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Major article

Cleaning of filtering facepiece respirators contaminated with mucin and *Staphylococcus aureus*

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Background: Decontamination, cleaning, and reuse of filtering facepiece respirators (FFRs) has been proposed to mitigate an acute FFR shortage during a public health emergency. Our study evaluates the ability of commercially available wipe products to clean FFRs contaminated with either infectious or noninfectious aerosols.

Methods: Three models of surgical N95 FFRs were contaminated with aerosols of mucin or viable *Staphylococcus aureus* then cleaned with hypochlorite, benzalkonium chloride, or nonantimicrobial wipes. After cleaning, FFRs were separated into components (nose pad, fabrics, and perforated strip), and contaminants were extracted and quantified. Filtration performance was assessed for cleaned FFRs.

Results: Mucin removal was <1 log for all wipe products on all components. Inert wipes achieved ~1-log attenuation in viable *S aureus* on fabrics from all FFR models—removal was less effective from nose pads and perforated edges. Both antimicrobial wipes achieved 3-5-log attenuation on most components, with smaller reductions on nose pads and greater reductions on perforated strips. Particle penetration following cleaning yielded mean values <5%. The highest penetrations were observed in FFRs cleaned with benzalkonium chloride wipes.

Conclusions: FFRs can be disinfected using antimicrobial wipe products, but not effectively cleaned with the wipes evaluated in this study. This study provides informative data for the development of better FFRs and applicable cleaning products.

A filtering facepiece respirator (FFR) is standard personal protective equipment to protect health care workers from respiratory threats such as pandemic influenza and tuberculosis.[1,2] An FFR in use will likely be contaminated through aerosol exposure, rendering it a fomite. During normal operations, an FFR should not significantly contribute to disease transmission because it is disposed of after each patient exposure. However, continual wear during a public health emergency increases the likelihood of an FFR acting as a fomite. Secondary bacterial infections are a major factor in mortality rates of influenza pandemics; thus, protecting individuals from viruses and bacteria (eg, during influenza pandemics) is important. Bacteria are typically more robust than viruses, so research focusing on bacteria should suggest ways to lower the chance that an FFR will act as a fomite.

For a pandemic lasting 42 days, the Centers for Disease Control and Prevention (CDC) estimate that US health care workers will require more than 90 million FFRs, implying a supply shortage.[3] Such shortages could also occur during and following a bioweapon attack. Smallpox (*Variola major*) and pneumonic plague (*Yersinia pestis*) are highly contagious agents considered offensive bioweapons. FFR shortages resulting from a biowarfare attack should be confined to a local area and shorter in duration than during an influenza pandemic. An emergency measure proposed to alleviate acute FFR shortages on any scale is decontamination, cleaning, and reuse.[3] Experimental data assessing feasibility of this option is needed to guide regulatory and legal decisions. Heimbuch et al[4] and Lore et al[5] demonstrated 3 energetic decontamination

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methods—microwave-generated steam, low-temperature moist heat, and ultraviolet germicidal irradiation—that inactivate H1N1 and H5N1 influenza viruses without significantly affecting FFR fit or function.[6,7] Other chemical and energetic methods have also shown promise for decontamination of FFRs,[8-10] but we found no studies that addressed decontamination of bacterial agents on FFRs.

The US Food and Drug Administration (FDA) requires cleaning and sterilization of reprocessed medical devices and demonstration of their functional performance,[11] but no reported data describe efficacy and compatibility of cleaning methods with FFRs. Sterilization and functional performance are relatively easy to assess; cleaning is harder to measure and no criteria are defined for "cleaned." The Medical Device User Fee and Modernization Act (MDUFMA) regards the common definition of a clean device—no visual contamination present—insufficient and requires that an objective, measurable endpoint be specified.[11] MDUFMA specifies no cleaning requirements for contaminants (eg, protein, microbe, and chemical), but requires that the reprocessor establish cleaning endpoints and the rationale for their selection. MDUFMA's only reference to a quantifiable value—sterilization following cleaning must achieve a sterility assurance level of 10^{-6}—may not apply to FFRs (non-sterile devices), leaving the criteria for both cleaning and disinfection to be defined.

FDA labels National Institute for Occupational Safety and Health (NIOSH)-approved surgical N95 respirators as single-use items, and no data have been reported from efforts to clean them. FFRs are porous, and therefore typically harder to clean than solid surfaces. Damage caused by cleaning is also a significant concern. Traditional methods to clean elastomeric respirators include washing with soap and treatment with disinfectants and disinfecting wipes.[12,13] Literature provided by respirator manufacturers clearly states that cleaning procedures should not be used on the filtering element and doing so disqualifies them as the FFR is the filtering element. New FFR cleaning methods are needed that are simple to perform, effectively remove the soil load, do not degrade the level of protection, require short regeneration times, and do not impart toxic residues. Long regeneration times eliminate methods that extensively wet the FFR. Soap washes and alcoholic solutions are also eliminated because they degrade FFR performance.[9] We chose to evaluate 3 wipe-based products as a readily available, inexpensive, and presumably nonaggressive cleaning technique with short FFR regeneration times.

This study was an off-label use of both the FFRs and the wipes, and the results are only an exploration of the concept of reuse. Neither endorsement nor censure of any products tested nor of the concept of cleaning and reusing FFRs is implied. We examined physical removal of deposited contaminants; measurements of disinfection were included because 2 wipe products include antimicrobial agents. Because bacteria typically tolerate environmental challenges better than viruses, we expect behavior of the bacteria tested to represent or underestimate sensitivity of a virus under similar conditions. This remains to be verified by additional testing.

MATERIALS AND METHODS

Contamination

Two challenge aerosols were applied to FFRs in separate tests, per American Society for Testing and Materials method 2721-10.[14] *Staphylococcus aureus* (ATCC 6538) was inoculated onto a trypticase soy agar plate and incubated overnight at 37°C. A swab of cells from the plate inoculated 50 mL trypticase soy broth in a 250-mL flask. The flask was incubated for ~18 hours at 37°C at 220 rpm. After incubation, the stock was removed from the incubator and diluted 1:2,000 in an artificial saliva buffer.[14]

Table 1
Filtering facepiece respirator (FFR) components evaluated

Code	Manufacturer	Model	Shape	Components tested	
FFR A	3M*	1860S	Cup	Internal	Fabric
					Nose pad
				External	Fabric
FFR B	3M*	1870	Flat-fold	Internal	Fabric
					Nose pad
				External	Fabric
FFR C	Kimberly-Clark†	PFR	Duck bill	Internal	Fabric
					Perforated edge strip
				External	Fabric
					Perforated edge strip

*The 3M Company, St Paul, MN.
†Kimberly-Clark Corporation, Irving, TX.

Cleaning studies

Three NIOSH-approved N95 respirators cleared as medical devices by FDA were selected for this study (Table 1). All 3 models are commonly used in US hospitals. Wipe products selected for this study were 504/07065 Respirator Cleaning Wipes (3M Company, St Paul, MN),[15] which contain benzalkonium chloride (BAC); HypeWipes (Current Technologies, Inc, Crawfordsville, IN),[16] which contain 0.9% hypochlorite (OCL); and Pampers wipes (Proctor & Gamble, Cincinnati, OH),[17] which contain no active antimicrobial ingredients (ie, inert). BAC and other quaternary ammonium disinfectants commonly appear in wipe products; the examples chosen are labeled for use on respirators. OCL was shown to decontaminate FFRs without significantly degrading performance, but created odor and oxidation problems.[8,9] The OCL wipe was included to measure the ability of a limited application (wiping vs immersion) to remove contaminants and minimize incompatibilities with FFRs. Alcohol- and soap-based wipe products were avoided because they are known to decrease FFR performance.[9]

Each FFR is comprised of different materials for which cleaning efficiencies vary (Table 1). *S aureus* was applied to both interior and exterior FFR surfaces (in separate experiments) to provide sufficient sensitivity for reliable analysis. Mucin was applied as a heavy loading (~1 mg/cm^2) only to exterior surfaces. FFR A was used as received. Only the flat front panel of FFR B and only 1 of the side panels (not containing the metal nose clip) of FFR C were used. No straps or metal nose clips were evaluated. For each independent test, 5 FFRs were loaded—3 cleaned as described below and 2 used to quantify the challenge. Two independent tests were performed for each condition, hence n = 6 for each FFR-wipe combination. After loading, FFRs were incubated at ~22°C for 30 minutes to clear aerosols from the test chamber. Each of the 3 test FFRs was wiped 3 times in turn with 4 faces of a fresh wipe product folded over twice. Total cleaning time per FFR was ~30 seconds; to ensure relatively constant wiping pressure and cleaning technique throughout the study, 1 technician cleaned all FFRs.

After cleaning (or set time for uncleaned samples), FFRs were incubated 15 minutes at room temperature before quantification of contaminants. A 38-mm round–hole punch (McMaster-Carr, Robbinsville, NJ), was used to cut 4 coupons from the external (to the wearer) surfaces of FFRs A and B, and 3 from the (internal) surfaces that would be exposed to the wearer's respiratory secretions; the nose cushion was removed and evaluated as a fourth sample. Three 38-mm coupons each were cut from internal and external fabrics of FFR C; a fourth sample was the perforated edge strip of the FFR. For mucin testing, each coupon was placed in a 50-mL centrifuge tube containing 10 mL sterile water and extracted for 10 minutes using a vortex mixer. A QuantiPro protein assay kit