



# Impact of surgical masks on fraction of inspired oxygen during oxygen therapy depends on the type of oxygen masks and respiratory conditions: volunteer- and simulation-based studies

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## Abstract

**Purpose** We investigated the impact of surgical masks (SM) during oxygen therapy using oxygen masks in volunteer- and simulation-based studies.

**Methods** Fifteen volunteers wore the Hudson RCI<sup>®</sup> or Open-Face Mask<sup>®</sup> with/without an SM. The fraction of inspired oxygen concentration (FIO<sub>2</sub>), end-tidal CO<sub>2</sub> (EtCO<sub>2</sub>), partial pressure of inspired CO<sub>2</sub> (PICO<sub>2</sub>), and respiratory rate (RR) were measured. The oxygen flow rate increased from 0 to 10 L/min. In the simulation-based study, FIO<sub>2</sub> was measured using a simulator that reproduced spontaneous breathing. RR was 12 or 24 bpm, and the tidal volume (Tv) was 300, 500, or 700 mL. The effect of oxygen mask fitting conditions was also examined. The primary outcome measure was FIO<sub>2</sub> at 6 L/min.

**Results** In the volunteer-based study, FIO<sub>2</sub> was reduced when the SM was used with the Hudson RCI<sup>®</sup> or Open-Face Mask<sup>®</sup>. The FIO<sub>2</sub> drop was larger with the Open-Face Mask<sup>®</sup> than with the Hudson RCI<sup>®</sup>. The RR, EtCO<sub>2</sub>, and PICO<sub>2</sub> significantly changed with the SM, but the differences were not clinically meaningful. In the simulation-based study, the SM with the Hudson RCI<sup>®</sup> did not reduce FIO<sub>2</sub>, but the SM with the Open-Face Mask<sup>®</sup> significantly decreased FIO<sub>2</sub> under several conditions. However, the SM with the Hudson Mask<sup>®</sup> reduced FIO<sub>2</sub> when the fit of the mask was inadequate. With the Open-Face Mask<sup>®</sup>, lower RR and Tv resulted in larger differences in FIO<sub>2</sub>.

**Conclusions** The SM decreased FIO<sub>2</sub> during oxygen therapy with oxygen masks. The impact of SM depended on the type of the oxygen mask, mask fitting, and respiratory condition.

**Keywords** Fraction of inspired oxygen · FIO<sub>2</sub> · Oxygen mask · Oxygen therapy · Surgical mask

## Introduction

Since the beginning of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) pandemic, infection prevention measures have become more important than ever. The coexistence of effective oxygen supply and droplet prevention in patients with respiratory symptoms is an urgent issue. The simple oxygen mask may disperse potentially infectious exhaled air, even when the nose and mouth are covered. Hui et al. showed that exhaled air at peak exhalation dispersed

into a surrounding distance of approximately 0.40 m when the simple oxygen mask was used at an oxygen flow rate of 4 L/min, breathing, 12 bpm, and a tidal volume of 500 mL [1]. Coughing could extend the dispersion distance beyond 0.4 m [2].

The use of a surgical mask significantly reduces cough-related aerosol dispersion, which is helpful for infection control [3, 4]. To prevent infection, patients on oxygen therapy may also be required to wear a surgical mask [5]. Some reports have investigated the risks of surgical masks during oxygen therapy using an oxygen mask [6–9]; however, the evidence regarding the conditions involved in the impact of the surgical masks on FIO<sub>2</sub> has been limited. Additionally, the presence of a surgical mask may cause difficulty in breathing and affect breathing patterns [10].

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This study aimed to investigate the impact of a surgical mask during oxygen therapy on the fraction of inspired oxygen concentration ( $\text{FIO}_2$ ). The volunteer and simulation-based studies were conducted using two types of oxygen masks with different mechanisms: simple and open designs. Our findings may be useful in cases where surgical masks must be worn during oxygen therapy for infection control.

## Methods

### Volunteer-based study

This study was reviewed and approved by the Ethics Committee of Tokushima University Hospital in advance (approval number: 3854). This clinical trial was registered at the University Hospital Medical Information Network center (UMIN000042557). Prior written informed consent was obtained from all volunteers. This randomized, cross-over, single-blind study complies with the CONSORT statement.

Male and female volunteers aged 20–60 years with an American Society of Anesthesiologists' physical status (ASA PS) score of 1–2 and Hugh-Jones of 1 were recruited at the Department of Anesthesiology, Tokushima University Hospital. The study was conducted in the operating room of Tokushima University Hospital. A sampling tube was inserted from the volunteer's nasal cavity toward the oropharynx by 13–15 cm to collect inhalation and exhalation samples. Volunteers wore the Hudson RCI® (Teleflex Inc., Pennsylvania, USA) or Open-Face Mask® (Atom Medical Inc., Tokyo, Japan) with or without a surgical mask (PRO-LANE® Level-1, Medicom Inc., Montreal, Canada) (Fig. 1). The elastics of the surgical mask were placed over the ears so that the mask covered the mouth and nose. The participants were instructed to use a headband when wearing the oxygen mask. The surgical mask was placed under the oxygen mask for volunteers equipped with both. The volunteers assumed a supine resting position and listened to their preferred music to relax. Breathing techniques were not specified or advised; volunteers breathed as they felt comfortable. The oxygen flow rate was increased from 0 to 10 L/min in increments of 2 L/min, and  $\text{FIO}_2$ , end-tidal carbon

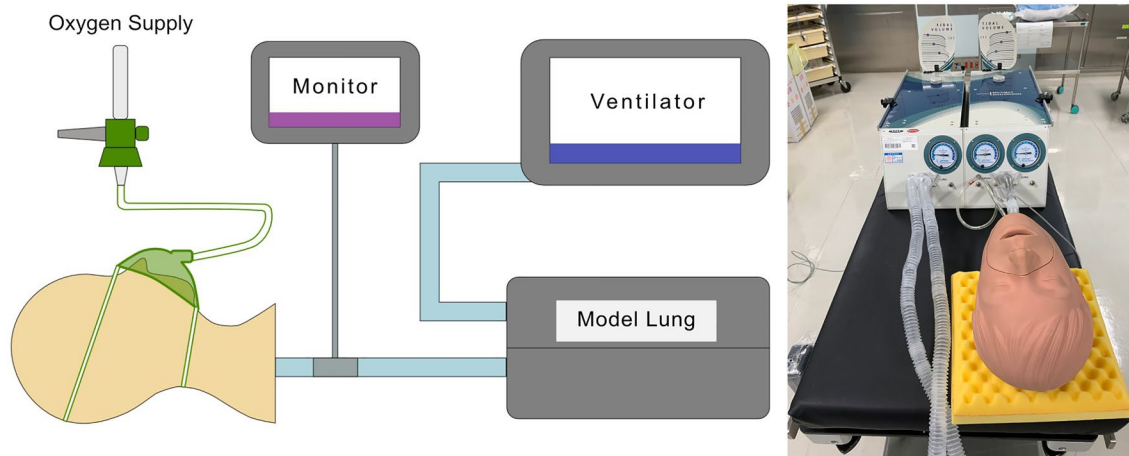
dioxide ( $\text{EtCO}_2$  mmHg), and partial pressure of inspired carbon dioxide ( $\text{PICO}_2$  mmHg) were measured from inhalation and exhalation samples (Sampling Flow Rate  $200 \text{ mL min}^{-1}$ , GF-220R and CSM-1502, NIHON KOHDEN, Tokyo). Measurements were started at least 1 min after each oxygen flow rate was changed. Five respirations were recorded when the  $\text{EtCO}_2$  waveform showed a good shape, which clearly appeared from phase 1 to phase 4 and avoided disruption of the  $\text{EtCO}_2$  waveform. The median of the data for five breaths was adopted. Volunteers drew lots randomly to determine the sequence of wearing a surgical mask. The washout period between the first and second sequence was at least 5 min, and the second measurement was started after confirming that the fraction of exhaled oxygen had returned to the first baseline. The observer was blinded to whether the volunteer was wearing a surgical mask. Volunteers were blinded to the oxygen flow rate, the values of samples from respirations, and the onset of data measurement. The primary outcome measure was  $\text{FIO}_2$  at an oxygen flow rate of 6 L/min with and without the surgical mask. The secondary outcome measures were the number of participants who had a decrease in  $\text{FIO}_2$  by 1 standard deviation (SD) due to the surgical mask.  $\text{FIO}_2$ ,  $\text{EtCO}_2$ ,  $\text{PICO}_2$ , and respiratory rate at each oxygen flow rate were also considered.

### Simulation-based study

We constructed a simulation model of oxygen therapy using an oxygen mask using the Dual Adult Lung Simulator (Michigan Instruments Inc., Michigan, USA) that can reproduce spontaneous breathing (Fig. 2). Two oxygen masks with different mechanisms were used: the Hudson RCI® (Teleflex Inc., Pennsylvania, USA), commonly referred to as the simple mask; and Open-Face Mask® (Atom Medical Inc., Tokyo, Japan), commonly referred to as the open-design mask.  $\text{FIO}_2$  was measured in these oxygen masks, with or without a surgical mask (PRO-LANE® Level-1, Medicom Inc., Montreal, Canada). The surgical mask was placed under each oxygen mask. The compliance of the lung simulator was  $0.05 \text{ L/cmH}_2\text{O}$ , and the airway resistance was  $5 \text{ cmH}_2\text{O/L/sec}$ . The respiratory rate was set at 12 or 24 bpm, and the tidal volume was

**Fig. 1** Experimental mask fitting. The mannequin wore the Hudson RCI® or open-Face Mask®, with or without a surgical mask





**Fig. 2** Experimental diagrams

set at 300, 500, or 700 mL. The oxygen flow rate was increased from 0 to 10 L/min in increments of 2 L/min, and  $FIO_2$  was measured from the sample in the trachea of the simulator (Sampling Flow Rate 200 mL/min, GF-220R and CSM-1502, NIHON KOHDEN, Tokyo, Japan). Measurements were started at least 1 min after each oxygen flow rate was changed. Data were collected in triplicate. The washout periods between the experiments were at least 5 min, and the subsequent measurement was started after confirming that the oxygen concentration inside the simulator had returned to the baseline. The primary outcome measure was  $FIO_2$  at an oxygen flow rate of 6 L/min with and without the surgical mask. The secondary outcome measures were  $FIO_2$  at each oxygen flow rate.

The following simulator-based experiments were also conducted to determine whether the fit of the oxygen mask would affect the impact of a surgical mask on  $FIO_2$ . As in the above experiment, two type of masks, the Hudson RCI<sup>®</sup> and Open-Face Mask<sup>®</sup> were worn with or without a surgical mask (PRO-LANE<sup>®</sup> Level-1). In a scenario where the oxygen mask was ideally worn, the rubber headband of the oxygen mask was securely attached so that there was as minimal space around the oxygen mask. In a scenario where the oxygen mask was roughly worn, the headband was not used and the oxygen mask was simply placed on the simulator's face. The respiratory rate was set at 12 bpm, and the tidal volume was set at 500 mL. The oxygen flow rate was set to 6 L/min, and  $FIO_2$  was measured from the sample in the trachea of the simulator. A gas sampling tube was also placed on the lips and on the surgical mask to measure oxygen concentrations. The oxygen ratio inside and outside the surgical mask was calculated.

### Statistical analysis

The sample size was determined as follows. The sample size of the volunteer-based study was determined to be 15. With this sample size, an effect size  $d_z$  of 0.8 can be detected with the paired  $t$  test when the  $\alpha$  error and power ( $1-\beta$ ) are set to 0.05 (two sided) and 0.8, respectively. The effect size of 0.8 corresponds to mean difference of 0.08 when the SD is set to be 0.1 in a volunteer-based study. Triplicate measurements were performed in the simulation-based study. This sample size of 3 can detect an effect size  $d_z$  of 3.3 when  $\alpha$  was set to 0.05 (two sided) and power to 0.8 with the Student's  $t$  test. The effect size of 3.3 corresponds to the mean difference of 0.1 when we estimated the standard deviation (SD) to be 0.03 in a simulation-based study. The sample size was calculated using G\* power version 3.1.9.6 (Heinrich Heine University, Düsseldorf, Germany).

Data are shown as the mean (SD) or [95% confidence interval (95% CI)]. Paired  $t$  tests were performed on paired samples in the volunteer-based study after confirming that the carryover effect and period effect of the cross-over design were denied by repeated measure analysis of variance (ANOVA). Ratios were compared by the chi-square test or Fisher's exact test if there were five or fewer cells. Student's  $t$  tests were performed in the values between the presence and absence of surgical masks in the simulation-based study. Comparisons of two factors were performed by two-way ANOVA followed by the Student's  $t$  tests (Bonferroni correction) as post-hoc tests. All  $p$ -values were two sided, and  $p < 0.05$  was considered statistically significant. Statistical analyses were performed using EZR (Saitama Medical Centre, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R version 4.0.3 (The R Foundation for Statistical Computing,

Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics. [11]

## Results

### Volunteer-based study

Fifteen volunteers were enrolled in the volunteer-based

### CONSORT2010 Extension to Randomized Crossover Trials, Flow Diagram

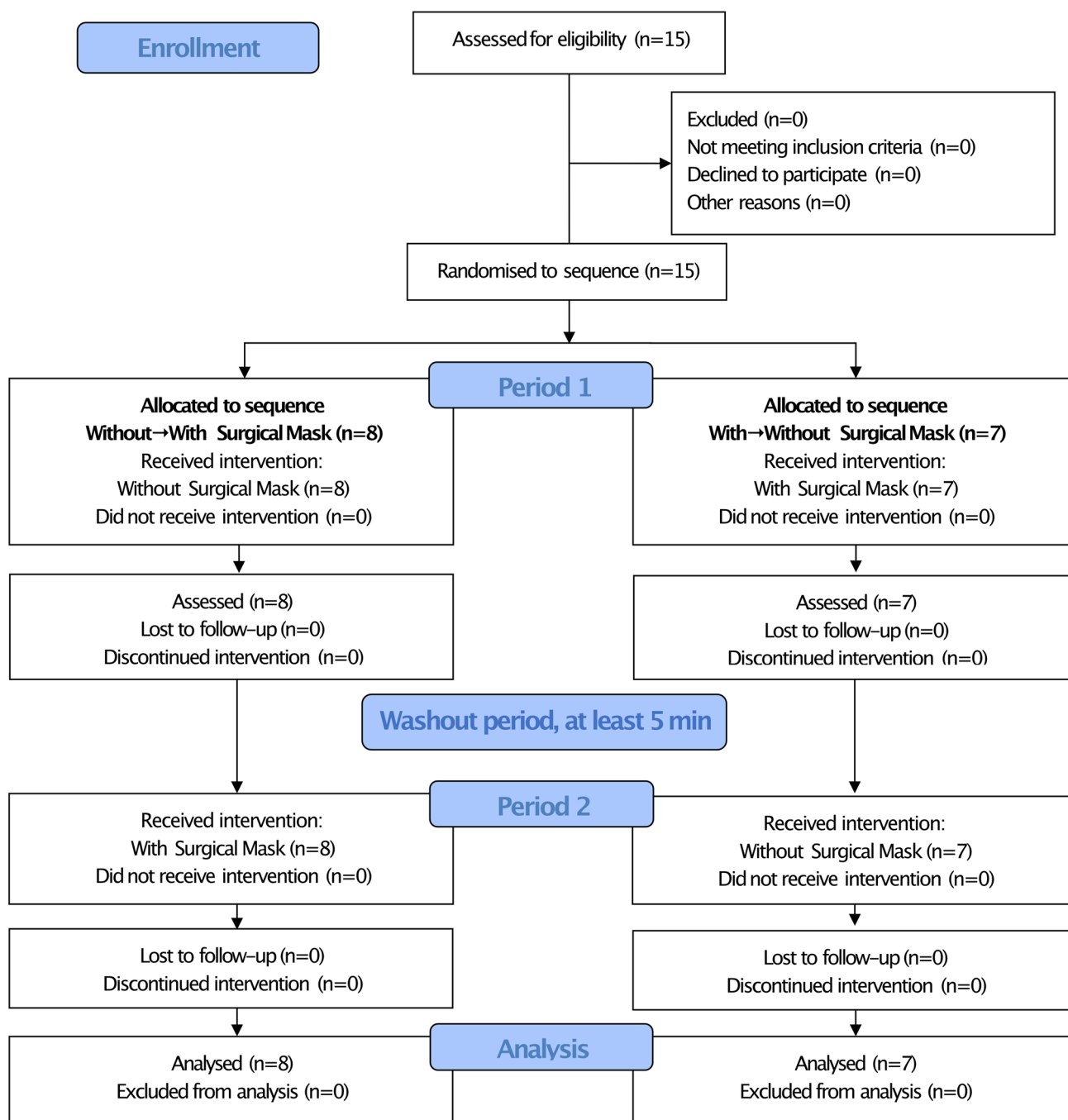


Fig. 3 Study flow diagram. n number

study (Fig. 3). The characteristics of the volunteers were as follows: 8 male (53.3%) and 7 female (46.7%); mean age 36.3 (8.4) years; mean height 163.5 (9.9) cm; mean body weight 58.7 (15.5) kg; and mean body mass index (BMI) 21.6 (3.4). At an oxygen flow rate of 0 L/min (baseline) there was no significant difference in  $FIO_2$ ,  $EtCO_2$ ,  $PICO_2$ , and respiration rate with or without a surgical mask.

The  $FIO_2$  significantly decreased when participants were wearing a surgical mask with the Hudson RCI®. The  $FIO_2$  at an oxygen flow rate of 6 L/min were 0.56 (0.08) and 0.49 (0.07) without and with a surgical mask, respectively, and the mean difference was  $-0.07$  (95% CI  $-0.13$  to  $-0.02$ ,  $p=0.011$ ) (Fig. 4a, Online resource 1). Additionally, the  $FIO_2$  significantly decreased when participants were wearing a surgical mask with the Open-Face Mask®. The  $FIO_2$  at an oxygen flow rate of 6 L/min was 0.48 (0.07) and 0.37 (0.10) without and with a surgical mask, respectively, and the mean difference was  $-0.12$  (95% CI  $-0.16$  to  $-0.07$ ,  $p<0.001$ ) (Fig. 4b, Online resource 1).

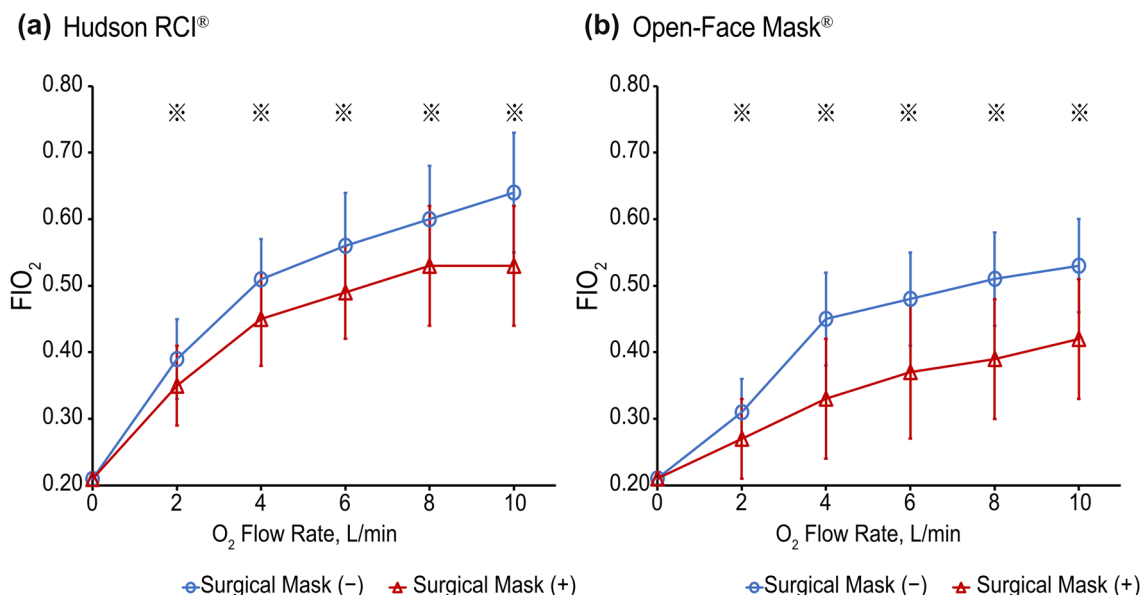
Six (40.0%) participants using the Hudson RCI® and 13 (86.7%) participants using the Open-Face Mask® experienced a decrease in  $FIO_2$  by 1 SD or greater due to the surgical mask, respectively. The Hudson RCI® resulted in significant fewer incidences of decreased  $FIO_2$  compared to the Open-Face Mask® ( $p=0.021$ ).

There were statistically significant differences in respiratory rate,  $EtCO_2$ , and  $PICO_2$  between with and without surgical masks. However, the mean difference was small (Online resource 1).

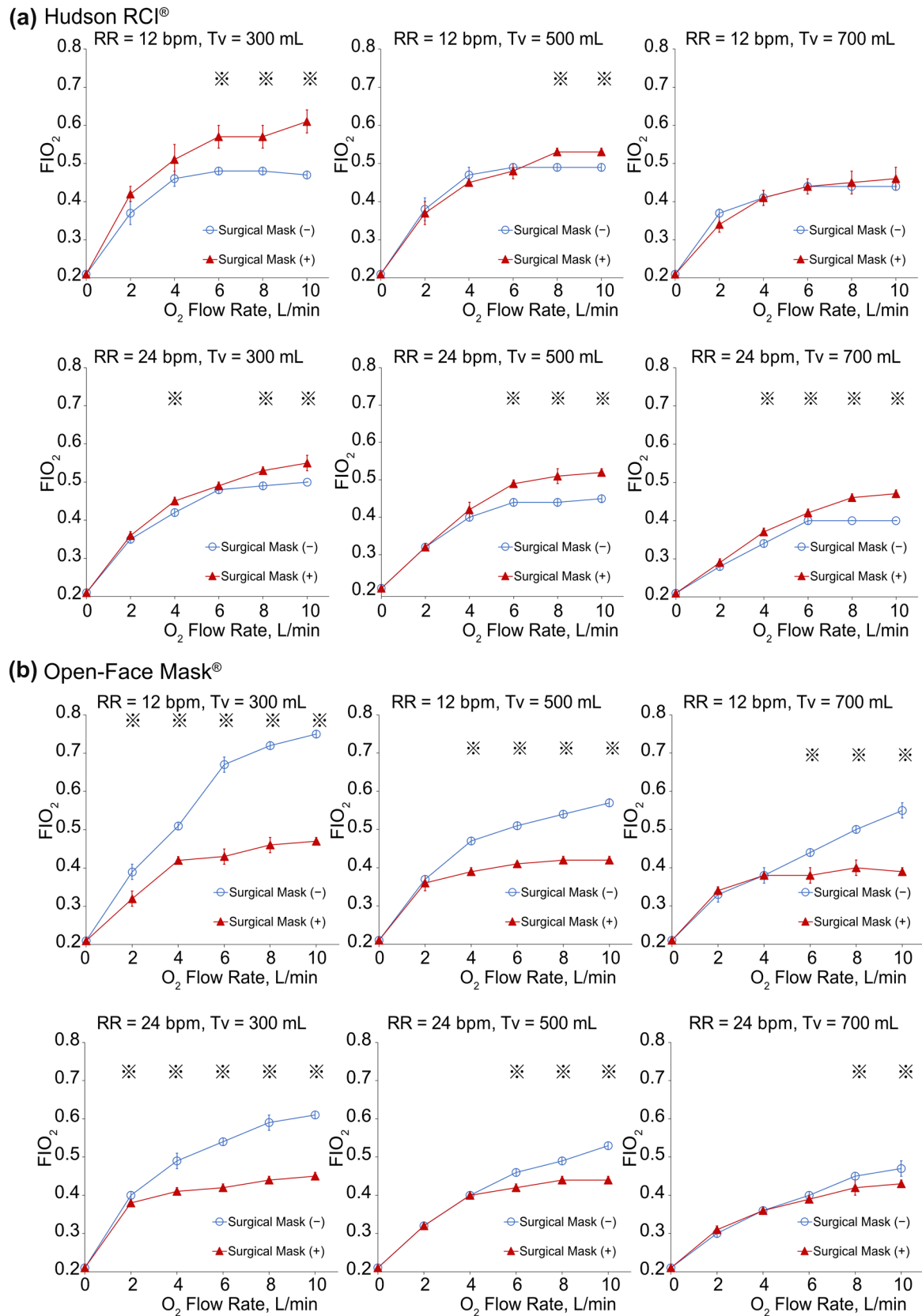
### Simulation-based study

When used with the Hudson RCI®, the surgical mask did not decrease  $FIO_2$  at an oxygen flow rate of 6 L/min at all respiratory conditions. Rather, the surgical mask significantly increased  $FIO_2$  under the following conditions: at a respiratory rate of 12 bpm and tidal volume of 300 mL, the  $FIO_2$  at an oxygen flow rate of 6 L/min were 0.48 (0.01) and 0.57 (0.03) without and with surgical masks, respectively, and the mean difference was 0.09 (95% CI 0.04–0.14,  $p=0.010$ ). At a respiratory rate of 12 bpm and tidal volume of 500 or 700 mL, there were no significant differences in  $FIO_2$  at an oxygen flow rate of 6 L/min with or without a surgical mask. At a respiratory rate of 24 bpm and tidal volume of 300 mL, there was no significant difference in  $FIO_2$  at an oxygen flow rate of 6 L/min. At a respiratory rate of 24 bpm and tidal volume of 500 or 700 mL, the  $FIO_2$  at an oxygen flow rate of 6 L/min was statistically significantly higher in the presence of the surgical mask, but the mean difference was small (Fig. 5a, Online resource 2).

When used with the Open-Face Mask®, the surgical mask significantly decreased  $FIO_2$  at an oxygen flow rate of 6 L/min at the following respiratory conditions: at a respiratory rate of 12 bpm and tidal volume of 300 mL, the  $FIO_2$  at an oxygen flow rate of 6 L/min were 0.67 (0.02) and 0.43 (0.02) without and with surgical mask, respectively, and the mean difference was  $-0.24$  (95% CI  $-0.28$  to  $-0.20$ ,  $p<0.001$ ). The mean difference in  $FIO_2$  reduced with an increase in tidal volume. At a respiratory rate of 24 bpm and tidal volume of 300 mL, the  $FIO_2$  at an oxygen flow rate of 6 L/min



**Fig. 4** The results of the volunteer-based study.  $FIO_2$  the fraction of inspired oxygen concentration. Data are given as mean (standard deviation SD). \*indicates statistically significant values



**Fig. 5**  $FIO_2$  at each breathing condition in the simulation-based study.  $FIO_2$  the fraction of inspired oxygen concentration; RR Respiratory Rate;  $Tv$  tidal volume. Data are given as mean (standard deviation  $SD$ ). \*indicates statistically significant values

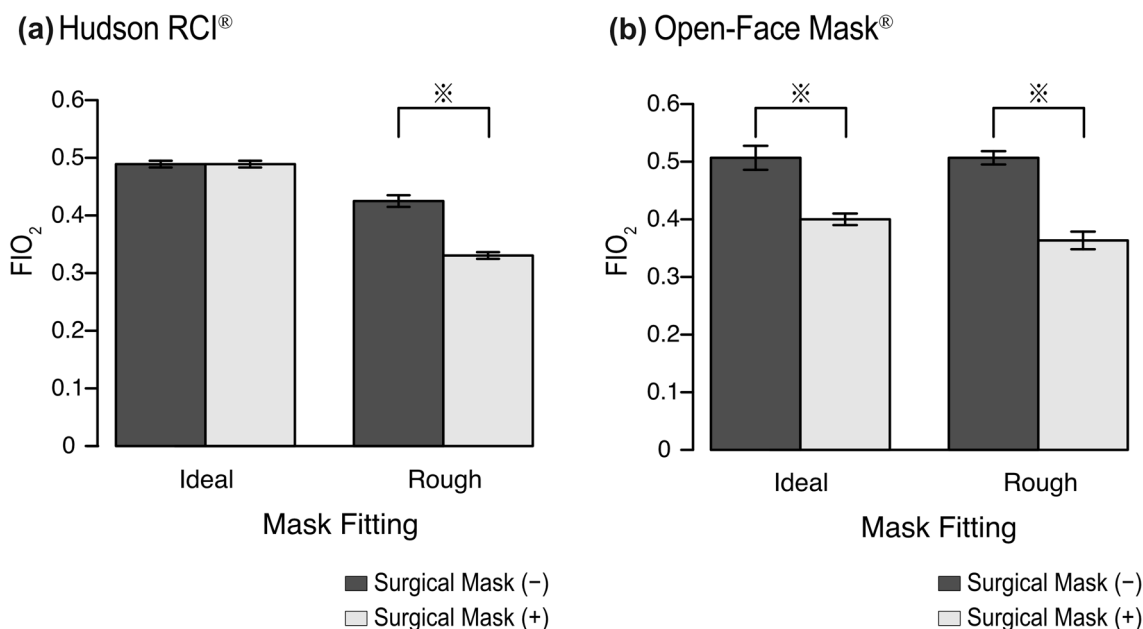
were 0.54 (0.01) and 0.42 (0.01) without and with surgical masks, respectively, and the mean difference was  $-0.12$  (95% CI  $-0.13$  to  $-0.11$ ,  $p < 0.001$ ). The mean difference in  $FIO_2$  reduced as the tidal volume increased. At a respiratory rate of 24 bpm and tidal volume of 700 mL, there was no significant difference in  $FIO_2$  at an oxygen flow rate of 6 L/min (Fig. 5b, Online resource 2).

The results regarding the impact of mask fitting and surgical masks on  $FIO_2$  are as follows. For the Hudson RCI®, there was a significant difference in the mask fitting factor ( $F [1, 8] = 726.07$ ,  $p < 0.001$ ), surgical mask factor ( $F [1, 8] = 130.67$ ,  $p < 0.001$ ), and the interaction effects ( $F [1, 8] = 130.67$ ,  $p < 0.001$ ). Post hoc tests revealed a significant effect of a surgical mask with the rough mask fit (with surgical mask  $<$  without surgical mask,  $p < 0.001$ ) but not the ideal fit ( $p = 1$ ) (Fig. 6a). The rough mask fit resulted in a significant larger difference in oxygen concentration inside and outside the surgical mask compared to the ideal fit [91.4% (2.6%), 73.8% (2.2%), respectively,  $p < 0.001$ ] (Online resource 3). As for the Open-Face Mask®, there was a significant difference in surgical mask factor ( $F [1, 8] = 208.33$ ,  $p < 0.001$ ) but not the mask fitting factor ( $F [1, 8] = 4.48$ ,  $p = 0.067$ ) and the interaction effects ( $F [1, 8] = 4.48$ ,  $p = 0.067$ ). (Fig. 6b).

### Discussion

In the present study, two oxygen masks with different mechanisms were used: the Hudson RCI®, commonly referred to as the simple mask, and the Open-Face Mask®, commonly referred to as the open-design mask. A volunteer-based study showed that the surgical mask reduced the  $FIO_2$  when the Hudson RCI® or Open-Face Mask® was also used. However, the incidence rate of large  $FIO_2$  drops was higher with the use of the Open-Face Mask® than the Hudson Mask®. The respiratory rate, the  $EtCO_2$ , and  $PICO_2$  were slightly changed by the surgical mask, but the differences were not clinically meaningful. These results support the findings of previous studies, which showed that the surgical mask did not provide clinically significant physiological impact [12, 13]. The decrease in  $FIO_2$  observed in the volunteers was unlikely to have been significantly affected by changes in breathing conditions.

The simulation-based study showed that no decrease in  $FIO_2$  was observed when the Hudson RCI® was combined with a surgical mask. However,  $FIO_2$  became significantly lower with a surgical mask when the Hudson RCI® was worn inadequately. This result may explain the risk of the lower  $FIO_2$  when volunteers wore surgical masks with the Hudson Mask® because mask fitting varies from person to person. It is possible that the presence of a surgical mask may have affected the fitting of the volunteer’s oxygen mask. On the other hand, the simulation-based study showed that the  $FIO_2$  was significantly decreased when



**Fig. 6**  $FIO_2$  at each mask fitting condition, the simulation-based study.  $FIO_2$  the fraction of inspired oxygen concentration. Data are given as mean (standard deviation, SD). \*indicates statistically significant values

the Open-Face Mask<sup>®</sup> was combined with a surgical mask despite an ideal fit. A reduced respiratory frequency and tidal volume was associated with a larger the difference in FIO<sub>2</sub>.

The mechanisms of oxygen supply in the simple and open-design oxygen masks are different. The simple oxygen mask allows oxygen to accumulate in the mask area. As our simulator-based study showed, if the simple oxygen mask can be fitted without gaps, it was possible to take in oxygen-enriched air from the mask area even when a surgical mask is used. However, if the simple oxygen mask is poorly fitted, a surgical mask may decrease FIO<sub>2</sub> because of the increased leakage around the mask. On the other hand, the open-type oxygen mask does not have any reservoir to accumulate oxygen. The open-design oxygen mask was designed to increase the oxygen concentration in the nose-mouth zone by blowing oxygen and allowing for oxygen-enriched air to move around the nose-mouth zone [14]. It is possible that subjects could not efficiently inhale air from the high-concentration oxygen area in the presence of the surgical mask, while the open-design oxygen mask has the advantage of reducing the amount of carbon dioxide that is rebreathed compared to a simple mask [14–16].

This study has the following limitations. The values obtained from the simulation-based and volunteer-based studies may be different from the values in actual clinical practice. Patients receiving oxygen therapy have varying degrees of respiratory function and status. The performance of a low-flow oxygen device depends on the respiratory rate, tidal volumes, and the fit of the mask [15, 17, 18]. Moreover, a variety of oxygen delivery devices are available in the market from different companies; the effect of surgical masks on other oxygen delivery devices remains unknown. However, similar open-design oxygen delivery devices, such as the OxyMask<sup>™</sup> (Southmedic Inc, Ontario, Canada), have the same basic principle as the open-type mask that was used in this study, which is to create a high-oxygen gradient in the nasal-mouth area, although there are minor differences. These open-design oxygen devices also carry a risk of lowering FIO<sub>2</sub> from normal values when a surgical mask is worn.

In this study, the surgical masks decreased FIO<sub>2</sub> when two different types of oxygen masks are used: the Hudson RCI<sup>®</sup> and Open-Face Mask<sup>®</sup>. Our results showed that the impact of the surgical mask on oxygen therapy depended on the type of the oxygen mask, mask fitting, and breathing condition.

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s00540-022-03083-2>.

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**Author contributions** MK: Conceptualization, Methodology, Investigation, Analysis, Writing—Original Draft; YI: Methodology, Investigation, Analysis; RK: Methodology, Investigation, Analysis; MM: Investigation, Visualization; KT: Conceptualization, Data Curation, Writing—Review and Editing, Supervision, Project administration.

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## Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

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