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American Journal of Infection Control 46 (2018) e49-e55

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Ultraviolet germicidal irradiation of influenza-contaminated N95 filtering facepiece respirators

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Key Words:
Disinfection
Decontamination
UVGI
Reuse
Soiling
Ultraviolet

Background: Safe and effective decontamination and reuse of N95 filtering facepiece respirators (FFRs) has the potential to significantly extend FFR holdings, mitigating a potential shortage due to an influenza pandemic or other pandemic events. Ultraviolet germicidal irradiation (UVGI) has been shown to be effective for decontaminating influenza-contaminated FFRs. This study aims to build on past research by evaluating the UVGI decontamination efficiency of influenza-contaminated FFRs in the presence of soiling agents using an optimized UVGI dose.

Methods: Twelve samples each of 15 N95 FFR models were contaminated with H1N1 influenza (facepiece and strap), then covered with a soiling agent—artificial saliva or artificial skin oil. For each soiling agent, 3 contaminated FFRs were treated with 1 J/cm^2 UVGI for approximately 1 minute, whereas 3 other contaminated FFRs remained untreated. All contaminated surfaces were cut out and virus extracted. Viable influenza was quantified using a median tissue culture infectious dose assay.

Results: Significant reductions (≥3 log) in influenza viability for both soiling conditions were observed on facepieces from 12 of 15 FFR models and straps from 7 of 15 FFR models.

Conclusions: These data suggest that FFR decontamination and reuse using UVGI can be effective. Implementation of a UVGI method will require careful consideration of FFR model, material type, and design.

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Respiratory protection devices are crucial for limiting the spread of airborne infectious disease, protecting health care workers (HCWs), their patients, and other users during outbreaks. The use of N95 filtering facepiece respirators (FFRs) has been recommended for protection against pandemic influenza, severe acute respiratory syndrome, and emerging infectious diseases where aerosol transmission is considered possible.[1-3] N95 FFRs are capable of capturing ≥95% of 0.3 µm airborne particles and generally are disposed of after a single use.[4] Stockpiling of personal protective equipment, such as N95 FFRs, for influenza pandemic preparedness has been an area of focus since the emergence of H5N1 influenza in 2005 and the 2009 H1N1 pandemic.[5] However, stockpiling goals for N95 FFR supplies may not meet the demand if a severe influenza pandemic were to occur. An estimated 60 million N95 FFRs are being held by US acute care hospitals collectively with state holdings varying from 14,000-32 million.[6] Assuming 20%-30% of the US population became ill, the number of N95 FFRs needed could range from 1.7-7.3 billion during an influenza pandemic.[7] FFR shortages for various health care facilities occurred during the 2009 H1N1 pandemic, providing more validation that shortages are likely to occur during a severe pandemic.[8-10]

One approach to mitigate a potential N95 shortage is to implement FFR decontamination and reuse (FFR-DR) strategies. FFR-DR aims to decontaminate FFRs without significantly affecting their performance. Recommendations for 2 types of supply conserving use strategies without decontamination are currently provided by the Centers for Disease Control and Prevention: extended use and limited reuse. Extended use refers to the use of the same N95 FFR by the same wearer for multiple encounters with patients without doffing the respirator.[11] Limited reuse refers to the use of the same N95 FFR for multiple encounters by the same wearer, but doffing after each encounter with restrictions in place to limit the number of times the same FFR is reused.[11] The National Institute for Occupational Safety and Health (NIOSH) specifies that use limitations for all filters

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Supported by the US Food and Drug Administration Medical Countermeasures Initiative Regulatory Science Extramural Research program (contract No. HHSF223201400158C). The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the US Food and Drug Administration.

Conflicts of interest: None to report.

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https://doi.org/10.1016/j.ajic.2018.02.018

on NIOSH-approved FFRs should consider hygiene, damage, and breathing resistance, and be replaced whenever they are damaged, soiled, or cause noticeably increased breathing resistance.[12] Implementation of these reuse practices is up to the respiratory protection program's manager and is dependent on the respiratory pathogen's characteristics (eg, route of transmission and severity of illness) and local conditions (eg, number of N95 respirators available and use rate).[11] Among the primary concerns for implementing an FFR extended use or limited reuse policy is the possibility of respirators becoming contaminated and subsequently acting as fomites, potentially spreading the disease. HCWs are well versed in self-contamination incidents that occurred during the severe acute respiratory syndrome and Ebola virus disease outbreaks and are concerned that extended use of FFRs may lead to self-infection.[13,14]

Although guidance for limited reuse and extended use of FFRs is currently available, implementation of FFR-DR strategies is a more complicated process. For reprocessed single-use medical devices, the US Food and Drug Administration (FDA) requires validation data regarding cleaning, sterilization, and functional performance.[15] Cleaning is generally performed before decontamination to ensure soiling materials do not interfere with the decontamination process. The common definition of a cleaned device—no visual contamination is present—differs from the Medical Device User Fee and Modernization Act of 2002, which states that the reprocessor must establish cleaning end points and rationale for their selection.[16] Cleaning FFRs is a difficult task because the N95 facepiece is an exposed filter and not compatible with standard laundering techniques. Additionally, research has been performed demonstrating that several FFR models cannot be effectively cleaned using various cleaning wipes.[17] According to the Institute of Medicine, any method decontaminating a disposable N95 FFR must remove the pathogen, be harmless to the user, and not compromise the integrity of the various parts of the respirator.[18] If the decontamination process can eliminate viable pathogens from the medical device in the presence of other organic material, the question arises of whether cleaning would still be required, especially during a public health emergency.

Several studies have previously been performed evaluating the efficacy of FFR decontamination methods. Heimbuch et al[19] evaluated 3 different energetic methods (microwave-generated steam [MGS], moist heat incubation [MHI], and ultraviolet germicidal irradiation [UVGI]) against H1N1 influenza-contaminated N95 FFRs. All 3 methods demonstrated >4-log reductions in viable virus. The results were subsequently duplicated using low-pathogenic H5N1 avian influenza by Lore et al[20] Fisher et al[21] demonstrated >4-log reductions in viable MS2 virus on FFR coupons using 0.6% sodium hypochlorite solution and MGS treatments ≥45 seconds. Vo et al[22] evaluated the disinfection efficiencies of sodium hypochlorite and UVGI on N95 respirators contaminated with droplets containing MS2 bacteriophage, and both approaches demonstrated multilog reductions in MS2 viability. Although there are currently no guidelines for the level of decontamination required for contaminated FFRs, multiple FFR-DR methods have shown significant reductions in virus viability. Currently, there are no published data on actual influenza contamination levels of FFRs in hospitals. However, Fisher et al[23] validated a predictive model for estimating the level of influenza contamination on FFRs and surgical masks resulting from aerosols in a health care setting. The estimated contamination level for the entire external surface of an FFR ranged from 10^1-10^5 viruses, depending on different scenarios using airborne influenza concentrations published in the literature.

The study described herein is a continuation of the UVGI-based FFR decontamination research performed by Heimbuch et al[19] in 2011. Although all 3 methods (MGS, MHI, and UVGI) demonstrated >4-log reduction in viable virus, some methods may be better suited for hospital use than others. The MHI method required the longest decontamination time (30 minutes) and the use of an oven set to 160°F. The MGS method was the shortest decontamination time (2 minutes), but there may be concerns over wattage variability among microwave ovens. Although the UVGI method required a 15-minute decontamination period, this method may be most suitable for large-scale applications due to simplicity of use and ability to rapidly scale. UVGI technologies for whole-room decontamination have already been developed and are commercially available.[24-26] Despite showing >4-log reduction in viable influenza, some limitations of the study were subsequently identified. The study authors listed the primary limitation as being the low number of FFR models evaluated. Also, the ultraviolet (UV) light dose (concentration × time) could likely be optimized for hospital use by increasing the concentration of UV rays (ie, source and distance between the substrate and the UV light source), and reducing the time required to achieve decontamination, making the method more conducive to hospital use by minimizing logistical burden. Additionally, the 2011 study[19] evaluated decontamination efficiency of influenza in the absence of soiling agents (ie, protective factors) that may shield the virus from the decontamination source. During real-world contamination events, influenza virus could very likely be shielded by organic soiling agents like saliva or skin oil, which can inhibit the effectiveness of decontamination techniques.[27-29]

The objective of the current study was to evaluate the UVGI decontamination efficiency of an intact FFR contaminated with both a pandemic influenza strain and a soiling agent to better simulate real-world contamination events. Fifteen N95 FFR models were contaminated with viable H1N1 influenza and either artificial saliva or artificial skin oil, then subsequently treated with UV light and evaluated for remaining viable virus.

MATERIALS AND METHODS

H1N1 influenza

H1N1 influenza A/PR/8/34 (VR-1469; American Type Culture Collection, Manassas, VA) was propagated in embryonic chicken eggs (Premium Specific Pathogen Free Eggs 10100326; Charles River Laboratories, Wilmington, MA) using standard World Health Organization protocols.[30] Virus titers were determined by a 50% tissue culture infectious dose ($TCID_{50}$) assay. Madin-Darby canine kidney cells (CCL-34; American Type Culture Collection) were passaged and maintained using World Health Organization-approved cell culture techniques.

Soiling agents

Mucin buffer was prepared and stored at 4°C.[31] Synthetic skin oil (Scientific Services S/D, Sparrow Bush, NY) was purchased, divided into 2.5-mL aliquots, and stored at 37°C until use. For testing, aliquots were heated to 70°C and poured into the base of a 100-mm Petri dish. Continual heat was applied until the layer became even and allowed to cool to room temperature.

Test respirators

Fifteen NIOSH-approved N95 FFR models were chosen for this study (Table 1), with consideration given to whether the product was cleared by FDA, its commercial availability, and its unique shapes and materials. All of the FFR models were cleared by the FDA as surgical N95 respirators, except for the EZ 22 (Moldex, Culver City, CA).

Table 1
N95 filtering facepiece respirators (FFRs) selected for this study

N95 FFR models	FFR shape
3M* 1860	Cup
3M* 1870	Flat-fold
3M* VFlex 1805	Flat-fold
Alpha Protech† 695	Flat fold
Gerson‡ 1730	Cup
Kimberly-Clark§ PFR	Pouch
Moldex‖ 1512	Cup
Moldex‖ 1712	Flat-fold
Moldex‖ EZ-22¶	Cup
Precept# 65-3395	Cup
Prestige Ameritech** RP88020	Pouch
Sperian†† HC-NB095	Cup
Sperian†† HC-NB295F	Flat-fold
U.S. Safety‡‡ AD2N95A	Cup
U.S. Safety‡‡ AD4N95	Flat-fold

*3M Company, Minneapolis, MN.
†Alpha Protech, Markham, Canada.
‡Louis M. Gerson Co, Inc, Middleboro, MA
§Halyard Health Inc., Alpharetta, GA.
‖Moldex, Culver City, CA.
¶Not cleared by the Food and Drug Administration as a surgical N95 respirator.
#Precept Medical Products, Inc, Arden, NC.
**Prestige Ameritech, North Richland Hills, TX.
††Honeywell Safety Products USA, Smithfield, RI.
‡‡Dentech Safety Specialists, Lenexa, KS.

UVGI device

The custom UVGI device was made of polished aluminum (Alloy 6061-T6 and Alloy 2024-T3; OnlineMetals.com, Seattle, WA) and measuring 40-in L × 16-in W × 13-in H with a tunnel extension measuring 18-in × 8-in W × 6-in H (Fig 1). The polished aluminum alloys were selected because they are UV reflective surfaces that do not alter the wavelength of the reflected light. Eight 32-in 254-nm UV-C bulbs with an irradiance of 0.39 W/cm^2 at 1 m (Fresh-Aire UV; Jupiter, FL) were incorporated into the device to deliver a UV dose of 1 J/cm^2 in approximately 1 minute (Fig 2). A sliding wire mesh rack was used to position the FFR during UV treatment. For temperature control, a cool air circulation system was incorporated into the device that consisted of an RTR-140 bath circulator (Neslab; Portsmouth, NH), 2 heat exchangers (AMS technologies, Martinsried, Germany), 2 80-mm 70-CFM double, ball-bearing, high-airflow fans (Vantec, Fremont, CA), and 5-in diameter polyvinyl chloride pipe.

An ILT-1254 radiometer (International Light Technologies, Peabody, MA), which measures 254-nm wavelengths, was used to measure UV output within the UVGI device. The UVGI device was initially validated by placing the radiometer in the same location as FFRs to be tested and taking UV measurements with the sensor facing upward, then on each side. UV measurements were then taken from the radiometer location shown in Figure 1, where UV output will be monitored for each test. The initial ratio in UV output between the 2 locations measured during the UVGI device validation was used to convert measurements taken during FFR testing to determine the UV dose per respirator. An OM-EL-USB-2 temperature and humidity data logger (Omega Engineering, Inc, Stamford, CT) was used to monitor environmental conditions within the device.

Decontamination studies

For each N95 FFR model, 12 intact FFRs were aseptically inoculated with 10 1-µL droplets of H1N1 influenza within a 2 cm^2 area on 4 areas of each FFR, delivering 7 $\log_{10}$ $TCID_{50}$ to each area. Each FFR was inoculated in the same 4 areas: the top, middle, and bottom of the facepiece's exterior (from the perspective of a donned FFR), and the strap (Fig 2). Inoculated surfaces were allowed to dry at room temperature in a biosafety cabinet for approximately 10 minutes.

Two conditions were evaluated: artificial saliva (mucin buffer) and artificial skin oil (sebum). Five 1-µL droplets of mucin buffer were applied directly over each dried influenza inoculation, allowing approximately 10 minutes of drying between droplet applications. A synthetic sebum overlay was prepared by pipetting 2.5 mL liquefied sebum into a 100-mm Petri dish, which was then swirled to create an even monolayer. A sterile triangle-shaped spreader was used to collect the sebum from the Petri dish. The collected sebum was then spread over the inoculum area at a density of approximately 1.25 mg/cm^2.

Each condition evaluated 6 influenza-contaminated FFRs. Three FFRs were each placed inside the UVGI device and individually treated for 60-70 seconds at an irradiance of approximately 17 mW/cm^2, resulting in a dose of ~1 J/cm^2. This dose was based on preliminary optimization studies using FFR coupons.[32] The UV dose is monitored during each test to ensure consistent treatment across experiments. Inoculated control masks were held at room temperature in a class II biosafety cabinet enclosure until the treated masks completed UVGI treatment.

After UV treatment, FFRs were transferred to a class II biosafety cabinet for processing. Inoculated areas on the FFR facepiece were removed using a 1.5-in circular die and placed in 50-mL centrifuge tubes containing 15 mL serum-free Eagle's minimum essential medium (EMEM). The FFR straps were cut at their points of attachment to the FFR, and each was placed in a 50 mL centrifuge tube containing 15 mL serum-free EMEM and vortexed for 20 minutes to extract the influenza virus. Extracts were subsequently serially diluted in serum-free EMEM and plated in quadruplicate in 24-well plates with confluent monolayers of Madin-Darby canine kidney cells, according to the World Health Organization protocol for a $TCID_{50}$ assay.[30] Plates were then incubated at 37°C in 5% carbon dioxide for 7 days. After the incubation period, each well was observed under a microscope for cytopathic effects, generally demonstrated by a disruption of the cell monolayer. Plates were subsequently stained with crystal violet-glutaraldehyde to confirm the presence of cytopathic effects.

Data analysis

UV dose was calculated based on standard methods for mathematical modeling of UV light using Equation 1:

$$\text{UV dose}\left(\frac{\text{J}}{\text{cm}^2}\right) = \text{Irradiance}\left(\frac{\text{W}}{\text{cm}^2}\right) \times \text{Time (s)} \quad (1)$$

To determine the level of viable virus recovered from each sampled location, the Spearman-Kärber formula was used to interpret the $TCID_{50}$ assay data.[33] To perform statistical analyses, Environmental Protection Agency guidance using half the detection limit (0.20 $\log_{10}$ $TCID_{50}$) for below-detection limit values was followed.[34] An unpaired, 2-tailed t test was used to compare UV-treated and control virus recoveries, as well as log reduction values for FFR facepieces and straps. Data were analyzed using statistical tools in GraphPad Prism 6 (Graph Pad Inc, La Jolla, CA).

RESULTS

Across all 180 FFRs tested, the mean UV dose per FFR was 1.1 ± 0.1 J/cm^2, the mean temperature was 21°C ± 2°C, and the mean relative humidity was 48% ± 6% within the UV device.

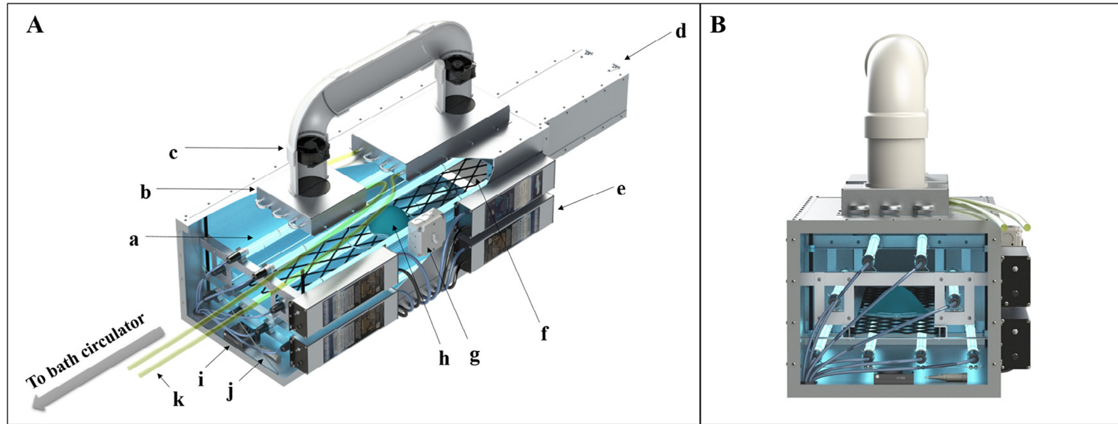

Fig 1. Ultraviolet germicidal irradiation device. (A) Top view: a, ultraviolet light light bulb; b, heat exchanger; c, fan; d, hinged door; e, power supply; f, sliding mesh wire shelf; g, power switch; h, filtering facepiece respirator (example); i, radiometer; j, temperature/humidity probe; k, ethylene glycol supply line. (B) Side view.

Fig 2. Locations of influenza droplets applied to filtering facepiece respirators.

Mucin-soiled FFRs

For mucin-soiled FFR facepieces, the mean viable influenza recovered from control surfaces was 4.29 ± 0.52 log $TCID_{50}$; for mucin-soiled FFR straps, the mean viable influenza recovered from control surfaces was 3.57 ± 0.78 log $TCID_{50}$ (Fig 3).

The mean log reduction ranged from 1.42-4.84 log $TCID_{50}$ for mucin-soiled facepieces and 0.00- 4.31 log $TCID_{50}$ for mucin-soiled straps. For mucin-soiled facepieces, the mean viable virus recovered from UV-treated samples was statistically significantly lower ($P < .05$) than control samples for all FFR models tested. For mucin-soiled straps, the mean viable virus recovered from UV-treated samples was statistically significantly lower than control samples for all FFR models tested except the VFlex 1805 (3M Company, Maplewood, MN), Alpha Protech 695 (Alpha Protech, Markham Canada), Moldex EZ 22, and the U.S. Safety AD2N95A (Dentech Safety Specialists, Lenexa, KS). The log reduction values observed for all mucin-soiled FFR straps were statistically significantly lower than their respective FFR facepieces.

Sebum-soiled FFRs

For sebum-soiled FFR facepieces, the mean viable influenza recovered from control surfaces was 4.10 ± 0.56 log $TCID_{50}$; for sebum-soiled FFR straps, the mean viable influenza recovered from control surfaces was 3.90 ± 0.65 log $TCID_{50}$ (Fig 4).

The mean log reduction ranged from 1.25-4.64 log $TCID_{50}$ for sebum-soiled facepieces and 0.08-4.40 log $TCID_{50}$ for sebum-soiled straps. For sebum-soiled facepieces, the mean viable virus recovered from UV-treated samples was significantly lower than control samples for all FFR models tested. For sebum-soiled straps, the mean viable virus recovered from UV-treated samples was significantly lower than control samples for all FFR models tested except the 3M 1860, Alpha Protech, and Moldex EZ 22.The log reduction values observed for the sebum-soiled FFR straps were significantly lower than the respective FFR facepieces.

DISCUSSION

In this study, evaluation of the UVGI decontamination method focused on log reduction rather than total absence of viable virus because the viral challenge was selected to far exceed what would may occur during a real-world contamination event. Based on the Fisher et al[23] model predicting influenza contamination levels of FFRs in hospitals from aerosol sources, the highest estimated contamination level (10^5 virus/FFR) would result in a loading concentration of 10^3 virus/cm^2 for a 200-cm^2 FFR, requiring a 3-log reduction to fully decontaminate. The virus loading concentration used in the current study is approximately 100-times higher than the loading concentration resulting from the highest contamination level estimated by Fisher et al.[23] Maximizing the loading concentration is important for laboratory studies in order to generate a measurable log reduction and overcome the virus loss resulting from variable extraction efficiencies of different materials, potential loss of viability due to environmental exposure, and the detection limit of the log-based viable assay (~0.50 $TCID_{50}$).

Compared with the Heimbuch et al[19] 2011 study that evaluated 6 FFR models, the current study provides a broader view of the diversity among FFR models currently available on the market. Across the 15 FFR models evaluated for this study there are considerable differences in FFR facepiece design, varying in overall shape (eg, cup, flat-fold, or pouch), material composition, and other design

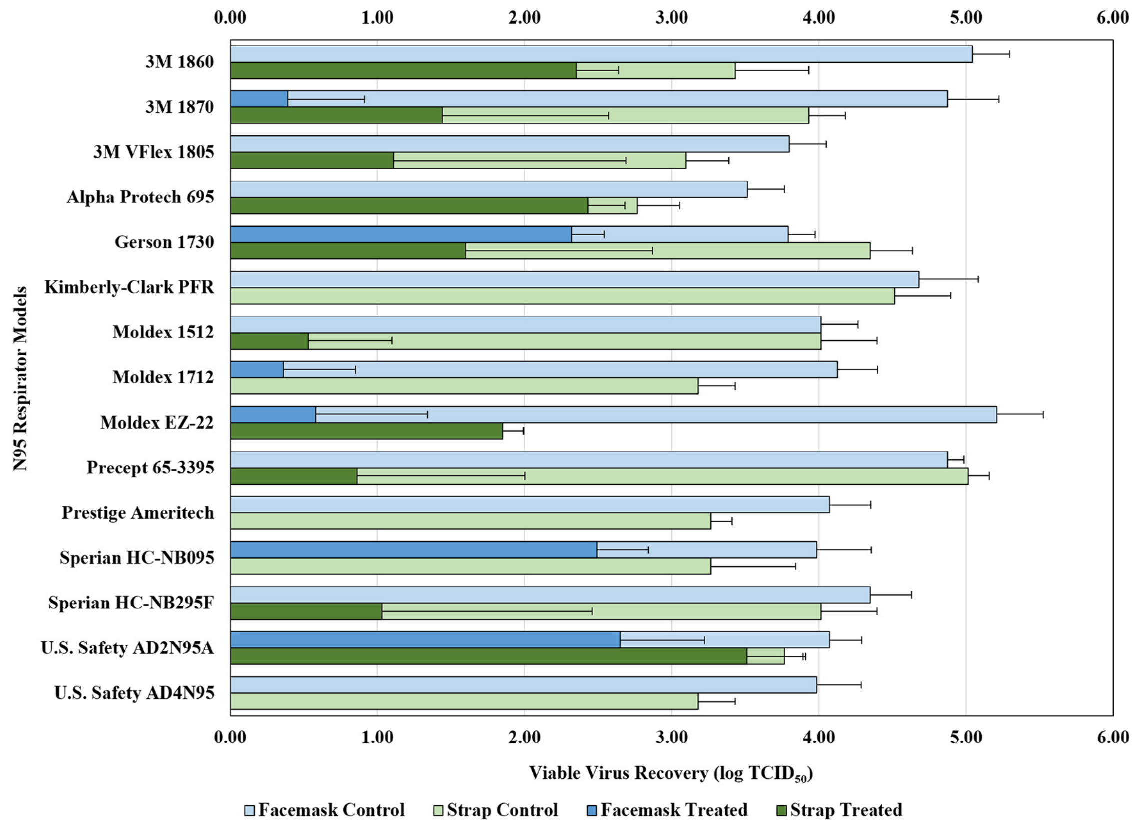

Fig 3. Viable virus recovered from mucin-soiled N95 respirators. Respirator manufacturers were 3M Company, Minneapolis, MN; Alpha Protech, Markham, Canada; Louis M. Gerson Co, Inc, Middleboro, MA; Halyard Health Inc., Alpharetta, GA; Moldex, Culver City, CA; Precept Medical Products, Inc, Arden, NC; Prestige Ameritech, North Richland Hills, TX; Honeywell Safety Products USA, Smithfield, RI; and Dentech Safety Specialists, Lenexa, KS.

features (eg, pleats and flaps). Variability in design between FFR models has the potential to influence the effectiveness of FFR-DR strategies, making it important to understand which design attributes may be less or more advantageous for a given decontamination method. Reductions in virus viability ≥3 log were considered significant because a 3-log reduction would be required to fully disinfect an FFR contaminated with the highest level of influenza contamination predicted by the Fisher et al[23] model. Significant reductions in influenza viability were observed on both mucin- and sebum-soiled facepieces for 12 of 15 FFR models post-UV treatment. The 3 remaining FFR models—Gerson 1730 (Louis M. Gerson Co, Inc, Middleboro, MA), Sperian HC-NB095 (Honeywell Safety Products USA, Smithfield, RI), and U.S. Safety AD2N95A—still demonstrated statistically significant reductions in virus viability. The facepieces from these 3 FFR models are relatively similar in appearance—white, cup-shaped, with slightly rough texture. The Gerson 1730 and U.S. Safety AD2N95A facepieces both appear to be hydrophilic, as indicated by the immediate absorption of the liquid inocula, whereas the Sperian HC-NB095 appears to be hydrophobic. Absorption of the viral inoculum away from the surface could potentially limit the UVGI decontamination efficiency because UV light is primarily effective for surface decontamination. Although the Sperian HC-NB095 facepieces did not appear hydrophilic, the relatively low log reduction may be attributed to the presence of horizontal ridges across the front of the facepieces, which may have created small shadowing effects while the mask was exposed to UV light. In general, the presence of shadows indicates the blocking of UV light, thus inhibiting UVGI efficiency. Although the data demonstrate UVGI can be effective, additional research would be required to define how specific FFR design attributes may influence UVGI efficiency, either individually or in combination.

Similar to the variability observed with FFR facepieces, FFR straps also vary in design (eg, material type, thickness, width, and elasticity), which may influence the effectiveness of FFR decontamination methods. Significant reductions in virus viability were observed for both mucin- and sebum-soiled straps from 7 of 15 FFR models post-UV treatment, whereas 5 FFR models demonstrated <3-log reductions for both soiling agents. Of these 5 FFR models, 4 models—3M 1860, U.S. Safety AD2N95A, Moldex EZ 22, and Alpha Protech 695—appear to have hydrophilic straps and thus absorption of the virus away from the surface could potentially limit UVGI effectiveness. As with FFR facepieces, shadowing during UVGI treatment could also influence the UVGI effectiveness on FFR straps. The presence of shadows are likely a greater concern for FFR straps than FFR facepieces due to their propensity to twist and orientation based on how much slack is available. Ultimately, FFR straps pose a logistic challenge for UVGI decontamination strategies. This is a significant finding because proper doffing techniques for FFRs require handling of the straps, increasing the likelihood of fomite transfer. Thus, FFRs with straps that are amenable to UVGI disinfection would be preferred. Unlike the facepiece component, straps could potentially be disinfected using a disinfecting wipe or similar approach, but determining the effectiveness of these methods would require additional research outside the scope of this study.

Addressing a limitation of the 2011 Heimbuch et al[19] study, soiling agents were used to shield the virus inocula, acting as protective factors. UVGI effectiveness has been shown to correlate with soil load, decreasing in disinfection efficiency as the soil load increases.[29]

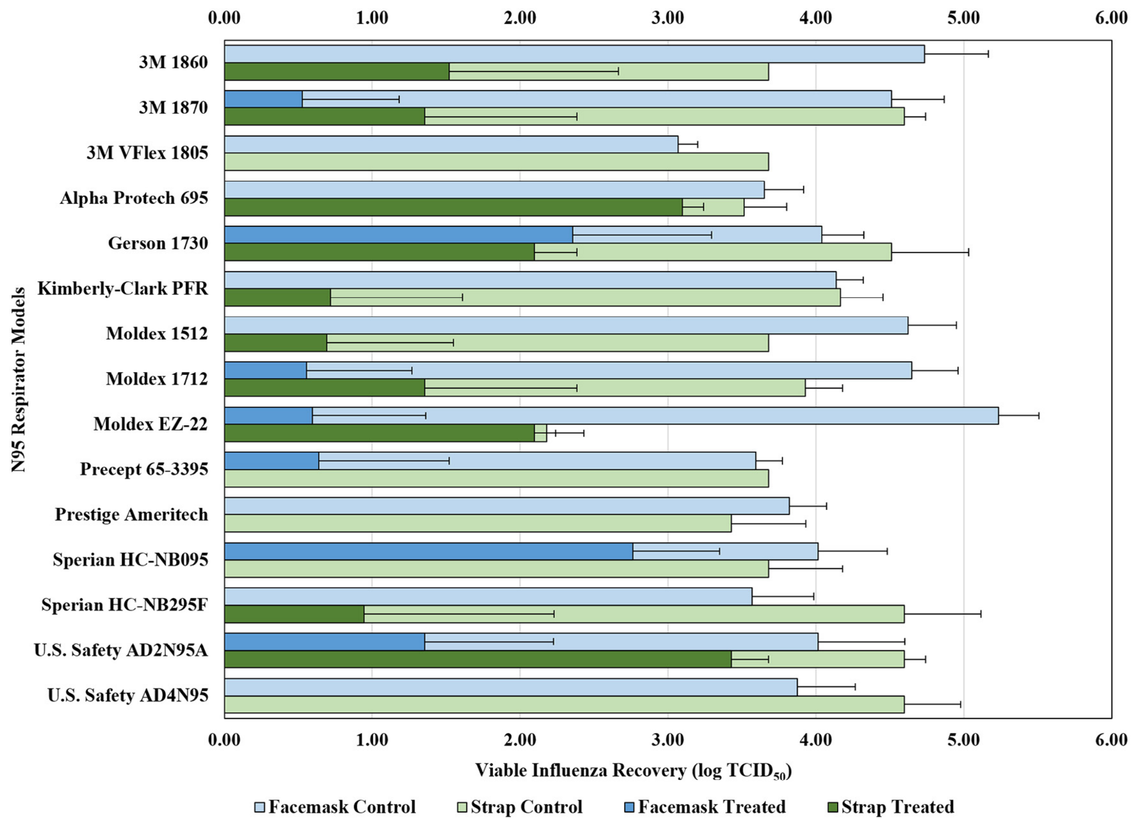

Fig 4. Viable virus recovered from sebum-soiled N95 respirators. Respirator manufacturers were 3M Company, Minneapolis, MN; Alpha Protech, Markham, Canada; Louis M. Gerson Co, Inc, Middleboro, MA; Kimberley-Clark Corp, Irving, TX; Moldex, Culver City, CA; Precept Medical Products, Inc, Arden, NC; Prestige Ameritech, North Richland Hills, TX; Honeywell Safety Products USA, Smithfield, RI; and Dentech Safety Specialists, Lenexa, KS.

As previously mentioned, the levels of sebum and mucin buffer used were intentionally high to act as a worst-case scenario. Pochi and Strauss[35] measured casual sebum levels of 51 male subjects with and without acne to determine a cause-and-effect relationship. They found that subjects with severe acne had a mean density of 0.18 ± 0.08 mg/cm^2 sebum on their face based on the samples taken. Compared with the sebum level of subjects with acne, the sebum challenge used in this study is approximately a 7-fold increase. For mucin buffer, 5 loadings were used for each influenza droplet to provide multilayered shielding against UVGI. Although the level of soiling agents used in this study may be considered excessive and thus a limitation, significant reductions in viable influenza were still observed for both soiling agents, indicating UVGI decontamination of influenza could be performed in the absence of cleaning.

Other potential limitations of the current research effort were identified. For the purposes of this study, only the exterior surface of the facemask was evaluated for UVGI effectiveness. If implemented in a hospital setting, a UVGI application would likely need to treat both the interior and exterior FFR surfaces, accounting for potential contamination resulting from either the environment or the user. Additionally, the soiling agents used were artificial and thus a difference in UVGI effectiveness between artificial and natural soiling agents could potentially occur. There was also some loss in viable virus between the inoculation and extraction of control samples. The source of this reduced fraction of viable virus could be attributed to natural decay of the virus or influenced by the material's extraction efficiency; the effect of either factor is unclear.

The study described herein addresses a significant concern for HCWs during an influenza pandemic—the unavailability of N95 FFRs. Although FFR-DR is a possible mitigation strategy for a potential N95 shortage, the research related to FFR-DR methodology is limited. If implemented, an FFR-DR strategy should not only be effective against the pathogen of concern while maintaining the respirator's performance specifications, but also must be compatible with HCW operations and logistics to be successful. This study demonstrates significant reductions in viable influenza under substantial soiling conditions after being exposed to ~1-minute UVGI treatment. UVGI-based FFR-DR would allow hospitals to treat FFRs in a quick and efficient manner, benefiting HCWs during a potential influenza pandemic. Follow-up research to better understand the effect of multiple UVGI cycles on N95 respirator durability and performance using the current study's conditions has also been performed and will be submitted for publication. Additionally, future work evaluating the effectiveness of UVGI on contaminated respirators under conditions that more closely resemble real-world contamination events would be beneficial.

CONCLUSIONS

The results of this study indicate FFR-DR can be effective. Building on the Heimbuch et al 2011 study,[19] this study evaluated the decontamination efficiency of an optimized UVGI dose (1 J/cm^2) delivered to an intact FFR contaminated with both H1N1 influenza and a soiling agent. Significant reductions in influenza viability (≥3 log) were observed for both soiling conditions (artificial saliva and artificial skin oil) on UVGI-treated facepieces from 12 of 15 FFR models and UVGI-treated straps from 7 of 15 FFR models. Log reductions were considered significant based on the decontamination efficiency required to fully disinfect the highest level of influenza contamination on FFRs predicted by Fisher et al.[23] For FFR-DR, FFR

facepieces pose the greatest challenge for disinfection, whereas FFR straps can likely be disinfected through alternative means (eg, disinfecting wipes). Implementation of a UVGI method will likely require careful consideration of FFR material type and design. These data are critically important for regulators and hospitals to understand whether UVGI-based FFR-DR technologies are being considered for deployment in the event of an influenza pandemic. They also provide the basis for future design of new FFR models that are highly amenable to FFR-DR.

Acknowledgments

The authors thank the National Institute of Occupational Safety and Health's National Personal Protective Technology Laboratory for its involvement in the study design and Chris Church and Bob McDonald of Applied Research Associates for preparing the ultraviolet germicidal irradiation device.

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