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Modified N95 Mask Delivers High Inspired Oxygen Concentrations While Effectively Filtering Aerosolized Microparticles

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Study objective: In a pandemic, hypoxic patients will require an effective oxygen (O_2) delivery mask that protects them from inhaling aerosolized particles produced by others, as well as protecting the health care provider from exposure from the patient. We modified an existing N95 mask to optimize O_2 supplementation while maintaining respiratory isolation.

Methods: An N95 mask was modified to deliver O_2 by inserting a plastic manifold consisting of a 1-way inspiratory valve, an O_2 inlet and a gas reservoir. In a prospective repeated-measures study, we studied 10 healthy volunteers in each of 3 phases, investigating (1) the fractional inspiratory concentrations of O_2 (F_IO_2) delivered by the N95 O_2 mask, the Hi-Ox^{80} O_2 mask, and the nonrebreathing mask during resting ventilation and hyperventilation, each at 3 O_2 flow rates; (2) the ability of the N95 mask, the N95 O_2 mask, and the nonrebreathing mask to filter microparticles from ambient air; and (3) to contain microparticles generated inside the mask.

Results: The F_IO_2s (median [range]) delivered by the Hi-Ox^{80} O_2 mask, the N95 O_2 mask, and the nonrebreathing mask during resting ventilation, at 8 L/minute O_2 flow, were 0.90 (0.79 to 0.96), 0.68 (0.60 to 0.85), and 0.59 (0.52 to 0.68), respectively. During hyperventilation, the F_IO_2s of all 3 masks were clinically equivalent. The N95 O_2 mask, but not the nonrebreathing mask, provided the same efficiency of filtration of internal and external particles as the original N95, regardless of O_2 flow into the mask.

Conclusion: An N95 mask can be modified to administer a clinically equivalent F_IO_2 to a nonrebreathing mask while maintaining its filtration and isolation capabilities. [Ann Emerg Med. 2006;48:391-399.]

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INTRODUCTION

There is worldwide concern about an imminent influenza pandemic. In this event, affected patients will back up in emergency departments (EDs)[1] and ambulances,[2] placing their staff at increased risk of infection. These considerations highlight the importance of transmission prevention strategies in the protection of ambulance and ED personnel. Currently, their personal protective devices include gloves, gowns, shoe covers, appropriate filter masks, and positive-pressure isolation hoods.[3] These barriers are sometimes ineffective because they are overwhelmed by prolonged exposure and large viral loads[4] or because they are not used properly, in time, or at all.[5-7]

Editor's Capsule Summary

What is already known on this topic

We protect health care workers from communicable disease by giving them protective equipment and using devices that decrease emission of infectious agents from the source patient.

What question this study addressed

This study shows that an N95 mask can be modified to deliver oxygen to a person in a manner similar to a nonrebreathing mask while providing significant emissions reduction.

What this study adds to our knowledge

It is possible to practically increase protection for clinicians treating infectious patients with airborne-transmissible diseases, without compromising oxygen therapy for the patient.

How this might change clinical practice

If faced with an influenza pandemic, another severe acute respiratory syndrome–like outbreak, or patients with a dangerous communicable illness, clinicians may be afforded another level of protection through use of a similar device without compromising patient care.

Reducing the shedding of infectious particles from contagious patients may provide additional protection for ambulance or ED personnel. Although it is commonly recommended that surgical masks be used on potentially infectious patients during periods of patient triage or transportation, it is readily acknowledged that such masks do not provide full protection from infection transmission.[3] Standard N95 masks may be more effective in containing potentially infectious particles but will not be suitable for most influenza patients ill enough to seek medical care, because these patients will require oxygen (O_2) therapy. O_2 therapy is commonly administered with the nonrebreathing O_2 mask, which is not designed to contain any respiratory droplets. In fact, these masks may actually increase the dispersal of respiratory droplets by jetting them through the mask's open side vents.[8,9] Somogyi et al[8] reported that the use of the Hi-Ox^{80} mask, which is designed specifically to deliver high fractional inspired O_2 concentrations (FiO_2), can provide respiratory isolation if a bacterial-viral filter is placed on its outlet port. However, the mask is expensive, unfamiliar to many, and not likely to be widely available in numbers sufficient for use as a first-line O_2 mask in the case of a pandemic.

The implementation and routine use of an entry-level isolation O_2 mask during initial patient contact could provide an extra measure of protection to front-line health care workers from potentially contagious patients. Our approach in designing such a mask was to add a nonrebreathing O_2 manifold to the familiar N95 mask, which provides excellent viral and bacterial filtration and is already widely distributed. We tested the effectiveness of this "N95 O_2 mask" in providing supplemental O_2 and compared it to the nonrebreathing mask and to the Hi-Ox^{80} mask. We then tested the effectiveness of the N95 O_2 mask in protecting the wearer from microparticles in the environment and compared it to the criterion standard in this regard, the N95 mask. We also tested how well the N95 and the N95 O_2 masks retained microparticles originating from inside the mask. Finally, although the nonrebreathing mask is not designed to provide respiratory protection or isolation, we included it in particle testing because it is common, at least in our institutions, to find health care workers who believe it confers some level of protection to the wearer or the health care provider.

MATERIALS AND METHODS

Study Design

This study is a prospective repeated-measures design. We divided the study into 3 phases. In phase 1, we tested the O_2 delivery characteristics of the N95 O_2 mask, the Hi-Ox^{80} mask, and the nonrebreathing mask at resting ventilation and hyperventilation, each at 3 O_2 flow rates (to view photographs of the masks, see Figure E1, available online at http://www.annemergmed.com). In phase 2, we tested the protection function (ie, the ability of the mask to filter microparticles from ambient air) of the N95 mask, the N95 O_2 mask, and the nonrebreathing mask. In phase 3, we tested the masks' isolation function (ie, the effectiveness of each mask in containing microparticles generated inside the mask). We did not include the Hi-Ox^{80} in particle testing, because its protective and isolation function would be that of the particular filter placed on its expiratory port, and this information is already well documented (eg, see Dellamonica et al[10]). Neither subjects nor investigators were blinded to the type of mask being used for any of the test phases.

Setting

All tests were conducted in a well-ventilated patient room at a university teaching hospital, with the door closed.

Selection of Participants

After receiving institutional ethics research board approval, we obtained signed informed consent from 10 volunteers for each of the 3 phases of the study. Subjects were recruited by posted advertisement. Inclusion criteria were healthy nonsmoking men (without facial hair) or women between the ages of 18 and 60 years, with no active respiratory disease.

Interventions

We tested the O_2 delivery characteristics of 3 masks as characterized by the FiO_2 that they supplied. The 3 O_2 masks we tested were the N95 O_2 mask (a modified 3M model 1870; 3M, St. Paul, MN), the modified Hi-Ox^{80} mask (VIASYS

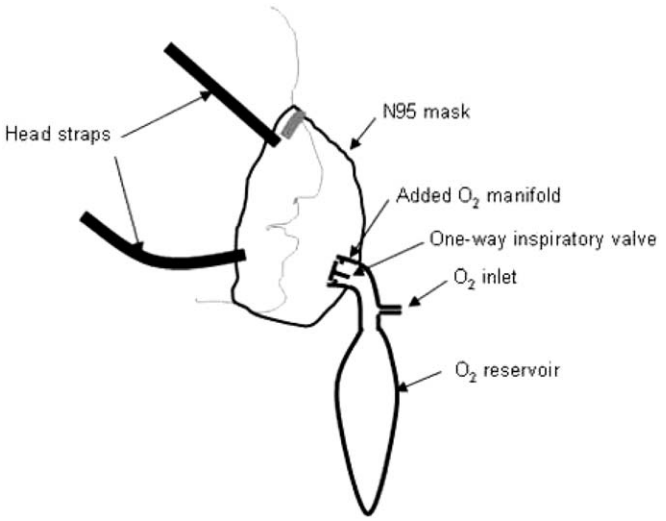

Figure 1. Schematic of an N95 mask modified by the addition of an oxygen manifold consisting of a 1-way inspiratory valve, an oxygen inlet and an oxygen reservoir.

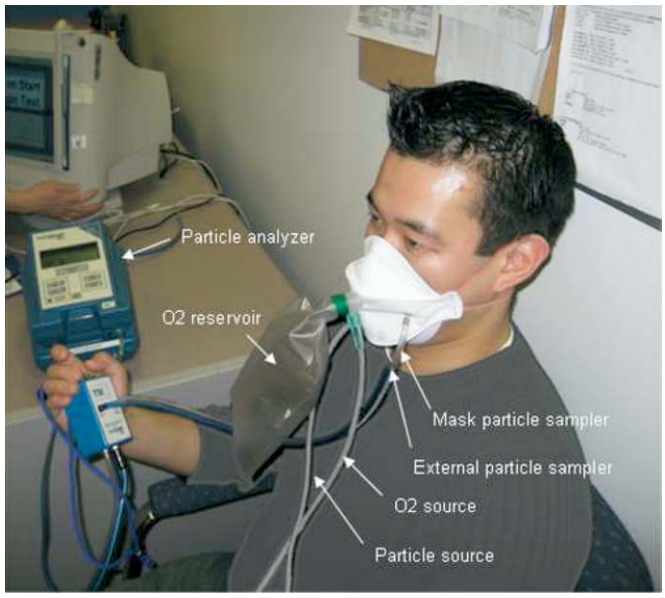

Figure 2. Particle testing setup. The N95 oxygen mask contains an internal gas sampling port and a separate port used for microparticle infusion.

HealthCare, Yorba Linda, CA) and the nonrebreathing mask (Airlife Adult Oxygen Mask; Cardinal Health, McGaw Park, IL).

We modified the N95 mask to allow for O_2 administration by adding an O_2 delivery manifold similar to that of a standard nonrebreathing mask. The manifold consisted of a 1-way valve, an O_2 inlet port, and an O_2 reservoir (Figure 1). The Hi-Ox^{80} mask was modified by placing a bacterial-viral filter (DAR Sterivent Mini; Mallinckrodt DAR, Mirandola, Italy) on its expiratory port.[8]

Subjects were fitted with the Hi-Ox^{80} and initially asked to breathe normally (resting condition). An O_2 flow of 2, 4, or 8 L/minute was selected randomly by draw. We chose these O_2 flow rates for 2 reasons. First, the Hi-Ox^{80} is rated to provide clinically useful FiO_2 at these flows.[11] Second, using lower flows with O_2 masks may be necessary in case O_2 supplies become limited, as when treating mass casualties (eg, during a pandemic). Subjects were not told of the O_2 flow being administered. Once end-tidal PCO_2 ($PETCO_2$) and end-tidal PO_2 ($PETO_2$) reached a steady state (defined as less than a 2 mm Hg change in $PETCO_2$ during 2 minutes), minute ventilation, $PETCO_2$, and $PETO_2$ were recorded for 2 minutes. Subjects were then asked to increase their minute ventilation sufficiently to reduce their $PETCO_2$ by 10 mm Hg below their resting values (hyperventilation) and maintain that level of $PETCO_2$. Once steady state was achieved at the target $PETCO_2$, minute ventilation, $PETCO_2$, and $PETO_2$ were again recorded for 2 minutes. Subjects then reestablished steady-state resting ventilation, after which the test was repeated for the other 2 O_2 flow rates. After testing the Hi-Ox^{80} at all 3 flow rates, the other 2 masks were tested (in random order) using the same protocol. The Hi-Ox^{80} mask was tested first because it is the only mask that permits measurement of minute ventilation. We were then able to use the $PETCO_2$ to match the minute ventilation when testing the other masks.

We tested the protective function of the masks by measuring the extent to which particles originating from ambient air leaked into the mask during normal breathing. We tested the N95 mask (3M model 1870, 3M, for 9 subjects; Aero mask, Aero Co, Southbridge, MA, for 1 subject), the N95 O_2 mask (constructed from the same models of N95 mask stated previously), and the nonrebreathing mask. Six of the subjects were hospital employees who had been previously fit-tested with N95 masks. We therefore used the same model of N95 mask for their tests. The remaining 4 subjects who were not previously fit-tested were arbitrarily supplied with the 3M model 1870. Although there is a possibility this may have introduced variability in our data, the arbitrary use of masks simulates cases in which this mask would be applied to a patient as an infectious barrier. Each mask was prepared in advance by inserting a gas sampling port into the mask material (Figure 2). The particle generator was turned on and infused microparticles freely into the closed room for 20 minutes before subject testing to increase the atmospheric particle concentration in the room to more than 200/cm^3. The test mask was placed on the subject's face, and subjects were instructed to breathe normally. After at least 2 minutes, we recorded particle concentrations outside the mask and then from inside the mask for 30 seconds each.

We tested the isolation function of the same 3 masks by measuring the extent to which particles originating from inside the mask leaked out into the surrounding air. Masks were prepared in advance by inserting sampling and particle infusion ports into the mask. Subjects were instructed to breathe

normally. Background particle concentrations were measured 6 cm in front of the mask during 30 seconds with the particle generator off. The particle generator was then turned on and the particles directed into the mask through a plastic tube attached to one of the ports. After an equilibration period of at least 60 seconds, we recorded particle concentrations for 30-second periods from inside the mask, 6 cm in front of the mask and 50 cm to the side of the mask. The latter location simulates the location of a health care worker's face while attending a patient.

Both protective and isolation tests were performed once for the N95 mask. For the N95 O_2 mask and the nonrebreathing mask, the tests were performed with O_2 flow rates of 2 and 10 L/minute.

Methods of Measurement

O_2 flow to the masks was controlled by a calibrated flow meter (Voltek Enterprises, Toronto, Ontario, Canada). Gas was sampled continuously from the oropharynx and analyzed for CO_2 (IR1507; Servomex Fairfax, CA) and O_2 (UFO130-2; Teledyne-AI, City of Industry, CA) partial pressures (PCO_2 and PO_2, respectively). Tidal gas was sampled from the oropharynx by a catheter inserted through a sealed port in the mask, which allowed accurate sampling of end-tidal gases without dilution from the high flows of O_2.

A particle generator, model 8026 (TSI Inc, Shoreview, MN), was used to generate a steady flow of ultrafine (approximately 0.2 μm) sodium chloride particles that are easily suspended in air. Particle concentrations were measured with Portacount Plus, model 8020 (version 2003 Rev K; TSI Inc), which is rated for detecting the concentration of particles as small as 0.02 μm.[12]

Data Collection and Processing

PCO_2 and PO_2 signals were digitized and recorded continuously by a data acquisition and analysis program (Labview; National Instruments, Austin, TX). $P_{ET}CO_2$ and $P_{ET}O_2$ were identified using a custom peak detection algorithm and converted to fractional concentrations ($F_{ET}CO_2$ and $F_{ET}O_2$). For each O_2 mask, ventilation, and flow combination, average $F_{ET}CO_2$ and minute ventilation (where applicable) were calculated during 2-minute steady states for each subject.

F_IO_2 was calculated for each breath from $F_{ET}CO_2$ and $F_{ET}O_2$ using the alveolar gas equation[13] (F_IO_2 is a flow-averaged value of the O_2 concentration during inspiration and is reflected in the exhaled concentrations of CO_2 and O_2). For each O_2 mask, ventilation, and flow combination, average F_IO_2s were calculated during 2-minute steady states for each subject.

During particle testing, on average, 15 to 20 discrete measurements were recorded for each 30-second sampling period and entered manually into a spreadsheet for analysis. For each subject, background concentrations recorded outside the mask were averaged.

Outcome Measures

We used F_IO_2 as the marker of effectiveness of O_2 delivery. We assumed the N95 mask to be the criterion standard for particle filtration; clinical equivalence was assumed for masks whose performances were comparable to that of the N95. The protective function of each mask was quantified by measuring the concentrations of particles inside the mask and expressing each discrete measurement as a percentage of average external concentrations. The isolation function of each mask was quantified by measuring the external particle concentrations while infusing particles into the mask and expressing each discrete measurement as a percentage of change from the average background concentrations measured before the particle generator was started.

Primary Data Analysis

Descriptive statistics and graphical methods were used to display our results. We used bar graphs to display average F_IO_2 values for all subjects. Box plots were used to display data points obtained during particle testing to illustrate the variability in particle concentrations that we observed over time.

RESULTS

All quantitative results are expressed as median (range).

With the Hi-Ox^{80} mask, subjects' minute ventilation and $P_{ET}CO_2$ (pooled for all O_2 flow rates) were 5.8 L/minute (2.3 to 9.5 L/minute) and 39.9 mm Hg (34.9 to 44.5 mm Hg), respectively, at rest and 14.9 L/minute (9.0 to 23.1 L/minute) and 29.2 mm Hg (24.7 to 33.9 mm Hg), respectively, during hyperventilation. The $P_{ET}CO_2$ (our marker for ventilation) for the N95 O_2 mask and the nonrebreathing mask (also pooled for all O_2 flow rates) was equivalent to that obtained by testing the Hi-Ox^{80} (39.6 mm Hg [32.8 to 45.7 mm Hg] and 38.2 mm Hg [33.1 to 44.1 mm Hg], respectively, at rest and 29.3 mm Hg [25.3 to 34.0 mm Hg] and 28.9 mm Hg [23.7 to 33.2 mm Hg], respectively, during hyperventilation).

The Hi-Ox^{80} consistently delivered a higher F_IO_2 than the other masks, with greater margins at higher O_2 flow rates (Figure 3). The F_IO_2 obtained from the N95 O_2 mask was clinically equivalent to that from the nonrebreathing mask for both resting ventilation and hyperventilation. During resting ventilation and at 8 L/minute O_2 flow, the F_IO_2 delivered by the Hi-Ox^{80} was 0.90 (0.79 to 0.96), consistent with that predicted by the package insert. Under these conditions, the F_IO_2 with the N95 O_2 mask and nonrebreathing mask was 0.68 (0.60 to 0.85) and 0.59 (0.52 to 0.68), respectively.

For protective function, the N95 O_2 mask provided the same efficiency of filtration of outside particles as the N95 mask at O_2 flow rates of 2 and 10 L/minute (Figure 4). Median particle concentrations inside the N95 and N95 O_2 masks at 2 and 10 L/minute were less than 1% of those outside the mask (0.0% to 3.0%). In contrast, high particle concentrations were found inside the nonrebreathing mask, with O_2 flow at 2 L/minute (53% [37% to 87%]) and with O_2 flow at 10 L/minute (17% [3% to 37%]).

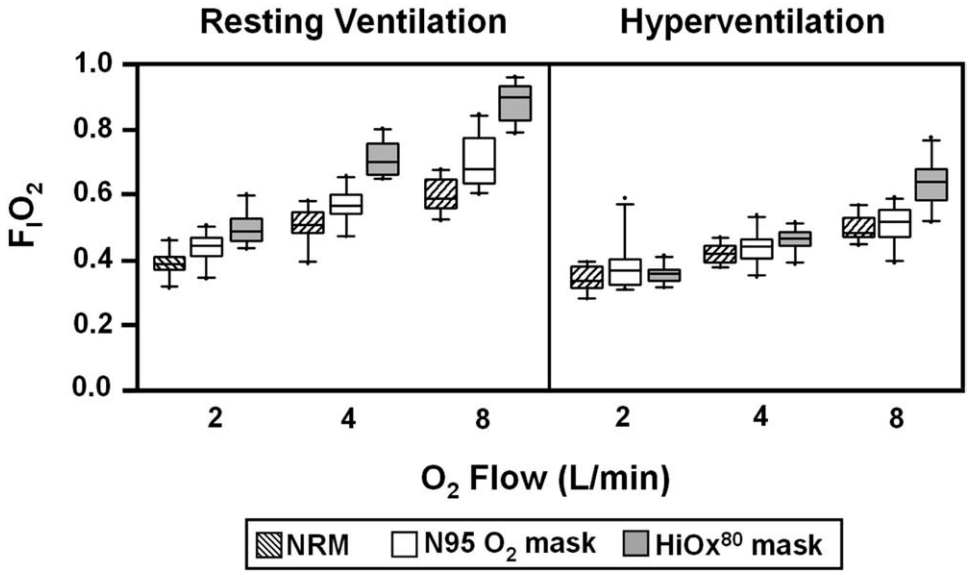

Figure 3. Median inspired fractional concentrations of oxygen (FIO_2) under all experimental conditions. Bar extensions show range of data.

For isolation function, the N95 O_2 mask provided the same efficiency of filtration of inside particles as the N95 mask. There was no increase in external particle concentrations above background values measured outside either mask, regardless of distance from the mask or O_2 flow into the N95 O_2 mask (Figure 5A, B). In contrast, particle concentrations measured outside the nonrebreathing mask were markedly higher than background values at 6 cm and 50 cm from the mask: 800% (62% to 3100%) and 450% (100% to 12,000%), respectively, when O_2 flow rates were 2 L/minute and 330% (15% to 1300%) and 95% (33% to 3000%) when flows were 10 L/minute.

LIMITATIONS

We studied the O_2 delivery characteristics of the 3 masks in healthy volunteers, not patients. The justification for this method is that the marker of effectiveness of O_2 delivery we studied—FIO_2—depends only on the characteristics of the mask, the O_2 flow, and the minute ventilation of the subject. The latter 2 were controlled in this study. Moreover, arterial partial pressure of O_2 and oxyhemoglobin saturation depend not just on the FIO_2 but also on such individual patient factors as the ventilation-to-perfusion ratio and shunt. Therefore, arterial blood gases and oxyhemoglobin saturation measurements in patients with pulmonary and other pathology are not required for evaluation of mask-specific O_2 administration efficiency.

We tested a group of 10 subjects for each phase of the protocol, but several subjects did not participate in all 3 phases of the study. However, for the phase of the study in which an individual subject did participate, he or she tested all 3 masks. Furthermore, the measured parameters of each phase of the study are totally independent of each other.

We studied the ability of the masks to filter microparticles, and we attempt to make inferences on their performance with other sized particles, such as respiratory droplets. Nevertheless, the 0.2-μm microparticles generated by the TSI particle generator are widely used to test for effectiveness of mask fit and filtration and are reasonable surrogates for such infectious particles as viruses (which are 20 to 300 nm), bacteria (tubercle bacillus; 0.2 to 0.6 by 1.0 to 10 μm),[14] and aerosolized respiratory droplets (>10 μm). In vitro testing has shown that N95 material prevents the penetration of approximately 95% of MS2 viruses (approximately 27.5 nm in diameter).[15]

The isolation function of the Hi-Ox^{80} mask with filter was not compared directly with that of the N-95 O_2 mask for 2 reasons. First, its isolation function would reflect the type of filter used, of which a large variety is available. Second, if the FIO_2 of the Hi-Ox^{80} is clinically necessary, the N95 O_2 mask is not a suitable alternative. We propose that the N95 O_2 mask provides an FIO_2 similar to, and therefore is a suitable alternative for, that of the nonrebreathing mask. Still, under some circumstances when isolation function is the critical issue, a direct comparison may be necessary.

Because of the nature of our study setup, it was not possible to blind subjects or investigators to the type of mask being used.

DISCUSSION

There are 2 main findings of our study. The first is that an N95 O_2 mask can deliver O_2 at least as effectively as a nonrebreathing mask. The second is that an N95 O_2 mask retains its filtration function for small particles in both directions. Although it is accepted that a properly fitted N95 mask provides the wearer with a high level of protection from inhaling external particles, our study is the first to demonstrate that the N95 filter material is also effective in preventing

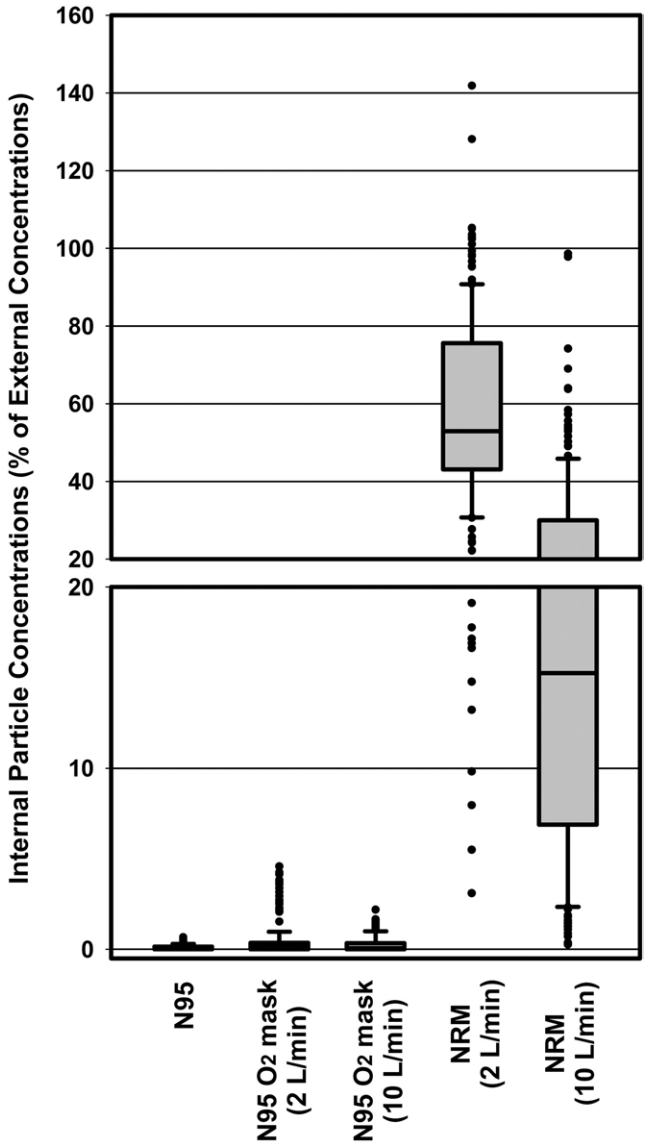

Figure 4. Protective function. Internal particle concentrations expressed as a percentage of external concentrations. Median values for the N95 mask and the N95 O_2 mask at 2 and 10 L/min of O_2 flow were all <1%. Median values for the nonrebreathing mask at 2 and 10 L/min of O_2 flow were 53% and 17%, respectively. The boxes outline the 25th and 75th percentiles, the bars indicate the 10th and 90th percentiles, and the dots indicate the outlying values. For quantitative data regarding the protection function of each mask, see Table E1 (available online at http://www.annemergmed.com).

particles originating inside the mask from escaping into the surroundings in vivo. This could not be assumed from its proven protective function, because the inside of the mask is exposed to moisture, higher gas flows and pressures, and much higher concentrations of particles than those present on the outside.

An implication of these findings is that the N95 O_2 mask may be effective in respiratory "isolation" by restricting the spread of similarly sized infectious particles from an infected patient. In contrast, whereas people are frequently admonished to cover their mouths with their hands when they cough or sneeze to protect others (a practice popularized during the 1918 influenza pandemic), we found that covering the mouth with the nonrebreathing mask provides no reduction in particle concentrations at 6 or 50 cm from the subject breathing at rest. Furthermore, persistence of high particle concentrations inside the nonrebreathing mask casts doubt on any assumption that O_2 flow into a nonrebreathing mask will in any way protect a patient from inhaling others' respiratory droplets.

Because no controlled studies outlining the full mechanisms of person-to-person transmission of influenza have been published,[16] we must make certain inferences from animal studies and observational and inoculation studies in humans. It appears that influenza is transmitted by droplets (>10 μm), aerosolized droplet nuclei (<10 μm), and by direct and indirect contact (see Bridges et al[16] and Salgado et al[17] for reviews). During the severe acute respiratory syndrome (SARS) outbreaks, it was assumed that reducing the dispersal of respiratory droplets from infected patients would help control the spread of infection. To this end, the World Health Organization guidelines state: "suspected cases should wear surgical masks until SARS is excluded."[3] Health Canada guidelines similarly recommend that a surgical mask be placed on the patient "until SARS is excluded or the patient is admitted into the room."[18] However, it is also recognized that a surgical mask "does not provide adequate respiratory protection to the wearer [ie, health care worker] if the infection is airborne." Recent studies in vitro have demonstrated that surgical masks can allow the penetration of more than 80% of virions 27.5 nm in diameter[15]—besides those that escape from the gaps in the mask seal to the face. The same would obviously apply to the isolation function of a surgical mask when worn by a contagious patient. Although quarantine of the patient may be effective in limiting contacts, it does not reduce the infectious load on those who enter the room and approach the patient or who participate in direct patient care.[19]

When O_2 is administered to a patient, respiratory isolation is even more problematic. Our study confirms earlier work demonstrating that standard O_2 masks do not provide effective containment of droplet or nuclei-sized particles and, furthermore, may even contribute to the pattern and extent of spread.[8,9] These considerations would be of greatest concern to such front-line health care workers as emergency medical services (EMS) and ED personnel who are required to attend symptomatic patients before any definitive diagnosis is made. The intensity of exposure is increased for these personnel for 2 reasons. First, they may have to provide high-risk interventions such as O_2 administration[9] and endotracheal intubation.[6] Second, the duration of exposure will likely be prolonged because filling of inpatient and critical care areas will result in

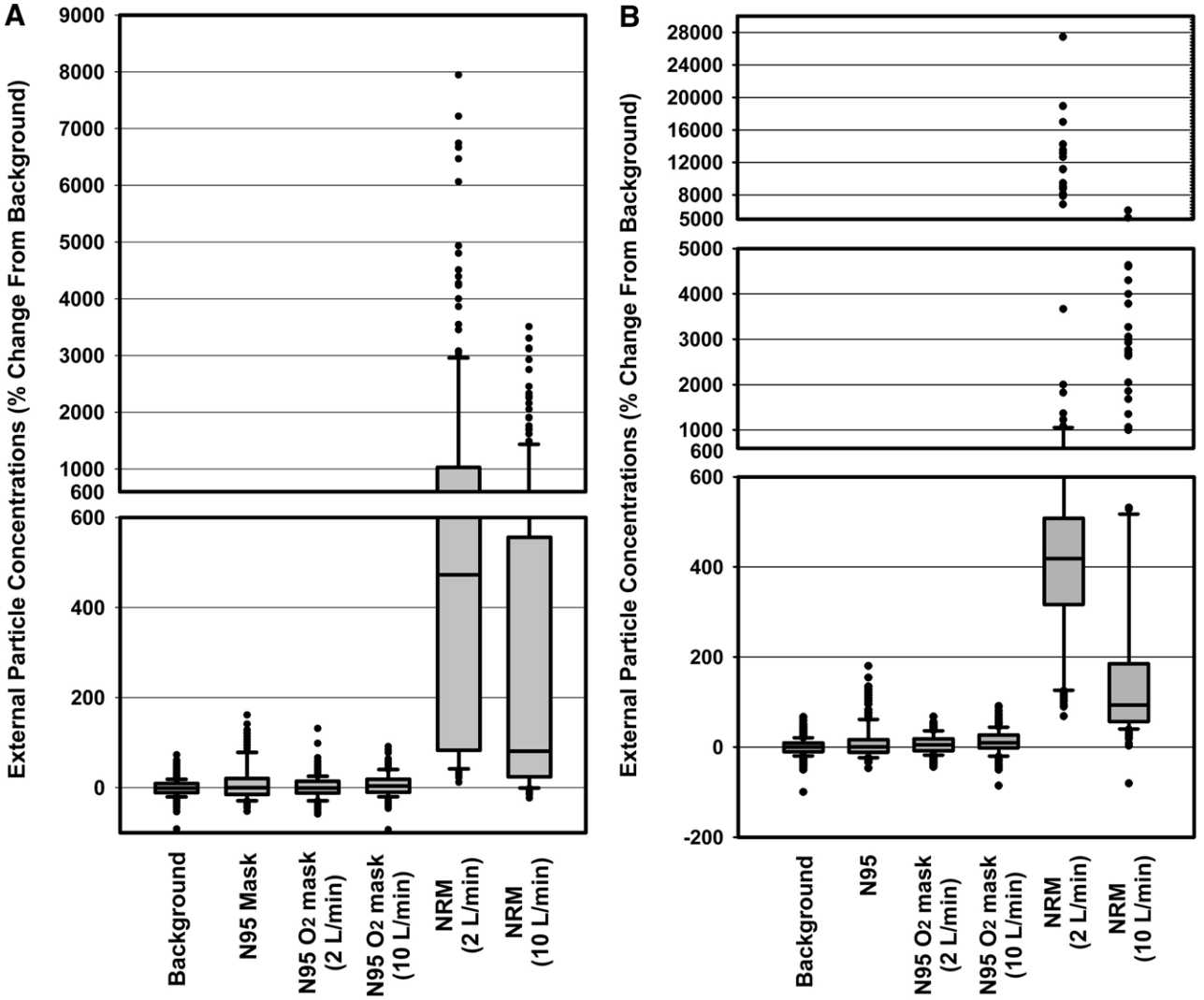

Figure 5. *A,* Isolation function at 6 cm. External particle concentrations measured at 6 cm from the mask, expressed as a percentage of change from background concentrations. Median values for the N95 mask and the N95 O_2 mask at 2 and 10 L/min of O_2 flow were indistinguishable from one another. Median values for the nonrebreathing mask at 2 and 10 L/min of O_2 flow were 800% and 330%, respectively. The boxes outline the 25th and 75th percentiles, the bars indicate the 10th and 90th percentiles, and the dots indicate the outlying values. *B,* Isolation function at 50 cm. External particle concentrations measured at 50 cm from the mask, expressed as a percentage of change from background concentrations. Median values for the N95 mask and the N95 O_2 mask at 2 and 10 L/min of O_2 flow were indistinguishable from one another. Median values for the nonrebreathing mask at 2 and 10 L/min of O_2 flow were 450% and 95%, respectively. The boxes outline the 25th and 75th percentiles, the bars indicate the 10th and 90th percentiles, and the dots indicate the outlying values. For quantitative data regarding the isolation function of each mask, see Tables E2 and E3 (available online at http://www.annemergmed.com). *NRM,* Nonbreathing mask.

"boarding" of patients in the ED and ambulances.[20] The risk to EMS workers appears to be particularly great when EMS are placed on hospital bypass because it leaves these workers in close quarters with sick patients for prolonged periods.

A number of limitations to the use of the N95 O_2 mask may arise in actual clinical practice. One would still have to rely exclusively on health care worker–worn barrier devices when patient isolation is impossible (as during endotracheal intubation or bronchoscopy[6]), as well as for patients for whom a good mask seal is difficult to obtain (for example, edentulous patients or patients with full beards). The N95 O_2 mask will also not be suitable for patients requiring an FIO_2 greater than 0.7, nebulized medication, invasive or noninvasive ventilatory assistance, or airway protection.

One would also expect that the limitations of the original N95 mask (eg, deterioration of filtration function with prolonged use, excessive handling, and accumulation of moisture) may also apply to the N95 O_2 mask. Indeed,

increased airflow resistance and the perception of increased work of breathing were commonly experienced by health care workers after prolonged N95 mask use during the SARS outbreak in Toronto. The increased resistance to breathing is likely due to moisture obstructing the pores in the mask material. Increased breathing resistance would reduce the ability of breathless patients to tolerate long-term use of the N95 mask. Although no detailed studies evaluating the duration of effectiveness of the N95 mask have been done,[21] these considerations indicate that the N95 O_2 mask may be best suited for short-term use, such as during ambulance transport, hospital triage, and transport from one hospital ward to another (eg from the patient room to the diagnostic imaging department). On the other hand, the inspiratory flow resistance may actually be *less* than that of the original N95 because the N95 O_2 mask includes an O_2 reservoir that provides the major part of the inspiratory volume, leaving only small volumes at low flows at end inspiration to be inhaled through the mask filter material.

We tested the masks for only a short period because they were intended to provide a short-term solution to O_2 delivery and respiratory isolation at initial patient contact. Extrapolation of these results to more prolonged use should be made with caution.

In conclusion, our study indicates that the N95 O_2 mask we constructed can deliver an F_IO_2 clinically equivalent to that provided by a nonrebreathing mask, although neither is as efficient as the Hi-Ox^{80}. Furthermore, the modification of the N95 mask for O_2 delivery retains the same filtration function as the N95 mask. This is the first study to confirm that the N95 mask, as well as our modified version of the mask, is effective in retaining microparticles originating *inside* the mask in vivo. Assuming that the kinetics of microparticle distribution studied in humans is a suitable model to study the risk of transfer of infection in humans, we conclude that for O_2-requiring patients, the N95 O_2 mask appears to provide protection and isolation performance equivalent to that of the N95 mask, whereas the nonrebreathing mask would provide none at all. Additional clinical studies are needed to confirm that O_2 administration through this N95 O_2 mask is well tolerated by patients and that its use actually reduces the risk of disease transmission from infectious patients to health care workers.

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Author contributions: HS, NS, and TA initiated the study and initial proof of concept. AM, MS, JH, HS, NS, TA, LF, TS, and RF conducted study design. AM, MS, JH, LF, and TS conducted data gathering. AM, MS, and JH analyzed data. AM, MS, and JH prepared the article. RF and JAF were the major contributors to the article. LF and TS contributed to the article. JAF was the study coordinator and supervisor. JAF takes responsibility for the paper as a whole.

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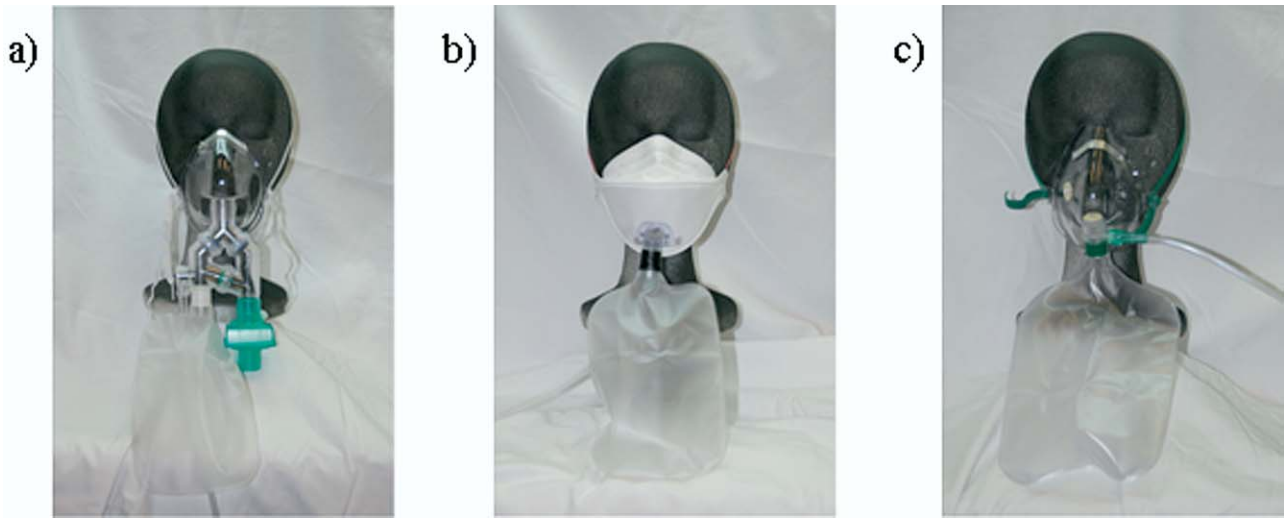

Figure E1. *A*, Modified Hi-Ox^{80} mask. *B*, N95 O_2 mask. *C*, Nonrebreathing mask.

Table E1. Particle concentrations from the protection phase of the study.*

Mask	Median	Range	Interquartile Range
N95 mask	0.07	0–0.67	0–0.15
N95 O_2 mask, 2 L/min	0.13	0–4.58	0–0.36
N95 O_2 mask, 10 L/min	0.06	0–2.19	0–0.33
NRM mask, 2 L/min	52.93	3.10–141.88	43.12–75.31
NRM mask, 10 L/min	15.26	0.27–98.60	6.90–29.90

NRM, Nonrebreathing mask.
*The protection function of each mask was quantified by measuring the concentrations of particles inside the mask and expressing each discrete measurement as a percentage of average external concentrations.

Table E2. Particle concentrations measured at 6 cm in front of the mask during the isolation phase of the study.*

Mask	Median	Range	Interquartile Range
N95 mask	−0.13	−52.73–161.29	−15.06–20.22
N95 O_2 mask, 2 L/min	−0.83	−58.74–131.36	−11.86–14.05
N95 O_2 mask, 10 L/min	3.69	−93.22–91.19	−9.91–18.69
NRM mask, 2 L/min	472.64	11.67–7944.91	82.97–1020.59
NRM mask, 10 L/min	80.81	−22.91–3509.63	24.87–555.24

*The isolation function of each mask was quantified by measuring the external particle concentrations while infusing particles into the mask and expressing each discrete measurement as a percentage of change from the average background concentrations.

Table E3. Particle concentrations measured at 50 cm to the side of the mask during the isolation phase of the study.*

Mask	Median	Range	Interquartile Range
N95 mask	0.17	−46.97–179.88	−11.64–16.52
N95 O_2 mask, 2 L/min	5.10	−44.31–67.51	−7.84–17.71
N95 O_2 mask, 10 L/min	9.81	−85.92–90.91	−2.05–26.62
NRM mask, 2 L/min	418.73	68.33–27442.17	317.48–506.74
NRM mask, 10 L/min	93.61	−80.64–6057.74	56.65–182.77

*The isolation function of each mask was quantified by measuring the external particle concentrations while infusing particles into the mask and expressing each discrete measurement as a percentage of change from the average background concentrations.