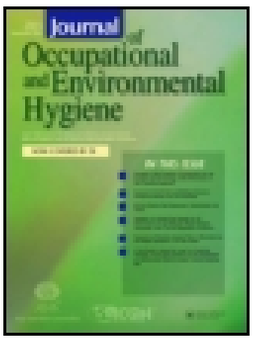

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CASE STUDY

Capture of 0.1-µm Aerosol Particles Containing Viable H1N1 Influenza Virus by N95 Filtering Facepiece Respirators

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BACKGROUND

Nosocomial infections pose an escalating threat to both patients and healthcare workers (HCWs). A widely recommended device for individual respiratory protection, the N95 filtering facepiece respirator (FFR) has been shown to provide efficient filtration of inert particles larger and smaller than the nominal most-penetrating particle size (MPPS) range, 0.03–0.3 μm. Humans generate respiratory aerosols in the MPPS range, suggesting that short-range disease transmission could occur via small infectious particles. Data presented here show that the N95 FFR will afford a significant measure of protection against infectious particles as small as a bare H1N1 influenza virion, and that the capture mechanism does not discriminate in favor of or against biological particles.

INTRODUCTION

Human transmission of influenza infections is a significant concern for the public health sector, as highlighted by the 2009 H1N1 pandemic[1] and recent outbreaks of H7N9 avian influenza.[2] Inhalation and inspiration of aerosolized influenza virus are two of the primary modes of human transmission for this disease. N95 FFRs certified by the National Institute for Occupational Safety and Health (NIOSH) are a principal device recommended for respiratory protection against infectious aerosols in the clinical setting. Devices carrying a NIOSH certification have shown the ability to remove ≥95% of particles of the conventional MPPS, 0.3 μm.[3] The MPPS for FFRs employing electret media is in the range of 0.03–0.1 μm.[4] An earlier study demonstrated that samples from five NIOSH-certified N95 FFR models captured >95% of viable H1N1 influenza aerosols with particle size distributions (PSDs) having count median diameters (CMDs) of 0.8 μm to evaluate influenza filtration when aerosolized in an artificial saliva medium.[5] To generalize the understanding of mechanical and viable capture efficiencies across the range of particle sizes capable of respiratory transmission of infections, this study challenged five N95 FFR models with viable H1N1 influenza and inert aerosols with CMDs of ~0.1 μm, representing particles near the MPPS for many types of filters, at 85 liters per minute (LPM).

MATERIALS AND METHODS

Triplicate specimens of five models of NIOSH-approved N95 FFRs, three inert (3M 1860S, 3M 1870, Kimberly–Clark) and two antimicrobial (SafeLife T5000, GSK Actiprotect), were challenged with aerosolized, viable H1N1 influenza and inert polystyrene latex (PSL) particles

with a CMD of 0.1 μm (Figure 1) at a continuous flow rate of 85 LPM. A Laboratory-Scale Aerosol Tunnel (LSAT) was used to challenge the FFRs with viable influenza and inert beads. A complete description of the aerosol system and procedure for this study has been previously reported.[5] Prior to each test, the LSAT was flushed with purified air for 30 minutes at a flow rate of 50 LPM. For each independent test (one FFR at one condition), an FFR was glue-sealed into a six-inch diameter sample holder as previously described,[5] then secured into the LSAT via stainless steel sanitary fittings.

Each FFR was first challenged with 0.1-μm PSL beads (Thermo Scientific, Waltham, MA). The beads were suspended in sterile water, then placed in a six-jet Collison nebulizer (BGI Inc, Waltham, MA), operating at 20 psi to generate the aerosol. Following a ten-minute equilibration period, three alternating upstream and downstream samples were taken using a Scanning Mobility Particle Sizer 3034 (TSI, Shoreview, MN). The air flow was then redirected to a HEPA filter, while the Collison nebulizer was replaced with another Collison nebulizer containing 30 mL of H1N1 influenza virus diluted to a concentration of 10^8 $TCID_{50}$/mL in an unbuffered 0.5% mucin suspension.

Following a ten-minute equilibration period, alternating viable samples were taken through the upstream and downstream ports. All-Glass Impingers (AGI-30, Ace Glass, Vinland, NJ), containing 20 mL of serum-free Eagle's Minimum Essential Medium (sf-EMEM, Hyclone Laboratories Inc, Logan, UT) supplemented with 1% penicillin/streptomycin and 1% L-glutamine (Sigma–Aldrich, St. Louis, MO), were used for collection. To minimize particle loss, the AGI-30s were directly attached to the isokinetic sampling ports on the LSAT. Sampling was initiated by opening the valve on the port, then applying a vacuum source to the AGI-30, which

sampled at ~12.5 LPM. After five minutes, the sampling port was closed, the vacuum was turned off, and the AGI-30 was placed on ice until viable plating was performed. A total of six samples (three upstream and three downstream, alternately sampled) were collected for each FFR. Following each run, the FFR was removed and HEPA filters were connected to the sampling ports. The LSAT was subsequently flushed with purified air at 60 ± 10 LPM for three hours. A manometer was used to monitor the pressure drop across the filter during each run.

RESULTS

The average upstream viable challenge for all FFR replicates was $8.78 \pm 0.02 \times 10^2$ $TCID_{50}/L_{air}$. For 0.1-μm particles, the mean particle filtration efficiency (PFE, [(counts upstream–counts downstream)/counts upstream] × 100) for all FFR models ranged from 99.17% to 99.995%, and the mean viable filtration efficiency (VFE, [(viable counts upstream–viable counts downstream)/counts upstream] × 100) ranged from 99.23% to 99.997%. A two-tailed, paired *t*-test comparing the mean PFE and VFE values showed no statistically significant difference (Figure 2). A two-tailed unpaired *t*-test comparing the PFE or VFE for 0.1-μm and 0.8-μm[5] particles showed no statistically significant difference ($p > 0.05$), except for the impressively consistent set of the Kimberly–Clark model challenged with inert particles ($p = 0.04$).

DISCUSSION

Several assumptions are made here: 1) The PSD of an equilibrated bioaerosol is defined by the solids content of the medium (the inclusion of a relatively small quantity of H1N1 virus to the aqueous mucin medium did not change the shape of the PSD); 2) the Collison delivers

~5×10^{11} droplets per mL of medium,[6] so ~99.98% of the particles studied here were inert, ~0.02% contained a single viral unit, and the number containing more than one is negligible; 3) in Figure 1, particles containing a virus can be expected to closely approximate spheres of unit density, so their actual size is accurately represented by measurements; and 4) even though the distributions in Figure 1 are systematically biased by the AGI efficiency curve (the values presented are progressively exaggerated with increasing size), the collection efficiency of 0.1-μm particles by the AGI-30 is uniform across the sample set, so it is not a factor in PFEs or VFEs, which are calculated as ratios. Because the virus provides a nucleus, it is reasonable to assume that the mean of the PSD of the rare virus-bearing particles will be slightly larger than that of the inert particles, which dominate the observed pattern.

The filtration efficiency of aerosols is highly dependent on particle size, as demonstrated by past studies[4] and predicted by filtration theory.[7] The upper range of MPPS values reported for electret N95 FFRs is ~0.1 μm, the particle size used for this study.[4] For this particle size, all five FFR models demonstrated PFE and VFE values >95% with no statistically significant differences. This study demonstrates that the N95 FFR models tested remove particles from the airstream, indiscriminate of viability. Particles that contain H1N1 influenza are equally affected by filtration mechanisms as inert particles of the same size. Thus, testing for both PFE and VFE, or biological filtration efficiency (BFE),[8] are unnecessary for determining FFR efficacy. Furthermore, consistent with earlier work,[5,8] the addition of the antimicrobials tested here does not inherently improve viable filtration performance.

The significance of these findings to healthcare workers (HCWs) is that the data establish a basis to estimate the level of protection that an HCW can be expected to experience from a

properly fitted NIOSH-certified FFR during exposure to infectious aerosols. Inhalation exposures received by a respirator wearer come from a combination of leakage around the face seal, direct penetration through the filter, and leakage through other apertures (e.g., penetrations of filters by staples used to secure FFR straps).[5] Because the FFR was sealed (i.e., a perfect fit) in our experiments, capture efficiencies for viable H1N1 influenza exceeding 99.3% represent a best-case scenario for fit. However, even when some inward leakage during routine respirator wear is factored in, these data suggest that an N95 FFR is capable of reducing inhalational exposure to H1N1 influenza or other infectious aerosols by a factor of 10 or greater if properly fitted and used as expected, similar to the attenuation of other workplace aerosols.

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The findings and conclusions of this manuscript are those of the authors and do not necessarily represent the views of HHS and its components, of NIOSH or of the US Air Force. The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or an implied endorsement of such products.

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FIGURES

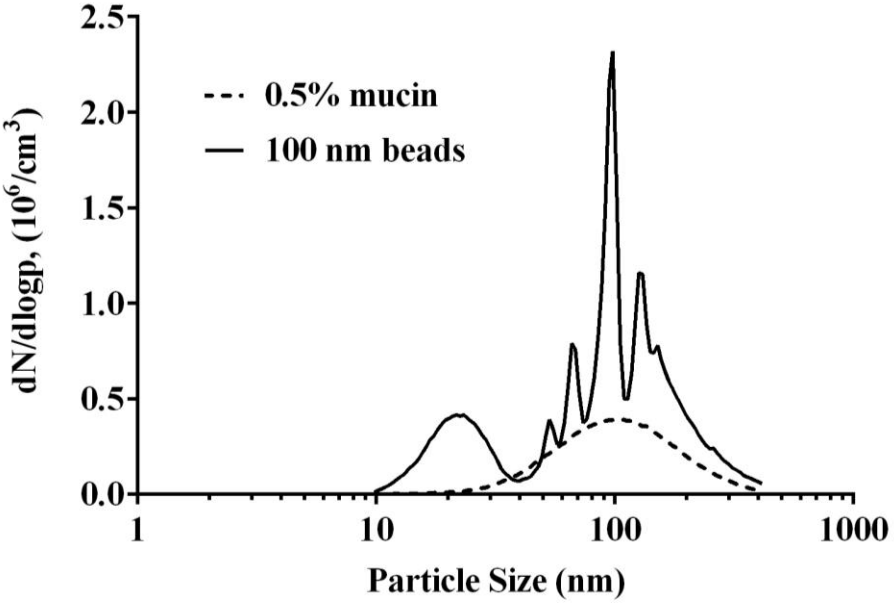

Figure 1. Particle Size Distribution Measured for
0.1-µm Polystyrene Latex Beads and 0.5% Mucin Buffer

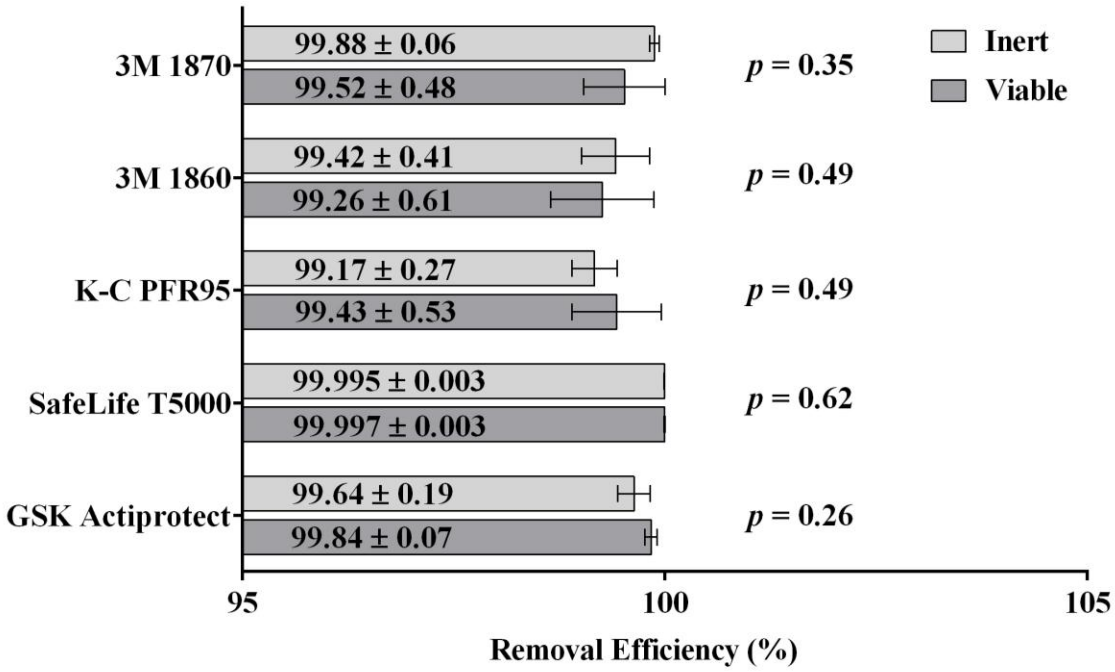

Figure 2. Viable and Inert Particle Removal Efficiencies Measured for Five Models of Filtering Facepiece Respirators (n = 3)