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ARTICLES

Aerosol penetration and leakage characteristics of masks used in the health care industry

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Background: Historically, surgical masks have been worn to protect patients from being infected by large, pathogen-containing aerosol droplets emitted by health care personnel. Today, emphasis has shifted from solely protecting the patient to protecting the health care worker as well. As a result of new procedures used in operating rooms and clinical areas, aerosolized hazardous agents in the submicrometer size range are being produced, posing a potential threat to health care workers.
Methods: Eight surgical masks were tested for aerosol particle penetration through their filter media and through induced face-seal leaks.
Results: The percentage of filter penetration ranged from 20% to nearly 100% for submicrometer-sized particles. In comparison, a dust-mist-fume respirator used in industrial settings had significantly less penetration through its filter medium. When the surgical masks had artificially induced face-seal leaks, the concentration of submicrometer-sized particles inside the mask increased slightly; in contrast, the more protective dust-mist-fume respirator showed a fourfold increase in aerosol penetration into the mask with an artificial leak 4 mm in diameter.
Conclusion: We conclude that the protection provided by surgical masks may be insufficient in environments containing potentially hazardous submicrometer-sized aerosols. (AJIC AM J INFECT CONTROL 1993;21:167-73)

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Surgical masks in the past were worn solely to protect patients from postoperative infection. These masks have been found to be effective barriers for retaining expelled droplets from the health care workers, which can be released through speaking, coughing, or sneezing.[1-5] Droplets larger than 100 μm quickly settle onto surfaces; therefore they generally do not reach the region of the nose and mouth. Droplets less than 100 μm in diameter evaporate rapidly to form stable droplet nuclei in the 1 to 4 μm size range.[6] These smaller particles can remain airborne for long periods, increasing the likelihood that they will be inhaled by someone.

Respiratory protection is important for health care workers as well as patients in the hospital environment, where many of today's procedures produce submicrometer-sized aerosol particles. For example, particles present in the laser plume generated during laser surgery have been found to have a median aerodynamic diameter of about 0.3 μm, with a range of 0.1 to 0.8 μm.[7] The aerodynamic diameter reflects the deposition behavior of a particle. Carbon vaporization, produced by a carbon dioxide laser at low irradiance levels, allows viable bacterial particles to be emitted,[8] as well as particles containing intact viral DNA.[9] Other surgical techniques have been shown to generate aerosolized blood-borne pathogens, which could be a possible source of infection.[10-13] Common surgical power tools have been shown to create blood-containing aerosols with particles less than 5 μm in diameter.[10] In another study, it was found that all of the aerosols produced had blood-containing particles in the respirable particle size range.[11] The respirable fraction of particles includes those small enough to enter the alveolar region of the lung during inhalation. The percentage of respirable particles depends on the definition used. It is approximately zero for 10 μm particles and increases with decreasing particle size.[14]

Other activities with the potential for creating particles in the submicrometer size range include treatments and procedures administered to patients with infectious tuberculosis. The number of tuberculosis cases has been increasing, and just recently multidrug-resistant tuberculosis has become a serious concern. Between 1990 and 1992, the Centers for Disease Control and Prevention investigated numerous outbreaks of multidrug-resistant tuberculosis in hospitals.[15, 16] These cases are associated with a high mortality rate. Health care workers' exposure to tuberculosis appears most likely to occur where clinical procedures can result in high concentrations of aerosolized droplet nuclei.[17] These procedures include bronchoscopy, autopsy, and physical therapy to the chest that induces coughing.[18] Rapid transmission to health care workers has been linked to proximity to patients with infectious tuberculosis during use of aerosolized pentamidine,[19] intubation and suctioning with mechanical ventilation,[20] prolonged intubation,[21] open-abscess irrigation,[22] and autopsy.[23, 24]

Exposure to aerosolized drugs administered to patients may also present a hazard. Pharmaceutical aerosols are frequently administered to treat asthma, chronic obstructive pulmonary disease, and pulmonary infections. For example, aerosolized ribavirin is used to treat respiratory syncytial virus infection. The small particle size generated allows drug penetration deep into the patient's lungs. During administration, the aerosols may escape into the room environment and be inhaled by the hospital staff.[25-27]

Because health care workers have the potential to be exposed to many types of hazardous agents, it is evident that masks need to be evaluated as to their efficiency in filtering submicrometer-sized particles as well as micrometer-sized particles. Particles smaller than 1 μm are considered to be in the submicrometer size range; those between 1 and 10 μm in size are considered to be in the micrometer size range.[28] Although a particular mask may offer protection against particles greater than 1 μm in size, this does not mean that it offers the same protection against particles less than 1 μm in diameter, as demonstrated by Chen and Willeke.[29]

CONSIDERATIONS FOR MASK TESTING

At present there is no standardized method for evaluating the performance of surgical masks, which makes comparisons between masks difficult. Not until recently have techniques become available for measuring smaller particles dynamically and in situ. Two methods presently in use for testing filtration of micrometer-sized particles are the in vitro bacterial filtration efficiency (BFE) test and the filtration efficiency test (FET). In the in vitro BFE test, *Staphylococcus aureus* bacteria, 0.8 μm in diameter, are suspended in droplets with a mean size of 2.3 μm.[30] In the FET test, polysty-

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rene latex spheres, 0.8 μm in diameter, are suspended in a spray with the same mean droplet size of 2.3 μm.[31] Both tests are designed to measure how efficiently masks prevent penetration of large droplets through the filtering face pieces. The tests require a filtration efficiency (defined as 100% minus the percentage of penetration) of 95% for the indicated challenge aerosol. This value is obtained by measuring the mass of aerosols collected on the filter and comparing it to the mass of aerosols incident to it.

Both methods depend on the size of the carrier droplets, which are larger than the particles contained therein. The required filtration efficiency of 95% thus indicates essentially the percentage of droplets prevented from penetrating the mask. It does not, however, directly measure the filtration efficiency for the potentially infectious submicrometer-sized particles. The quoted 95% efficiency may therefore mislead health care workers into a false sense of security. For instance, Wadsworth and Davis[32] found that when a surgical mask was challenged with 0.3 μm dioctyl phthalate aerosol particles the filtration efficiency was only 31% compared with the manufacturer's stated efficiency of 98.9% (which was based on the BFE test). The difference between the two methods is simply the size of the test particle. The BFE test and FET use particles suspended in micrometer-sized droplets, whereas the dioctyl phthalate aerosol uses submicrometer-sized aerosol particles. A test method that evaluates masks for both of these size ranges is therefore needed.

When a mask is worn, aerosol particles can reach the region of the nose and mouth by (1) directly penetrating through the mask's filter material or (2) penetrating through leaks at the face-seal. It is difficult to measure both routes of entry independently and thus distinguish one from the other. Face-seal leakage becomes more significant as the pressure drop across the filter increases, as found in studies of more protective respirators.[29] As the pressure drop increases, more particles are drawn into the mask through gaps between the mask and the face.

One of our objectives in this study was to find a meaningful way to evaluate filtration efficiencies of surgical masks. Because surgical masks may not offer enough protection in atmospheres containing small-sized particles, a National Institute for Occupational Safety (NIOSH) and Health and Mine Safety and Health Administration (MSHA)-approved dust-mist-fume (DMF) respirator used in industry was also tested for comparison. In industrial settings, respiratory protective devices are referred to as respirators, whereas in the health care industry they are referred to as masks. Industrial respirators may offer better protection to the wearer when they are made of thicker material that has a tighter weave. The National Institute for Occupational Safety and Health and the Mine Safety and Health Administration are responsible for approving respirators worn against harmful agents.

METHODS

Eight surgical masks with different filter materials and mask shapes (molded cone vs flat) were evaluated. A DMF respirator was also evaluated, simply as a comparison for the surgical masks. Masks were chosen from four different manufacturers, referred to as A, B, C, and D. All testing was performed on mannequins to study precisely filter penetration versus face-seal leakage, as well as the effect of leak size. Penetration studies were performed by sealing the surgical mask or DMF respirator to the mannequin with petroleum jelly, to simulate a tight seal to a wearer's face.

The test aerosol was produced from corn oil, a preferable aerosol because its particle size is unaffected by humidity. A size-fractioning aerosol generator, previously described by Chen and associates[33, 34] was utilized in the experimental setup. Conventional nebulizers produce a large amount of submicrometer-sized particles, but not many micrometer-sized particles. The nebulizer was modified to increase the fraction of the larger-sized particles of concern. The particle size–balanced output was diluted with clean air and carried to a mixing chamber where the aerosol was uniformly distributed. The volume of the test chamber was approximately 2 m^3.

The corn oil aerosol particles were measured over aerodynamic diameters ranging from 0.1 to 4 μm. The challenge aerosol concentration was about 800 particles/cm^3 and the geometric standard deviation was 2.0. Aerosol penetration measurements were performed by mounting the surgical mask/respirator on the mannequin and comparing measurements of the aerosol concentration inside the mask to the concentration outside the mask. A Laser Aerosol Spectrometer (LAS-X; PMS Inc., Boulder, Colo.) was used in this study to measure particles in the range of 0.1 to 1 μm and an Aerodynamic Particle Sizer (model APS-33B; TSI Inc., St. Paul, Minn.) was used to measure particles in the range of 1 to 4 μm. The Aerodynamic Particle Sizer measures aerodynamic size directly, whereas the Laser Aerosol Spectrometer, a light-scattering instrument, measures optical sizes. Because corn oil does not absorb light and its density is approximately 1

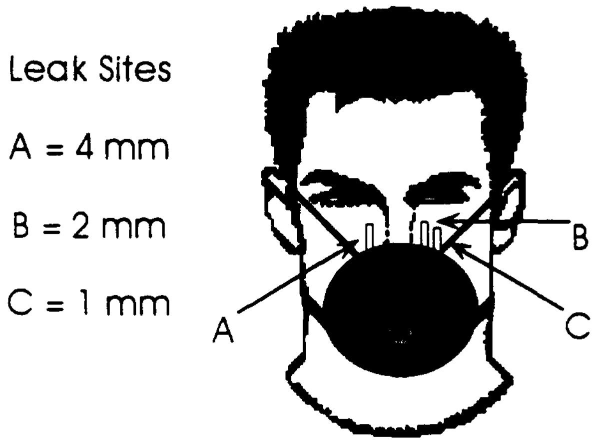

Fig. 1. Placement of artificial leaks.

gm/cm^3, the optical size can be assumed to be equivalent to the aerodynamic size.[35] Both measuring instruments record the number concentrations of particles of specific sizes. One advantage of these instruments is that through their use the filtration efficiency may be measured for each particle size, in contrast to older methods that yield only an overall efficiency for a particle size distribution with a given mean size and spread.

Each of the measuring instruments was connected to a personal computer for data collection. The sampling flow rates of the Aerodynamic Particle Sizer and the Laser Aerosol Spectrometer were 5 L/min and 0.06 L/min, respectively. The challenge flow rate through the masks was 32 L/min, which is the NIOSH-recommended flow for respirator filter testing[36] and also representative of the average breathing rate for a subject with a light to moderate work load. The data points shown in the figures represent the average of 10 random penetration measurements, with the error bars bracketing the 95% confidence interval of the mean.

When no induced face-seal leaks were present, the percent penetration reflected the number of aerosol particles passing through the filter material. When air flows through a filter, a resistance is created; therefore the pressure drop across the mask was also recorded.

Face-seal leakage is another route by which aerosol particles may reach the nose and mouth region. The total number of particles reaching the inside of the mask is thus the result of penetration through the mask's filtering material plus leakage around the perimeter of the mask. It has been shown that molded cone-shaped masks can have leaks classified as circular or rectangular in shape.[37] Circular holes are more likely to occur around the bridge of the nose; rectangular or slit-like leaks are more likely to occur along the cheek of the wearer. For a rectangular leak and a circular leak of the same cross-sectional area, a greater percentage of particles penetrate through the circular leak[38]; circular holes were therefore used to simulate a worst-case condition. The two best-performing surgical masks (on the basis of filtration efficiencies) and the DMF respirator were tested with three different leak diameters. The leaks were simulated with hypodermic needles. All leaks were glued to the mannequin at the bridge of the nose, had inner diameters of 1 mm, 2 mm, or 4 mm, and had the same path length of 25 mm (Fig. 1).

RESULTS

The dependence of aerosol filter penetration on aerodynamic particle diameter is depicted in Fig. 2. Each line demonstrates how the filter medium of a particular surgical mask performed over the specified particle size range when no leaks were present. The eight surgical masks performed quite differently, as did masks from the same manufacturer.

The worst performing mask, A1, had an aerosol filter penetration of approximately 100% for the particle sizes of 0.2 to 1 μm; hence, most submicrometer-sized particles passed directly through the filter. As the diameter of the particle increased, the aerosol penetration decreased. For example, with the same mask, the percentage penetration dropped by half at a particle size of approximately 4 μm. Mask A2, a better-performing mask made by the same manufacturer, had an aerosol filter penetration of 40% at a size of 0.2 μm and about 0.5% at 4 μm. The two best-performing surgical masks (according to submicrometer-sized aerosol penetration through their filter media) were masks A4 and D1. These masks were similar in performance, with 20% penetration at 0.2 μm and approximately 1.5% penetration at 4 μm.

Five of the eight surgical masks had filtration efficiencies of 95% or greater for 2.3 μm particles. The BFE test and FET require that surgical masks attain 95% collection efficiency against a droplet spray with a mass median aerodynamic diameter of about 2 to 3 μm. Surgical masks with a collection efficiency less than 95% at 2.3 μm may also satisfy this requirement, because many of the droplets in the test spray are larger than 2.3 μm and have more mass per droplet and because filter collection efficiency increases rapidly as droplet diameter increases beyond 2.3 μm.

The pressure drop across the masks ranged from 0.2 mm water gauge (wg) for the worst-performing mask to 1.8 mm wg for the best-performing mask. In general, the pressure drop

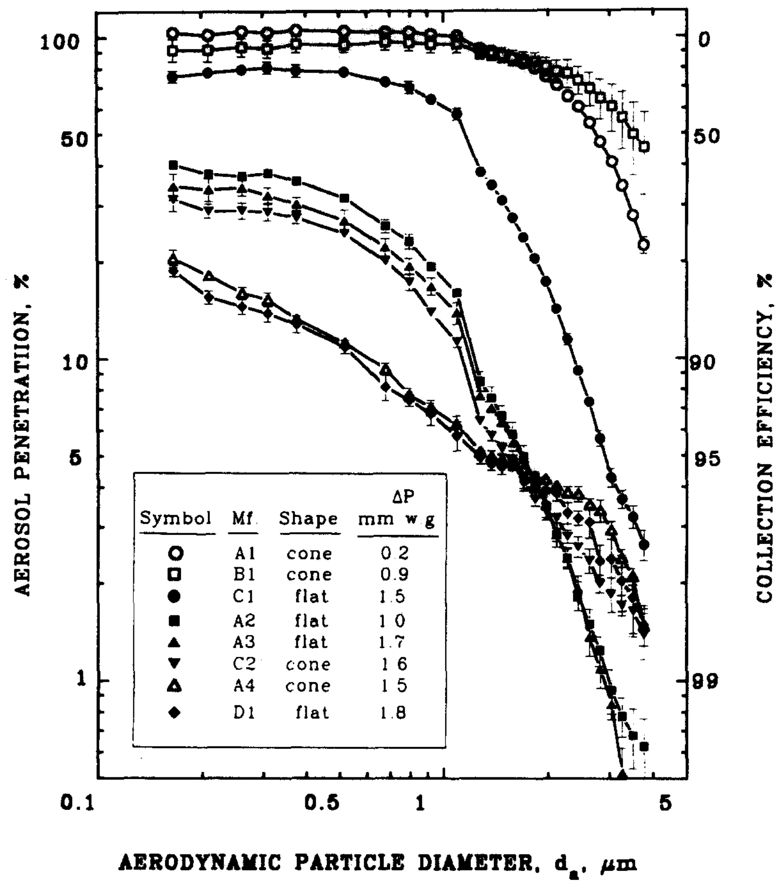

Fig. 2. Aerosol penetration through the filter media of eight surgical masks. *Mf*, Manufacturer and model; *ΔP*, pressure drop.

increased as percent penetration decreased. The larger pressure drop generally indicates a thicker material, which in turn increases breathing resistance across the mask.

To evaluate overall mask protection, one must evaluate penetration through face-seal leaks as well as through the filter. Fig. 3 depicts the effect of different sized leaks on aerosol penetration for two surgical masks and the DMF respirator. Except for the situation in which no leak was present, the aerosol penetration measurements reflect combined penetration through the filter and the artificial leaks. Surgical masks D1 and A4 had the best filtration efficiencies, as shown in Fig. 2. For both masks, small artificial leaks did not greatly affect the aerosol penetration. For surgical mask D1 (a flat-shaped mask), the percent penetration was 20% at 0.15 µm with no artificial leaks; the percent penetration was still about 20% at 0.15 µm with 1 and 2 mm leaks but increased to 25% with a 4 mm leak. This difference in penetration with different leak diameters increased with increasing particle size. The pressure drop for this mask decreased by only 10% when the largest leak (4 mm) was tested. The performance of surgical mask A4 (a cone-shaped mask), was similar to that of the flat-shaped D1. In practical use, however, the flat-shaped mask is more likely to have larger leaks than is the cone-shaped mask because of the way it attaches to the wearer's face. A larger amount of aerosol particle penetration through face-seal leaks is potentially expected with flat-shaped masks. Their overall protection values may therefore be lower.

Fig. 3 also depicts the performance of a DMF respirator. With no artificially induced leaks, the DMF respirator had an aerosol filter penetration of 5% for 0.15 µm particles; when 1 mm, 2 mm, and 4 mm leaks were added, the aerosol penetration was 6%, 8%, and 20%, respectively, for this particle size. This difference in penetration with different leak diameters increased with increasing particle size. With no face-seal leaks, the DMF respirator had a percentage penetration through the filter of 5% for 0.15 µm particles, compared with 20% for the best performing surgical masks. The effect of an induced leak on aerosol penetration differed for different filter materials. As

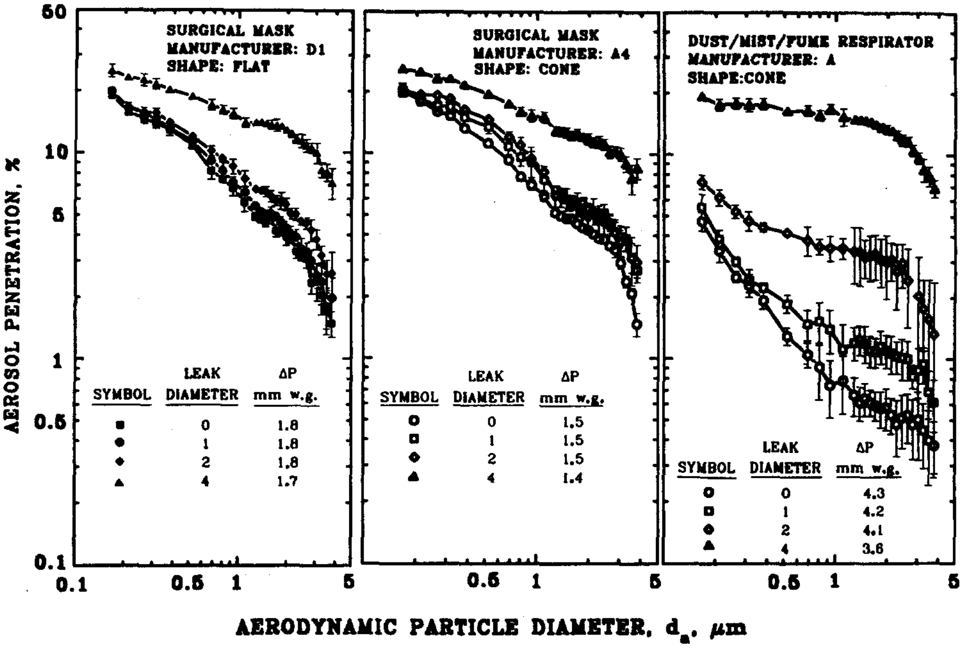

Fig. 3. Aerosol penetration dependence on leak diameter. *ΔP*, Pressure drop; d_a, aerodynamic particle diameter.

shown in Fig. 3 for a 4 mm leak, the aerosol particle penetration of micrometer-sized particles was greater for the higher-performance DMF respirator than for the lower-performance surgical masks. This observation can be attributed to the higher pressure drop across the DMF filter material. With no face-seal leaks, the surgical masks had pressure drops of 1.8 and 1.5 mm wg, compared with a pressure drop of 4.3 mm wg for the DMF respirator; this difference was caused by the thickness and tight weave of the DMF filter material. In turn, as the pressure drop increases, more particles are drawn into the mask around the perimeter of the face seal. Therefore, the higher the pressure drop due to the filter medium, the more important a leak becomes in allowing particles to enter the mask.

DISCUSSION

From the results obtained, we conclude that the protection provided by the tested surgical masks may be insufficient in environments where submicrometer-sized aerosols are present. There are at least 190 important biologic agents that cause infection,[39] and at least some of these agents may be transmitted by inhalation of submicrometer-sized infectious particles. The aerodynamic behavior of different biologic aerosols may be quite different, and differences in the infectious dose may pose varying degrees of risk.

Perimeter leakage preferentially increased the penetration of micrometer-sized versus submicrometer-sized particles. Perimeter leakage may be an important consideration in the future if more efficient filtration media are used in surgical mask designs.

When a better-performing respirator is worn, the wearer has to overcome an increased breathing resistance. This increases the likelihood that particles in the breathing zone may be pulled into the mask through face-seal leaks. Because many health care procedures and operations can last for hours, a highly protective respirator may become uncomfortable and cumbersome to the wearer because of the higher breathing resistance.

Because better respiratory protection may be needed for certain situations in the health care industry, methods commonly used by industrial hygienists should be considered for hospital settings. In addition, methods to evaluate the fit or seal of these respirators to the wearer's face need to be employed.[40] Presently, there are two types of fit testing: qualitative and quantitative. Both methods expose the respirator wearer to a test agent. In a qualitative fit test, the wearer reports whether he or she can detect an odor or taste the test agent. In a quantitative fit test, the concentration of the test agent is measured both inside and outside the respirator. Of the two methods, quantitative fit testing is both more accurate and more reliable. Fit tests help ensure that a respirator provides adequate protection on the wearer and that it fits properly to each wearer's face. To ensure an adequate seal, quantitative fit tests must be performed periodically, because fit tests can only detect current face-seal leakage.

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