Innovative dual-function protective scope mask and filtration system for aerosol generating ENT scope procedures

Hui Sing Chew | Marcus Tan | Acharyya Sanchalika | Gabriel Tan | Eu Chin Ho | Brenda Sze Peng Ang | Rupesh Agrawal | Seng Beng Yeo

1Department of Otorhinolaryngology, Tan Tock Seng Hospital, Singapore, Singapore
2The Biofactory Pte Ltd, Singapore, Singapore
3Clinical Research and Innovation Office, Tan Tock Seng Hospital, Singapore, Singapore
4Department of Infectious Diseases, Tan Tock Seng Hospital, Singapore, Singapore
5National Centre for Infectious Diseases, Singapore, Singapore
6National Healthcare Group Eye Institute, Tan Tock Seng Hospital, Singapore, Singapore
7Singapore Eye Research Institute, Singapore, Singapore

Correspondence
Hui Sing Chew, Department of Otorhinolaryngology, Tan Tock Seng Hospital, 11 Jalan Tan Tock Seng, Singapore 308433, Singapore.
Email: hui_sing_chew@ttsh.com.sg

Funding information
Ng Teng Fong Healthcare Innovation Program Grant, Grant/Award Number: NTF_SEPT2020_I_C1_D_03

Abstract
Background: Aerosol-generating procedures (AGPs), such as nasoendoscopy, are considered high-risk during the COVID-19 pandemic due to risk of virus aerosol transmission. We aim to evaluate the efficacy of an innovative system in reduction of aerosol contamination.

Methods: Pilot study involving 15 healthy volunteers performing aerosol-generating activities with the prototype, compared with and without a standard surgical mask.

Results: We found an increased frequency of smaller-sized particle emissions for all four expiratory activities. The particle emission rate with the prototype mask was significantly slower over time for the smallest sized particle (0.3 μm) during breathing, speaking and singing compared with similar activities without the mask (p < .05). We found similar trends for coughing for larger particles but that did not reach statistical significance.

Conclusion: The innovation offers good protection against aerosol transmission through the physical barrier of the mask, the negative pressure environment within the mask, and the unit’s dual filtration function.

Level of evidence: Level 2b.

KEYWORDS aerosol, COVID-19, nasoendoscopy, prevention, transmission

1 INTRODUCTION

Coronavirus disease 19 (COVID-19) virus transmission occurs through respiratory droplets, aerosols, and contact with contaminated surfaces.1–3 Studies have shown that viruses can remain viable on surfaces for hours to days.4 Standard surgical masks have been shown to be effective in reducing the emission of virus particles to the environment in droplet form but not in aerosols.5,6 As such, aerosol-generating procedures (AGPs), such as endoscopies (nasoendoscopy/laryngoscopy/bronchoscopy), are considered high-risk procedures.

Findings of high viral load in nasal/nasopharyngeal samples of asymptomatic individuals and prolonged viral existence have been reported.7 Community spread has also occurred among asymptomatic individuals. Since the COVID-19 pandemic, the World Health Organization has recommended airborne, droplet, and contact precautions when AGPs are performed.8 The infection control recommendation is to perform these AGPs for COVID-positive subjects in negative pressure rooms with postprocedure terminal cleaning to prevent environmental contamination and disease spread.

Rooms with negative pressure are scarce and costly resources in hospitals and are normally available only in inpatient wards. During the pre-COVID-19 pandemic, these AGPs were performed in normal pressure clinic consultation rooms. Few health care facilities have sufficient resources to cater to the volume of AGPs if they must be done...
in negative pressure rooms. It is also technically impossible, if not extremely costly, to convert existing clinic consultation rooms into negative pressure rooms. Terminal cleaning is also time-consuming, requiring at least 30 min. The consequent reduction in scope volumes translates to increased waiting time, reduced efficiency and patient satisfaction, and delayed diagnoses.

When these AGPs are performed in an emergency or semiurgent setting (where it is impossible to push patients to a single bedded/ negative pressure room for the scope), there is also an additional risk of spread of disease via aerosols generated to other patients and health care workers.

As clinical services resume despite the pandemic and the ongoing threat of future respiratory viral epidemics, we need to explore ways to conduct these AGPs safely and in a logistically sustainable and cost-efficient manner.

Through care delivery redesign, we developed and piloted an innovative protective mask and filtration system for patients undergoing AGPs. The prototype allows AGPs to be performed safely and efficiently as per pre-COVID-19 pandemic clinical settings. The objective of this study was to evaluate the effectiveness of this novel scope mask and filtration system in reducing particle emission/aerosol transmission compared with a standard 3 ply medical-grade surgical mask and without any mask.

## METHODS AND MATERIALS

### 2.1 Prototype design

The prototype was developed jointly between Tan Tock Seng Hospital Otorhinolaryngology Department and The Biofactory Pte Ltd. Patent PCT International Application No: PCT/SG2021/050674 (Title: Facial cover for a patient undergoing medical procedure). Critical input was obtained and considered from an infectious disease physician and infection prevention practitioner to ensure that the product met the infection control recommendation. Ethics approval from the institutional review board (National Healthcare Group Domain Specific Review Board) was obtained prior to the commencement of the study (DSRB number: 2020/01023). All methods were performed in accordance with the relevant guidelines and regulations.

The prototype comprises the following features (Figure 1):

1. Silicone transparent scope mask (to be applied onto the patient’s face) with the following ports:
   a. One-way self-sealing instrumental ports (nasal access): Dimensions allow access for standard-sized flexible and rigid nasoendoscopes, flexible videostroboscopes, and other common ENT instruments.
   b. One-way inlet airflow port for unfiltered ambient air to enter the mask.
   c. Exhaust suction port connected to the filter unit.
2. Dual inlet H13 high-efficiency particulate air (HEPA) filtration system with adjustable airflow.

Medical-grade silicone was chosen as the material of the mask due to its relatively transparency, good biocompatibility, comfort on skin, chemical inertness, and heat resistance (desirable features for easy decontamination). The mask was designed to be able to fit most faces, while the nasal access instrument ports allow access to all common standard-sized ENT instruments available in the clinic setting. The suction port of the silicone mask was connected to a medical-grade HEPA (H13 prefilter) filtration device with 99.97% efficiency for the removal of particles as small as 0.3 \( \mu \). The high flow of air through...
the inlet airflow port and evacuation of air/aerosols via the suction port allows for significant air exchange (129 air exchanges/min or 7780 air exchanges/h) and for a negative pressure environment of more than –60 pascals within the internal environment of the mask relative to the atmosphere. Figure 2 shows the scope mask in use with good scope visualization of the laryngeal anatomy.

The HEPA filtration system has a dual inlet system that is able to simultaneously filter the clinic room when the scope system is in use, while also being to also function as just a standalone air filtration device for the room when the scope system is not in use. The air filtration system is capable of providing up to 12 air exchanges for room sizes of up to 80 m$^3$. Refer Supporting information for the instructional video (Video S1).

2.1.1 | Prototype evaluation: Study design, population, and settings

This was a balanced $7 \times 3 \times 4$ experiment. The response, emission particle count, is evaluated at 7 different time points with 3 different mask interventions for 4 expiratory activities. A total of 15 healthy nonpregnant English-speaking individuals above the age of 21 years old were recruited. These participants were health care workers (staff members from the hospital) who were not part of the study team. They were randomly approached by the research assistant. Informed written consent was obtained for their participation in this study, all data collected were anonymized and no identifiable images/information were collected in the study. Reimbursement was provided for the participant’s time and participation in the study. Subject shown in the photo illustrations in this article belongs to our second author who had given his consent for the release of the photos.

The three different mask interventions evaluated were:
1. Prototype mask.
2. Standard medical-grade 3 ply surgical mask.
3. No mask.

2.1.2 | Experimental setup and prototype evaluation

The prototype efficacy in reducing aerosol transmission was evaluated with the use of a LIGHTHOUSE Solair 3100 particle counter in an enclosed transparent acyclic box measuring $1.2 \times 1.2 \times 0.4$ m (Figure 3). Study participants were each tasked to perform the following activities: (1) Normal breathing. (2) Speaking—“Monday to Sunday.” (3) Singing—first four verses of “Happy Birthday.” (4) Coughing—five forceful cough. The particle counter sampling tubing port was positioned 30 cm in front of the subject. This distance was set to reflect the usual scope distance between the procedurist and the patient. The particle counter was set to obtain 7 cycles of 10 consecutive seconds of recording once activated. A HEPA H13 scrubber was used to supply filtered air in the acrylic enclosure for 2 min prior to the start of each activity to ensure a stable baseline particle count prior to the start of each activity. For Activity 1 (breathing), the study subject was instructed to breathe quietly for the entire cycle. For Activities 2–4 (speaking, singing, and coughing), the subject was signaled to commence each of the activities at the start of the second cycle. For all the activities, the first cycle (first 10 s) of particle counter recording was referred to as the baseline count. Recording was completed at the end of the seventh cycle for each activity. Both differential particle count/cubic meter (m$^3$) and cumulative particle counts/m$^3$
were captured for particle sizes of 0.3, 0.5, 1, and 5 μm. Each participant was issued with a brand-new piece of the prototype for the experiment purpose. The same set of experiments was repeated with the participants wearing a standard medical-grade 3 ply surgical mask and without any mask.

### 2.1.3 | Sample size

For this pilot study, an exploratory sample size of 15 participants was decided based on feasibility in recruitment during the study period. This comprises of 13 females and 2 males above age of 21 years of age were recruited. Informed consent was obtained from all subjects for study participation. All data collected were anonymized and no identifiable images/information were recorded from the study. The subject shown in the photographic illustration in this article (Figures 1–3) is our second author who had given his consent for the release of the photographs in an online open-access publication.

### 2.2 | Statistical analysis

The distribution of different particle sizes (differential counts for 0.3, 0.5, 1, and 5 μm particles as well as cumulative up to 5 μm) during the first 10 s of expiratory activities (referred to as baseline) are summarized using medians along with interquartile ranges separately for three types of mask interventions. These distributions were compared across four activities as well as three mask types using Kruskal–Wallis nonparametric tests, and p values are reported.

The baseline distributions of all particle sizes were also summarized using the median and interquartile range and compared across three mask interventions using the Kruskal–Wallis test. The longitudinal trends of these distributions are estimated using linear mixed effect models separately for four expiratory activities. Marginal means of the particle emission rate per second (slopes) for each type of mask intervention are reported along with 95% confidence intervals. The p values from the tests comparing these trends are reported after applying Tukey’s method of adjustment for pairwise comparison. Experiments with no mask were considered controls. All tests were at a two-sided 5% statistical significance level, and R version 4.1.1 was used for the analysis.

### 3 | RESULTS

Table 1 qualitatively suggests a higher frequency of smaller particles in the emission in all three mask interventions for all four expiratory activities (vertical comparison). When no mask was on, there was no difference in the baseline concentration of particles for the four activities (horizontal comparison). For both standard and prototype masks, we found an increasing trend in the concentration regardless of the particle size from breathing to coughing, but the difference was not statistically significant.

At baseline during the first 10 s of the experiment, we did not find any significantly different distribution of any particle size across the mask interventions for any expiratory activity (Table 2). In regard to the effectiveness of the prototype mask in reducing particle emissions, we observed a slower rate of particle emission when the prototype mask was used compared with without a mask across all four types of activities. The particle emission rate over time was significantly slower for the prototype mask for the smallest sized particle (0.3 μm) during breathing, speaking, and singing compared with no mask. We found similar trends for coughing as well as for larger particles but that did not reach statistical significance, possibly due to very high variability in measurements.

| Intervention       | Particle size in μm | Particle counts based on expiration activity |
|--------------------|---------------------|---------------------------------------------|
|                    | Breathing Speaking  | Singing Coughing |
| No mask            |                     |                              |                              |
| 0.3                | 397,714 (134,443)   | 384,153 (178,833)             | 371,016 (80,094)             | 379,491 (87,192) |
| 0.5                | 26,486 (27,228)     | 30,300 (25,533)               | 25,215 (32,313)              | 37,928 (25,109)  |
| 1.0                | 18,222 (19,766)     | 14,620 (18,964)               | 17,375 (18,328)              | 19,918 (19,070)  |
| Cumulative         | 487,766 (201,294)   | 424,412 (211,252)             | 434,794 (104,143)            | 432,675 (125,861) |
| Standard mask      |                     |                              |                              |
| 0.3                | 358,514 (132,642)   | 407,249 (94,608)              | 368,685 (109,652)            | 410,639 (90,582) |
| 0.5                | 25,215 (16,951)     | 31,995 (18,752)               | 29,452 (25,003)              | 42,166 (37,292)  |
| 1.0                | 12,713 (19,282)     | 17,587 (18,752)               | 15,892 (16,209)              | 25,427 (28,817)  |
| Cumulative         | 397,926 (191,335)   | 461,704 (91,430)              | 408,308 (136,554)            | 493,063 (97,892) |
| Prototype mask     |                     |                              |                              |
| 0.3                | 347,920 (123,001)   | 410,639 (98,846)              | 433,099 (83,696)             | 441,574 (64,096) |
| 0.5                | 15,468 (23,520)     | 29,876 (13,561)               | 34,750 (28,075)              | 31,783 (12,713)  |
| 1.0                | 7416 (15,362)       | 18,858 (16,104)               | 27,122 (28,287)              | 19,282 (12,819)  |
| Cumulative         | 391,993 (148,428)   | 462,763 (88,808)              | 478,443 (118,233)            | 491,368 (52,866) |

*p values were obtained from Kruskal-Wallis test.
| Activity | Particle size in μm | Intervention | Particle count at baseline | p Value | Average rate of change in particle emission per second (95% CI) | p Value |
|----------|---------------------|--------------|---------------------------|---------|---------------------------------------------------------------|---------|
| Breathing | 0.3                 | No mask      | 397,714 (134,443)         | .502    | 2045 (1293–2796)                                             | Ref     |
|          |                     | Standard mask| 358,514 (132,642)         | .436    | 1421 (669–2172)                                              |         |
|          |                     | Prototype mask| 347,920 (123,001)         | .001    | 273 (–478 to 1025)                                           |         |
|          | 0.5                 | No mask      | 26,486 (27,228)           | .539    | 17.86 (–108 to 143.5)                                        | Ref     |
|          |                     | Standard mask| 25,215 (16,951)           | .987    | 4.41 (–121 to 130.1)                                         |         |
|          |                     | Prototype mask| 15,468 (23,520)           | .474    | –82.89 (–209 to 42.8)                                       |         |
|          | 1.0                 | No mask      | 18,222 (19,706)           | .432    | 25.1 (–130 to 80.3)                                         | Ref     |
|          |                     | Standard mask| 12,713 (19,282)           | .980    | –38.3 (–144 to 67.0)                                         |         |
|          |                     | Prototype mask| 7416 (15,362)            | .926    | –51.1 (–156 to 54.2)                                         |         |
|          | Cumulative          | No mask      | 487,766 (201,294)         | .433    | 2038 (1158–2917)                                             | Ref     |
|          |                     | Standard mask| 397,926 (191,335)         | .536    | 1387 (507–2266)                                              |         |
|          |                     | Prototype mask| 391,993 (148,428)        | .006    | 139 (–741 to 1019)                                           |         |
| Speaking | 0.3                 | No mask      | 384,153 (178,833)         | .371    | 2516 (1643–3389)                                             | Ref     |
|          |                     | Standard mask| 407,249 (94,608)          | .389    | 1163 (290–2037)                                              | .069    |
|          |                     | Prototype mask| 410,639 (98,846)         | <.001   | –114 (–987 to 759)                                           |         |
|          | 0.5                 | No mask      | 30,300 (25,533)           | .955    | 24.5 (–305 to 353.7)                                         | Ref     |
|          |                     | Standard mask| 31,995 (18,752)           | .993    | –58.6 (–388 to 270.6)                                        |         |
|          |                     | Prototype mask| 29,876 (13,562)          | .423    | –260.6 (–590 to 68.6)                                       |         |
|          | 1.0                 | No mask      | 14,620 (18,964)           | .962    | –12.1 (–282 to 258)                                         | Ref     |
|          |                     | Standard mask| 17,587 (19,282)           | .630    | –157.8 (–428 to 112)                                        |         |
|          |                     | Prototype mask| 18,858 (16,104)          | .694    | –141.6 (–412 to 129)                                        |         |
|          | Cumulative          | No mask      | 424,412 (211,252)         | .533    | 2528 (1437–3620)                                             | Ref     |
|          |                     | Standard mask| 461,704 (91,430)          | .106    | 947 (–145 to 2039)                                           |         |
|          |                     | Prototype mask| 462,763 (88,808)         | <.001   | –516 (–1608 to 576)                                         |         |
| Singing  | 0.3                 | No mask      | 371,016 (80,094)          | .073    | 2736 (2021–3451)                                             | Ref     |
|          |                     | Standard mask| 368,685 (109,652)         | .023    | 1402 (687–2117)                                              |         |
|          |                     | Prototype mask| 433,099 (83,696)         | <.001   | 830 (115–1545)                                               |         |
|          | 0.5                 | No mask      | 25,215 (32,313)           | .555    | –191 (–456 to 73.6)                                         | Ref     |
|          |                     | Standard mask| 29,452 (25,003)           | .993    | –172 (–437 to 92.9)                                          |         |
|          |                     | Prototype mask| 34,750 (28,075)          | .999    | –191 (–456 to 73.8)                                         |         |
|          | 1.0                 | No mask      | 17,375 (18,328)           | .468    | –5.05 (–116 to 105.8)                                        | Ref     |
|          |                     | Standard mask| 15,892 (16,209)           | .989    | –15.75 (–127 to 95.1)                                        |         |
|          |                     | Prototype mask| 27,122 (28,287)          | .191    | –139.61 (–250 to –28.8)                                     |         |
|          | Cumulative          | No mask      | 434,794 (104,143)         | .095    | 2540 (1655–3424)                                             | Ref     |
|          |                     | Standard mask| 408,308 (136,554)         | .091    | 1214 (330–2099)                                              |         |
|          |                     | Prototype mask| 478,443 (118,233)        | .004    | 499 (–385 to 1384)                                           |         |
| Coughing | 0.3                 | No mask      | 379,491 (87,192)          | .263    | 1797.3 (137–3457)                                            | Ref     |
|          |                     | Standard mask| 410,639 (90,582)          | .986    | 1988 (330–3646)                                              |         |
|          |                     | Prototype mask| 441,574 (64,096)         | .307    | 60.6 (–1597 to 1719)                                         |         |
|          | 0.5                 | No mask      | 37,928 (25,109)           | .229    | –159.4 (–727 to 409)                                        | Ref     |
|          |                     | Standard mask| 42,166 (37,292)           | .936    | –19.6 (–587 to 548)                                         |         |
|          |                     | Prototype mask| 31,783 (12,713)          | .973    | –70.3 (–638 to 497)                                         |         |
|          | 1.0                 | No mask      | 19,918 (19,070)           | .272    | –103.2 (–405 to 199)                                        | Ref     |
|          |                     | Standard mask| 25,427 (28,817)           | .919    | –33.6 (–335 to 268)                                         |         |
|          |                     | Prototype mask| 19,282 (12,819)          | .962    | –55.7 (–357 to 246)                                         |         |
Table 2 (Continued)

| Activity  | Particle size in μm | Intervention | Particle count at baseline | p Value | Average rate of change in particle emission per second (95% CI) | p Value |
|-----------|---------------------|--------------|----------------------------|---------|---------------------------------------------------------------|---------|
| Cumulative| No mask             | 432,675 (125,861) | .379                       | 1389.6 (~1006 to 3785) | Ref                |
| Standard  | mask                | 493,063 (97,892)  | 1934.8 (~461 to 4331)      | .945    |
| Prototype | mask                | 491,368 (52,866)  | –65.4 (~2461 to 2330)      | .671    |

In Table 2, a positive slope indicates a rise in the average particle count over time, whereas a negative value indicates a decreasing longitudinal trend. Our experimental data showed a significant rise in the cumulative environmental aerosol count of 0.3–1 μ even during normal respiration (breathing) without any mask. This rise was reduced by the use of a surgical mask and remained at almost negligible levels (close to zero value) when the prototype mask was in use (Figure 4A–D). When compared with no mask and the standard surgical mask, under experimental conditions, the mean fold reduction in the rate of rise of cumulative particle counts resulting from prototype mask usage was estimated to be 4.89 and 1.83 for speaking, 5 and 2.43 for singing, and 21 and 29 for coughing, respectively.

Descriptive analysis revealed that the data on particles of 5 μ size and above had intermittent errors due to counter limitations in the detection of particles of 5 μ and above. In further analysis, it was found that the intersubject variability was very high, and modeling of these particle sizes did not result in cogent or useful information. Hence, our data reference particles up to 1 μ in size.

4 | DISCUSSION

COVID-19, with its high infectivity and associated morbidity and mortality, has drastically changed our lives and clinical and medical practices over the past 1–2 years. At present, COVID-19 is far from disappearing and will likely become endemic with new variants arising with time. Even before COVID-19, the past two decades have seen other deadly contagious respiratory virus outbreaks, such as SARS in 2002–2004 and swine flu in 2009. In the future, COVID-19 is unlikely to be the last respiratory transmitted infectious disease that humans will encounter.

Since the onset of the COVID-19 pandemic in 2020, there have been multiple innovations described aimed at reducing aerosols and resultant infectivity during AGPs. Ventilation hoods have been described in the literature, but they are large and bulky devices without scope access or convenient to use when sitting erect in an ENT clinic examination chair. On the other hand, simple improvisations have also been suggested, such as a hole being made in a standard surgical mask, under experimental conditions, the mean fold reduction in the rate of rise of cumulative particle counts resulting from prototype mask usage was estimated to be 4.89 and 1.83 for speaking, 5 and 2.43 for singing, and 21 and 29 for coughing, respectively.

Descriptive analysis revealed that the data on particles of 5 μ size and above had intermittent errors due to counter limitations in the detection of particles of 5 μ and above. In further analysis, it was found that the intersubject variability was very high, and modeling of these particle sizes did not result in cogent or useful information. Hence, our data reference particles up to 1 μ in size.

Table 2 (Continued)

| Activity | Particle size in μm | Intervention | Particle count at baseline | p Value | Average rate of change in particle emission per second (95% CI) | p Value |
|----------|---------------------|--------------|----------------------------|---------|---------------------------------------------------------------|---------|
| Cumulative | No mask         | 432,675 (125,861) | .379                       | 1389.6 (~1006 to 3785) | Ref                |
| Standard | mask              | 493,063 (97,892)  | 1934.8 (~461 to 4331)      | .945    |
| Prototype | mask             | 491,368 (52,866)  | –65.4 (~2461 to 2330)      | .671    |

In Table 2, a positive slope indicates a rise in the average particle count over time, whereas a negative value indicates a decreasing longitudinal trend. Our experimental data showed a significant rise in the cumulative environmental aerosol count of 0.3–1 μ even during normal respiration (breathing) without any mask. This rise was reduced by the use of a surgical mask and remained at almost negligible levels (close to zero value) when the prototype mask was in use (Figure 4A–D). When compared with no mask and the standard surgical mask, under experimental conditions, the mean fold reduction in the rate of rise of cumulative particle counts resulting from prototype mask usage was estimated to be 4.89 and 1.83 for speaking, 5 and 2.43 for singing, and 21 and 29 for coughing, respectively.

Descriptive analysis revealed that the data on particles of 5 μ size and above had intermittent errors due to counter limitations in the detection of particles of 5 μ and above. In further analysis, it was found that the intersubject variability was very high, and modeling of these particle sizes did not result in cogent or useful information. Hence, our data reference particles up to 1 μ in size.

4 | DISCUSSION

COVID-19, with its high infectivity and associated morbidity and mortality, has drastically changed our lives and clinical and medical practices over the past 1–2 years. At present, COVID-19 is far from disappearing and will likely become endemic with new variants arising with time. Even before COVID-19, the past two decades have seen other deadly contagious respiratory virus outbreaks, such as SARS in 2002–2004 and swine flu in 2009. In the future, COVID-19 is unlikely to be the last respiratory transmitted infectious disease that humans will encounter.

Since the onset of the COVID-19 pandemic in 2020, there have been multiple innovations described aimed at reducing aerosols and resultant infectivity during AGPs. Ventilation hoods have been described in the literature, but they are large and bulky devices without scope access or convenient to use when sitting erect in an ENT clinic examination chair. On the other hand, simple improvisations have also been suggested, such as a hole being made in a standard surgical mask, under experimental conditions, the mean fold reduction in the rate of rise of cumulative particle counts resulting from prototype mask usage was estimated to be 4.89 and 1.83 for speaking, 5 and 2.43 for singing, and 21 and 29 for coughing, respectively.

Descriptive analysis revealed that the data on particles of 5 μ size and above had intermittent errors due to counter limitations in the detection of particles of 5 μ and above. In further analysis, it was found that the intersubject variability was very high, and modeling of these particle sizes did not result in cogent or useful information. Hence, our data reference particles up to 1 μ in size.

4 | DISCUSSION

COVID-19, with its high infectivity and associated morbidity and mortality, has drastically changed our lives and clinical and medical practices over the past 1–2 years. At present, COVID-19 is far from disappearing and will likely become endemic with new variants arising with time. Even before COVID-19, the past two decades have seen other deadly contagious respiratory virus outbreaks, such as SARS in 2002–2004 and swine flu in 2009. In the future, COVID-19 is unlikely to be the last respiratory transmitted infectious disease that humans will encounter.

Since the onset of the COVID-19 pandemic in 2020, there have been multiple innovations described aimed at reducing aerosols and resultant infectivity during AGPs. Ventilation hoods have been described in the literature, but they are large and bulky devices without scope access or convenient to use when sitting erect in an ENT clinic examination chair. On the other hand, simple improvisations have also been suggested, such as a hole being made in a standard surgical mask, using cut-out gloves to line the opening. As surgical masks are opaque, there is no good visualization for instrumentation behind the mask. Surgical masks also do not protect against leakage of aerosols or droplets from the corners of the mask, and more so if the mask fits poorly. Ference et al. had described a 3D printed N95 respirator fitted opaque scope mask made from a tough polylactic acid, which is connected to normal suction device. This mask is also not entirely sterilizable. In contrast, our scope mask is made of soft transparent silicon which is biocompatible and comfortable on skin, and allows for good visualization of the facial anatomy. The entire scope mask and straps are fully sterilizable, and reusable to reduce environmental waste. In addition, the suction of our device is connected to a dual function HEPA that allows the air to be safely filtered before release to the environment. A major advantage of our system is the dual function HEPA of our system also allows for filtration of the ambient room air during scope procedures or at other times when scope procedures are not being performed.

Our initial experimental results demonstrate that environmental contamination from aerosols occurs during various AG activities and even during quiet breathing at rest. The data also show that our prototype mask yields superior results for reducing aerosol emissions into the environment when compared with a three-layered medical-grade surgical mask. This finding is supported by previous studies by Leung et al. and Milton et al. which showed that while standard medical-grade 3 ply surgical masks are effective in reducing droplet emission, they are not as effective for aerosols. With regard to aerosol size, our prototype demonstrated the greatest effectiveness against smaller aerosols of 0.3 μ. This is of clinical significance and important in viral infectivity, as smaller aerosols are known to remain airborne, spread more easily throughout a room and can be more easily inhaled.

From the aspect of innovation, our protective scope mask/hood system is the first of its kind in the market to be connected to a portable filtration system with at least a level 13 HEPA filtration. The product ensures that environmental contamination is reduced in a synergistic manner. First, the physical barrier of the mask, coupled with constant suction/airflow, creates a localized negative pressure environment within the mask via its connection to a medical-grade air filtration system. Second, the medical-grade air filtration system on its own independently ensures more than 12 air exchanges in a standard consultation room of up to 80 m³, and this filtration of the room continues even when the scope system is not in use. This prototype therefore provides comprehensive adherence to all the standard precautions and recommendations set out in Centers for Disease Control and Prevention with regard to source control, as well as optimization of engineering and environmental controls. The dual function of the system makes it unnecessary to procure a separate HEPA filtration system, thus reducing cost and saving space. The system is inherently portable and can easily be relocated to different wards or consultation rooms wherever an AGP, such as a nasoendoscopy or flexible laryngoscopy, needs to be performed.
Last, the mask can be reused for environmental friendliness and sterilization achieved by thermal disinfection or autoclaving.

Our scope mask and filtration system allow for commonly performed aerosol-generating ENT scope procedures to be safely conducted in the usual default clinic setting, without the need for expensive negative pressure rooms or frequent downtime for terminal cleaning of rooms. We are already evaluating clinic end-user acceptability and feedback on this device. In addition to aerosols, the efficacy of this prototype system for reducing droplet contamination has also been studied, and we are at the stage of data processing and analysis. The results of the product’s efficacy in reducing droplet contamination and clinical end user acceptability will be presented in future reports. Further development of the mask will follow, and likely be for incorporating oral access aerosol generating procedures, such as rigid stroboscopy, oral biopsies, speech therapy, oesophagogastroscopy, and so forth.

In any ongoing pandemic, the safety and morale of health care workers is of utmost importance, and the bedrock of this is to ensure a safe environment for health care workers to practice in. Even better if a safe environment can be achieved in a cost-effective, logistically simple and practical manner.

4.1 Study limitations

The limitations of this study include its small sample size, possible interference from ambient aerosol levels, duration of sampling, and single sampling position (presently only at the expected distance between health care workers and sources). The four aerosol generating activities were performed by study subjects without the scope being in situ, although these four activities represent how aerosols are generated during scope procedures. Our study does not look at or try to detect or quantify the virus load in aerosols or its attendant transmissibility.

5 | CONCLUSION

Our simple-to-use, dual-function portable protective scope mask and filtration system will allow nasal scope procedures as well as flexible laryngoscopy to be performed safely and efficiently in the current COVID pandemic setting. The increased safety was supported by our systematic quantification of aerosols emitted into the environment during “scope-provoked” aerosol generating activities, which was greatly reduced by the prototype mask. Use of this protective mask and filtration system in clinical practice might help reduce disease spread during the current COVID-19 pandemic or other future unknown respiratory disease epidemics through both source control of contamination and reduction of environmental contamination. This provides a safer environment for both health care workers and patients. Its portable nature, dual function as a portable HEPA filtration unit, and autoclavable option for the filtration mask are designed to provide greater cost effectiveness, environmental friendliness, logistics efficiency, and space savings in restricted clinical environments.

AUTHOR CONTRIBUTIONS

Hui Sing Chew- Principal Investigator/Inventor of prototype. Study conceptualisation, design, and conduct. Prototype development and
evaluation. Data analysis, manuscript drafting/writing. Marcus Tan- Co-Inventor. Prototype design and development. Study design and conduct. Data analysis, manuscript review/editing. Acharyya Sanchalika- Data analysis and manuscript writing (statistics). Gabriel Tan- Prototype design and development. Study design and troubleshoot. Eu Chin Ho- Prototype evaluation, logistics support, manuscript review/editing. Brenda Sze Peng Ang- Prototype evaluation, logistics support, manuscript review/editing. Rupesh Agrawal- Prototype evaluation and manuscript review/editing. Seng Beng Yeo- Prototype evaluation, data analysis and manuscript review/editing.

ACKNOWLEDGMENTS
The prototype development and evaluation were funded by the Ng Teng Fong Healthcare Innovation Grant No: NTF_SEP-T2020_1_C1_D_03. We would like to acknowledge our research assistant Ms Quek Lixian, clinic manager Nursing Officer Alynn Lim, and Dr Wei Xin for their kind assistance with the logistics and administrative matters throughout the study.

CONFLICT OF INTEREST
The first author Dr Hui Sing Chew from Tan Tock Seng Hospital and Coauthor Dr Marcus Tan from The Biofactory Pte Ltd. are inventors for the pending patent. The other coauthors (Mr Gabriel Tan, Dr Eu Chin Ho, Prof Brenda Sze Peng Ang, and Prof Rupesh Agrawal) are listed as contributors to the pending patent.

ORCID
Hui Sing Chew https://orcid.org/0000-0002-2443-3359

REFERENCES
1. Ong SWX, Tan YK, Chia PY, et al. Air, surface environmental, and personal protective equipment contamination by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from a symptomatic patient. JAMA. 2020;323(16):1610-1612. doi:10.1001/jama.2020.3227
2. Chan JFW, Yuan S, Kok KH, et al. A familial cluster of pneumonia associated with the 2019 novel coronavirus indicating person-to-person transmission: a study of a family cluster. Lancet. 2020; 395(10223):514-523. doi:10.1016/S0140-6736(20)30154-9
3. Liu J, Liao X, Qian S, et al. Community transmission of severe acute respiratory syndrome coronavirus 2, Shenzhen, China, 2020. Emerg Infect Dis. 2020;26(6):1320-1323. doi:10.3201/EID2606.200239
4. van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. N Engl J Med. 2020;382(16):1564-1567. doi:10.1056/NEJMC2004973
5. Leung NHL, Chu DKW, Shiui EYC, et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. Nat Med. 2020;26(5):676-680. doi:10.1038/s41591-020-0843-2
6. Milton DK, Fabian MP, Cowling BJ, Grantham ML, McDevitt JJ. Influenza virus aerosols in human exhaled breath: particle size, culturability, and effect of surgical masks. PLoS Pathog. 2013;9(3):e1003205. doi:10.1371/JOURNAL.PPAT.1003205
7. Zhou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. N Engl J Med. 2020;382(12):1177-1179. doi:10.1056/NEJMC2001737
8. Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations. Modes of transmission of the COVID-19 virus. 2020. doi:10.3201/eid2606.200239
9. McGain F, Humphries RS, Mora JC, Timms P, Hill F, French C. Aerosol generation during surgical tracheostomy in a patient with COVID-19. Crit Care Resusc. 2020;22(4):391-393. doi:10.1016/j.ccrres.2020.04.022
10. Cubillos J, Querrey J, Rankin A, Moore J, Armstrong K. A multipurpose portable negative air flow isolation chamber for aerosol-generating procedures during the COVID-19 pandemic. Br J Anaesth. 2020;125(1):e179-e181. doi:10.1093/bja/ebz617
11. Workman AD, Wellin DB, Carter BS, et al. Endonasal instrumentation and aerosolization risk in the era of COVID-19: simulation, literature review, and proposed mitigation strategies. Int Forum Allergy Rhinol. 2020;10(7):798-805. doi:10.1002/ALR.22577
12. Ferece EH, Kim W, Oghalai JS, et al. COVID-19 in the clinic: human testing of an aerosol containment mask for endoscopic clinic procedures. Otolaryngology, 2022;166(4):669-675. doi:10.1177/01945998211029184
13. Noti JD, Lindsley WG, Blachere FM, et al. Detection of infectious influenza virus in cough aerosols generated in a simulated patient examination room. Clin Infect Dis. 2012;54(11):1569-1577. doi:10.1093/CID/CIS237
14. Lindsley WG, King WP, Thewlis RE, et al. Dispersion and exposure to a cough-generated aerosol in a simulated medical examination room. J Occup Environ Hyg. 2012;9(12):681-690. doi:10.1080/15459624.2012.725986
15. Infection Control: Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) | CDC. Accessed December 13, 2021. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

SUPPORTING INFORMATION
Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Chew HS, Tan M, Sanchalika A, et al. Innovative dual-function protective scope mask and filtration system for aerosol generating ENT scope procedures. Laryngoscope Investigative Otolaryngology. 2022;7(5):1376-1383. doi:10.1002/lio2.913