INTRODUCTION

Hypoxemia and cough are the main symptoms among patients with coronavirus disease (COVID-19), and hypoxemia is the primary reason for hospital admission. Oxygen therapy is the mainstay therapy for treating hypoxemia. Although our research group previously designed and reported an oxygen mask aimed at isolating infected patients, that kind of mask must be tightly fitted to the patient's face, is limited to short-term use, and is not suitable for long-term use.

High-flow oxygen through nasal cannula therapy (HFNC) is widely used and has become a vital treatment for bridging low-flow oxygen therapy with tracheal intubation among hospitalized patients with deteriorating respiratory function. HFNC uses
a nasal cannula without a tightly fitted mask and is associated with increased patient-reported comfort and a reduction in the severity of dyspnea; this treatment is suitable for long-term use. HFNC is recommended for use in well-ventilated negative pressure rooms with attending healthcare professionals equipped with complete personal protective equipment. Furthermore, many researchers have recommended that surgical masks (SMs) be placed over the nasal cannula to reduce aerosol dispersion.

However, aerosol infection control within HFNC, which even recent reports have pointed out is not an aerosol-generating procedure but is rather an aerosol dispersion procedure, has not yet been established. Although many barrier devices (including devices both without and with negative pressure in the barrier) have been reported in the literature, few barrier devices are suitable for HFNC, and aerosol infection control procedures during HFNC have not yet been established.

In this study, we hypothesized that a novel combination of semi-closed barrier devices (SBs) with a personalized exhaust (PE) can provide additional protection for healthcare professionals without negative pressure inside. We examined the function of three protective isolation measures (an SB, a PE, and an SM) as well as a combination of the three measures in a single cough simulator model applied to HFNC; the effectiveness of each modality and combination was quantified using particle counters and laser airflow visualization.

2 | MATERIALS AND METHODS

2.1 | Study design

High-flow oxygen through nasal cannula with an airflow of 60 L/m administered through a nasal prong was performed on a single cough simulator manikin to investigate aerosol leakage to the surroundings. Using this aerosol-generating simulator, we examined the effects of three isolation measures implemented to prevent leakage (an SB, a PE, and an SM), measured via an isolation function based on measurement counts and visualization of aerosols.

We implemented a prospective, repeated-measures study design. This investigation was divided into two phases. In Phase 1, we tested the isolation function (ie, the effectiveness of the isolation measures for containing aerosols generated inside the device and in preventing leakage to the bedside space) for three protective isolation measures (an SB, a PE, and an SM) individually and in combination, as well as with and without HFNC.

Sixteen different combinations of the three measures under HFNC or non-HFNC conditions were selected randomly. In Phase 2, we tested the isolation function by visualizing aerosols using a red laser sheet under 12 different combinations of the three protective isolation measures under HFNC conditions with a 1 or 2 L simulated cough.

2.2 | Setting

The tests were conducted in a simulation center room (floor area: 11.1 m², height: 2.4 m, volume: 26.5 m³) at a university teaching hospital; the door to the simulation room was closed.

To avoid the effect of airflow produced by sources other than HFNC, the air conditioner, which does not have ventilation function, was turned off during the test (during breaks within the test, the air conditioner for temperature control and PE [described later in Methods] with the air purifier for active room air change were, however, turned on).

We conducted the test in a room with a temperature set to 24.3–25°C and a humidity of 55–59%.

2.3 | Cough simulation

A simulator manikin (ALS simulator; Laerdal Medical) lay supine at a 10° inclination on a hospital bed, with its head tilted slightly to the right. The manikin mimicked single cough-emitted aerosols; a 1 L capacity aerosol stored in a 2 L volume calibration syringe (Minato Medical Science) was discharged with free fall of the cylinder from the oral cavity through a 7.5 mm tracheal intubation tube reversely intubated from the front neck of the simulator manikin (Figure 1C). Aerosol generators (Laskin Nozzle Generator 6D, Air Techniques International) were used to generate 0.3–10 μm of oil-based hydrogenated 1-decene homopolymer (PAO-4) test aerosol. We measured the resulting distribution of aerosols via a six-channel particle
counter (Airborne Particle Counter PP8306, Particles Plus, Tokyo, Japan) (Figure 1D). The distribution of aerosols is similar to an active cough as described in the literature. 14

The generator was active for approximately 2 s at the priming 2 L cylinder. We trapped aerosols in the syringes and made a reproducible flow via a naturally vertically falling piston (1.2 s at 1 L, 2.4 s at 2 L) to simulate single cough-emitted aerosols; 1 L is the middle range for cough expiratory volume in healthy volunteers. 15

2.4 | High-flow oxygen through nasal cannula

We conducted HFNC with a Hamilton 6C (Hamilton Medical AG) nasal cannula (Fisher & Paykel, size M, Figure 1C). We did not operate a humidifier to prevent aerosols from being added to the environment of the study setting.

2.5 | Semi-closed barrier device

The SB was provided along with mobile telescopic home drying racks (DCM, TM H18-MH1417; width 860–1420 mm, height 1150–1780 mm, depth 460–815 mm), which are reusable after wiping for sterilization, as well as soft translucent polyethylene sheets (2.5 m x 3 m) fixed with clips. We installed the sheet such that its edges were lower than the bed floor (Figure 1C), allowing medical professionals to approach patients easily by inserting their forearms for care or treatment (such as providing dietary assistance to patients and collecting blood samples). The volume of the SB over the bed surface was 0.8 m³.

Although many types of barrier devices have been reported on in the literature, 13 we chose to investigate the SB that has been used in the emergency room of our hospital since the start of the COVID-19 pandemic. To prevent aerosol dispersion, many barrier devices, including closed, semi-closed, and semi-open devices mainly designed for short-term use (eg, tracheal intubation, endoscopy, and tracheostomy), are necessary to create a tight seal and suction to increase the isolation effect through negative pressure. 16-18 However, a tight seal may increase the risk of hypercarbia as well as cause difficulties for healthcare professionals in terms of treating and caring for patients. 19 Fidler et al. 17 found increased aerosol leakage through arm apertures with a tighter seal on the opposite side of the barrier device. In contrast, our SB allows leakage from the bottle edge of the transparent soft area around the bed edge, avoiding aggregating leakage through the space opened by inserting forearms under a soft transparent barrier sheet.

2.6 | Personalized exhaust

Yang et al. reported on a PE as an air distribution method targeting the microenvironment around the human body; this method is used to prevent cross-infection in open areas without producing negative pressure (that is, preventing the transmission of exhaled contaminated air via suction at 10–20 L/s, which is equivalent to 600–1200 L/min). 20,21 A PE works by extracting air locally and does not cause negative pressure if the contaminated air is expelled from the room and balanced with supply airflow. 20,21 In this study, we used an air purifier with a HEPA filter (Niti-on, Figure 1A) for a PE. Exhausted air was expelled outside the room to change room air and to avoid air turbulence inside the room. The air purifier was evacuated at an air volume...
of 33.3 L/s (2000 L/min) and an air speed of 4.3 m/s from a 10-cm diameter suction hole installed 0.5 m above the head for gas exhaust around the upper body of the manikin. This exhaust (air change) volume is equivalent to 4.53 air changes per hour (ACH) of the room (26.5 m$^3$ volume) and 150 ACH of SB volume (0.8 m$^3$). We set a larger exhaust volume compared with that reported by Yang et al.,$^{20}$ as the semi-closed structure allows extensive volume work without producing negative pressure by extracting air locally, balanced with airflow supply outside the SB and accelerating air change inside.

### 2.7 | Phase 1: Isolation function test

#### 2.7.1 | Measurement of aerosols with particle counters

We set a particle counter (PP8303; Particles Plus) at 0.4 m, with two other identical particle counters placed 0.6 m and 1.5 m away from manikin’s mouth at a 0.8 m height from the floor (Figure 1C). We recorded particle concentrations for 30 s periods at three points (0.4 m, 0.6 m, and 1.5 m). The second location simulates the location of a healthcare professional’s face while attending a patient. We also recorded the temperature and barometric pressure at each of the three points. Airborne particle counters, typically used for indoor air quality testing in semiconductor clean rooms, laboratories, and operating rooms, use laser diodes and photodetectors to count particles by collecting scattered light from particles as they pass through sample inlets. To investigate the dispersal of cough-emitted aerosols during HFNC, we recorded concentrations of 0.3, 1, and 5 μm particles per cubic foot continuously with synchronized data loggers. The measured particle size was ±5 μm; envelopes <5–10 μm in diameter are not called droplets but are rather called airborne particles or infectious droplet nuclei. Airborne particles remain suspended in the environment for a period of time, depending on a number of factors, including air circulation, humidity, and atmospheric pressure (which is a possible route of virus transmission).$^{22}$ The particle counter sample time was set to 10 s for smoothing and sweep ambient air continuously; 10 s was selected for smoothing and eliminating the high-frequency components of particle count signals. The flow rate was set to 2.83 L min$^{-1}$.

### 2.8 | Phase 2: Isolation function test

#### 2.8.1 | Visualization of aerosols

A red laser sheet (KLD-VN; Katokoken) was irradiated vertically from 1.5 m to the right side of the manikin’s mouth (Figure 1B, at 1.5 m). The red laser, with a wavelength of 638 nm and a laser head output of 5 W, was converted to a light sheet of approximately 1 mm thickness. Light scattered from the aerosol was captured using a video camera (HC-WX970 M Panasonic) set at 60 fps. To improve aerosol visibility, a non-light transmission sheet was installed in front of the ventilator for HFNC. To investigate the dispersal of cough-emitted aerosols during HFNC, 1 or 2 L of gas-containing aerosol generated by the aerosol generator were discharged.

### 2.9 | Interventions

For Phase 1, eight different conditions were repeated five times in combination with three measures (an SB, a PE, and an SM), with and without HFNC. All the experiments were video-recorded. For Phase 2, eight different conditions were conducted for combinations of an SB, a PE, and an SM (with and without HFNC). Before starting each condition, we confirmed that the 1 μm particles decreased and reached the plateau level on the monitor of the particle counter outside (at 0.6 m) in Phase 1 of the study; aerosols were discharged as a cough. In Phase 2 of the study, we confirmed a decrease in aerosols by visual inspection.

### 2.10 | Data collection and processing

During the Phase 1 test, discrete measurements were recorded automatically for each 10 s sampling period. The isolation function of each measure (an SB, a PE, and an SM) or a combination of these measures was quantified as leakage by measuring aerosol concentrations after aerosol discharge from the manikin’s mouth; each discrete measurement was measured as the percentage of change from the average background concentrations measured for a 30 s period before the aerosol discharge. The percentage of change was averaged over the course of 120 s. The quantification procedure was adopted from a previous report published by two of the study authors.$^1$ The average post-aerosol discharge period of 120 s (for quantification) was determined as the change in concentration at three points peaked within 2 min in the pilot experiment as well as based on the results of the Phase 2 study. The results of eight conditions repeated five times with and without HFNC were statistically analyzed.

### 2.11 | Statistical analyses

After repeating the study procedures five times under eight different combinations of the three measures (an SB, a PE, and an SM) with or without HFNC, we analyzed the quantification of isolation (ie, the average percentage of change for 120 s from the average background concentrations measured for 30 s) to analyze the statistical effects of the three measures on leakage within the eight examined conditions. The Kruskal-Wallis one-way analysis of variance on ranks and Tukey tests were performed using SigmaPlot software ver.14.5 (Systat Software). Statistical significance was set at p < 0.05. In addition, using multiple linear regression analysis, the effects of an SB, a PE, and an SM on leakage at the 0.6 m and 1.5 m
points in three-size aerosols were examined to analyze the effects of each protective measure on leakage.

3 RESULTS

3.1 Phase 1

In the case of cough models with HFNC, the leakage of the 0.3 μm aerosol at the 0.6 m point decreased when SB + PE isolation measures were added to non-SM (p < 0.034) or SM alone conditions (p < 0.036). In addition, the leakage of 1 μm of aerosol at the 0.6 m point decreased when the SB + PE isolation measure was added to the non-treated group (p < 0.040) or to the group treated with SM alone (p < 0.021); leakage also decreased at the 1.5 m point when the SB + PE isolation measure was added to the non-treated group (p < 0.006). In addition, leakage of the 1-μm aerosols at the 0.4 m point increased within the SB + SM treatment as compared with treatment with PE alone (p < 0.039) or PE + SM (p < 0.024). On the other hand, the leakage of 5-μm aerosols did not decrease due to the three isolation measures (Figure 2).

Multiple linear regression analysis showed the following trends (see Appendix S1). The SB reduced 0.3 μm and 1 μm particle counts at 0.6 m and 0.3 μm and 1 μm particle counts at 1.5 m, although 5 μm particle counts were not reduced at the level of statistical significance. The PE reduced 0.3 μm and 1 μm particle counts at 0.6 m and reduced 1 μm particle counts at 1.5 m but did not reduce 5 μm particle counts at the level of statistical significance. The SM reduced 0.3 μm and 1 μm particle counts but did not reduce 5 μm particle counts at 0.6 m. All three measures did not reduce 5 μm particle counts at both 0.6 m and 1.5 m. Finally, we found that the barometric pressure inside the SB with a PE was comparable to that outside the SB.

3.2 Phase 2

The leakage of aerosols was scattered on the red laser sheet. Figure 3 shows an example of exhaled flow from a simulated manikin visualized using the laser sheet imaging technique for each condition. The spread of aerosols was confirmed on a laser sheet from a light source placed at the 1.5 m point. In the SM condition, the lateral spread was conspicuous. In the PE condition, the upward spread of the suction direction was conspicuous. In the SB condition, the aerosols were observed inside, and delayed leakage was observed outside. No aerosol leakage was observed in the SB + PE group. These 1 L cough results are consistent with the qualitative evaluation conducted in Phase 1 of the current study. Even with the 2 L cough result, there was no aerosol leakage with SB + PE.

Interestingly, the aerosol spread looked different under the same conditions and appeared to reflect different spatial spread patterns. This difference may explain the variation in the observed quantitative differences in Phase 1, even under the same conditions (see Appendix S1).

4 DISCUSSION

To the best of our knowledge, this is the first report to evaluate isolation measures quantitatively and qualitatively in terms of SB leakage. The results of this study, if confirmed, could be used to inform long-term patient management of HFNC. Although an SB alone did not prevent the leakage of aerosols, the novel combination of a semi-closed barrier device with a PE prevented aerosol leaks of 0.3 and 1 μm particles in the HFNC single cough model. This result is partially consistent with previous reports showing that the effectiveness of barrier devices depends on the use of suction devices that induce negative pressure inside, although the novel combination evaluated in our study reduced aerosol leakage without negative pressure inside.13,16,23,24

There are two differences between our study, which examined the effects of a PE during HFNC, and previously reported studies. First, the flow volume of the PE was higher than the suction flow volume in our study. Second, the presented barrier device has a semi-closed structure.

Although Daniel et al25 reported that the suction rate must exceed the oxygen flow rate and expiration rate of human breath in the case of an almost sealed barrier enclosure, we set the PE flow volume (which corresponds to the suction flow volume in their studies) at a higher flow rate than in their investigation.

In our study, we set the PE flow volume at a higher level to compensate for the inflow of outside air to the SB as well as for the large cough ventilation volume. PE flow volume is equivalent to a 120 ACH, considering air change inside the SB, which is ten times higher than what is generally recommended for negative pressure rooms.25

Although the US Food and Drug Administration alerted healthcare facilities of the potential increased health risk to patients and healthcare providers from barrier devices without negative pressure on August 21, 2020,26 an SB + PE can achieve isolation without negative pressure but with sufficient air flow by a PE (compensating for the high flow produced by HFNC and cough). On the other hand, the semi-closed structure of the SB has at least two advantages. First, the SB contributes to patient safety. A tightly sealed barrier device places patients at risk of hypercapnia, although the SB combined with a PE reduces this risk by promoting the inflow of outside air, and the high-flow gas of the HFNC further reduces the risk. Second, medical professionals can easily manage patients because they can contact the patient by thrusting their hand through the protective barrier during care and treatment.

There was a large variation in particle counts even within the same conditions in the quantitative study, which may be due to the spatial heterogeneity of aerosol distribution caused by a single cough. That is, a slight difference in the direction of the airflow of a cough, even under the same study conditions, could result in variations in aerosol concentrations at the measurement point. In the laser studies, we detected aerosols in laser sheets projected from a laser source placed at the 1.5 m measurement point that were not identical even under the same conditions; we believe this variation suggests spatial heterogeneity of aerosol distribution. Although
the PE flow volume was effective in this cough model, further research is needed to generalize these results to clinical practice.

4.1 Limitations

Despite the substantial strengths of this study, we acknowledge some limitations. First, we conducted this study in a non-ventilated room, which differs substantially from a well-ventilated hospital room. For example, in a hospital room with air flow from the patient’s feet to their head, aerosol exposure to healthcare professionals due to coughing may be reduced as compared with that in a non-ventilated room, and research in real hospital rooms is necessary for future investigations. Another limitation of the current study is that the cough simulations did not accurately simulate coughing in patients. Specifically, the amount of cough ventilation volume in the study was appropriate, although the cough flow was less than previously reported, and aerosol dispersal may be lower than that in reality. In addition, the 5 μm particles were not influenced by PE + SB in this study. Therefore, we conclude that aerosols >5 μm in size could be easily blocked by the SB and may not require a PE or an SM to prevent leakage. However, these results should be extrapolated to larger aerosols and droplets with caution. The feasibility of an SB and a PE as well as adequate PE flow rates in clinical practice should be studied in the future.

FIGURE 2 Isolation functions of each device or a combination of devices were quantified as leakage at each measurement point, expressing discrete aerosol concentration measures as the percentage of change from background concentrations measured before aerosol discharge for an average of 30 s. The quantifications were averaged for 120 s after aerosol discharge. This figure depicts box plots of the medians and interquartile ranges of the quantification (for 0.3, 1, and 5 μm particles at 1.5, 0.6, and 0.4 m, respectively) with and without an SB, a PE, and an SM. PE, personalized exhaust; SB, semi-closed barrier device; SM, surgical mask.
CONCLUSION

We found that the novel combination of a PE and an SB reduced the leakage of 0.3–1 μm aerosols even with HFNC. This may reduce the exposure of infectious aerosols from patients and contribute to improving the safety of medical professionals as well as likely reducing the rate of nosocomial infections. It is crucial to implement these procedures as measures against the appearance of mutant strains of severe acute respiratory syndrome coronavirus 2 as well as within future emerging respiratory infectious diseases.27

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CONFLICT OF INTEREST

The authors have no actual or potential conflicts of interest to declare.

AUTHOR CONTRIBUTIONS

Ryohei Matsui involved in writing—original draft (lead), conceptualization (supporting), formal analysis (lead), methodology (lead), and investigation (lead). Hiroshi Sasano involved in conceptualization (lead), methodology (supporting), and writing—original draft (lead). Takafumi Azami involved in conceptualization (lead), methodology (supporting), and writing—review and editing (equal). Hisako Yano, Hiromi Yoshikawa, and Kazunori Imai involved in conceptualization (supporting), and writing—review and editing (equal). Yota Yamagishi and Yuka Miyazaki involved in investigation (supporting), and writing—review and editing (equal). Takahiro Goshima and Marechika Tsubouchi involved in writing—review.
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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher’s website.

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