Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks?

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Background: Respiratory protection devices are used to protect the wearers from inhaling particles suspended in the air. Filtering face piece respirators are usually tested utilizing nonbiologic particles, whereas their use often aims at reducing exposure to biologic aerosols, including infectious agents such as viruses and bacteria.
Methods: The performance of 2 types of N95 half-mask, filtering face piece respirators and 2 types of surgical masks were determined. The collection efficiency of these respiratory protection devices was investigated using MS2 virus (a nonharmful simulant of several pathogens). The virions were detected in the particle size range of 10 to 80 nm.
Results: The results indicate that the penetration of virions through the National Institute for Occupational Safety and Health (NIOSH)-certified N95 respirators can exceed an expected level of 5%. As anticipated, the tested surgical masks showed a much higher particle penetration because they are known to be less efficient than the N95 respirators. The 2 surgical masks, which originated from the same manufacturer, showed tremendously different penetration levels of the MS2 virions: 20.5% and 84.5%, respectively, at an inhalation flow rate of 85 L/min.
Conclusion: The N95 filtering face piece respirators may not provide the expected protection level against small virions. Some surgical masks may let a significant fraction of airborne viruses penetrate through their filters, providing very low protection against aerosolized infectious agents in the size range of 10 to 80 nm. It should be noted that the surgical masks are primarily designed to protect the environment from the wearer, whereas the respirators are supposed to protect the wearer from the environment. (Am J Infect Control 2006;34:51-7.)

N95 filtering face piece respirators and surgical masks are commonly used to protect the human respiratory system against fine airborne particles that are known to be associated with various respiratory and heart diseases.[1] The aerosol particles of biologic origin, eg, viruses, bacterial cells, bacterial and fungal spores, fragments, and pollen grains, may cause major health effects, including infectious diseases. The adverse health effects of the biologic particles, particularly pathogenicity, depend not on the mass of the inhaled particles but on the number of particles. Viral particles, or virions, are one of the smallest known bioaerosol agents, with a particle diameter ranging from 20 to 300 nm.[2] Because of their small size, virions can easily penetrate through the human respiratory system and may cause diseases, such as colds, flu, measles, mumps, pneumonia, rubella, or chickenpox. The respiratory protection devices are usually tested using nonbiologic particles as the challenge aerosol, although their use often aims at reducing exposure to biologic particles. The results on the protection of filtering face piece respirators against submicron and supermicron particles have been widely reported in the literature.[3-9] The data on the penetration of nanosize sodium chloride particles through the N95 respirators have been recently reported by our research team.[10] It is acknowledged that the penetration of biologic particles through respirator filters may differ from that of their corresponding nonbiologic simulants. The attempts to

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Supported in part by the Kosciuszko Foundation (American Center for Polish Culture).

0196-6553/$32.00

doi:10.1016/j.ajic.2005.08.018

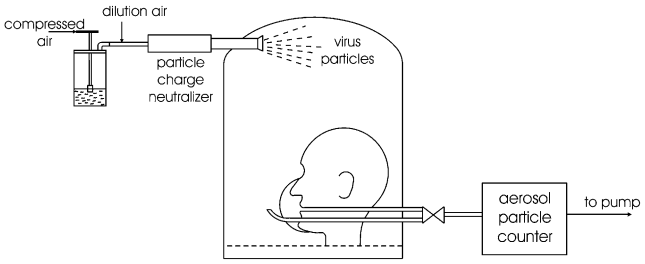

Fig 1. Experimental setup.

evaluate the respirator performance directly with biologic particles have been primarily focused on airborne bacteria.[7,11-16]

N95 filtering face piece respirators are certified under NIOSH 42 CFR 84 regulations.[17] Uncharged sodium chloride (NaCl) particles of 300 nm in diameter are utilized as the tested aerosol. The penetration, P, of such particles through a certified N95 respirator cannot exceed 5%; thus, the efficiency, E, of the respirator, which is calculated as $E = 100\% - P$, must be at least 95%. Surgical masks are not NIOSH certified. The performance of some masks has been evaluated when they were challenged either with latex sphere particles or aerosolized bacteria. The particulate filtration efficiency, PFE, is defined as the percentage of monodispersed nonneutralized latex particles that do not pass through the face mask at a specific inhalation flow rate. The F 2299 test method utilizes a light-scattering particle counted in the size range from 100 to 5000 nm and airflow test velocities from 0.5 to 25 cm/s.[18] The bacterial filtration efficiency, BFE, can be determined by 2 methods: in vitro using a biologic aerosol of *Staphylococcus aureus* or in vivo (modified Greene and Vesley test) when the masks are worn by a subjects while he/she enunciates the word ''chew'' 120 times over a 2-minute period, and viable aerosol particles are collected onto agar plates of the Andersen sampler. The filtration efficiency is calculated by comparing the concentration levels determined when the subject does and does not wear the mask, respectively.[19,20]

The studies on the respiratory protection against airborne biologic agents have been recently reviewed by Rengasamy et al.[21] From this and other reviews, it is clearly seen that there is a lack of direct measurement data on the efficiency of respirators and health care masks against aerosolized viral particles.

METHODS

Experimental setup

Figure 1 depicts the schematic diagram of the experimental setup. The challenge aerosol was generated using a 6-jet Collison nebulizer (BGI Inc., Waltham, MA), which was supplied by a compressed air system. Before entering the nebulizer, the air was purified by passing through a high-efficiency particulate air (HEPA) filter. Generated aerosol was diluted by clean air, which was also derived from the compressed air system, and then passed through an ^{85}Kr source charge neutralizer (Model 3054; TSI Inc., Minneapolis, MN). Charge-neutralized aerosol was supplied to the top part of the test chamber. The tested respirators and surgical masks were sealed by silicon sealant to the face of a manikin, which was placed inside the chamber. A bubble-producing liquid was used to assure that there were no leaks between the tested devices and the manikin's surface. The sealant surface was covered by this liquid, and the compressed air flowing through the respirator or surgical mask caused bubbles formation in case of a leak. The places at which the leakages were detected were additionally sealed and checked for leaks again. This leak-detection method allows identifying microleaks; however, it may not be sufficient to identify the leaks below 100 nm.

The experiments were carried out at 2 different constant flow rates: 30 L/min (which simulates inhalation at light workload) and 85 L/min (which simulates inhalation at heavy workload). These specific flow rates were controlled by a rotameter adjacent to an air supply pump. The aerosol generation system and the test chamber were located inside a class II biosafety cabinet (Sterilchem GARD; Baker Co., Sanford, ME). The particle concentrations and size distributions outside and inside the tested respiratory protection device were determined using a wide-range particle spectrometer (WPS; model 1000 XP, configuration A; MSP Corp., Shoreview, MN). The WPS is a device that combines 3 different instruments, namely the differential mobility diameter (DMA), the condensation particle counter (CPC) and the laser particle spectrometer (LPS). The combination of the 2 first instruments allows counting the particles of 10 to 500 nm, whereas the LPS covers the particle diameter range between 350 and 10,000 nm. The electrical mobility analysis utilized in the DMA is the most efficient and commonly used technique for measuring the aerosol particle size distribution in the nanometer size range (suitable for MS2 virions used in this study).

MS2 viruses

MS2 is a bacteriophage that contains single-stranded RNA, consisting of 3569 nucleotides.[22] Single MS2 virion with a referred physical diameter of approximately 27.5 nm contains 180 copies of the coat protein, which form a near spherical icosahedral shell. This small RNA virus infects only male *Escherichia coli* bacteria by injection of its RNA and A-protein.[23,24]

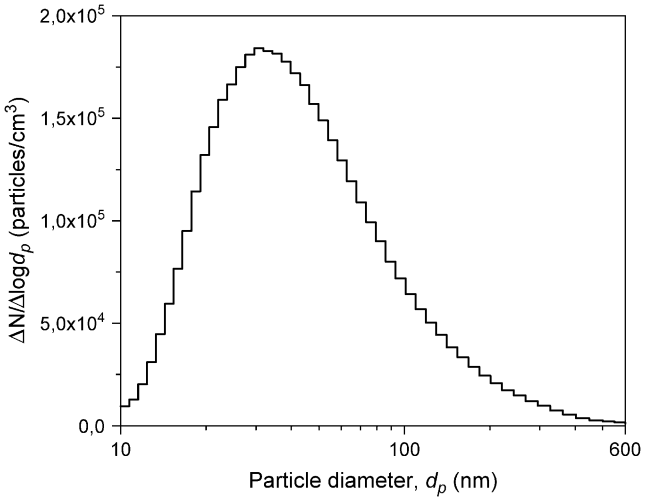

Fig 2. The particle size distribution of the aerosolized MS2 virions measured by the WPS.

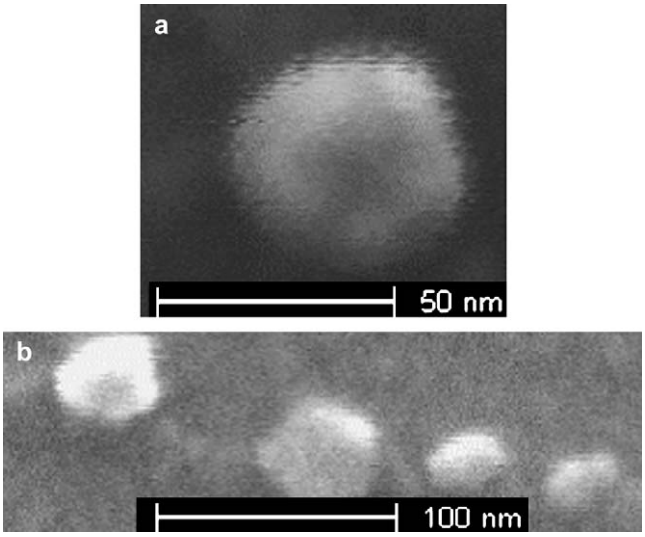

Fig 3. Scanning electron micrographs of the dried MS2 viral suspension (10 times concentrated) used for aerosolization: (a) a single MS2 virus particle (Magnification = ×400,000), (b) dispersed single virus particles (Magnification = ×200,000).

Stock suspension of MS2 virus was prepared by adding 9 mL Luria-Bertani broth (prepared using ultrafiltered deionized water) to freeze-dried phage vial (ATCC 15597-B1). This suspension was serially diluted, and the final suspension used for the aerosolization experiments had 10^8 to 10^9 plaque-forming units (pfu/mL) of MS2 virus. In some experiments, the suspension was prepared by plate lysis and elution (using the host *Escherichia coli;* ATCC 15597, strain C3000). MS2 phage titer was determined by using a modified plaque assay protocol of Adams.[25]

The size distribution of the aerosolized virus particles, measured by WPS, is presented in Fig 2. It is seen that the peak is for the particles of approximately 30 nm, which is in a good agreement with the referred size of a single MS2 virion (27.5 nm). However, in addition to these particles, the population of the WPS-detected aerosol particles includes smaller as well as much larger particles. We assume that some of the larger ones can be agglomerated virions. The contribution of large agglomerates is expected to be relatively low because the scanning electron microscope analysis revealed very few of the large agglomerates in the suspension prepared for this study. Digital micrographs of MS2 virus particles taken by using a scanning electron microscope (SEM) (Phillips XL-30 ESEM; FEI Co., Hillsboro, OR) are presented in Fig 3. The stock suspension used for aerosolization experiments was also utilized for the electron microscopy. On the other hand, large MS2 agglomerates have been observed in the MS2 viral suspension by other investigators. For instance, Hogan et al referred to the agglomerates larger than 200 nm seen on the SEM images obtained from a liquid viral suspension.[26] It should be acknowledged, however, that the above study utilized a much more concentrated suspension (0.0749 g/L of MS2) compared with the one we used for our SEM analyses. Nevertheless, the agglomerates in the suspension can be broken during aerosolization. In this study, we did not use a dryer, so the water content of the particles aerosolized by the Collison nebulizer could not fully evaporate, thus increasing the number of larger particles that carry single viruses or viral agglomerates. Similarly, in the field, the viruses are usually carried by droplets nuclei or other larger airborne particles.[27] As to the particles smaller than a single virion, which were detected by the aerosol particle counter, we speculate that these can be the fragments of some virions formed during the freezing-drying process.

We anticipate that some nonvirus-containing particles could be generated in addition to the virions. To reduce the influence of these particles in our aerosol count and concentrate on the specific particle size range that is primarily populated by virions, we limited our analysis to 50% of the total population of the WPS-detected particles, among which there were particles larger and smaller than the peak size. It is seen that the particle size distribution curve is rather steep below approximately 30 nm so that the size range from 10 to 30 nm covers only 12.5% of the total particle count. To make the postulated 50% of the total count, another 37.5% of particles were taken from the range above 30 nm. As a result, the particle diameter range of 10 to 80 nm was considered as the MS2 virions in this study.

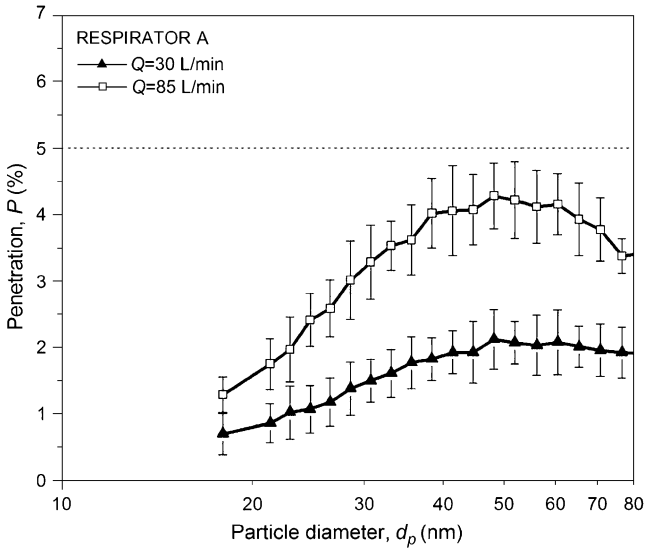

Fig 4. Effect of the inhalation flow rate on the fractional penetration of MS2 virus through respirator A (n = 5). Each point on the graphs represents the mean value of the particle penetration, and the error bars represent the standard deviations for respirators.

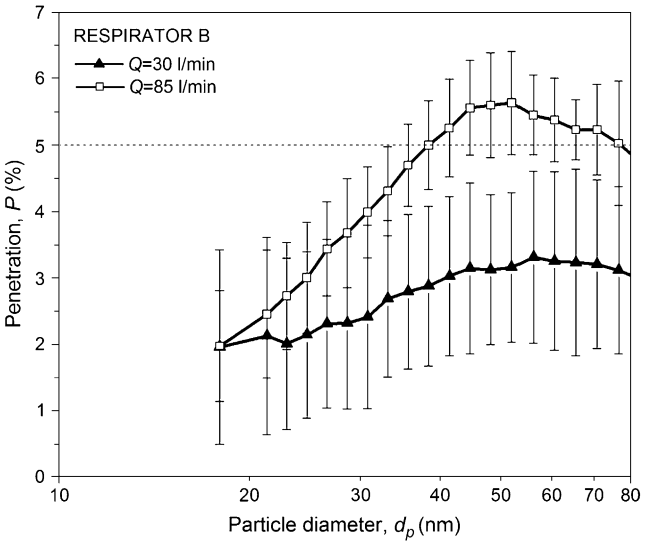

Fig 5. Effect of the inhalation flow rate on the fractional penetration of MS2 virus through respirator B (n = 5). Similar to Fig 4, the points and error bars represent the mean values and the standard deviations, respectively.

N95 respirators and surgical masks

Two different models of N95 filtering face piece respirators and 2 different models of surgical masks were evaluated in this study. The N95 respirators were obtained from 2 different manufacturers. Both respirators had multilayer structure, and the main layers of filters were composed of polypropylene fibers with electrical charge. The N95 respirators were chosen using the performance data presented by Coffey et al.[28] One of the respirators is characterized by relatively high fit-factor value (respirator A) and the other one by lower fit factor (respirator B).[28]

Two types of the surgical masks, SM1 and SM2, used in this study were made by the same manufacturer and were both fluid resistant. According to their manufacturer, BFE (determined by the modified Green and Vesley method) of SM1 was above 96%, whereas BFE of SM2 exceeded 99% and its collection efficiency for 200-nm latex spheres was at least 95% at a flow rate of 28.3 L/min.

The N95 filtering face piece respirators and the surgical masks used in this study were sealed to the face of the manikin, so their efficiency determined during experiments is defined as the efficiency of the filter material. The actual field-measured efficiency may be lower if there are some leakages between the wearer's face and the material of the respirator or surgical mask.

Penetration

The concentration of the particles was measured outside [$c_{out}(d_p)$] and inside [$c_{in}(d_p)$] of each tested N95 filtering face piece respirator or the surgical masks by the WPS. Based on the results obtained for each channel of the aerosol measurement instrument, the penetration of the particles with given diameter (which is the fraction of the particles that pass through the filter) was determined as:

$$P(d_p) = \frac{c_{in}(d_p)}{c_{out}(d_p)} \cdot 100\% \quad (1)$$

Because some channels of the WPS detected very few particles, the results obtained for 2 or more channels were combined to achieve representative data. This was done in cases in which there were fewer than 50 particles per channel. This approach allowed us to eliminate accidental deviations of the penetration data in case very few particles per channel are detected. Generally, according to the WPS manufacturer, the particle fractional concentration can be accurately determined within a range of <1 particle/cm^3 to 10,000 particles/cm^3.[29]

RESULTS

The penetrations of MS2 virions through respirator A at flow rates of 30 and 85 L/min are presented in Fig 4. Each point represents the penetration mean

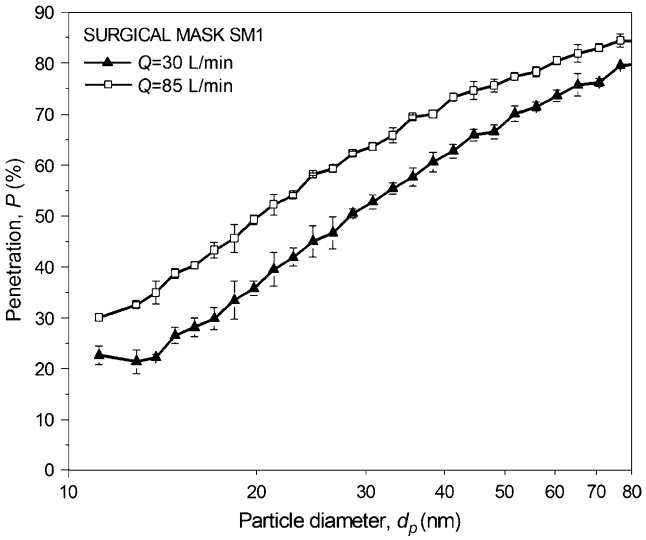

Fig 6. Effect of the inhalation flow rate on the fractional penetration of MS2 virus through the surgical mask SM1 (n = 2). Each point represents the mean penetration value, and the error bars represent the standard deviation.

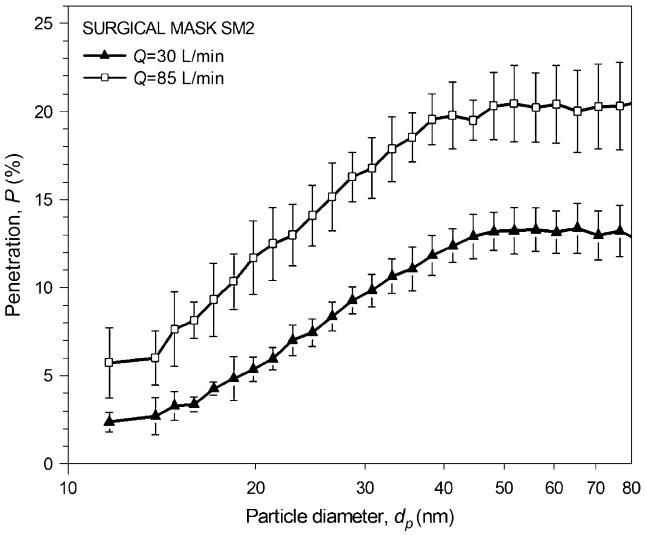

Fig 7. Effect of the inhalation flow rate on the fractional penetration of MS2 virus through the surgical mask SM2 (n = 3). Each point represents the mean penetration value, and the error bars represent the standard deviation.

value determined for 5 identical respirators, and the corresponding error bars represent the standard deviation. Figure 5 depicts the results of similar experiments carried out for respirator B. All values of the virion penetration through respirator A are below 5% as anticipated because this is a certified N95 respirator. However, for respirator B, the penetration exceeds the 5% threshold at the higher inhalation flow rate with the mean value of 5.6%. We found that, in the size range of 10 to 80 nm, the maximum penetration occurred at the particle diameter of approximately 50 nm. Our previous study conducted with NaCl particles[10] revealed that 300 nm is not the most penetrating particle size through N95 respirators at a flow rate of 85 L/min as is conventionally believed and postulated in the respirator evaluation standard. Instead, the maximum penetration was observed for particles of 40 to 50 nm.[10] We have shown that, for a mechanical filter (when the particle deposition on fibers occurs because of diffusion, direct interception, and inertial impaction), the particle diameter of approximately 300 nm is rightfully believed to be the most penetrating particle size, although it may slightly vary depending on the filter's structure and other factors. However, the N95 filtering face piece respirators are composed of charged fibers. This property leads to a considerable shift of the maximum penetration toward smaller particles because the additional polarization force has a great importance in the process of the particle deposition on fibers. Similar results were reported by Martin and Moyer, who found that the maximum penetration of particles through the fiber-charged N95 respirators occurred in the 50- to 100-nm size range.[9] Thus, it should be emphasized that the certified N95 respirators will protect their wearers properly against the particles of 300 nm and larger, but their performance may be below the threshold for aerosol particles of the nanosize range. The penetration values of the nanoparticles through N95 respirators depend on their filter media characteristics.

Figure 6 and Fig 7 present the evaluation data obtained with 2 types of surgical masks, SM1 and SM2, which are widely used to control human inhalation exposure to airborne infectious agents in health care environments (although the surgical masks were designed to protect the environment from the wearer). Two identical SM1 masks and 3 identical SM2 masks were tested. Similarly to the experiments conducted with the N95 respirators, 2 inhalation flow rates, 30 and 85 L/min, were tested. These data show that the penetration of MS2 virions through the surgical masks is much higher than that observed for N95 filtering face piece respirators. For example, at 85 L/min, the particle penetration curve for SM2 reaches a plateau at 20.5%, whereas, for SM1, the penetration increases with increasing particle size to 84.5% for particles of 80 nm in diameter. The fibers of the surgical masks are not electrically pretreated, and these devices act like poor mechanical filters. In the absence of electrostatic effects, based on theoretic calculations, the diameter of approximately 300 nm is anticipated to be the maximum penetrating particle size for these masks.

Table 1. Paired *t* test comparison of the penetration values obtained for MS2 viruses and sodium chloride particles

Type of respiratory protection device	Inhalation flow rate, Q (L/min)	P value
Respirator A	30	.004*
	85	.220
Respirator B	30	.156
	85	.532
SM1†	30	.997
	85	.962
SM2†	30	.716
	85	.608

*$P_{MS2} > P_{NaCl}$.
†Type of surgical mask.

The data presented in this paper resulted from the experiments carried out with the clean unloaded respiratory protection devices. In this light, the penetration values presented in Fig 4 to Fig 7 represent the initial penetrations of virions through the N95 respirators and surgical masks. Because the fibers of N95 filtering face piece respirators are charged, the penetration through these respirators increases with the time because of the reduction in fiber charges, which was proven experimentally by Martin and Moyer.[9] Martin and Bergman showed that the filter degradation resulting from its exposure to aerosol depends not only on the amount of the deposited particles but also on the time over which the aerosol deposition occurred.[30] However, after achieving a certain level of the filter loading, the pretreated respirator filter (''electret'') starts behaving like a mechanical filter, and the penetration decreases. This means that the initial virion penetration through the N95 respirators obtained in our experiment may somewhat differ from that found in the field during a long-term use of the respirator in bioaerosol-contaminated environments. The penetration through the surgical masks should decrease during the filtration process because of loading because they act as mechanical filters from the very beginning.

For all filtering face piece respiratory protection devices, the penetration increases with increasing inhalation flow. Although the flow rate of 85 L/min used in this study simulates a heavy workload and is utilized in the respirator certification tests, some studies refer to even higher inhalation flow rates.[21] At those rates, the penetration is anticipated to be even greater compared with the values reported in this paper.

The data on the virion penetration obtained in this study were compared with the results of our earlier experiments in which the same respiratory protection devices were challenged with nonbiological (sodium chloride) particles.[10] The comparison was performed using paired *t* tests (utilizing program Origin 6.0, OriginLab Corp., Northampton, MA). The data sets obtained for sodium chloride and MS2 virus were combined in the same manner into 10 size fractions for N95 respirators and into 11 channels for surgical masks in the size range from 10 to 80 nm. The results presented in Table 1 indicate that, generally, the penetrations of MS2 virions and sodium chloride particles through the tested respiratory protection devices were not significantly different. Thus, nonbiological particle simulants can be used for assessing the performance of these devices against virions of similar shape and the same size. The only exception is respirator A operated at 30 L/min, in which case the *t* test revealed significant difference between the penetration of sodium chloride and MS2 virions. However, even in this case, the difference between the penetration of biologic and nonbiologic particles did not exceed 1%.

The penetration data presented in this paper were obtained using manikin-based tests. Thus, the respirators and surgical masks were sealed to the manikin's face. Such procedure eliminated the leakages, which can occur when a subject wears the personal respiratory protection devices. In real life, the leaks may lead to considerably increased particles penetration. Coffey et al indicated that, without proper fit testing, the wearer of a respirator cannot achieve the desired protection level.[31] Therefore, it seems critical to perform a proper fit test before wearing a N95 filtering face piece respirator.

CONCLUSIONS

Two types of N95 half-mask respirators and 2 types of surgical masks were challenged with aerosolized MS2 virus. The experiments were carried out following a manikin-based protocol. The results indicate that N95-certified respirators may not necessarily provide a proper protection against virus, which is considerably smaller than the accepted most penetrating particle size of 300 nm used in the certification tests. Thus, the protection against the airborne viral agents provided by some N95 respirators may fall below 95%, especially at higher inhalation flow rates. The efficiency of the surgical masks is much lower than that of the N95 respirators so that the MS2 virions penetrate readily through the surgical masks. The performance tests conducted with surgical masks challenged with latex spheres of ~300 nm or bacterial particles may underestimate the penetration of nanosize virions.

The authors thank the NIOSH for providing equipment for aerosol measurements and the Kosciuszko Foundation for support.

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