

Effect of Decontamination on the Filtration Efficiency of Two Filtering Facepiece Respirator Models

Dennis J. Viscusi, William P. King, and Ronald E. Shaffer*

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochran's Mill Rd., P.O. Box 18070, Pittsburgh, PA 15236

* Correspondence author and Email: RShaffer@cdc.gov

ABSTRACT

Respiratory protective devices such as National Institute for Occupational Safety and Health (NIOSH) certified disposable filtering facepiece respirators (FFRs) are often recommended for use by healthcare workers and the general public for infection control. However, during a wide-scale breakout of a disease spread by human-to-human transmission via infectious aerosol, shortages of FFRs are likely. One possible solution to the potential shortage is to reuse the FFR after decontamination to remove any infectious material. However, little data exists on the effects of various decontamination methods. In this study, two models of FFRs (one N95 and one P100) were treated with ten decontamination processes at two conditions each. Filtration performance of the treated respirators plus two controls was assessed using a poly-dispersed sodium chloride aerosol test method similar to that used by the NIOSH for respirator certification. Decontamination using an autoclave, 160° C dry heat, 70% isopropyl alcohol, and soap and water (20 minute soak) caused significant filter degradation to both N95 and P100 FFRs. The particle penetration levels were greater than allowed for NIOSH certification. Filtration performance after decontamination using bleach, ethylene oxide, and a microwave oven was degraded for both respirator models, although particle penetration levels were still less than the NIOSH certification criteria. The decontamination methods that had the least effect on particle penetration involved hydrogen peroxide (vaporized and liquid forms) and UV radiation. Future research should consider low-temperature decontamination methods such as vaporized and liquid hydrogen peroxide, ethylene oxide, microwave radiation for 2 minutes or less, UV radiation, and 10% diluted household bleach for further study.

Keywords: healthcare workers, N95 respirator, pandemic influenza, P100 respirator, filtering facepiece respirator, decontamination, filtration, filter degradation

INTRODUCTION

The Occupational Safety and Health Administration (OSHA) respiratory protection standard 29 CFR 1910.134 regulates the use of respirators in the workplace and requires employers to provide their employees with respirators that have been certified by the National Institute for Occupational Safety and Health (NIOSH) according to the standards promulgated in 42 *Code of Federal Regulations* Part 84 Respiratory Protective Devices; Final Rules and Notice (42 CFR 84, 1995). NIOSH-certified filtering facepiece respirators (FFRs) are often used for respiratory protection because of their low cost and availability. Many public health leaders predict that it is only a matter of time before a pandemic influenza outbreak will occur (Bailar et al., 2006). In the event of a pandemic outbreak involving human-to-human

airborne transmission of infectious organisms, healthcare workers and the general public will have increased reliance on disposable FFRs for infection control. Current Centers for Disease Control and Prevention (CDC) guidance recommends that once an FFR is worn in the presence of an infected patient, it should be considered potentially contaminated, treated as infectious waste, and touching the outside of the respirator should be avoided. The FFR should not be reused by the same person or another co-worker (CDC, 2007a).

A shortage of respirators is likely during a pandemic. According to a recent report from the National Academies' Institute of Medicine (IOM), over 90 million N95 FFRs will be needed to protect workers in the healthcare sector during a 42-day influenza pandemic outbreak (Bailar et al., 2006). Additional respirators would be needed for workers in other sectors and the general public as well. Most hospitals only keep a limited number of respirators in their inventory (Roberge, 2007). During the SARS outbreak in 2003, 18,000 N95 FFRs were utilized daily at Sunnybrook Hospital in Toronto, Canada (Rubinson et al., 2005). Likewise, nearly 100,000 FFRs were used daily in hospitals during the SARS outbreak in Taiwan (Roberge, 2007). The U.S. Strategic National Stockpile has plans for 100 million N95 FFRs to be available nationwide (Bailar et al., 2006). Furthermore, many of the manufacturers produce respirators overseas or rely on foreign distributors for key components. In a global event it may be difficult to transport resources to the location with the greatest demand. Current respirator manufacturing techniques make it difficult to increase production to meet unexpected demand. Therefore, FFR reuse in an emergency situation, such as a pandemic, needs to be considered as a possible solution to a respirator shortage.

Respirator reuse is a complicated issue. In general, respirator service life is limited by considerations of hygiene, damage, and breathing resistance (NIOSH, 1996). In dusty or dirty workplace settings, the respirator filter can become loaded with trapped particulates (i.e., filter loading), which can cause changes in breathing resistance, and, in extreme cases, filtration performance. Although hospital settings tend to have relatively low concentrations of inert particulates in the air, the potential for infectious agents exists. Thus, reuse in a pandemic situation is more dependent upon infection control procedures and hygiene than on respirator loading considerations.

Many medical devices are reusable because they have been built to withstand a decontamination process which removes or otherwise renders inactive any infectious material on the device (Springthorpe and Sattar, 1990). Manufacturers of FFR devices have stated that their products are likely to deteriorate with standard levels of disinfection (e.g., chemicals, heat, and radiation) (Bailar et al., 2006). However, little or no data exists in the peer-reviewed literature on the effects of decontamination on FFR performance. Although the effects of decontamination on FFR filter media and other materials of construction are largely unknown, some decontamination methods have been shown to cause damage to office materials (Lucas et al., 2004), museum objects (Solazzo et al., 2004), and polymeric biomaterials (Fischbach et al., 2001) and previous laboratory studies (Jasper et al., 2005; Jasper et al., 2006) have shown that direct exposure to liquid solvents decreases electret polypropylene filter media performance. The lack of definitive data specific to decontamination of FFRs caused the IOM to conclude that *"DHHS should sponsor and/or conduct research that will lead to understanding the efficacy of simple decontamination techniques (e.g., bleach, microwave radiation, or ultraviolet light) that could routinely be employed without having negative effects on respirator integrity."* (Bailar et al., 2006).

In this report, the effect of ten commonly available decontamination methods at two different conditions each on the initial instantaneous filtration performance of one model each of two different classes of FFRs (N95 and P100) is reported. The goals of this study are (1) to identify decontamination methods that cause significant changes in filtration performance or obvious changes to the physical appearance of the FFR so that safety professionals, healthcare workers and other respirator users do not attempt to decontaminate FFRs using these methods without taking extreme precautions; and (2) to identify decontamination methods that are suitable for further study. However, it is important to note that

a lack of a significant change in filtration performance or physical appearance does not imply that reuse can be done until further research is completed.

MATERIALS AND METHODS

Respirator Selection

The current 42 CFR 84 regulation provides for nine classes of particulate filters for use with negative pressure air purifying respirators, with three categories of resistance to filter efficiency degradation (series N, R, and P) which have three levels of filter efficiency associated with them (95%, 99%, and $\geq 99.97\%$). The N-series is not resistant to oils, the R-series is resistant to oils but has a one shift use limitation and the P-series is oil resistant and has a service life defined by the manufacturer. N95 and P100 FFRs make up the majority of products currently certified by NIOSH and are most commonly used in a healthcare setting (Fennelly, 1997).

More than 1000 models of FFRs are currently approved by NIOSH. An exhaustive study of all models and types of FFRs was not practical in this initial study because of the urgent need to supply data on the effects of decontamination to the public before an outbreak occurs. Thus, for this study, as described in the following paragraph, a selection strategy was used to choose a few representative respirator types for testing. One key variable that may impact the change in filtration performance caused by decontamination is the resistance to filter efficiency degradation. Electrostatic or electret filter media are produced by imparting a static electric charge on split polypropylene fibers to enhance their capture efficiency. The drawback to electret filter media is that, when exposed to certain chemicals, the electrostatic charges on the fibers are lost, which causes degradation to the filtration performance and increases particle penetration through the filter. In general, studies have shown that various organic solvents (e.g., ethanol, isopropyl alcohol, toluene, and xylene), when applied in liquid form, cause significant change to the laboratory filtration performance of respirators containing electret filter media, (Kanaoka et al., 1984; Martin and Moyer, 2000; Janssen et al., 2003; Jasper et al., 2005; Jasper et al., 2006). Most N95 class respirators use only electret filter media. P100 class respirators can be comprised of mechanical filter media, electret filter media, or a combination of both. Electret filter media used in P100 class respirators have been treated to improve their performance against oily aerosols so they can pass the NIOSH certification requirements (Barrett and Rousseau, 1998). Compared to the electret filter media used in the production of N95 FFRs, few studies on the degradation of electret media used in P100 respirators have been performed.

For this study, two classes of FFRs were used; the N95 class believed to be the most easily degraded FFR class and the P100 class believed to be more resistant to filter degradation. A single respirator model from the same manufacturer was selected for both FFR classes tested. Both respirator models used in this study contained electret filter media and were purchased at the same time prior to testing.

Each model tested was from the same manufacturing batch for each model used in this study to ensure consistency for comparison of filtration efficiency throughout the experiments. Only two models were selected due to the urgent need to quickly obtain some data prior to a pandemic event involving infectious aerosols. However, the N95 respirator model selected for this study is in the U. S. Strategic National Stockpile (United States' national repository of necessary medical supplies, designed to supplement and re-supply state and local public health agencies in the event of a national emergency, especially bioterrorism, anywhere and at anytime within the United States or its territories) (CDC, 2007b) and should be broadly applicable to a large number of end users.

Decontamination Method Selection

There are a vast number of possible decontamination methods with varying degrees of performance and possible negative effects. As stated in the IOM report, "*Any method of decontaminating a disposable N95 filtering facepiece respirator must remove the viral threat, be harmless to the user, and not compromise the integrity of the various elements of the respirator*" (Bailar et al., 2006). These general criteria were used as the basis for selection of decontamination methods and test conditions. Priority was given to those decontamination methods/processes that have the best potential for significantly reducing the number of infectious virus particles on the FFR, are readily available in hospital settings, and are completed in less than 12 hours. Decontamination methods meeting these criteria would provide to the worker on his/her next shift i.e., 12 hours later, assuming a 12-hour shift (common in healthcare workplaces), a reduced risk of handling a contaminated FFR and potentially allow the device to be reused. The selection process also took into account the toxicity, permissible exposure limits, and the physical and chemical properties of the candidate decontamination methods.

Two classes of decontamination were considered for this study, chemical and non-chemical treatments. Chemical decontamination can be achieved using specific chemical substances to destroy or inactivate infectious organisms. Non-chemical disinfecting modalities include dry heat (oven), moist heat (autoclave), microwave and ultraviolet radiation. Chemical methods of decontamination include several classes of disinfectants that would likely be effective against viruses, pandemic influenza, and SARS:

- 1) Halogens (Clorox bleach, Betadyne®, etc.)
- 2) Alcohols (ethanol, isopropyl alcohol (IPA), etc.)
- 3) Oxidants (hydrogen peroxide, ozone, etc.)
- 4) Acids, non-irritating (acetic acid, citric acid, peroxyacetic acid, etc.)
- 5) Aldehydes (formaldehyde, glutaraldehyde, etc.)
- 6) Quaternary ammonium compounds (Zephiran, Roccal, etc.)
- 7) Phenolic compounds (Lysol, etc.)
- 8) Alkalis (sodium hydroxide, ammonium hydroxide, sodium carbonate, etc.)
- 9) Biguanides (chlorhexidine, etc.)

Many candidate agents from the above-listed classes are commonly found in the home or hospital, are inexpensive, and are generally effective against viruses (Dvorak, 2005). Soap and water, though technically not classified as a chemical decontaminant, was included as a method that would be available to all, effective against human immunodeficiency virus (HIV) (Li et al., 2004) and easily employed without harm to the user.

A risk analysis was used to determine appropriate conditions (time, concentration, temperature, etc.) for the various decontamination strategies. Beginning with a list of 24 possible decontamination strategies (Table I), a decision was made to consider the ten most likely candidate methods within the resource limitations of the study. Several methods (ozone, sodium hydroxide, ammonium hydroxide, calcium hypochlorite, hydrochloric acid, supercritical CO₂) were removed from consideration due to their lack of availability to the public or healthcare community; additionally other methods (Betadyne®, iodine, glutaraldehyde, sodium carbonate, Virkon) were eliminated from consideration because of likely facial irritant and respiratory effects. Other chemical decontamination solutions (citric acid, acetic acid, peracetic acid, formaldehyde, quaternary ammonium compounds, phenolic compounds and chlorhexidine) were removed from consideration due to potential skin irritant and sensitization effects. Ethanol was eliminated from consideration because it essentially duplicated the properties of isopropanol and isopropanol is considered to be slightly more virucidal. Tap water was also added as a negative control. Although the degrading effects of alcohols on FFRs containing electret filter media are well-known, 70% IPA was also included in the final list to serve as a positive control.

The list of 10 identified methods that appears to be most likely to meet the criteria for successful decontamination without posing undue risk to the user is found in Table II. Columns two and three of Table II identify the recommended concentration/property and contact times found in the literature to be considered effective against viruses.

Table I. List of 24 Candidate Decontamination Methods

Soap and water	Isopropyl Alcohol
Bleach	Moist Heat (Autoclave)
Calcium hypochlorite	Dry Heat (Oven)
Virkon	UV light radiation
Peracetic acid	Supercritical CO ₂
Sodium hydroxide	Ozone
Sodium carbonate	Microwave Radiation
Hydrochloric Acid	Ethylene oxide
Chlorhexidine	VHP
Citric Acid	Glutaraldehyde
Formaldehyde	Ethanol
Liquid hydrogen peroxide	Ammonium Hydroxide

Table II. List of Decontamination Methods, Recommended Concentrations, Recommended Effective Contact Times, and Test Conditions

Decontamination Methods	Recommended Concentration /Property	Recommended Effective Contact Time	1st Test Condition Less aggressive	2nd Test Condition More aggressive
Autoclave ^{1,2,5}		30 min.	15 minutes	30 minutes
IPA ^{2,3,5}	70%	10 to 30 min.	dunk 1 second	dunk 1 minute
Bleach ^{1,2,3,5}	0.5% in tap water	10 to 30 min.	dunk 30 minutes @ 0.525%	dunk 30 minutes @ 5.25%
H ₂ O ₂ ^{2,3,4}	6%	30 minutes	dunk 3%	dunk 6%
Microwave ^{3,4}	26mW/cm³	2 minutes	2 minutes	4 minutes
Soap & water ^{1,2}	1 g/liter	2 minutes	2 minutes	20 minutes
UV ^{2,3,4,5}	254 nm	15 minutes	30 minutes	480 minutes
Dry heat ^{1,2,5}	160-180° C	60 minutes	80° C	160° C
VHP ^{2,5}	58%	28 minutes	STERRAD® NX	STERRAD® 100S
Ethylene oxide ^{2,3,5}	500-1000 mg/L	1-12 hours	3M 4XL 883mg/L	3M 5XL 725 mg/L

¹Fraise (1999), ²Canadian Medical Association (1998), ³DeBenedictis (2007), ⁴Dvorak (2005), ⁵CFR (2002)

Experimental Design

A series of experiments was performed on one N95 and one P100 respirator model using the ten identified methods of decontamination at two different conditions (e.g. soaking at two different chemical concentrations or lengths of time) plus two controls (no decontamination, water). The conditions were specific to the ten methods selected, but in general were chosen so that one is considered more aggressive, while the other was considered less likely to degrade filtration performance. Sample size

was determined using unpublished data and assuming a population difference, δ , of ≥ 3 standard deviation units between the as-received and the maximum allowable penetration. With $\alpha = 0.05$, a statistical power of ≥ 0.8 was achieved with $n = 4$, which was deemed adequate to achieve the goals of the study.

Filtration performance was measured in quadruplicate on a set of respirators "as-received" and on another set of treated respirators within 72 hours after the decontamination treatment was completed (or received as in the case of ethylene oxide or vaporized hydrogen peroxide since these two treatments were not done in-house). During the period of data collection, the researchers used the TSI 8130 instruments belonging to the NPPTL Technology Evaluation Branch. The TSI 8130 instruments were used when they were available (primarily on Mondays when certification testing was not being performed). The 72-hour air drying time is a divergence from the 12-hour decontamination selection criteria, however limited access to the TSI 8130 instruments resulted in the necessity to adjust the test method to a 72-hour air drying time (over the weekend). A given FFR can only be tested once and may not be used again because the waxing process (discussed below) renders the same mask unusable for subsequent testing. In addition to filtration performance, a visual inspection of the respirator was done post-decontamination to note any obvious changes to the respirator (e.g., straps, nose clips, exhalation valves, etc.). The P100 respirators used in this study had an exhalation valve and those respirators' exhalation valves were sealed closed with beeswax during initial filtration efficiency testing so as not to bias the penetration measurements. As such, we cannot report how the decontamination processes may affect the exhalation valve or its proper operation.

Equipment

TSI Model 8130 Automated Filter Tester (AFT) (TSI, Inc., St. Paul, MN) was used to measure filter penetration (Pen). The TSI 8130 delivers a solid polydisperse sodium chloride (NaCl) aerosol which meets the particle size and size distribution criteria set forth in 42 CFR 84 Subpart K, Section 84.181.(g) for NIOSH certification (CFR, 1995). The TSI Model 8130 AFT produces a particle concentration of 12 - 20 mg/m³ and generates an initial instantaneous filter penetration result. To meet NIOSH certification requirements, the NaCl aerosol must have a count median diameter (CMD) of 0.075 ± 0.020 micrometer and a geometric standard deviation (GSD) not exceeding 1.86 and be neutralized to the Boltzmann equilibrium state as outlined in the above regulation. All tests were conducted at room temperature with a continuous air flow of 85 L/minute in accordance with all of the NIOSH certification criteria for challenging N-series filters, with two exceptions. All filters were tested without any relative humidity pretreatment or loading.

Particle penetration through the FFR was determined using a cubic Plexiglas box (20 x 20 x 10 cm³) placed between the filter chucks (sample holding mechanism on the ATF). The top and bottom removable 1/8" aluminum plates (20 x 20 cm) of the Plexiglas box have a circular hole (25 cm²) in the center of each plate. The FFR was placed on the bottom plate with its concave side facing the hole. The periphery of the FFR was sealed to the bottom plate with melted beeswax. The bottom plate with the FFR was placed under the Plexiglas box just above the downstream side of the filter holder, so that the convex side of the FFR was facing the aerosol upstream side of the filter holder followed by the addition of the top plate. The Plexiglas box containing the FFR was then placed between the two chucks of the filter holder and aligned vertically to keep the holes of the Plexiglas box centered with respect to the filter chucks. Airtight sealing was maintained using continuous and precisely cut gasket material between the plates and the box, a minimum of vacuum grease (lubricant and pore filler), and the pressure created by closing the filter chucks.

Treatments/Controls

Data Collection Procedures

As-received 2 untreated (as-received) out-of-the-box respirators of each model were tested during each testing session on five different days for a total of ten control samples for each N95 and P100 respirator model sampled. This was done to ensure day-to-day consistency during testing.

Tap Water This treatment involved submerging the test respirators in tap water for 30 minutes and was included as a control to reveal any effect due to immersion in tap water and air drying.

Liquid decontamination methods Liquid chemical treatment solutions were made by appropriate dilutions with tap water and reagents: hydrogen peroxide; Fisher 30% stabilized H₂O₂, Bleach; Fisher 5.25% Sodium Hypochlorite (NaOCl) with 0.20% Sodium Hydroxide (NaOH); Henry Shein Isopropyl alcohol (IPA), 70%; Ivory bar soap, 1g/L, shaved from the bar and diluted in tap water. Based upon the capacity of the treatment vessel used, either 4 or 8 respirator samples were placed (submerged) into a dishpan or 4L beaker containing 3-5 liters of treatment solution. A second dishpan, when needed, was used to keep respirators submerged for the specified time interval. Respirators were removed, hung on a pegboard and air-dried for 72 hours, prior to filter penetration testing.

Ultraviolet radiation (0.24mW/cm²) Respirators were placed on the working surface of a laminar flow hood, Sterilgard III, (The Baker Company, Sanford, ME) fitted with a 40W ultraviolet light for general decontamination. The intensity is reported as the average obtained at nine positions over the area used with a UVX Digital Radiometer with MODEL UVX-25 sensor (254nm filter) (VWR Lab Shop, Batavia, IL). For both treatments, samples were turned over after 50% exposure to allow treatment of the inside as well as the outside of the respirator.

Dry Heat (oven) Respirators were placed in a metal pan on racks of a Fisher Isotemp 500 Series (Fisher Scientific, Pittsburgh, PA) laboratory oven at the specified temperature and turned over midway through the exposure period.

Microwave 26mW/cm³-(750W/ft³) Exposures were carried out in a standard commercially available 2,450-MHz microwave oven, Sharp Model R-305KS (Sharp Electronics, Mawwah, NJ) with revolving glass carousel. Although rated at 1100W on the 100% full power setting, we obtained an average power measurement of 750 W/ft³ from four evaluations at various evenly spaced representative locations in the oven using the power determination method recommended by the manufacturer. In both treatments (2 min. and 4 min.) the samples were irradiated for half the time, promptly turned over, and irradiation was repeated for the remainder of the allotted time.

Autoclave 121°C (15 psi) All samples were sealed in a standard poly/paper autoclave bag and treated in a Market Forge Automatic Sterilmatic Steam Pressure Sterilizer (Everett, MA) for the specified time period. The respirators were then air-dried for 72 hours prior to filter testing.

Ethylene oxide (EtO) The two treatment conditions (EtO 3M Steri-Vac 4XL [3M, St. Paul, MN] sterilizer processed in the warm cycle of 55° C and 883 mg/L ethylene oxide gas and EtO 3M Steri-Vac 5XL [3M, St. Paul, MN] sterilizer processed in the warm cycle of 55° C and 725 mg/L ethylene oxide gas) are different model instruments using the same process but differing in some aspects (e.g. gas concentration, chamber volume, and duration). Respirators tested using these treatments were shipped to and from a commercial facility specializing in low-temperature sterilization methods. Four FFR samples were placed in standard poly/paper pouches and treated with EtO. All respirator samples were exposed to EtO for one hour followed by a four-hour aeration interval. The respirators were shipped back to the investigators and subsequently tested in house for filtration efficiency within 72 hours of receipt.

Vaporized Hydrogen Peroxide (VHP) The two treatment conditions (STERRAD® NX Standard cycle and STERRAD® 100S [Advanced Sterilization Products, Irvine, CA] Standard cycle) were different model instruments using the same process (Hydrogen Peroxide gas plasma) differing only by duration and capacity. Respirators tested using these treatments were shipped to and from a commercial facility specializing in low-temperature sterilization methods and were tested in-house for filtration efficiency within 72 hours of receipt from the commercial facility. The STERRAD® sterilization process is less effective when used on cellulose based products; hence the use of Tyvek/Mylar pouches was required. As there are no hazardous residues inherent as a result of the STERRAD® process, no aeration interval was necessary.

Statistical Analysis

Ideally, a decontamination method would not affect (particularly increase) the particle penetration characteristics of the treated respirators. The working (null) hypothesis was that the difference between average treated and untreated respirator penetration is zero. The Chi-square test showed no significant deviations from normal distribution and was done with the calculator available at <http://jumk.de/statistic-calculator/>. The t-statistic was calculated for all treatments (10 decon methods x 2 conditions x 2 respirator types). P, the probability of observing the given t-statistic or larger (in magnitude) by chance, was then calculated and listed in Table III. Statistical analyses were calculated using Microsoft Excel. The relative significance of the observed changes in penetration is included in the discussion of each treatment below.

The average penetration level was further compared to the appropriate maximum allowable penetration for that class of respirator (5% for an N95 FFR and 0.03% for a P100 FFR). This second comparison was added because the filtration performance of the as-received respirators far exceeded the NIOSH requirements. Some of the treatment/respirator combinations resulted in changes in filtration performance that were significantly different ($p < 0.05$) than the as-received but still were below the NIOSH certification criterion.

Data Collection Procedures

A total of 20 treatments (10 decontamination methods x 2 conditions) and 1 control (water) were applied to four samples ($n=4$) of each N95 and P100 FFR model used in this study. A total of 94 N95 [(20 x 4) treatments + (1 x 4) water controls + (1 x 10) as-received controls = 94] and 94 P100 FFRs were used. Average N95 and P100 penetration results obtained from all treatments and controls are summarized in Table III and in the text below.

RESULTS AND DISCUSSION

Effect of Decontamination Treatments on FFR Penetration

As-received Average “as-received” respirator particle penetration results were all considerably less than the NIOSH certification criteria. The results for N95 FFRs are consistent with the recent average initial penetration results from five different manufacturers which ranged from 0.61% to 1.24% (Rengasamy et al., 2007).

Tap Water No significant visible changes were observed. As expected, average filter penetration was unchanged for either respirator model (Table III). These results are similar to those observed by Moyer and Bergman (2000). They assessed filter penetration on three different

manufacturers' N95 FFR and found that water dipping for 15 seconds had a minimal effect on filter penetration as compared to intermittent sodium chloride exposure.

Autoclave For both treatment conditions (30 and 15 minutes), the N95 FFRs were deformed, shrunken, stiff and mottled. No remarkable visual changes were observed in the P100 respirators, though the respirator media itself felt softer. Both treatment conditions markedly increased the average penetration for both classes of respirator (Table III). This observation is not surprising given the general push towards low temperature sterilization methods for sensitive materials and equipment. Temperature greater than 80° C will likely affect the performance of a filter. The maximum filter operating temperature for non-woven polypropylene is 90-100° C (Hutten, 2007), suggesting that any decontamination method requiring high heat may cause similar deleterious effects. Furthermore, steam autoclave and heat sterilization are well-known to strongly affect polymer properties and this property has been used to advocate low-temperature sterilization methods such as UV irradiation (Fischbach et al., 2001).

Table III. Summary of the Means and Standard Deviation Penetration (% Pen.) for the 10 Decon Methods and 2 Controls. Bolded Values (in the % Pen. columns) Indicate that the Penetration Level Exceeds NIOSH Criteria. T-test Probability (P*) Values ($P \leq 0.05$ Bolded) are also Calculated as the Probability of Observing the Given t-statistic or Larger by Chance.

N95			Treatment			P100		
avg. % Pen.	std. dev.	t-test P*	Method	Aggressiv e Level	n	avg. % Pen.	std. dev.	t-test P*
0.7	0.267	n/a	As-received	n/a	10	0.006	0.003	n/a
0.72	0.202	0.417	water	tap	4	0.007	0.002	0.264
18.7	5.263	0.003	Autoclave	Less	4	0.059	0.011	0.001
34.4	9.963	0.003	Autoclave	More	4	1.426	1.423	0.070
17.8	5.508	0.004	IPA	Less	4	0.412	0.126	0.004
21.6	1.337	0.000	IPA	More	4	0.805	0.625	0.042
0.68	0.124	0.454	Bleach	Less	4	0.009	0.004	0.092
3.79	3.446	0.085	Bleach	More	4	0.027	0.048	0.220
0.57	0.152	0.139	UV	Less	4	0.008	0.002	0.093
0.79	0.082	0.165	UV	More	4	0.011	0.013	0.245
0.75	0.242	0.372	H ₂ O ₂	Less	4	0.006	0.002	0.330
0.71	0.148	0.459	H ₂ O ₂	More	4	0.005	0.001	0.106
38.8	1.269	0.000	Soap & water	Less	4	0.014	0.004	0.004
34.9	4.599	0.000	Soap & water	More	4	0.147	0.05	0.006
1.2	0.729	0.136	EtO 3M5XL	Less	4	0.007	0.001	0.057
1.29	0.35	0.019	EtO 3M4XL	More	4	0.008	0.003	0.148
0.5	0.213	0.094	STERRAD® NX	Less	4	0.006	0.002	0.437
0.75	0.166	0.339	STERRAD® 100S	More	4	0.008	0.002	0.087
0.84	0.258	0.192	heat	Less	4	0.008	0.001	0.061
1.13	0.662	0.148	microwave	Less	4	0.006	0.002	0.437
1.77	0.617	0.022	microwave	More	4	0.009	0.006	0.186

Isopropyl alcohol Fading of strap ink was the only visible change observed. As expected, both treatment conditions (1 second and 1 minute submersion) resulted in markedly increased average penetration for both respirator classes (Table III). As observed in previous studies (Martin and Moyer, 2000; Janssen et al., 2003), exposure to IPA was found to be severely degrading to N95 and P100 filters containing electret filter media. This was possibly due to changes in the density and/or spatial distribution of the electret charges on the surface of the polymer fibers by the liquid phase application (Jasper et al., 2005).

Bleach The aluminum nose bands were tarnished by both treatments (0.525% and 5.25% bleach) after a 30-minute submersion. For the 0.525% treatment, average penetration was not significantly changed for N95 samples but average penetration significantly increased for P100 samples though not beyond the NIOSH certification criteria of 0.03% (Table III). Treatment with 5.25% bleach resulted in stiffening of filter media and elastic straps for both respirator models, though to a lesser degree for the more diluted treatment. N95 average penetration was increased from baseline, but was still less than the 5% maximum specified by NIOSH certification. P100 penetration results were more variable, although the average penetration was not significantly increased. As noted elsewhere (Akdog et al., 2007), other materials used in personal protective equipment (e.g. Kevlar) degrade significantly when exposed to aqueous chlorine solutions, so slight changes in filtration performance seen here with a single application of bleach at the highest concentration level tested are not surprising. Despite these concerns, continued study of decontamination using diluted bleach concentrations is warranted, given the ease of obtaining bleach and its widespread use for cleaning surfaces in hospital settings and home use.

Ultraviolet radiation No significant visible changes were observed for any samples after either treatment. The average penetration results for N95 respirators were not significantly affected by either treatment. The P100 respirators' penetration was unchanged by the 30-min. treatment. For the 480-min. treatment, P100 penetration results were significantly more variable compared to the baseline, but remained less than 0.03% (Table III). These findings are somewhat similar to those found during a study on the effect of UV irradiation on the surface properties of polymeric biomaterials used for tissue engineering (Fischbach et al., 2001). The data reported in that study indicated that it was important to control the duration of UV exposure and that irradiation for 2 hours was appropriate.

Liquid hydrogen peroxide Submersion in 3% hydrogen peroxide for 30 minutes exhibited no visibly observable changes for any samples. Average penetration was not significantly increased for either model respirator, but was significantly more variable for the P100 respirator. The same treatment with 6% hydrogen peroxide for 30 minutes slightly faded label ink on the fabric of the respirator. The average penetration was not significantly changed for the N95 respirator when compared to baseline and remained well below the NIOSH 5% criteria. The P100 penetration results were significantly more variable compared to baseline but remained less than 0.03% (Table III).

Soap and water For treatments of submersion in the soap and water solution for 2 and 20 minutes, no visible changes were observed for any samples. Average penetration was markedly increased for N95 respirators at both time intervals. For the P100 samples, the 2 min. treatment resulted in a slight increase in penetration while the 20 min. treatment significantly increased average penetration (Table III). Since, as noted earlier, dipping in water had essentially no effect, it would follow that the soap was likely to be responsible for the increase in filter penetration. It is possible that the soap removed the charge on the fibers similar to the effect observed with IPA exposure. This observation is consistent with one other study (Biermann et al., 1982) that found that the addition of a surfactant to an ionic water solution resulted in a dramatic decrease in filter efficiency for permanently charged electro-fibrous filters. The severe degradation seen here with soap and water suggest that other possible decontamination methods involving soap (e.g. washing machine, dishwasher) may have similar effects, but would need to be verified experimentally.

Ethylene oxide For both treatments the P100 straps were darkened slightly. The average penetration was slightly increased for both respirator models though not beyond their respective NIOSH certification criteria (Table III). EtO 3M 5XL was found to be slightly less degrading than EtO 3M 4XL. A study by Lucas et al. (2004) evaluated the effects of ethylene oxide gas on a variety of office supplies, personal items and equipment and found that although there were no visibly obvious signs of degradation to many of these items, ethylene oxide caused adhesive failure and some distortion to paper products and cloth first-aid tapes. However, EtO is a popular low temperature decontamination method and further study on FFRs is warranted.

Vaporized hydrogen peroxide Aluminum nosebands were slightly tarnished and visibly not as shiny when compared with their as-received counterparts after both STERRAD[®] treatments. For both treatments, average penetration of both respirator models was not significantly increased and remained below NIOSH certification limits. STERRAD[®] NX was found to be slightly less degrading than STERRAD[®] 100S, but the difference was not statistically significant (Table III). Vaporized hydrogen peroxide is an established technique for decontamination of heat-sensitive medical devices and equipment (Krause et al., 2001) and thus, the lack of a change in filtration performance is not surprising. The material safety data sheet (MSDS) for the P100 respirator used in this study indicated 10-30% cotton composition. The cotton is located in the straps and not in the filter media. The MSDS sheet for the N95 FFR did not list cotton as one of the ingredients. Because cellulose absorbs the hydrogen peroxide, care must be exercised so that the decontamination process is not compromised by the materials of construction used in the FFR. Further research will be necessary to determine what effect, if any, the cellulose component has on decontamination efficacy.

Dry Heat At a temperature of 80° C, no visible changes were observed after 60 minutes for either type respirator, however a small increase in average penetration was observed for both the N95 and the P100 (Table III). For treatment at 160° C, both types of respirators were largely melted and unusable after only 22 minutes. No further penetration tests were attempted using dry heat. This result is not surprising. Though the actual melting point for polypropylene is 165° C, the maximum operating temperature for polypropylene is 90-100° C, after which it will begin to soften and melt (Hutten, 2007).

Microwave For treatments of two minute duration, no visible changes were observed for any samples. Average penetration was unchanged for P100 respirators and N95 average penetration was increased slightly. After 4 minutes of microwave exposure, the N95 filter media melted at the ends of the aluminum nose bands and formed visible holes. N95 filter penetration was significantly increased. For one P100 sample tested, the face seal (a large black inner liner used to enhance respirator fit) was melted when the face seal was placed face-down on the circular glass plate (carousel) for the second half of the treatment. The melted sample was not tested for filter penetration. When the order of FFR orientation on the glass plate was reversed, melting was avoided. The remainder of the replicates was treated in this manner to obtain 4 treated FFRs for filter testing. The P100 penetration was somewhat increased and significantly more variable (Table III). The likely cause of the increased filter penetration and melting issues seen with the FFRs studied was the temperature increase caused by the microwave irradiation. In a recent study (Park et al., 2007) involving the decontamination of wastewater contaminated kitchen sponges, scrubbing pads, and plastic syringes using a household type microwave oven, the mean inside temperatures of wet kitchen sponges could reach 90° C after one minute of irradiation. In this study, melting and decreased filtration performance was also observed at 160° C for dry heat. Reducing the dry heat to 80° C reduced these effects greatly. Although internal temperature measurements of the dry respirators during microwave irradiation were not performed, it is likely that the temperatures increased during the microwave cycle and surpassed 80° C sometime during the four minute cycle. Thus, the selection of appropriate parameters for microwave decontamination of FFRs is critical and future work in this area is warranted given the ubiquity and relative ease of operating a microwave oven.

Overall, among the 19 decontamination processes tested from which filtration data could be obtained, six decontamination methods applied to the N95 FFRs and five decontamination methods applied to the P100 FFRs caused mean filter penetration values that exceeded the corresponding NIOSH certification criterion and eight decontamination methods applied to the N95 FFRs and five decontamination methods applied to the P100 FFRs resulted in mean penetration levels that were statistically different from the as-received (no decontamination) FFRs. In general, decontamination methods that had a negative impact on the filtration performance of the N95 FFRs also degraded the filtration performance of the P100 FFRs tested. This result was not unexpected since both models of FFRs tested utilize electret filter media. As expected, the overall penetration levels for the two classes were very different from each other. Only for the most aggressive conditions employing Autoclave and IPA did the average post-decontamination filter penetration result for the P100 FFR exceed that of the as-received N95 FFR model. For most of the decontamination methods tested, the conditions considered to be the most aggressive level resulted in increased average filter penetration for both the N95 and P100 models tested. This suggests that optimization of the conditions used in the decontamination methods or perhaps synergistic combinations of two or more decontamination methods may be useful in minimizing reductions in filtration performance, while maximizing the efficiency of rendering trapped virus particles inactive.

CONCLUSIONS

Little or no data currently exists exploring the ability to possibly decontaminate a disposable FFR. This study represents a starting point in answering the question "Can a disposable FFR be decontaminated for possible reuse in the event of an impending influenza pandemic?" Further research will be needed to determine whether infectious organisms (or appropriate surrogates) can survive the decontamination process and if decontamination changes respirator fit. To expedite the dissemination of preliminary results, only one N95 and one P100 respirator model were tested for each of 20 decontamination treatments. In this study, all methods involving heat greater than 80° C significantly degraded FFR filter efficiency. Average filtration efficiency of N95 and P100 FFRs was degraded beyond 5% and 0.03%, respectively by decontamination using autoclave, 160° C dry heat, 70% IPA, and soap and water (20 minute soak). Submerging an N95 or P100 FFR in water and passively air drying had no statistically significant effect on filtration performance for the tested models. Among the ten decontamination methods studied, the two methods involving hydrogen peroxide (liquid and VHP) and UV radiation caused the least change in filtration performance. It must be emphasized that these findings are exploratory and the data presented in this study are applicable only to the FFRs tested, and that other FFRs may be more easily degraded while others may be less affected. Future research should consider low-temperature processes such as liquid hydrogen peroxide, VHP, ethylene oxide, microwave (two minutes or less), UV radiation, and 10% diluted household bleach for further study as potentially useful methods of FFR decontamination.

Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health (NIOSH). Mention of company names or products does not constitute endorsement by NIOSH.

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