

Reuse of Filtering Face Piece Respirator During COVID 19 Pandemic: A Narrative Review

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ABSTRACT

The COVID 19 pandemic has taken the world by a storm. The health care workers, world over, are juggling dual responsibilities of handling the surge of patients in hospitals, while at the same time protecting themselves from getting infected, as availability of personal protective equipment (PPE) is not keeping pace with its requirement. The Filtering Facepiece Respirator (FFR) is one of the most important components of PPE, as the infection mostly spreads via the respiratory route. Due to shortage of FFRs, hitherto considered an article to be discarded after each patient contact, there arises a need to explore the possibility of its extended use and re-use. This review examines the scientific evidence and guidelines available for re-use of FFR.

Keywords: N95, Filtering Face Piece Respirator, Reuse, Mask, COVID19

Abbreviations:

FFR: Filtering Face piece Respirator; PPE: Personal Protective Equipment; SARS-CoV-2: severe acute respiratory syndrome coronavirus 2; HCW: Health Care Worker; CDC: Center for Disease Control and Prevention, USA; TCID: tissue culture infection doses; PFU: plaque-forming units; IQR: Inter-quartile Range

Introduction

The world today is gripped by COVID 19, an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It was identified in Wuhan, China in December 2019 and as of 10th September, 2020, more than 27.7 million cases have been reported across at least 188 countries in the world and has resulted in almost 899,916 deaths. The exact mode of person to person transmission is still being elucidated, but so far it is largely thought to occur via respiratory droplets and fomites. Most secondary infections are described amongst close family contacts and in health care settings where personal protective measures have not been used [1]. Hence, for health care settings, air-borne precautions are universally recommended, of which Personal Protective Equipment (PPE) is an essential component.

In terms of COVID 19, PPE refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and respirators or other equipment designed to protect the wearer from contracting the infection. However, due to the magnitude of world-wide spread and the speed at which this spread has occurred, there had been a global shortage in supply of PPE. Further, waste clearance of disposable components of PPE is another problem because this comes under the category of biomedical hazardous waste. Over the last several months, the world has witnessed an exponential increase in the amount of biomedical waste generation, largely due to disposable components of PPE, which are most ideally to be disposed off by incineration. However, the availability of sufficient incinerators and, hence, the capability to effectively dispose off these may be limited. To tackle these problems of limited availability and safe disposal, several measures have been adopted which include making guidelines for risk based allocation of different components of PPE in different sites and situations of health care and replacing single-use with reusable PPE that is cleaned between uses to reduce the amount of waste.

The most important component of PPE is the filtering facepiece respirator (FFR), commonly known as face mask. FFR, which at one time was considered single use is now being evaluated for extended use, re-use and decontamination so that health care workers can be protected. The purpose of this article is to review the scientific evidence regarding safety and efficacy of reuse of FFR.

Filtering Facepiece Respirator (FFR) recommended to be used in the current SARS-CoV-2 pandemic is N95 mask. It is a disposable half facepiece mask which filters out particles like dust, mists and fumes, large droplets and small particle aerosols. It filters out at least 95% of airborne particles, its performance stems from its ability to remove these contaminants in aerosols in the inhaled air through its filter and by conforming to the shape of the face and maintaining a seal so that air does not leak in through gaps. Most N95 FFRs have a filter made of polypropylene and a shell and coverweb of polyester. Many have an adjustable metallic nose clip made of aluminium which can be pinched to maintain a proper seal. The straps are usually made of thermoplastic elastomer which are polymer chains displaying a spiral pattern. When deformed due to the application of a force, these assume a linear structure with cross-links at some points along their axes and these cross-links help it to achieve its initial structure. Stretching beyond its elastic limit may break the crosslinks causing permanent deformation which will affect the fit and performance of the FFR.

In ideal circumstances, it is recommended that the FFR should be discarded after each patient encounter. An extended use of FFR is allowed when there are repeated encounters with multiple patients suffering from infection with the same pathogen as may occur when such patients are cohorted in a location.

In times of a pandemic, limited re-use of single use respirators without decontamination has been suggested by CDCs National Institute for Occupational Safety and Health (NIOSH) as a strategy to conserve available supplies [2]. The parameters which may be considered for formulating guidelines for reuse of FFRs for a particular situation would be risk of self-contamination to the Health Care Workers (HCW) on re-use, the preservation of the functionality of the FFR which in turn is determined by its filtering capacity and its fit and finally the need for reuse which will be dictated by a demand-supply mismatch.

Risk of self-contamination of HCW on re-use of mask

For SARS-COV2 virus which can easily get transmitted through contact, this risk will depend upon the degree of contamination of the mask, and the duration for which the virus remains viable on the mask. The contamination will presumably be more whenever

the mask is worn at a time when some aerosol generating procedure has been carried out or the mask is soiled with respiratory or nasal secretions, blood or other body fluids from a patient. Needless to say, in such a situation the mask should be discarded.

The survival of various corona viruses on different surfaces has been evaluated in a number of studies, though we could not find any which tested its survival on N95 masks. Lai et al reported that the survival time on paper for SARS CoV virus strain GUV6109 varies with dose of inoculum [3]. An inoculum of 10^4 plaque-forming units (PFU) survives for <5 minutes while an inoculum of 10^6 PFU may survive for upto 24 hours at room temperature [3]. Usually the viral titer in nasopharyngeal aspirate specimens is $10^{2.2}$ tissue culture infection doses (TCID₅₀)/mL [4]. In another study, 10^5 viral titer of the P9 strain of SARS CoV virus survived on paper for 4 to 5 days [5,6]. Doremalen et al conducted an experiment to compare surface stability of SARS CoV 2 with SARS CoV 1 on different surfaces and found that the virus was quite stable on polypropylene; viable virus could be detected up to 72 hours post application though by then the viral titer was greatly reduced (polypropylene from $10^{3.7}$ to $10^{0.6}$ TCID₅₀/mL after 72 hours), quite similar to the stability kinetics of the older virus [7]. Polypropylene is a major component of the filter in most N95 masks.

Chin et al measured the stability and infectivity of the virus at different temperatures and on different surfaces including surgical masks. They found that the virus was highly stable at 4°C with only 0.7 log unit reduction in infectious titre on day 14 when incubated in virus transport medium. However, when temperature was increased to 70°C, time taken for virus inactivation was reduced to 5 mins. At a temperature of 37°C, which is closer to the environmental temperature for Indian summers, the inactivation time was 2 days while at 22°C, it was 14 days. The virus stability on different surfaces was tested at room temperature (22°C) and for the outer surface of surgical masks, a detectable level of the virus was seen even at 7 days, though it was 0.1% of the inoculum [8].

Filtering capacity of the FFR

There have been few simulation studies which evaluate the filtering capacity of an N95 mask on storage or intermittent aerosol exposure. Viscusi et al tested the filtering efficacy of 21 models of unused N95 after storage for a variable period from 6 years up to 10 years and found that most masks retained their filtering efficacy following storage [9]. Another study was done by Moyer et al which showed that when masks are exposed to aerosols intermittently, their performance decreases [10]. Also the dose of aerosol is far less than the recommended testing dose used for certification of these masks. However, the decline occurs slowly over a period of several weeks. So it seems that intermittent use of the FFP for only the initial few weeks may not significantly affect the filtering efficacy of the mask (Table 1).

Author	Testing condition	Testing strategy	Result	Comment
Viscusi(9)	21 models of unused N95 stored at 15 to 32°C, 20 to 80% RH for ≥6 years	Polydisperse NaCl aerosol loading test with 200mg NaCl for 90 to 100 mins	Most N95 FFRs stored for up to 10 years in warehouse and laboratory conditions, will likely maintain their filtration performance following storage	These were new FFRs
Moyer(10)	Intermittent weekly loading of NaCl effect on filter efficiency	5±1 mg NaCl weekly for several weeks	Two of the three filter models showed sodium chloride filter penetrations exceeded 5%, with total loading of approx. 45 and 65 milligrams, far lower than the continuous loading of 200 mg used for certification	Amount of electrostatic filter degradation from aerosol exposure does not just depend only on the amount deposited on the filter, but, also, on the time over which that deposition occurs

Table 1: Studies on FFR Performance: preservation of filtering capacity

Fit of FFR: FFR fit is a major factor which determines its efficacy in protecting the wearer from the infectious agent which might easily leak into a loosely fitted FFR. A recent study found that most of the aerosol contaminants that enter an N95 FFR worn by person are the result of face seal leakage and not low filtration performance [11]. Several researchers have studied fit characteristic for FFRs on repeated donning (Table 2).

Author	Testing condition	Testing strategy	Result	Comment
Bergman(12)	6 N95 FFR models tested, 20 donnings, Assessed fit factor, nose clip breakage and head strap break	Automated Fit testing at 22±2°C, RH 50%±10, Fit factor >100 minimum satisfactory	Fit factor gradually decreases after multiple consecutive donnings Best levels of FF were observed for 5 donnings	FF ≥100 seen in 55-65% tests on 20 th donning
Vuma (13)	4 models of N95, 25 subjects, 6 donnings, Fit factor assessed	Automated Fit tester used. Fit factor >100 minimum satisfactory	After the sixth donning, about 70% of study subjects had satisfactory results with fit factors ≥100. The percentages of failed respirator fit tests increased up to Test 3, but then stabilized at about 30%	Average overall fit test scores gradually deteriorated with successive donning and doffing but did not fall to the unsatisfactory score of <100 (median score after the sixth donning =150)
Roberge (14)	3 models of N95, 5 wear periods of 15 mins with 15 mins break	Electromechanical tensometer used to measure force in Newtons at tethering device	Progressive decline in load generated. Greatest decrement occurred within first 15 mins of use. Total decrement over 5 donnings is less than 1 Newton	It is feasible that the load decrements noted in Donnings 3–5, though statistically significantly different from Donnings 1 and 2, are still sufficient to pass a fit test
Degeysys(15)	2 shapes of N95, dome-shaped (3M 1860) versus duckbill (Kimberly-Clark 46727 or Halyard 46867)	Qualitative fit test using standardized hood and 3M FT-32 bitter testing solution.	38.2% of failed the fit test; 12 of 17 (70.6%) duckbill masks failed, 14 of 51 (27.5%) dome-shaped masks failed. Dome-shaped masks: failure associated with increased donnings/doffings (median, 15 [IQR, 13-18] vs 8 [IQR, 4-12]; P < .001), and increased hours worn (14 [IQR, 10-30] vs 12 [IQR, 6-16]; P = .048)	Limitation was study's cross-sectional design

Table 2: Studies on FFR performance on re-use: fit preservation

Bergman et al studied fit of 6 N95 FFR models over 20 donnings using automated fit testing. They concluded that though Fit Factor progressively declined after multiple donning, an acceptable level was still maintained in a majority of wearers for first 5 donnings [12]. Vuma showed similar conclusions in 25 study subjects using 4 models of N95. At the end of 6th donning, the median fit factor was still acceptable [13]. Roberge studied the force generated at tethering devices during multiple donnings and showed a progressive decline in force which they presumed to be due to some cross-link breakage of elastomers. However, the cumulative decline was one Newton over 6 donnings [14]. Ideally such a simulation study should be combined with one which measures fit as tension in tethering device is not the only determinant of fit.

As can be seen, most of the above studies have been conducted in laboratories, not in clinical environments. Recently, Degeys et al conducted a cross-sectional study to assess N95 fit in health care workers on their clinical shift. They assessed 2 types of N95 masks, dome-shaped and duckbill, during different stages of extended/re-use by using a standardized hood and bitter tasting solution. Duck-bill masks failed the fit test in 70.6% participants, while the dome-shaped masks failed in 27% cases. The median number of donnings/doffings in failures was 15 (IQR 13-18) versus 8 (IQR 4-12, $p < 0.001$) in those who passed the test [15].

Recommendations for reuse of FFR: Centers for Disease Control and Prevention (CDC) has put forth guidance on extended use and limited reuse of N95 FFR for health care settings [2]. The salient features of the document are: Any respirator which is obviously damaged, hard to breathe through, no longer forms an effective seal with face, contaminated with bodily fluids, respiratory secretions or blood, or worn during an aerosol generating procedure should be discarded. Respiratory contamination can be minimized by revised PPE donning and doffing sequence taking care not to contaminate the inner surface, strict hand hygiene, prevention of droplet spray contamination by procedure mask and a face shield over N95 respirator and minimizing unnecessary contact with the respirator. Respirators must not be shared amongst users. They should be stored in an area where they do not touch each other, are not damaged or deformed. It is suggested that they be either hung in a storage area or placed in a breathable container such as a paper bag to avoid microbial propagation which might occur when stored in a plastic bag. Containers should be regularly cleaned or disposed. FFR wearers should perform a user seal check each time they don an FFR. In absence of manufacturers recommendations, reuses should be limited to no more than 5. One suggested strategy is to issue five respirators to each healthcare worker caring for patients with suspected or confirmed COVID-19. The HCW will wear one respirator each day and store it in a breathable paper bag at the end of each shift. The order of FFR use should be mentioned by numbering them on the strap and repeated with a minimum of five days between each FFR use. If supplies are even more constrained and even 5 respirators per HCW are not available, decontamination and reuse has been suggested as a last resort measure. In such cases a qualitative FFR fit performance evaluation using test solutions like saccharin, isoamyl acetate, denatonium benzoate, etc have been suggested. In this the wearer dons the FFR to be re-used, followed by a test hood into which the test agent is released. The wearer performs 7 breathing exercises for 15 seconds each, and if he detects the test agent, the FFR is considered to be compromised [16].

In light of the above evidence, it should be prudent to say that there is still not sufficient data on safety of reuse of N95 FFRs as there are many factors which affect its function and contamination over time and most of the scientific evidence available so far is from simulation studies. However, in times of dire need, such a reuse has been allowed by authorities provided certain precautions are exercised and such reuse should be limited to a maximum of 5 times. Also, the HCWs should get adequate training in donning and doffing of FFRs and in assessing proper fit. There is need to conduct more research in real life situations to assess the risk of infection in HCW reusing FFRs.

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