. After authorizing the use of FFRs certified by other regions of the world, decision-makers in many countries have published alerts, particularly concerning the 'KN95' type.

Methods: This paper investigated the filtration performance of different FFRs using an experimental setup already employed during several studies on FFRs filtration performance. Its high-resolution measuring devices permit to determine filtration performance according to the normative criteria: the pressure drop and the filtration efficiency. Eight different FFRs have been used: four NIOSH-approved FFRs and four not NIOSH-approved with a 'KN95' shape available during the beginning of the COVID-19 pandemic.

Results: The data show a high disparity between different FFRs purchased by healthcare establishments, and between those that are NIOSH-approved and those that are not NIOSH-approved. The results confirm that the NIOSH certification offers good protection according to the normative criteria. The 'KN95' types present pressure drops which correspond to the normative value, however their efficiencies are lower than the efficiencies of FFRs certified by NIOSH and lower than 95% at the most penetrate particle size.

Conclusions: FFRs marking is not sufficient to conclude on the FFRs' efficiency. Visual inspection can not determine which samples are counterfeit or have manufacturing defects.

Keywords: COVID-19; filtering facepiece respirator; filtration efficiency; respirator certification

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What's important about this paper

 Given the high demand for filtering facepiece respirators during the COVID-19 pandemic, we evaluated the performance of NIOSH-certified 'N95' FFRs and non-NIOSH-certified 'KN95' FFRs. The NIOSH-certified FFRs performed well within the normative criteria, while all four KN95-FFRs did not comply. There was no clear way to identify counterfeit or deficient FFRs through visual inspection.

Introduction

In early June 2020, John Hopkins University counted more than 7 million confirmed cases and more than 400 000 deaths related to COVID-19. In Canada and during this same period, more than 80 000 confirmed cases and almost 8000 deaths associated with COVID-19 have been recorded. World Health Organization (2020) reports that COVID-19 is transmitted by people via three routes: from droplets, by contact and by airborne via aerosol. In Canada (Health Canada, 2020), the wear of medical mask, such as N95 filtering facepiece respirator (FFR) is mainly recommended in healthcare establishments. It should be combined with other essential infection control measures, such as hand hygiene and physical distancing. Medical masks and N95 FFRs, or FFP2 or equivalent, must be reserved for healthcare workers and other medical first responders. As a result of the COVID-19 pandemic, the exponential use of N95 FFRs in healthcare facilities has resulted in a shortage of FFRs' and medical masks' supply (OECD, 2020). In this context, health centers have sought to supply differently, with FFRs certified by other regions of the world, as proposed by government authorities (CDC, 2020a; Health Canada, 2020).

A filtering facepiece (FFR) differs from other air purifying respirators (APRs) by the fact that it is composed only of the filter medium. It is shaped to match as roughly as possible to the shape of the face. Unlike other types of APR, FFRs are disposable. Its filtration performance is characterized by two parameters determined in well-controlled flow rate conditions: its filtration efficiency *E* as well as its pressure drop, Δp .

The FFR pressure drop Δp is defined as the differential pressure between upstream and downstream of the FFR (equation (1)). It characterizes the resistance of the FFR to the airflow. In other words, it represents the FFR's 'breathability'.

$$\Delta p = p_{\text{upstream}} - p_{\text{downstream}} \tag{1}$$

The FFR's filtration efficiency E is given as a function of the concentrations downstream and upstream of the FFR following equation (2), and without taking into account penetration through faceseal leakage:

$$E = 1 - P = 1 - \frac{C_{\text{downstream}}}{C_{\text{upstream}}}$$
(2)

Generally, filter media can come in two forms:

- Filters with nonelectrically charged fibers: The mechanisms involved in filtration are then the Brownian diffusion, the interception, and the inertia (impaction and sedimentation). These mechanisms are associated to the 'mechanical' filtration. The most penetrating particle size (MPPS) is then located around 300 nm (Baron and Willeke, 2001; Brochot *et al.*, 2019).
- Filters with electrostatic charged fibers: These 'electret' filters use an additional filtration mechanism, capture by electrostatic force. In 'electrets', MPPS is less than 100 nm, located between 30 m and 70 nm (Balazy *et al.*, 2006; Huang and Chen, 2007; Rengasamy *et al.*, 2007, 2008; Brochot *et al.*, 2020).

Electrets offer more comfort for users because they offer lower resistance to the airflow. They are therefore generally used for making FFRs. Their filtration performance therefore mainly depends on the aerosols' electrical charge and the fibers' charge. Whether for a mechanical filter or an electret MPPS varies then from one model to another (depending on the physical characteristics of the media) and is highly dependent on operating conditions, such as the type of medium, the particles' shape or the particles' electrical charge (Kim *et al.*, 2006; Boskovic *et al.*, 2008; Buha *et al.*, 2013).

There are several types of FFR certification around the world. In Canada, Health Canada states that equivalent masks approved under other standards are also acceptable, such as KN95 and FFP2 for medical use, if the manufacturer can provide evidence that they have been tested and meet the appropriate standards. A comparison of filtration performance measurements according to USA, European and Chinese certifications seems to indicate that the FFP2 and the KN95 are 'similar', on paper, with the N95.

In the 42 CFR Part 84 certification process (Code of Federal Regulations, 1995), N95 FFRs are tested using charge-neutralized NaCl aerosol, with an 85 l min⁻¹ constant flow rate. The NaCl aerosol test has a count

median diameter of about 0.075 µm and a geometric standard deviation of 1.86. Concentration measurements are collected upstream and downstream with an aerosol photometer or equivalent instruments. The concentration ratio gives the FFR efficiency, and the total initial efficiency cannot be below 95%. This measurement does not take into account leaks located at the interface between the FFR and the face. Pressure drops are measured at an 85 l min⁻¹ inhalation constant flow rate and must not exceed the limit value of 343 Pa (equivalent to 3.43 mbar). The certified FFR must, among other things, mention 'NIOSH' and the approval number associated with its certification.

Two Chinese certifications can currently be used to certify KN95-FFRs. Indeed, the GB2626-2006 standard is being replaced by the GB2626-2019 standard. The transition period started on 31 December 2019 and was scheduled to end on 1 July 2020. However, on 11 June 2020, the Standardization Administration of China issued a notice to extend the implementation date of the new standard. This standard has expanded the certification tests and tightened some criteria. For example, the maximum pressure drop of an FFR KN95 has reduced from 350 Pa (GB2626-2006) to 210 Pa (GB2626-2019) at 85 l min-1 inhalation flow rate. The minimum filter efficiency remains 95% at 85 l min⁻¹ and tested with NaCl. These two certifications provide that the FFRs must be marked by its media level and the standard number, for example 'GB2626-2006 KN95'.

However, during the pandemic period, results from different samples obtained by some laboratories, including our laboratory, showed that some of these FFRs did not meet the requirements for their use. The CDC and Health Canada, among others, then alerted to the counterfeits found on various masks they tested, and recalled the goods after the noncompliance tests (CDC, 2020b; Government of Canada, 2020; HSE, 2020). Tables are thus accessible to check the list of NIOSHapproved N95 respirators. Although these tables have been updated regularly, not all NIOSH-approved N95 are listed. Also, a good counterfeit would not necessary be detected by using this list. It is not possible then, by a simple visual evaluation, to determine which FFRs are counterfeits (intentional or unintentional defects).

During this pandemic period, our laboratory provided filtration performance measurements for more than 150 types of FFRs in order to facilitate decision-making assistance for some Quebec public organization for their choice of employees' protection in the field. The evaluation of FFR was coordinated by the National Institute of Public Health of Quebec (INSPQ). These evaluations were organized into two parts: the 'fit test' evaluation and the performance measurement. INSPQ chose FFRs to send to Concordia University laboratory and decided, according to the results, to use them or not.

The purpose of this paper is then to demonstrate the disparity that exists between the different FFRs that one can currently find during the beginning of this crisis, to discuss about the use of these FFRs, and to alert about the risk entailed using counterfeits or poor quality FFRs. To do so, one will focus on eight different types of FFRs: four are NIOSH-certified FFRs and purchased by the laboratory before the pandemic from large manufacturers specializing on FFRs, and four are not NIOSH-certified FFRs with a KN95 shape and retrieved at the beginning of the pandemic.

Materials and methods

Filtering facepiece respirators

Four NIOSH-certified FFRs were selected in this study. These FFRs were purchased by the laboratory before the pandemic period, as part of a different project. These FFRs come from three different large well-known companies, and their different characteristics are presented in Table 1. All have the required marking on the FFR. In this paper, these four FFRs here will be noted NIOSH-FFRs.

Four other FFRs were chosen for this study to represent FFRs received in the laboratory for testing. These FFRs contain all the characteristics of the majority of FFRs received and they are the most representative of the FFRs available during the crisis. They do not have NIOSH certification. All of these FFRs look like a 'KN95' (Fig. 1): a flat fold FFR with ear loops that are sealed or stapled, with a 'coffee filter' shape and without specific markings on the FFR or with a 'GB2626-2006' marking. The characteristics of these four FFRs are also presented in Table 1. In this paper, these four FFRs here will be noted KN95-FFRs. As presented in the introduction, KN95-certified FFRs must mention their media level and the standard number on masks. It should be noted that KN95-FFR 1 and KN95-FFR 3 do not meet these requirements. Also, none of the FFRs mentions the new GB2626-2019 certification.

Experimental filtration performance test setup

The test bench used during this study (Fig. 2) allows to measure the filtration performance of one FFR as a function of numerous parameters (particle diameter, filtration velocity, relative humidity in the test chamber, time of use). This experimental setup has already resulted in

	FFR description					
	Manufacturer	FFR shape	Adjustable nose clip	Head bands/ear loops		
NIOSH-FFR 1	Manuf. 1	Molded	Yes	Head bands sealed		
NIOSH-FFR 2	Manuf. 1	Flat fold	Yes	Head bands stapled		
NIOSH-FFR 3	Manuf. 2	Molded	No	Head bands stapled		
NIOSH-FFR 4	Manuf. 3	Molded	No	Head bands sealed		
KN95-FFR 1 (nothing written or sealed on the FFR)	_	Flat fold	Yes	Ear loops stapled		
KN95-FFR 2 ('KN95, GB2626-2006' written on the FFR)	_	Flat fold	Yes	Ear loops sealed		
KN95-FFR 3 ('KN95' sealed on the FFR)	_	Flat fold	Yes	Ear loops sealed		
KN95-FFR 4 ('KN95' sealed and 'GB2626-2006' written on the FFR)	—	Flat fold	Yes	Ear loops sealed		

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Figure 1. Representative picture of KN95-FFRs shape used in this study.

several studies already published: Bahloul *et al.* (2014), Mahdavi *et al.* (2014, 2015), and Brochot *et al.* (2015, 2020). During the pandemic it permits to compare samples received with an N95 FFR conventionally used in the laboratory via the measurement of the pressure drop Δp (mbar) and the efficiency *E* (%) of an FFR at initial.

Sodium chloride (NaCl) particles are generated by a 6-jet collison nebulizer (CN 2425, BGI Inc., Waltham, MA, USA) based on a 0.1% (v/v) NaCl solution. The polydispersed aerosol thus generated comprises particles ranging from 20 to 600 nm and centered at around 70 nm, based on the electrical mobility diameter. The generated particles are then brought to Boltzmann equilibrium using a Kr85 neutralization source. NaCl particles are then diluted in a filtered airflow, regulated to a relative humidity below 30% and then sent to the test chamber. The test chamber has been designed to provide a controlled environment: the velocity and the particle concentration are homogeneous over the entire section and stable around the filtering facepiece. The FFR is installed on a plate and sealed with adhesive tape. The constant inhalation flow rate is fixed at the rear of the plate at 85 Liters per min. This flow rate is measured using a TSI 4043 flowmeter (TSI Inc., Shoreview, MN, USA). Two sampling probes (with the same length) allow to collect the aerosol upstream and downstream of the FFR. Pressure drop measurements are obtained using a FLUKE 922 pressure sensor (Fluke Corp., Everett, WA, USA). This instrument has a measuring range of \pm 40 mbar, with a reading accuracy of $\pm 1\%$. These measurements are made using sampling probes. A Scanning Mobility Particle Sizer (SMPS) then allows the particle size distribution measurement of the sample collected by the probes. This collected aerosol is selected according to its electric mobility diameter, by the electrostatic classifier used with a long-Differential Mobility Analyzer (Long-DMA TSI 3082, TSI Inc., Shoreview, MN, USA), and the concentration is measured by a Condensation Particle Counter (CPC TSI 3752, TSI Inc., Shoreview, MN, USA). Efficiency is then obtained via the ratio of average concentrations, expressed in number, downstream, and upstream, as defined in equation (2).

One can note that although this test bench is not one used for certification, it is close to the normative conditions of FFRs certification tests. It differs in some aspects presented here. Unlike normative tests,



Figure 2. Experimental test bench used to measure the FFRs' filtration performance.

the filtration efficiency calculated with this test bench are measurements according to the particle diameter (expressed in electric mobility), and not a total mass measurement efficiency. It shows the difference in FFR efficiency according to the particle size. In addition, the particle counter, which is more sensitive to small particles than the photometer, is more suitable for detecting leaks, specifically for particles smaller than 100 nanometers.

Measurement methodology

Each FFR was tested without conditioning. An adhesive tape is installed on the outline of the FFR to eliminate leaks between the FFR and the support plate. In order to ensure no leaks, the pressure drop is measured during the adjustment of the FFR on the plate. During positioning, the greatest pressure drop measured represents the best position, and it is verified that this pressure drop is then stable. The filtration performance measurements are then obtained according to the following procedure.

After checking the level of NaCl solution in the generator 6-jet collison and setting the flow rate to 85 l min⁻¹, the FFR is installed on the support and the pressure drop is measured using the sampling probes. Using the SMPS, the particle size distributions are then performed downstream (3 scans), then upstream (3 scans) using a mechanical valve. The mean of the two scans downstream and upstream (expressed in particles per cubic centimeter) are used to calculate the filtration efficiency. The curves presented below are the efficiencies with at least 100 particles per cubic centimeter measured downstream. The aerosol generation stability has been verified during the test period. Moreover, the aerosol generation has been compared on the tests (N = 5) and the aerosols variation is less than 15%. The pressure drop is then checked again, as well as the flow rate verification. This pressure drop permits to verify that there are no changes in the FFR position. The FFR is then removed from the plate and another FFR is tested according to the same protocol. The whole test measurement takes about 30 min.

For each type of FFR five (5) samples were tested. The choice to test 5 samples is mainly motivated by the fact that the tests are not certification tests but verification. In addition, the urgency of the situation at the start of the COVID-19 pandemic required a rapid and efficient assessment of the filtration performance of all samples received at the laboratory. The results presented in this paper are then the mean and the standard deviation of the five samples (N = 5).

Results and discussions

The filtration efficiency curves of the four NIOSHcertified FFRs (NIOSH-FFRs) are presented in Fig. 3. The filtration efficiency curves of the four non-NIOSHcertified FFRs (KN95-FFRs) are presented in Fig. 4. Table 2 summarizes the average pressure drops, the



Figure 3. Mean efficiencies (*N* = 5) ± standard deviation for NIOSH-FFRs selected in this study (top left: NIOSH-FFR 1, top right: NIOSH-FFR 2, bottom left: NIOSH-FFR 3, bottom right: NIOSH-FFR 4).

minimum efficiencies and the MPPS for all the FFRs tested in this study.

The results confirm that the NIOSH-FFRs have pressure drops below the standard value and that efficiency (expressed in number) is greater than 96% when the applied flow rate is 85 l min⁻¹. The '*breathability*' of this type of FFR is therefore good due to the use of a medium 'electret' during the manufacture of FFR. One can also observe that the standard deviations (for pressure drops and efficiencies) are very small. In addition, the MPPS is less than 50 nm for the four types of FFR.

On the KN95-FFRs, pressure drops are lower than the maximum value of the standard. One can however observe a great variability in the results, as well as a great dispersion of the measurements for each type (standard deviation), unlike the NIOSH-FFRs values. The average filtration efficiency curves show a lower efficiency for KN95-FFRs compared with NIOSH-FFRs. The results show that the FFRs with marking as required by the GB2626-2006 standard (i.e. KN95-FFP2 and KN95-FFP4) do not guarantee the filtration performance required. The well marked KN95-FFP4 has a filtration efficiency curve lower than the other three KN95-FFRs. Even more, KN95-FFP1 (without marking) presents higher filtration efficiency curve than KN95-FFP3 and KN95-FFP4. One can also observe a great variability in these types of FFR as well as a large measurement dispersion for each type (high standard deviation). This shows that filtration performance will not be the same depending on the sample used, and this protection cannot be guaranteed with this type of FFR. One can also observe that MPPS are larger than 100 nm for



Figure 4. Mean efficiencies (N = 5) ± standard deviation for KN95-FFRs selected in this study (top left: KN95-FFR 1, top right: KN95-FFR 2, bottom left: KN95-FFR 3, bottom right: KN95-FFR 4).

 Table 2. Minimum efficiency and MPPS range comparisons between NIOSH-approved and not NIOSH-approved FFRs selected in this study.

	Pressure drop $(N = 5)$	Minimum efficiency $(N = 5)$	MPPS range	
	(mean ± standard deviation)	(mean ± standard deviation)		
NIOSH-FFR 1	(0.74 ± 0.02) mbar	$(98.16 \pm 0.75)\%$	<50 nm	
NIOSH-FFR 2	(0.61 ± 0.03) mbar	$(98.35 \pm 0.48)\%$	<50 nm	
NIOSH-FFR 3	(1.08 ± 0.03) mbar	$(97.47 \pm 0.74)\%$	<50 nm	
NIOSH-FFR 4	(0.93 ± 0.04) mbar	$(97.29 \pm 0.23)\%$	<50 nm	
KN95-FFR 1	(1.00 ± 0.38) mbar	$(92.50 \pm 3.50)\%$	>150 nm	
KN95-FFR 2	(0.93 ± 0.03) mbar	$(95.06 \pm 1.465)\%$	<50 nm	
KN95-FFR 3	(1.30 ± 0.49) mbar	$(80.90 \pm 245.30)\%$	>150 nm	
KN95-FFR 4	(0.62 ± 0.23) mbar	$(70.33 \pm 24.14)\%$	>150 nm	

three of the four FFRs tested here. These results seem to show that the medium used for the FFR manufacture was not necessarily an 'electret'.

Conclusions and limitations

The purpose of this paper was to show the differences in efficiency between different FFRs. This study showed that the marking on FFRs, whether printed or sealed, does not allow to conclude that the FFR is enough efficient. It is therefore impossible, by a simple visual evaluation, to determine which samples are counterfeit, or which samples contain manufacturing defects, intentional or not. This pandemic period has shown the difficulty of obtaining effective FFRs, although official communications have been made and assistance tools have been put in place. Although, the four KN95-FFRs were selected to best represent all the FFRs received at the laboratory, these cannot represent all the FFRs manufactured during the pandemic period. Also, the results presented in this paper are the whole FFR's filtration performance, but it does not reflect its performance during its use. Faceseal leaks and the FFR's fit during use are not taken into account in these tests. To properly use FFRs, wearers must have information available, perform training and pass a 'fit test'.

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Conflict of interest

The authors do not have any conflict of interest regarding this research. The findings and conclusions in this article are solely those of the authors.

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