



HHS Public Access

Author manuscript

Am J Infect Control. Author manuscript; available in PMC 2022 September 22.

Published in final edited form as:

Am J Infect Control. 2021 April ; 49(4): 416–423. doi:10.1016/j.ajic.2021.01.017.

New technique to evaluate decontamination methods for filtering facepiece respirators

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Abstract

Background: A major concern among health care experts is a shortage of N95 filtering facepiece respirators (FFRs) during a pandemic. One option for mitigating an FFR shortage is to decontaminate and reuse the devices. The focus of this study was to develop a new evaluation technique based on 3 major decontamination requirements: (1) inactivating viruses, (2) not altering the respirator properties, and (3) not leaving any toxic by product on the FFR.

Methods: Hydrophilic and hydrophobic FFRs were contaminated with MS2 virus. In the solution-based deposition, the virus-containing liquid droplets were spiked directly onto FFRs, while in the vapor-based and aerosol-based depositions, the viral particles were loaded onto FFRs using a bio-aerosol testing system Ultraviolet germicidal irradiation (UVGI) and moist heat (MH) decontamination methods were used for inactivation of viruses applied to FFRs.

Results: Both UVGI and MH methods inactivated viruses (>5-log reduction of MS2 virus; in 92% of both method experiments, the virus was reduced to levels below the detection limit), did not alter the respirator properties, and did not leave any toxic byproduct on the FFRs.

Conclusions: Both UVGI and MH methods could be considered as promising decontamination candidates for inactivation of viruses for respirator reuse during shortages.

Keywords

N95 respirator; MS2 virus; Disinfection; UVGI; Moist heat; Infection control

Particles containing viruses expelled during human respiratory events, such as coughing, sneezing, talking, and breathing, serve as vehicles for respiratory pathogen transmission.¹ According to the Centers for Disease Control and Prevention, respiratory viruses, such as

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Conflicts of interest: None to report.

influenza, may be transmitted among humans in 3 ways: (1) contact transmission which involves transport of the virus from virus-contaminated hands or objects (eg, fomites) to the mucous membranes (eg, by touching the eye, nose, or mouth); (2) droplet-spray transmission, which occurs when large respiratory droplets containing virus ($>100\ \mu\text{m}$ aerodynamic diameter) are expelled by an infected person, travel a short distance through the air, and deposit immediately onto the mucous membranes of another person; and (3) aerosol transmission (droplet nuclei, generally $5\ \mu\text{m}$) which occurs via inhalation of virus particles.^{1,2} The relative importance of these routes of transmission has not yet been fully characterized and may differ by virus. Some research points to a larger role for droplet nuclei,^{3,4} while other research suggests that droplets are the principal means of transmitting respiratory infections.^{5,6}

Currently, the world has been dealing with the outbreak of a new coronavirus known as Severe Acute Respiratory Syndrome-related (SARS)-CoV-2. The World Health Organization declared a global pandemic on March 11, 2020. Globally, the number of cases and deaths continue to increase daily according to the data from the World Health Organization.⁷ Health care workers and first responders use respirators to protect themselves and to reduce the spread of SARS-CoV-2 and other respiratory viruses associated with inhaling small and large particles from airborne contaminants. Wearing a respirator by an infectious person may also help reducing the spread of airborne transmissible diseases. N95 filtering facepiece respirators (FFRs) are used ubiquitously in health care, especially during previous pandemics or outbreaks, such as the 2003 SARS coronavirus outbreak and during the 2009 H1N1 influenza pandemic. When a respirator is used in a contaminated environment, viruses and bacteria may be deposited on the outer surface and the inner layers of the respirator. Respirators contaminated by infectious aerosol or droplets may serve as fomites. Fomites are inert materials that can aid the dissemination of infectious microorganisms. FFRs are typically discarded after each patient-encounter to prevent contamination and cross-contamination. Like the current FFR shortages being experienced during the COVID-19 pandemic, analogous shortages also occurred during the 2003 SARS outbreak due to increased demand of respirators.⁸ The issue of a respirator shortage during a widespread influenza pandemic was previously addressed by the Institute of Medicine, which released a report entitled 'Reusability of Facemasks during an Influenza Pandemic', which called for research to develop appropriate strategies for handling contaminated FFRs and for FFR reuse during shortages.^{1,9} Reuse of respirators raises the risk of contamination of the wearer or environment by pathogens present on the mask surface or depths of the filter material, unless a decontamination or disinfection process is employed.

Some FFR decontamination methods have previously been published. The studies of Viscusi et al^{10,11} and Bergman et al¹² specifically targeted air flow and filtering effects using vaporized hydrogen peroxide, dry heat, and moist heat (MH) decontamination methods without loading viral particles. The studies of Vo et al¹³ and Heimbuch et al¹⁴ focused on virucidal activity, but none of the studies published so far, have provided evidence for the safe reuse of respirators previously contaminated. A valid FFR decontamination method must contain all 3 major requirements: (1) inactivating viruses on the FFR materials, (2) demonstrating that the technologies applied do not alter the physical and mechanical properties of the FFR, such as respirator shape, filtration efficiency, breathing resistance,

and fit, and (3) not leaving any toxic byproduct on the FFR after its application. The decontamination method must be compatible with the material used in the fabrication of the FFR. For example, FFRs contain a metal noseband that could cause sparking and/or melting if microwave irradiation is used.¹¹ Ultraviolet germicidal irradiation (UVGI) and MH decontamination methods are widely compatible with respirator materials¹⁴ and therefore were selected as decontaminating methods against viruses on FFRs in this study.

The process used to deposit viruses on surfaces may influence the effectiveness of the decontamination methods under evaluation.¹⁵ Recently, several aerosol-based^{6,14} and vapor-based¹⁶ deposition types have been reported to mimic airborne (particles $<10 \mu\text{m}$ aerodynamic diameter) and droplet (particles in a range of 10–100 μm) contamination, respectively. However, there is no standard deposition; no study covers all our 3 major decontamination requirements, and reports comparing decontamination efficacy for viruses applied to FFRs using different depositions, such as liquid droplets, vapor particles, and aerosol droplet nuclei are lacking. The goals of this study were: (1) to develop a new paradigm by which UVGI and MH decontamination methods should be evaluated, based on all 3 major decontamination requirements and (2) to compare the efficacy of the decontamination methods across varying virus loading types: solution-based (large liquid droplets), vapor-based (wet aerosol particles), and aerosol-based (dry aerosol particles or droplet nuclei) depositions.

MATERIALS AND METHODS

MS2 suspension solutions' preparation and respirator selection

Preparation of MS2 virus.—The bacterial strain, *Escherichia coli* (*E. coli*, ATCC 15597) and bacteriophage-MS2 (designated as MS2 virus; ATCC 15597-B1) were obtained from the American Type Culture Collection (ATCC; www.atcc.org). MS2 was selected for the study based on its moderate resistance to disinfectants, survivability, ease of preparation and assay, and nonpathogenicity.¹⁷ A culture medium 271B¹³ was used for growth of *E. coli* and preparation, recovery, assay, and storage of MS2. MS2 coliphages were enumerated using an overlay agar assay method,¹³ and the final MS2 suspension of 10^{11} plaque forming units per milliliter (PFU/mL) was obtained. This suspension was designated as a stock MS2 suspension.

Preparation of suspension solutions.—All MS2 suspension solutions (generator or spiking fluid) were prepared by diluting the stock MS2 suspension into 271B medium to the final suspension concentration of approximately 10^7 PFU/mL and 10^8 PFU/mL for aerosol/vapor-based depositions and solution-based deposition, respectively. These concentrations were chosen to ensure that we could measure the target 4-log reductions for both UV and MH decontamination methods.^{13,14} In the aerosol-based deposition, the virus particles were allowed to dry under testing conditions of low relative humidity and a high percentage of the dry-air solution, thus the virus was in the form of droplet nuclei.

N95 respirator selection.—Two N95 FFR models (N95 sample G and N95 sample N) from 2 manufacturers (Table 1) were selected randomly from previously tested models in our laboratory.¹⁶ These are NIOSH-approved FFRs and are commonly used by health care

workers for protection against particulate hazards. These models have a multilayer structure, and the main layer is composed of polypropylene fibers with electrical charges; however, the N95 sample G has a hydrophilic outer layer, while the N95 sample N has a hydrophobic outer layer.

Assessing the FFR properties against UV and MH decontamination methods

Before performing the UVGI and MH decontamination for inactivation of viruses on FFRs, these decontamination methods were investigated using filter observational analysis and filter performance to determine if the decontaminations would change the FFR properties.

Observational analysis.—Predecontamination and postdecontamination (without exposure to any virus) FFRs were carefully inspected for any visible sign of degradation in the texture (softness, coarseness, roughness, visible changes of strap, etc.).

Filter performance.—A Model 8130 Automated Filter Tester (TSI, Inc., St Paul, MN) equipped with an 8118 motorized sodium chloride generator was used to evaluate the FFR performance (filter aerosol penetration and airflow resistance) for all predecontamination and postdecontamination FFRs. All tests were conducted at ambient conditions with a continuous airflow of 85 L/min in accordance with NIOSH certification test procedures¹⁸ which meet the criteria established in 42 CFR 84 for challenging N-series.

Assessing the efficacy of the UVGI and MH decontamination methods Loading viruses onto FFRs

Solution-based deposition: Large liquid droplets (1 μ L/droplet) of the 1×10^8 PFU/mL MS2 suspension were spiked directly to the FFR surface using a micro-pipette (1- μ L droplet corresponds to a diameter of approximately 1 mm). The solution-based deposition was intended to simulate loading associated with a sneeze. The droplets were applied in 3 rows of 3 droplets across the square (2 cm x 2 cm) section of the FFR with the spacing of 4 mm between droplets. A total of 9 droplets in each square section represents 2.25×10^5 PFU/cm². The spiking was conducted inside an exposure chamber at ambient conditions. Once the spiking onto the FFR was completed, the contaminated FFR was immediately decontaminated.

Vapor-based deposition: The bio-aerosol respirator testing system (BARTS-II) previously developed in our laboratory¹⁶ was used to generate vapor particles containing MS2 at a temperature of 25 °C and a relative humidity (RH) of 90%. The vapor-based deposition was intended to simulate loading associated with wet aerosol particles that contribute to transmission in close proximity, retaining original particle size without significant evaporation. MS2 vapor particles were loaded onto FFRs using a breathing simulator at a cyclic-flow waveform of 30 L/min (1.2 L/stroke x 25 strokes/min) for 22 minutes as previously described by Vo et al.¹⁶ With the average area of each FFR being tested ~ 148 cm² (excluding the area sealed by silicone to the face of the head form), the theoretical MS2 loading level was calculated according to the method of Vo et al¹⁶ and found to be 2×10^5 PFU/cm² (0.2 mL/min of 1×10^7 PFU/mL MS2 suspension leaving

nebulizer and 22-minutes loading time). Once the vapor-based loading was completed, the contaminated FFR was immediately decontaminated.

Aerosol-based deposition: The BARTS-II was also used to generate MS2 aerosol particles (droplet nuclei; particle sizes $<10 \mu\text{m}$ aerodynamic diameter) at the desired temperature of 23 °C and 35% RH. MS2 droplet nuclei were loaded onto FFRs using a breathing simulator for 22 minutes with the viral loading level of $2 \times 10^5 \text{ PFU/cm}^2$, using the same procedure as described in the vapor-based deposition type. The aerosol-based deposition was intended to simulate loading associated with dry aerosol particles. Once the aerosol-based loading was completed, the contaminated FFR was immediately decontaminated.

Assessing the efficacy of the UVGI decontamination method

UVGI decontamination procedure: For the UVGI decontamination experiment, the UV light was applied right after loading MS2 virus on the FFRs. The contaminated FFRs were irradiated with a 40W UV-C lamp inside a biological safety cabinet (Model SG403A; Baker Company, Sanford, ME; Fig 1) with a wavelength peak at 254 nm. The UV intensity on the sample surface was measured using an UVX-25 Digital Radiometer (Model E28457; Cole-Parmer, Vernon Hills, IL). The contaminated FFRs were irradiated for 5 minutes at different UV intensities (generated by changing the distance of the FFR surface [$\sim 1 \text{ cm}$ from the top of FFR where sample coupons were used for viral assay analysis] to the UV-lamp; Table 2). The applied UV doses (mj/cm^2) were calculated as a product of average UV intensity (mW/cm^2) at the respirator sample and the irradiation time (s). For these experiments, the UVGI decontamination was only applied to the viral-contaminated side of the FFR. To ensure that the temperature and RH did not adversely affect UVGI decontamination efficacy, all UVGI decontamination experiments were carried out at $25 \pm 1 \text{ }^\circ\text{C}$ and $50 \pm 3\%$ RH. UV-decontaminated and control (no UVGI decontamination) FFRs were cut into square shaped (2 cm x 2 cm) coupons (5 coupons were cut from top, center, bottom, left, and right areas of each FFR) and each coupon was then placed in 10 mL of 271B medium in a 50-mL conical tube for the viral recovery process.

Virus recovery and UVGI decontamination efficacy: MS2 from these coupons was extracted by agitating them with a vortex mixer set on high for 2 minutes. The coupons were then discarded, and the supernatant was assayed for viable MS2 as described by Vo et al.¹³ The efficacy of the decontamination (ED) of MS2 was calculated as the log reduction:

$$\text{ED} = \log(N_0/N_d) \quad (1)$$

where N_0 is the mean number of viable MS2 applied to the control coupons and N_d is the number of viable MS2 recovered from test coupons after decontamination.

Assessing the efficacy of the MH decontamination method

Before assessing the efficacy of the MH decontamination method, the survival of MS2 virus on the FFR samples at 0, 30, 60, 90, 120 minutes under ambient conditions was determined as a control experiment.

MH decontamination procedure: MH decontamination was carried out using an electronic steamer (Oster Steamer, Model # 5712; www.amazon.com; Fig 2). The steamer had 2 levels; the first level consisted of the electronic controller (Fig 2A) and a water reservoir chamber (Fig 2B) while the second level consisted of an FFR decontamination chamber (Fig 2C) and a thermometer (Fig 2D). The water chamber was filled with 1 L of tap water. During the decontamination process, the exhaust steam ports of the decontamination chamber were in the open position (Fig 2) to remove excess air and maintain a desired temperature of approximately 80 °C. After test FFRs were loaded with MS2 virus and placed into the FFR decontamination chamber, the steamer was started. The FFRs were decontaminated for different periods of time (Table 2). MH-decontaminated and control (no MH decontamination) FFRs were cut into square shaped coupons for the viral recovery process.

Virus recovery and MH decontamination efficacy: MS2 recovery and MH decontamination efficacy were determined as described in the UVGI decontamination section.

Data analysis

All tests from this study were replicated 3 times. The mean and standard deviation were calculated using Microsoft Excel for Office 365 software (Microsoft Corporation, Redmond, WA). To compare the filter aerosol penetration and filter airflow resistance for predecontamination and postdecontamination FFRs, paired t tests with 2-tailed distribution were run, also using Microsoft Excel for Office 365 software. P values of $<.05$ were considered significant.

RESULTS

Assessing the FFR properties against UV and MH decontaminations

All predecontamination and postdecontamination FFRs were inspected and found that neither UV nor MH decontamination method caused any observable physical changes to the FFRs.

Results of filter aerosol penetration tests on predecontamination and postdecontamination FFRs are summarized in Table 3. In the UV decontamination experiments, average percent penetrations were not significantly different between predecontamination (2.21% and 0.31%) and postdecontamination (2.99% and 0.72%) for both sample-G and sample-N FFRs, respectively (Table 3) with all $P>.05$. In the MH decontamination experiments, average percent penetrations were also not significantly different between predecontamination (2.23% and 0.32%) and postdecontamination (2.81% and 0.41%) for both sample-G and sample-N FFRs, respectively (Table 3) with all $P>.05$.

Results of filter airflow resistance tests on predecontamination and postdecontamination FFRs are also summarized in Table 3. In the UV decontamination experiments, the filter airflow resistances were not significantly different between predecontamination (10.71 and 11.32 mmH₂O) and postdecontamination (1037 and 11.41 mm H₂O) for both sample-G and sample-N FFRs, respectively (Table 3) with all $P>.05$. In the MH decontamination

experiments, the filter airflow resistances were also not significantly different between predecontamination (10.72 and 1134 mm H₂O) and postdecontamination (10.43 and 10.93 mm H₂O) for both sample-G and sample-N FFRs, respectively (Table 3) with all $P > .05$.

Assessing the efficacy of decontamination methods

Assessing the efficacy of UV decontamination—The average MS2 virus recovered from the untreated FFRs for each test ranged from 5.51 to 6.15 log₁₀ (Tables 4 and 5). A summary of the UVGI decontamination results by applied UV dose is given in Tables 4 and 5. Generally, higher UV doses yielded higher log reductions of MS2 (Tables 4 and 5). In general, the UVGI with an irradiation dose of 1,488 mJ/cm² provided an average >5-log reduction of MS2 virus for both hydrophilic and hydrophobic N95 FFRs (Tables 4 and 5). In 93% of our experiments, the virus was reduced to levels below the detection limit at the irradiation dose of 1,488 mJ/cm² used.

UV decontamination results varied among the 3 deposition types applied, with the highest decontamination efficacy for aerosol-based deposition, followed by vapor-based, and then the solution-based depositions for both hydrophilic sample-G and hydrophobic sample-N FFRs at the same UV dose level (Tables 4 and 5). The results showed that the solution-based method yielded significantly different viral reductions compared with the vapor-based and aerosol-based methods ($P < .05$) for both hydrophilic sample-G and hydrophobic sample-N FFRs. However, when comparing between the vapor-based and aerosol-based methods, the aerosol-based method yielded significantly higher viral reductions compared with the vapor-based method ($p < .05$) for hydrophobic sample-N FFRs, but no significant differences between the 2 deposition types for hydrophilic sample-G FFRs with all $P > .05$.

Within each deposition type, the decontamination efficacy for hydrophilic sample-G FFRs (5.25-log reductions) was slightly greater compared with the values for hydrophobic sample-N FFRs (5.01-log reductions) for solution-based and vapor-based depositions using the same UV dose level of 1,488 mJ/cm² (Tables 4 and 5). However, the decontamination efficacy for hydrophilic sample-G FFRs (5.79-log reductions) was lower compared with the values for hydrophobic sample-N FFRs (5.89-log reductions) for aerosol-based deposition using the same UV dose of 1,448 mJ/cm² (Tables 4 and 5).

Assessing the efficacy of MH decontamination—As a control experiment, the survival of MS2 virus on the FFR samples without MH decontamination was determined and found to be 5.93×10^5 , 5.89×10^5 , 5.84×10^5 , 5.74×10^5 , and 5.73×10^5 PFU/mL for 0, 30, 60, 90, 120 minutes, respectively. Comparison of these results indicated that ~97% of the viral particles on these FFR samples (ie, without MH decontamination) were viable at 2 hours under ambient conditions. A summary of the MH decontamination results is given in Tables 6 and 7. As expected, increasing the MH decontamination time yielded higher log reductions of MS2 virus (Tables 6 and 7). In general, the MH decontamination at 80°C for 30 minutes provided an average >5-log reduction of MS2 virus for both hydrophilic sample-G and hydrophobic sample-N FFRs (Tables 6 and 7). In 92% of our MH experiments at 80°C for 30 minutes, the virus was reduced to levels below the detection limit.

MH decontamination results varied among the 3 deposition types applied, with the highest decontamination efficacy for aerosol-based deposition, followed by vapor-based, and then solution-based depositions at the same MH decontamination time (Tables 6 and 7). Within the 15-minutes MH decontamination, the solution-based method yielded significantly lower viral reductions compared with the vapor-based and aerosol-based methods ($P < .05$) for both hydrophilic sample-G and hydrophobic sample-N FFRs, but no significant differences in reductions across deposition types for both sample-G and sample-N FFRs for a longer time of MH decontamination (20 minutes), with all $P > .05$. There were no significant differences in viral reductions ($P > .05$) between the vapor-based and aerosol-based deposition types for both hydrophilic sample-G and hydrophobic sample-N FFRs.

Within each deposition type, the decontamination efficacy for hydrophilic sample-G FFRs (5.12–5.51-log reductions of MS2) was slightly greater than for the hydrophobic sample-N FFRs (5.03–5.49-log reductions) for solution-based and vapor-based depositions, respectively, at 80°C for 30 minutes MH decontamination time (Tables 6 and 7). However, the decontamination efficacy for hydrophilic sample-G FFRs (5.75-log reductions) was slightly lower compared with the values for the hydrophobic sample-N FFRs (5.89-log reductions) for aerosol-based deposition at 80°C for 30 minutes MH decontamination time (Tables 6 and 7).

DISCUSSION

Some major requirements of FFR decontamination, such as the protective performance of FFR, the presence of toxic byproduct on the FFR, and the effectiveness of the decontamination methods, must be determined before the reuse of FFRs can be recommended. The FFRs treated with UV and MH decontamination methods were inspected and neither method caused any observable physical changes to the FFRs. The results also show that these decontamination methods did not degrade the performance, with no significant differences in particle filtration efficiency or airflow resistance when comparing predecontamination and postdecontamination FFRs. Additionally, Salter et al¹⁹ reported that chemical off-gassing is not a concern for the UV and MH decontamination methods that were used in this study.

The efficacy of UVGI was a function of UV dose. UV decontamination was more effective when UV doses were increased, due to larger numbers of radicals generated. UVGI results varied among the 3 deposition types applied. In the solution-based deposition, the virus was in a large volume of suspension medium that landed on the FFR surface as large droplets to provide environmental protection to viruses^{20,21}; therefore, viruses with protective components from the suspension medium might have provided protection against UV-induced damage. In the aerosol-based deposition, the virus particles were allowed to dry. Thus, the virus was in the form of droplet nuclei; viruses without any environmental protection might be more susceptible to UV irradiation. Within each deposition type, the UV decontamination efficacy of MS2 virus on the hydrophilic FFRs was slightly greater compared with the values for the hydrophobic FFRs for both solution-based and vapor-based depositions. This may be explained by the fact that liquid droplets and vapor particles were able to absorb onto the hydrophilic FFR materials, resulting in dry virus particles

and reducing protective components. Thus, viruses on the hydrophilic FFRs might be more susceptible to UV irradiation, resulting in the slightly greater decontamination efficacy.

Because ~97% of the viruses loaded were still viable at 2 hours of storage, the effect of the storage parameters is negligible when compared to the numbers of viable viral particles recovered from FFR samples after undergoing the MH decontamination. For all 3 deposition types under the same MH decontamination temperature at 80 °C, increasing the decontamination time yielded higher log reductions of MS2 virus. The possible explanation for the high efficacy of the MH decontamination is that the MH method provided a stable moist-heat environment in the FFR decontamination chamber delivering MH to the outer as well as inner surfaces of the FFRs while UV light may not have reached the entire surfaces of respirator showing relatively lower efficacy. Within the 15-minutes MH decontamination, the solution-based method yielded significantly lower viral reductions compared with the vapor-based and aerosol-based methods, but no significant differences for longer decontamination time (>20 minutes) for both hydrophilic and hydrophobic FFRs. This may be explained by the fact that liquid droplets did not dry under the moist decontamination conditions while vapor and aerosol particles could absorb water vapor in the steam chamber to form vapor droplets; thus, for both hydrophilic and hydrophobic FFRs, virus particles in all 3 deposition types may have stayed in the similar form of vapor droplets and had the similar effect to heat decontamination.

The new evaluation technique to evaluate UVGI and MH decontamination methods for FFRs preserved performance, left no residual toxicity, and inactivated MS2 virus. This evaluation technique with varying virus loading types: solution-based, vapor-based, and aerosol-based depositions may help to ensure the decontamination method is effective no matter the mechanism of contamination. All 3 varying virus loading types used in this study could be repeatably and reproducibly achieved. In the efficacy of viral testing, assessment of repeatability and reproducibility is of great significance for validation of a decontamination method. ASTM International requires evaluation of both repeatability (within-laboratory precision) and reproducibility (between-laboratory precision) of a test method before it becomes a standard method.²²

MS2 was used as a surrogate for SARS-CoV-2 because both are respiratory viruses that may be transmitted among humans in similar ways, such as contact transmission, droplet-spray transmission, and aerosol transmission. Thus, the method of loading viral challenge on the FFRs to simulate viral particle transmissions for biological decontamination methods may be similar. Therefore, MS2 would be a good choice for use to evaluate decontamination methods for FFRs because of its nonpathogenicity.

It has been shown previously that some existing decontamination methods using commercially available aqueous solutions such as vaporized hydrogen peroxide (VHP) and ethylene oxide (EO) have some adverse effects on respirators and other materials in health care.^{11,19,23} These studies showed no significant effect on filter penetration or resistance for N95, surgical N95, and PI 00 FFRs after one cycle of decontamination treatment. However, 3 cycles of decontamination treatment showed negative effect on filtration performance.¹² Goyal et al²⁴ employed condensing HVP to evaluate the inactivation of a number of

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structurally distinct viruses such as human adenovirus, feline calicivirus, TGEV virus. Avian influenza, and Swine influenza viruses. Goyal et al²⁴ reported similar decontamination efficacy results with >4-log reduction when using the VHP decontamination method.

Although, the VHP and EO methods appear to show similar results on decontamination efficacy, filter penetration, and airflow resistance, it is not clear whether these methods leave any residual toxic substances on the FFRs. Any residual toxic material on the FFRs is likely to be a health concern for the user. The UVGI and MH methods described in our study are equally effective in disinfecting viruses with no residual toxicity. Thus, this new evaluation technique based on 3 major decontamination should be further characterization of other decontamination techniques such as VHP and EO evaluations. The UVGI and MH methods inactivated MS2 virus (>5-log reduction) consistently. This study shows the importance of virus deposition method and its influence on the decontamination of viruses. The UVGI method showed that decontamination was more effective for the wet aerosol representing cough-or sneeze-expelled droplets as well as dry aerosol representing exhaled aerosol particles of infected individuals. Above all, the UVGI and MH methods are more practical and less expensive than the VHP and EO decontamination methods.

We are optimistic that these data of both UVGI and MH decontamination methods evaluated in this study may help lead to solutions to address a shortage of FFRs caused by pandemic. Both UVGI and MH decontamination methods provide practical solutions that can be applied in many settings. The MH method may be useful for home use or any environment outside of a professional health care facility. The MH method can be applied by small organizations based on its simplicity and its availability. Although the UVGI method produces an advanced scalable platform designed to meet the needs of larger organizations, many types of UVGI systems are currently used in hospitals and other organizations for surface sterilization and biological safety cabinets. Adapting these systems for decontamination and reuse of FFRs could be a low-cost option for hospitals and organizations. It should be noted that the decontamination in this study was conducted close in time after virus was loaded onto FFRs, so it would not probably be the case in practice for reusing FFRs, which might be put aside in clinics for later decontamination. Thus, the actual decontamination-dose levels needed in the practice place may be lower than decontamination doses used in this study.

Study Limitations:

It must also be noted that in this study we chose solution-based, vapor-based, and aerosol-based depositions to simulate loading associated with a sneeze, wet aerosol particles that contribute to transmission in close proximity, and dry airborne particles, respectively that could be readily and reproducibly achieved using our experimental setup. Thus, the data presented in this study may not mimic exactly the composition and size of droplet particles from human respiratory secretions. Future studies should look for new suspension media and other methods of generating particles to better approximate composition and size of particles from human respiratory secretions. The data presented in this study are only 2 out of the hundreds of FFR models available. We acknowledge this limitation and recommend evaluating additional hydrophilic/hydrophobic FFRs.

CONCLUSION

The results show that the new evaluation technique to evaluate UVGI and MH decontamination methods for FFRs preserved performance, left no residual toxicity, and inactivated MS2 bacteriophage; therefore, both UVGI and MH decontamination methods could be considered as promising decontamination candidates for inactivation of viruses for respirator reuse during shortages.

The effectiveness of the UV and MH decontaminations depended on the decontamination doses (UV doses or MH decontamination time) and FFR model (hydrophilic and hydrophobic materials). Increasing the UV doses or MH decontamination time yielded higher reductions of MS2 virus for all 3 deposition types. Although the effectiveness of these decontaminations also depended on the method used to deposit viruses onto FFRs, each loading type was intended to simulate loading associated with different viral particle transmissions; thus, the results from this study should inform the selection of loading types for specific interests, such as large droplets produced by coughing and sneezing, vapor particles produced by talking and breathing in close proximity, or airborne viral particles.

ACKNOWLEDGMENTS

The authors thank Drs. Michelangelo Di Giuseppe and F. Selcen Kilinc-Balci, Mr. Edward Fisher, and Ms. Caitlin McClain (NIOSH/NPPTL, Pittsburgh, PA) for their valuable review comments for the manuscript.

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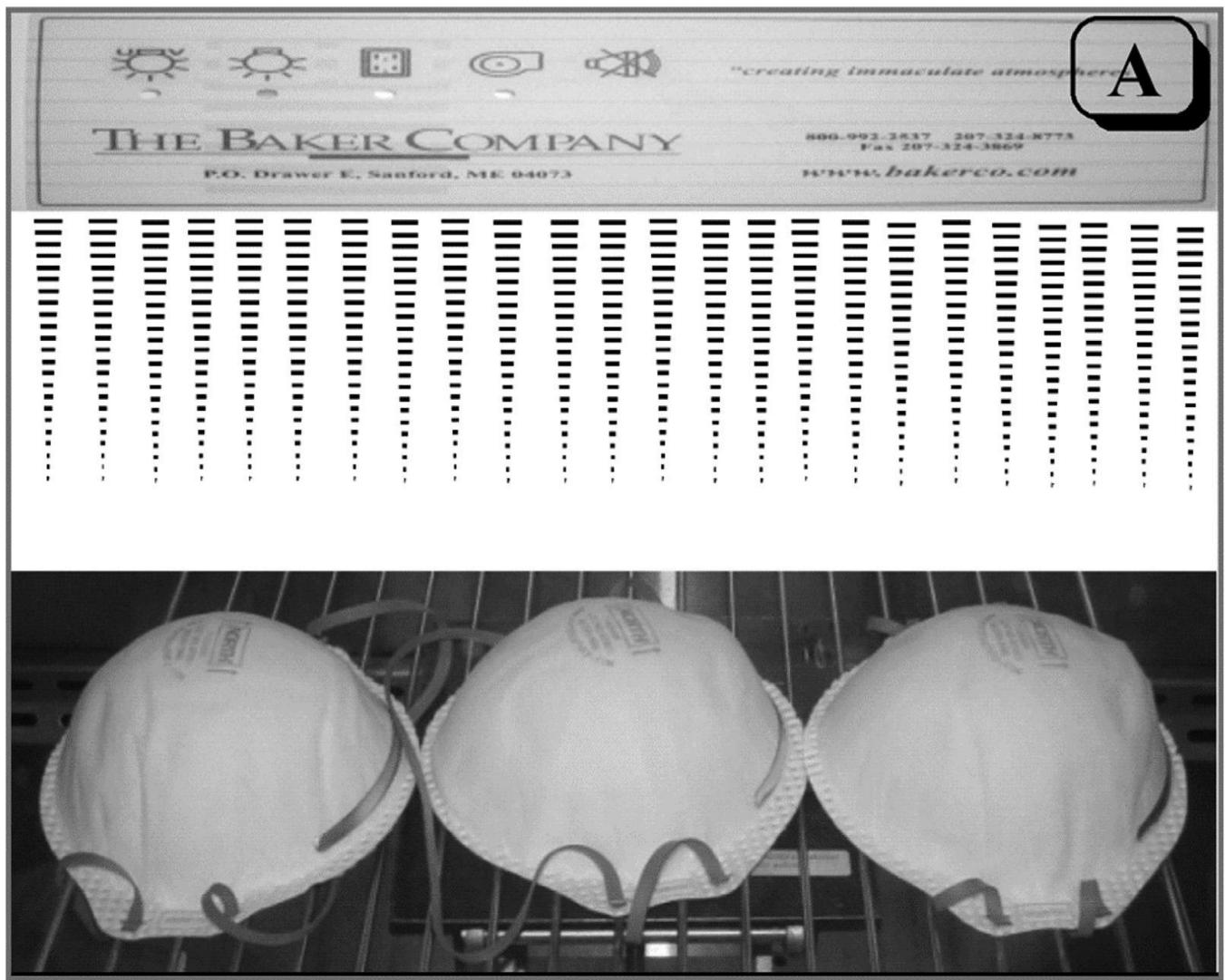


Fig 1.
Decontamination of FFRs using UV irradiation method.

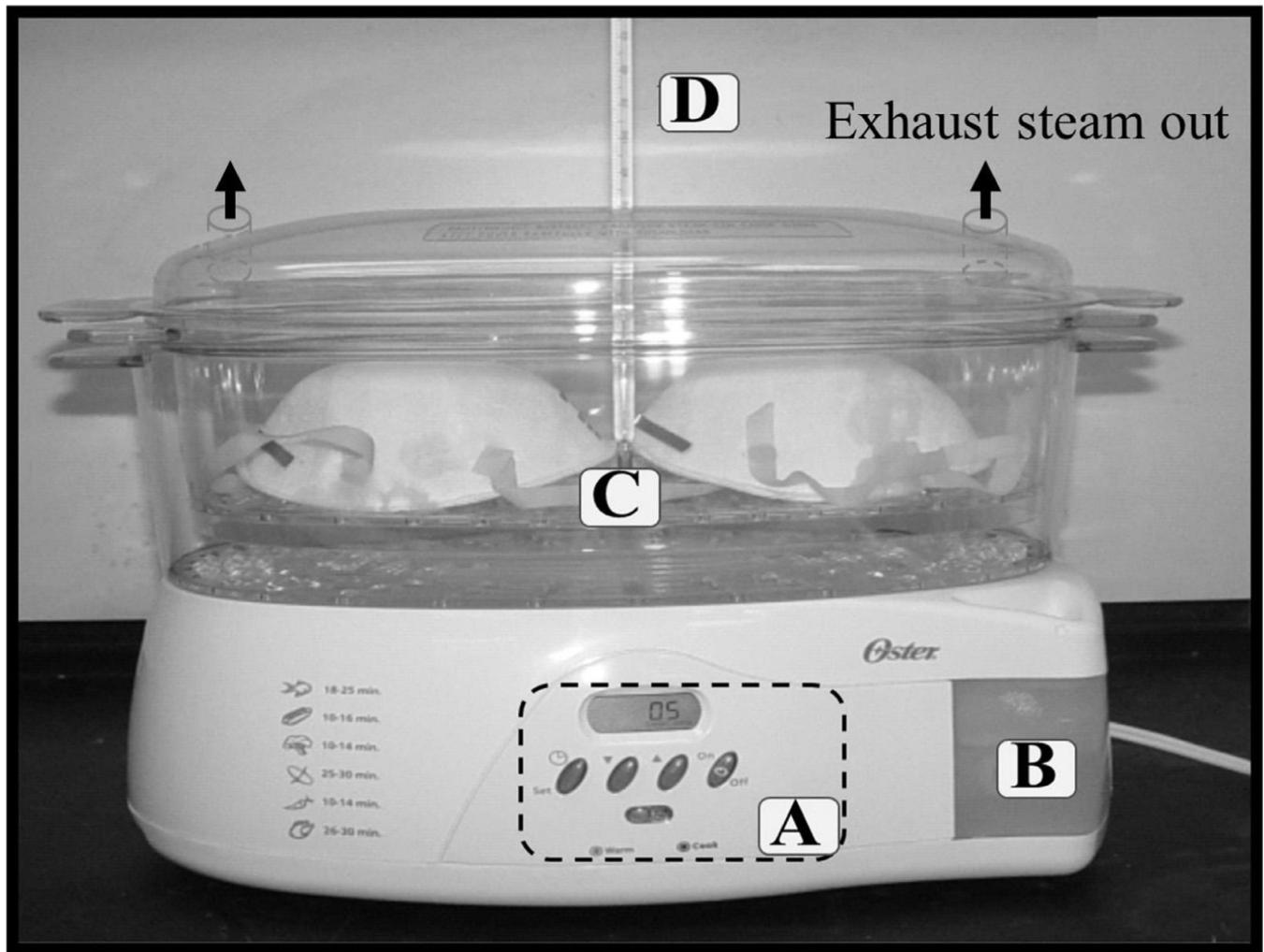


Fig 2.
Decontamination of FFRs using MH decontamination method with a steam controller (A) water reservoir (B), FFR chamber (C), and thermometer (D).

FFRs tested and material characteristics

Table 1

FFR sample	FFR type	Respirator features	Characteristics (Number of layers, materials)
Sample G N95 FFR	Hydrophilic outer-layer FFR	Cup shape without exhalation valve, nonadjustable straps, metal nosepiece, 1 size	Three layers: Layer 1: hydrophilic materials (outer-layer) Layer 2: hydrophobic materials (middle-layer) Layer 3: hydrophilic materials (innermost-layer)
Sample N N95 FFR	Hydrophobic outer-layer FFR	Cup shape without exhalation valve, nonadjustable straps, metal nosepiece, 1 size	Four layers: Layer 1: thin hydrophobic materials (outer-layer) Layer 2: combination of thin hydrophobic and hydrophilic materials (middle layer-A) Layer 3: thick hydrophobic materials (middle layer-B) Layer 4: thin hydrophilic materials (innermost-layer)

Test parameters of the UV and MH decontamination methods

Table 2

UV decontamination	UV decontamination				MH decontamination		
	UV decon time (min)	Distance from lamp to FFR surface (cm)	UV intensity on FFR surface (mW/cm ²)	UV dose (mJ/cm ²)	Steam decon time (min)	Temperature at N95 respirator's location	
0 (control)				0	0 (control)		(21 ± 2 °C)
5	56	0.3	90	5		80±3°C	
5	30	0.84	252	10		80±3°C	
5	15	1.60	480	15		80±3°C	
5	10	2.46	738	20		80±3°C	
5	5	4.96	1488	25		80±3°C	
			30			80±3°C	

Table 3

Summary data of filter airflow resistance, aerosol penetration, and filtration efficiency for N95 FFRs following UV and MH decontaminations

FFR type	Decontamination method	Tested FFR samples	Average initial resistance (mm H ₂ O)* (%P)*	Average initial sodium chloride penetration (%P)*	Filtration efficiency (%)*
sample-G N95 FFR	UV	Untreated FFR (control)	10.71 ± 0.61	2.21 ± 0.67	97.79 ± 0.78
		Treated FFR	10.37 ± 0.12	2.99 ± 0.43	97.01 ± 0.47
		Untreated FFR	10.72 ± 0.61	2.23 ± 0.68	97.77 ± 0.83
	MH	Treated FFR	10.43 ± 0.21	2.81 ± 0.31	97.19 ± 0.29
		Untreated FFR	11.32 ± 0.50	0.31 ± 0.06	99.69 ± 0.02
		Treated FFR	11.41 ± 1.05	0.72 ± 0.05	99.28 ± 0.03
sample-N N95 FFR	UV	Untreated FFR	11.34 ± 0.50	0.32 ± 0.06	99.68 ± 0.02
		Treated FFR	10.93 ± 0.32	0.41 ± 0.05	99.59 ± 0.03

* Mean ± RSD (RSD: relative standard deviation; n = 3).

Table 4
Effectiveness of the UV decontamination method in inactivating viable MS2 virus on hydrophilic sample-G FFRs

UV dose (mJ/cm ²)	Liquid droplet deposition			Vapor deposition			Aerosol deposition		
	MS2 recovered (log) [*]		ED [†]	MS2 recovered (log) [*]		ED [†]	MS2 recovered (log) [*]		ED [†]
	MS2 recovered (log) [*]	ED [†]	MS2 recovered (log) [*]	ED [†]	MS2 recovered (log) [*]	ED [†]	MS2 recovered (log) [*]	ED [†]	MS2 recovered (log) [*]
0 (control)	5.56 ± 0.32	Not determined	6.15 ± 0.19	Not determined	6.08 ± 0.14	Not determined	6.08 ± 0.14	Not determined	Not determined
90	5.09 ± 0.19	0.47 ± 0.41	5.44 ± 0.25	0.71 ± 0.27	5.27 ± 0.19	0.71 ± 0.27	5.27 ± 0.19	0.81 ± 0.10	0.81 ± 0.10
252	4.49 ± 0.46	1.07 ± 0.30	4.73 ± 0.38	1.42 ± 0.30	4.50 ± 0.24	1.42 ± 0.30	4.50 ± 0.24	1.58 ± 0.41	1.58 ± 0.41
480	3.83 ± 0.23	1.73 ± 0.41	4.01 ± 0.23	2.14 ± 0.29	3.82 ± 0.15	2.14 ± 0.29	3.82 ± 0.15	2.26 ± 0.21	2.26 ± 0.21
738	3.12 ± 0.17	2.44 ± 0.10	3.39 ± 0.21	2.76 ± 0.26	3.20 ± 0.14	2.76 ± 0.26	3.20 ± 0.14	2.88 ± 0.25	2.88 ± 0.25
1488 [‡]	0.31 ± 0.32	5.25 ± 0.26	0.29 ± 0.26	5.86 ± 0.49	0.10 ± 0.23	5.86 ± 0.49	0.10 ± 0.23	5.98 ± 0.49	5.98 ± 0.49

^{*}Log: Log reduction is unitless that correlates to a 10-fold reduction.

[†]Mean ED (effectiveness of the decontamination) ± RSD (n = 3).

[‡]1,488 mJ/cm²; at this UVG dose, 94% of our experiments yielded to levels below minimum detection limit (B-MDL).

Table 5

Effectiveness of the UV decontamination method in inactivating viable MS2 virus on hydrophobic sample-N FFRs

	UV dose (mj/cm ²)	Liquid droplet deposition		Vapor deposition		Aerosol deposition				
		MS2 recovered (log)		ED*	MS2 recovered (log)		ED*	MS2 recovered (log)		ED*
		MS2 recovered (log)	ED*	MS2 recovered (log)	ED*	MS2 recovered (log)	ED*	MS2 recovered (log)	ED*	
0 (control)	5.51 ± 0.20	Not determined	6.08 ± 0.19		Not determined	6.04 ± 0.11		Not determined		
90	5.22 ± 0.27	0.29 ± 0.10	5.41 ± 0.20		0.67 ± 0.45	4.87 ± 0.10		1.17 ± 0.18		
252	4.53 ± 0.40	0.98 ± 0.17	4.73 ± 0.23		1.35 ± 0.55	4.05 ± 0.19		1.99 ± 0.31		
480	3.96 ± 0.36	1.55 ± 0.22	3.99 ± 0.17		2.09 ± 0.38	3.56 ± 0.26		2.48 ± 0.16		
738	3.42 ± 0.28	2.09 ± 0.62	3.47 ± 0.21		2.71 ± 0.23	2.62 ± 0.13		3.42 ± 0.28		
1488 †	0.50 ± 0.38	5.01 ± 0.29	0.39 ± 0.51		5.69 ± 0.37	0.25 ± 0.21		5.79 ± 0.32		

* Mean ED (effectiveness of the decontamination) ± RSD (n = 3).

† 1,488 mj/cm²; at this UVGI dose, 93% of our experiments yielded to levels below minimum detection limit.

Table 6

Effectiveness of the MH decontamination method in inactivating viable MS2 virus on hydrophilic sample-G FFRs

Steam decon time (min)	Liquid droplet deposition		Vapor deposition		Aerosol deposition	
	MS2 recovered (log)		ED*	MS2 recovered (log)	ED*	MS2 recovered (log)
	MS2 recovered (log)	ED*				
0 (control)	5.93 ± 0.21	Not determined	6.18 ± 0.16	Not determined	6.16 ± 0.09	Not determined
5	5.41 ± 0.36	0.52 ± 0.30	5.33 ± 0.23	0.85 ± 0.30	5.23 ± 0.16	0.93 ± 0.26
10	4.69 ± 0.21	1.24 ± 0.29	4.37 ± 0.46	1.81 ± 0.38	4.27 ± 0.25	1.89 ± 0.38
15	3.97 ± 0.22	1.96 ± 0.47	3.79 ± 0.31	2.39 ± 0.29	3.71 ± 0.24	2.45 ± 0.30
20	3.39 ± 0.31	2.54 ± 0.39	3.19 ± 0.12	2.99 ± 0.36	3.14 ± 0.13	3.02 ± 0.29
25	2.62 ± 0.29	3.31 ± 0.10	2.51 ± 0.23	3.67 ± 0.29	2.36 ± 0.28	3.80 ± 0.28
30 [†]	0.29 ± 0.53	5.12 ± 0.39	0.67 ± 0.53	5.51 ± 0.39	0.41 ± 0.24	5.75 ± 0.32

* Mean ED ± RSD (n = 3).

[†] 30 min: at 30 min decontamination time, 93% of our experiments yielded to levels below minimum detection limit.

Table 7

Effectiveness of the MH decontamination method in inactivating viable MS2 virus on hydrophobic sample-N FFRs

Steam decon time (min)	Liquid droplet deposition		Vapor deposition		Aerosol deposition	
	MS2 recovered (log)		ED*	MS2 recovered (log)	ED*	MS2 recovered (log)
	MS2 recovered (log)	ED*				
0 (control)	5.92 ± 0.23	Not determined	6.15 ± 0.14	Not determined	6.14 ± 0.12	Not determined
5	5.73 ± 0.33	0.19 ± 0.42	5.36 ± 0.26	0.79 ± 0.30	5.09 ± 0.09	1.05 ± 0.41
10	5.19 ± 0.41	0.73 ± 0.19	4.35 ± 0.21	1.80 ± 0.39	4.20 ± 0.23	1.94 ± 0.35
15	4.45 ± 0.18	1.47 ± 0.30	3.81 ± 0.18	2.34 ± 0.29	3.61 ± 0.17	2.53 ± 0.41
20	3.81 ± 0.22	2.11 ± 0.29	3.29 ± 0.25	2.86 ± 0.18	3.04 ± 0.29	3.10 ± 0.28
25	2.91 ± 0.19	3.01 ± 0.26	2.51 ± 0.16	3.64 ± 0.10	2.23 ± 0.11	3.91 ± 0.10
30 [†]	0.89 ± 0.21	5.03 ± 0.32	0.66 ± 0.53	5.49 ± 0.29	0.25 ± 0.21	5.89 ± 0.23

* Mean ED ± RSD (n = 3).

[†] 30 min: at 30 min decontamination time, 92% of our experiments yielded to levels below minimum detection limit.