Titre: Title:	Effectiveness of SplashGuard Caregiver prototype in reducing the risk of aerosol transmission in intensive care unit rooms of SARS-CoV-2 patients: a prospective and simulation study
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Date:	2024
Type:	Article de revue / Article
Référence: Citation:	Buratti, C. R., Veillette, M., Bridier, A., Aubin, C.-É., Lebrun, M., Ammaiyappan, A. K., Vanoli, E., Crawford, C., Duchaine, C., & Jouvet, P. (2024). Effectiveness of SplashGuard Caregiver prototype in reducing the risk of aerosol transmission in intensive care unit rooms of SARS-CoV-2 patients: a prospective and simulation study. Journal of Hospital Infection, 144, 75-84. https://doi.org/10.1016/j.jhin.2023.11.007

Titre de la revue: Journal Title:	Journal of Hospital Infection (vol. 144)
Maison d'édition: Publisher:	Elsevier
URL officiel: Official URL:	https://doi.org/10.1016/j.jhin.2023.11.007
Mention légale: Legal notice:	

Journal of Hospital Infection 144 (2024) 75—84

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

Effectiveness of SplashGuard Caregiver prototype in reducing the risk of aerosol transmission in intensive care unit rooms of SARS-CoV-2 patients: a prospective and simulation study

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ARTICLE INFO

Article history:
Received 6 September 2023
Accepted 20 November 2023
Available online 29 November 2023

Keywords:
Airborne virus transmission
COVID-19
Intensive care unit
3D simulation

SUMMARY

Background: The contagiousness of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) is known to be linked to the emission of bioaerosols. Thus, aerosol-generating procedures (AGPs) could increase the risk of infection among healthcare workers (HCWs).

Aim: To investigate the impact of an aerosol protection box, the SplashGuard Caregiver (SGGC) with suction system, by direct analysis of the presence of viral particles after an AGP, and by using the computational fluid dynamics (CFD) simulation method.

Methods: This prospective observational study investigated HCWs caring for patients with SARS-CoV-2 admitted to an intensive care unit (ICU). Rooms were categorized as: SGCG present and SGCG absent. Virus detection was performed through direct analysis, and using a CFD model to simulate the movement dynamics of airborne particles produced by a patient's respiratory activities.

Findings: Of the 67 analyses performed, three samples tested positive on quantitative polymerase chain reaction: one of 33 analyses in the SCCG group (3%) and two of 34 analyses in the non-SGCG group (5.9%). CFD simulations showed that: (1) reduction of the gaps of an SGCG could decrease the number of emitted particles remaining airborne within

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https://doi.org/10.1016/j.jhin.2023.11.007

the room by up to 70%; and (2) positioning HCWs facing the opposite direction to the main air flow would reduce their exposure.

Conclusions: This study documented the presence of SARS-CoV-2 among HCWs in a negative pressure ICU room of an infected patient with or without the use of an SGCG. The simulation will help to improve the design of the SGCG and the positioning of HCWs in the room.

Introduction

The coronavirus disease 2019 (COVID-19) pandemic, caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has affected more than 760 million people worldwide, with 6.9 million deaths as of 1st June 2023 [1]. The contagiousness of SARS-CoV-2 is associated with the emission of viral aerosols by infectious patients, and by the fact that they can remain viable and infectious for hours and even days on surfaces [2,3]. The risk of healthcare workers (HCWs) developing infectious diseases because of contact with patients is well recognized [4], and increased during the COVID-19 pandemic [4—6].

Aerosol-generating procedures (AGPs) may increase the exposure of HCWs to airborne infectious agents [7,8], although there is a lack of evidence on the subject [9]. AGPs, along with normal respiratory activities such as breathing and coughing, lead to the shedding of airborne particles into the environment, and these can be virus-laden when emitted by an infectious patient [10]. The diameter of airborne particles ranges between 100 nm and 1 mm (droplets) before evaporating and forming a droplet nuclei or aerosol [11,12]. It is considered that particles with diameter <10 μm can remain airborne and initiate infection at both short and long distances, and can propagate further than 1 m from the source, remaining infectious in the air for up to 3 h [2,10]. High-risk AGPs are considered to be those that involve the manipulation of high viral load tissues, such as endotracheal intubation or extubation, airway suctioning, gastric tube insertion and non-invasive ventilation [13—15]. However, a recent study showed that upper airway suctioning was not associated with a higher aerosol concentration, and this was actually lower compared with breathing and coughing [16].

As a result, clinicians have developed protective devices, such as the SplashGuard Caregiver (SGCG), with the aim of minimizing the exposure of HCWs to aerosols during AGPs, thus providing more freedom to perform these AGPs. The SGCG was proposed as a redesigned 'aerosol box', originally invented by a Taiwanese anaesthesiologist (Figure 1) [17—19]. It consists of a large Plexiglas box installed above the patient's head and torso that contains six doors for simultaneous access by HCWs [18,19]. These openings have optional press-fit plugs and a high-efficiency particulate air (HEPA) filter, allowing them to be connected to continuous suction to create a negative environment, which provides an extra shield to minimize the spread of viral particles. Some reports described that the SGCG can reduce the exposure of HCWs to virus during endotracheal intubation in the operating theatre, and suctioning in the emergency room [15,20,21].

The aim of this study was to investigate the impact of the SGCG prototype on the presence of viral particles on HCWs' foreheads, and in the air near HCWs responsible for treating patients hospitalized with COVID-19 in an intensive care unit (ICU). Furthermore, it was proposed that the movement of aerosols produced by a patient in an ICU room should be modelled using three-dimensional (3D) computational fluid dynamics (CFD) [20] to simulate air flow as well as the movement of numerous airborne particles produced by a patient's respiratory activity (conventional breathing and coughing), with and without the use of the SGCG. From this, the impact of each scenario on the local concentration of potentially virus-laden airborne particles can be better understood, as it is essential to find ways to mitigate risks for frontline workers.

Methods

A prospective single-centre cohort study was undertaken from April to June 2021. The study included patients admitted to an ICU, who tested positive for COVID-19, and HCWs. The primary outcome was evidence of a decrease in the proportion of active SARS-CoV-2 viral particles in samples collected from HCWs' foreheads and in the patient's environment among those who used the SGCG during AGPs. Regardless of whether or not an SGCG was used, all HCWs wore the personal protective equipment (PPE) recommended by the World Health Organization and the Centers for Disease Control and Prevention during an AGP, which included N95 respirator, gown, gloves, eye protection (goggles or face shield) and apron. AGPs include endotracheal intubation/extubation, oropharyngeal or endotracheal aspiration, gastric tube placement, use of nasal cannula in spontaneous breathing, ventilatory assistance with high-flow nasal cannula, and other non-invasive ventilation [13]. The study was approved by the Ethics Committee of Centre Hospitalier Universitaire Sainte-Justine (No. MP-21-2020-2870), and all patients provided written informed consent prior to inclusion in the study.

In a second step, a 3D CFD model [22] was made of an ICU room containing a virtual patient with and without an SGCG during normal breathing or coughing. This considered all morphological characteristics of the ICU room in terms of ventilation (negative pressure, temperature, inlet/outlet positions and mass flow rates) and architecture (exact room dimensions and geometry, door position, patient position and additional unit particularities). The 3D CFD model is able to evaluate the local concentration of particles present in the environment over time, considering their size (droplets and aerosols), initial position and spreading velocity (normal breathing or coughing), and environmental factors such as the air flow induced by the room's ventilation system. A commercial Lattice Boltzmann-based method code, PowerFLOW [23], was used to run the numerical simulations and generate numerical results. The

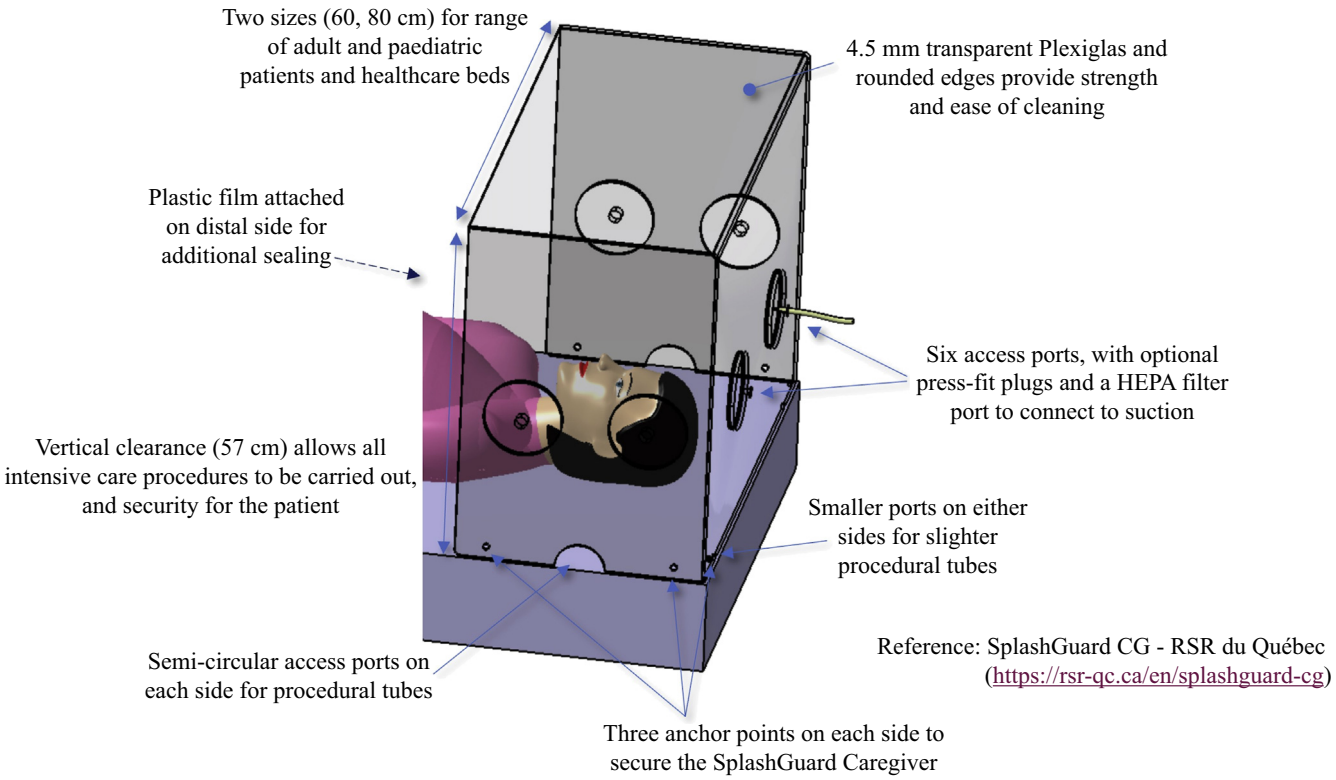

Figure 1. SplashGuard Caregiver prototype. Source: adapted from Jouvet and Aubin [19]. HEPA, high-efficiency particulate air.

underlying principles of this technique have been described in detail by Crawford *et al.* [22].

Protective measure against aerosols of viral particles (Figure 1)

The SGCG is an acrylic box, placed over the patient's head and upper torso. It contains six different access doors (two at the front and two on each side) which allows several HCWs to perform procedures related to the upper airways simultaneously, while limiting the amount and distance of infected particles projected into the environment. In addition, two smaller semicircular openings on the side allow the introduction of the breathing circuit and suction equipment, as well as the oxygen tubing for bag-valve-mask ventilation or the non-rebreather mask. To provide extra protection against aerosolization, in the absence of procedures, shutters occlude the orifices, and a plastic film covers the rest of the patient's torso/pelvis for additional sealing. The shutters have optional press-fit plugs with a HEPA filter that can be connected to a negative pressure suction system, leading the air from inside the SGCG to the usual medical gas exhaust duct. Finally, the SGCG has six anchor points on the base, which provides more stability. The user manual detailing the use of the SGCG (Class 1 reusable medical device) can be consulted using the following link: https://rsr-qc.ca/Splashguard-cg/.

Virus detection

Environmental sampling for SARS-CoV-2 was performed using personal pumps and sampling cassettes: (1) in the ambient air before the AGP; (2) in the air of patients inside the SGGC; (3) in the air 1 m from the patient after the AGP; and (4) through a swab on the forehead of each HCW after an AGP. The techniques performed for viral detection are detailed below.

Air samples

Stationary and personal air samples were collected using Institute of Occupational Medicine (IOM) air samplers loaded with 25-mm gelatin filters (SKC, Eighty Four, PA, USA). For stationary samples, a flow rate of 10 L/min was achieved using a calibrated regulator connected to suction present in the room [24]. Personal samples were collected at a flow rate of 3 L/min using a GilAir Plus Personal Air Sampling Pump (Sensidyne, Saint Petersburg, FL, USA). After collection, gelatin filters were dismounted from the IOM devices, solubilized in 2 mL of Gibco's viral transport medium (VTM; ThermoFisher, Winnipeg, Canada), and stored at -80 °C until analysis.

Swab samples

The forehead of each HCW was swabbed using a HydraFlock 6″ sterile flock swab (Puritan, Guilford, ME, USA) at the end of treatment. Swab samples were eluted in 1 mL of VTM and stored at -80 °C until analysis.

RNA extraction of samples

RNA was purified using 400 µL of each sample using a MagMAX™Viral RNA Isolation Kit (Applied Biosystems, Vilnius, Lithuania). Purified RNA was eluted in 50 µL of elution buffer and stored at −80 °C until quantification. A no template control was performed for each lot of samples threated.

Quantitative PCR

Briefly, each sample was amplified in triplicate, targeting ORF1b of the SARS-CoV-2 genome. Viral genome quantities

were estimated by averaging the results of all replicates based on a ORF1b plasmid standard curve with a lower limit of detection of 1 plasmid per quantitative polymerase chain reaction (qPCR), corresponding to a cycle threshold value of 38. The protocol has been described in detail elsewhere [24,25].

3D computational fluid dynamics model [22]

The simulations were based on the digital twin of the same patient room in which the samples were taken, as described above. It includes the room furniture and devices in place, including the bed, as well as the position of the HCW. The ventilation details were also reproduced based on the technical specifications (Figure 2A), with an air mass flow outlet at the centre of the room, above the bed, which extracts 1410 m^3/h from the room. A secondary outlet is located in the bathroom and extracts 168 m^3/h. These airflow rates were measured directly at each ventilation vent by the facilities department using an anemometer. In addition, an inlet is located above the main door and allows 935 m^3/h of air inside the room. Finally, a 20-mm gap was modelled between both room doors and the floor in order to allow air to enter the room from the corridor, and balance the mass flows injected and extracted from the room. Overall, this corresponded to 11 air changes per hour within this ICU room. The baseline scenario corresponded to the patient lying on the bed without an SGCG (Figure 2B). Two modified scenarios were also modelled, corresponding to the same patient with an SGCG: one with a gap between the plastic film and the Plexiglas box of 140 mm at the base (Figure 2C); and one with a 20-mm gap (Figure 2D). The SGCG was modelled in the configuration where the negative pressure suction system is active. The patient was modelled in detail, considering skin temperature as well as a detailed geometry of the upper respiratory airways of an adult. In all three cases, the distribution of particles dispersed in the environment by the air flow was analysed after being shed by the patient's normal breathing respiratory activities. The breathing rate was set at 12 L/min and the emission rate was chosen in order to have a concentration of emitted particles of 100 particles/L [26]. The size distribution used in the model for these emitted airborne particles, which are considered to be reduced to droplet nuclei, is a normal distribution centred around 3.2 μm [27]. It was considered that each of these particles can contain one or more virions and is potentially infectious when inhaled in sufficiently large quantities. It

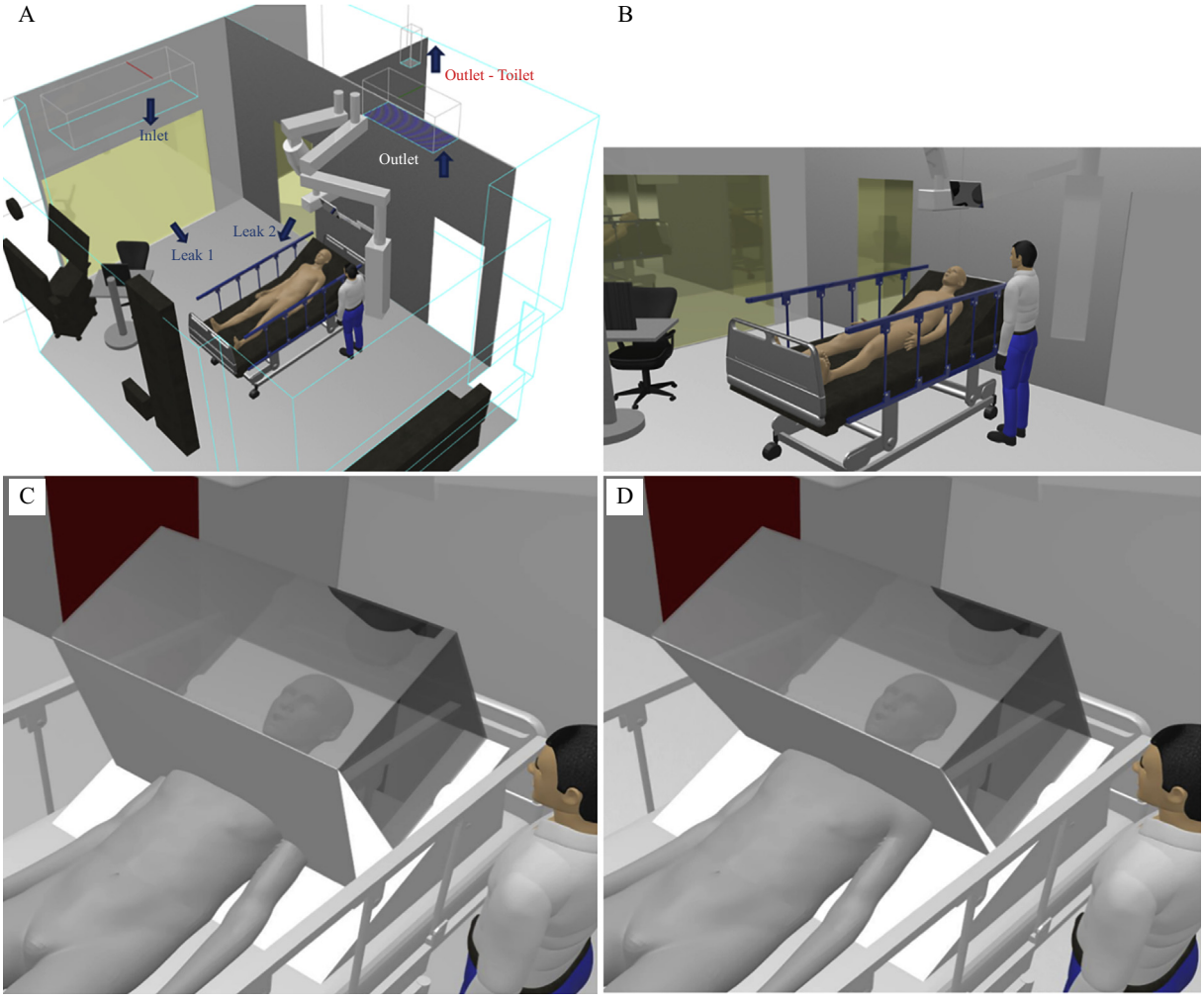

Figure 2. Intensive care room simulation. (A) Room model. (B) Individual without SplashGuard Caregiver (SGCG). (C) First configuration of individual with SGCG (140-mm gap). (D) Second configuration of individual with SGCG (20-mm gap).

Table I
Characteristics of the sample and comparison in prevalence of quantitative polymerase chain reaction (qPCR) samples between SplashGuard Caregiver (SGCG) and non-SGCG groups

	SGCG absent (*N*=9)	SGCG present (*N*=5)	*P*-value
Age (years)	2 (1 month–40 years)	33 (21–40)	0.01[a]
Weight (kg)	11 (3.5–70)	101 (80–107)	0.001[a]
Procedure (*N*)			NA
	Transfer (*N*=1) HFNC (*N*=2) Trach (*N*=2) EITc (*N*=1) HFOV (*N*=3)	NIV (*N*=3) HFNC (*N*=2)	
Before AGP			
Time exposure (min)	250 (203–290)	250 (180–320)	0.83[a]
qPCR in room air (N)	Negative (*N*=9)	Negative (*N*=5)	NA
After AGP			
Time exposure (min)		240 (180–320)	NA
qPCR in SGCG air (N)		Negative (*N*=4) NA (*N*=1)	NA
Time exposure (min)	35 (21–135)	60 (20–78)	0.52[a]
qPCR in HCW air (N)	Negative (*N*=12) Positive (*N*=1)	Negative (*N*=11) Positive (*N*=1)	1.00[b]
Time exposure (min)	2 (1–2)	2 (2–2)	0.69[a]
qPCR in HCW forehead (N)	Negative (*N*=12) Positive (*N*=1)	Negative (*N*=12) Positive (*N*=0)	1.00[b]

Time exposure, exposure time of the pump or swab of the respective qPCR collection; Transfer, transferring the patient to the ward; HFNC, care of patient with high flow nasal cannula; Trach, care of a patient with tracheostomy tube; EITc, endotracheal intubation care; HFOV, care of patient with high-frequency oscillatory ventilation; NIV, care of patient with non-invasive ventilation; AGP, aerosol-generating procedures; NA, not assessed; HCW, healthcare worker.
$P \leq 0.050$ was considered to indicate significance: (a) Mann-Whitney *U*-test; (b) Fisher's Chi-squared test.
Data are presented as median (minimum and maximum), and number of subjects is presented as absolute value (*N*).

should also be noted that the use of different oxygen support devices or the practice of a specific type of AGP were not considered in the simulation, and that only a standardized adult patient was modelled (no child patient was modelled).

Statistical analysis

Qualitative data are expressed as absolute frequencies (*n*) and percentages. Continuous quantitative variables are expressed as medians (minimum and maximum) considering non-parametric distribution, and analysis was performed using the Mann–Whitney *U*-test. The qPCR results of patients that used an SGCG and their HCWs were compared with samples taken from rooms of patients without an SGCG using Fisher's Chi-squared test. Statistical analyses were performed using SPSS Version 21.0 (IBM Corp., Armonk, NY, USA).

Results

Phase 1 (qPCR analysis)

Fourteen batches of samples were included, and 67 analyses were performed in the room with SARS-CoV-2-positive patients. Median age was 11 years (range 1 month–40 years) and median weight was 54 kg (range 3.5–107 kg). Only three samples were identified as qPCR positive: one in the SCCG group (one of 33 analyses: 3%) and two in the non-SGCG group (two of 34 analyses: 5.9%). The exposure time of the qPCR collection devices (pump or swab) did not differ significantly between the groups. On Chi-squared analysis, no difference was found between the groups. In addition, none of the HCWs were infected. Although feedback was not collected from patients and HCWs about their tolerance to the SGCS, there were no records of the need for early removal of the device when it was prescribed. Table I shows the details for individuals in the SGCG and non-SGCG groups, including age, weight, AGP performed, time of exposure and all qPCR analyses for SARS-CoV-2.

Phase 2 (simulation analysis)

An aerodynamic analysis was conducted using CFD. Airflow leakages were observed through the thin gap below the two room doors, due to the room being under negative pressure (Figure 3A). Due to this gap and the position of the extraction vent of the heating, ventilation and air conditioning (HVAC) system above the patient, air flows enter the room under the two perpendicular room doors, colliding at high velocities (>1 m/s) before merging and propagating towards the ceiling on the opposite side of the room.

The SGCG and the patient are in the path of the turbulent flow which forms between the room doors and the HVAC outlet, and deflects towards the ceiling (Figure 3B). It is important to note that this air flow is able to enter the SGCG through the opening created by the plastic film, creating strong recirculation inside, and can exit through the opposite opening, near the

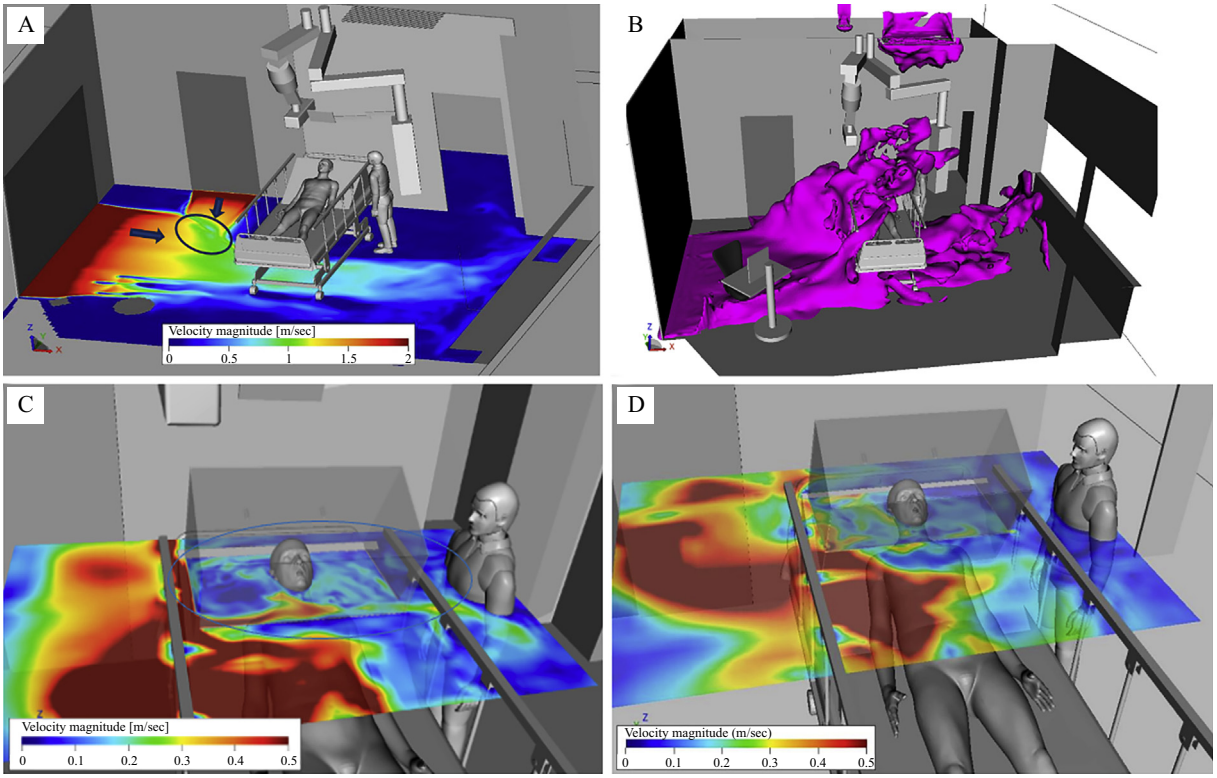

Figure 3. Simulation analysis. (A) Airflow leakage through the gap between the doors and the floor (two-dimensional map — velocity magnitude). (B) Airflow leakage inside the room and around the SplashGuard Caregiver (SCGC) [three-dimensional (3D) envelope — velocity magnitude >0.4 m/s]. (C) 3D visualization of the air flow entering the SGCG through the opening created by the plastic film (140-mm-gap scenario). (D) Air flow does not enter the SGCG through the reduced opening created by the plastic film (20-mm-gap scenario).

HCW (Figure 3C,D). The air renewal induced by the suction at the back of the device is not as efficient as that induced by the air flow passing through the opening created by the plastic film, regardless of the size of the gap (Figure 3C,D).

After performing the aerodynamic simulation and analysis, the particles emitted during the breathing and coughing cycle were introduced in the simulation and followed. In the first scenario (no SGCG), the potentially infectious exhaled particles follow the air flow described in Figure 3C, and disperse throughout the room because of the mixing ventilation (Figure 4A). Over time, these particles are either extracted by the ventilation outlet, deposit on surfaces (walls, tables, ceiling, medical equipment) or remain airborne. In the second scenario (SCGC with a large gap), the emitted particles are trapped and accumulate within the protective device. However, due to the air flow going through the SGCG, as depicted in Figure 4B, these particles end up exiting through the opening on the right side of the SGCG, near the HCW. Furthermore, as the presence of the SGCG reduces the velocity of the air flow that reaches the other side (<0.4 m/s), the particles entrained stay near the HCW for a longer period (Figure 4B). Finally, in the third scenario (SGCG with a small gap), the particles tend to remain within the protective box and only a few escape through the gap. A quantitative analysis is presented in Figure 5, which represents the cumulative number of particles that go through the orange box modelled virtually around the HCW (Figure 4D), located on the left side of the patient. As shown in Figure 1, the number of particles passing within breathing distance of the HCW was reduced by 17% when an SGCG (with a gap between the plastic film and the Plexiglas box of 140 mm) was added compared with the baseline scenario, and reduced by 93% when the gap was reduced to 20 mm. Thus, placing a HCW behind the patient or to the right would lower their exposure to higher particle concentrations.

A more detailed analysis was performed in order to better understand the local dynamics of particle concentrations within the room depending on the scenario, as showcased in Figure 6. In the baseline configuration, after 100 s of physical time, all the emitted particles in the room either remained airborne (36%), were extracted efficiently by the ventilation system (63%) or deposited on surfaces (1%). This shows that the room had good natural ventilation. In the second configuration (SGCG with 140-mm gap), over half of the particles shed by the patient escaped the SGCG and were in the room (58%), which confirms the previous observations that the air flow within the room tends to enter the SGCG through the gap and exit on the other side. Overall, the number of particles remaining airborne in the room (32%) was comparable to baseline, whilst a lower amount was extracted (23% through ventilation and 7% through the SGCG). A large proportion of particles remained airborne within the SGCG (35%). Finally, the third configuration (SGCG with 20-mm gap) showcases an improved situation as only 10% of the emitted particles remained airborne in the room after 100 s. Seventy-two percent of particles remained airborne within the SGCG, and only 14% were extracted by its ventilation mechanism. It is important to note that the accumulation of aerosols within the SGCG can become an issue when it is removed after the AGP, as they will be released in the room's

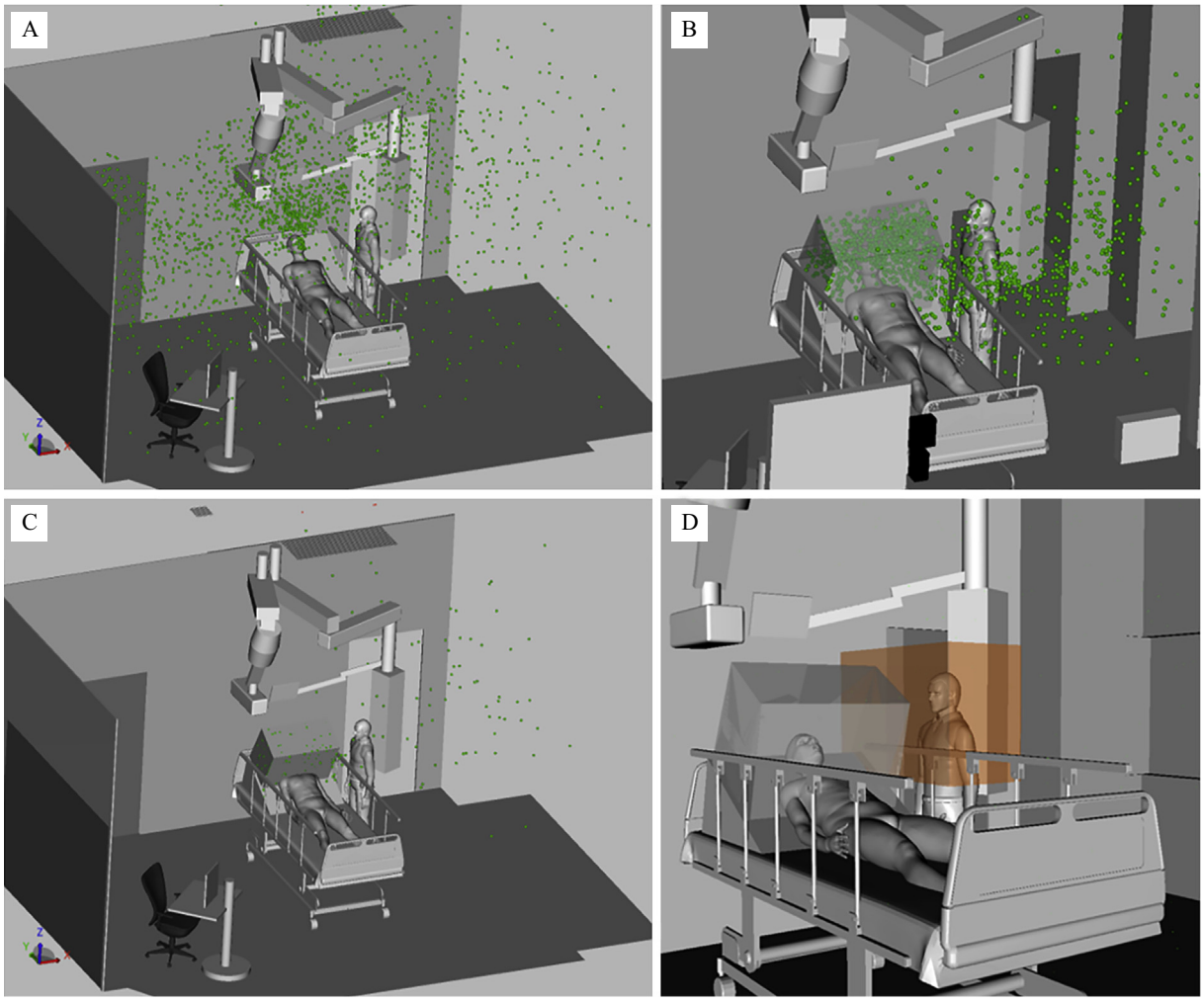

Figure 4. Three-dimensional visualization of the numerically modelled airborne particles emitted by a patient and dispersed throughout the room. (A) In the baseline configuration at t = 25 s. (B) In the first SplashGuard Caregiver (SGCG) configuration (140-mm gap) at t = 25 s. (C) In the second SGCG configuration (20-mm gap) at t = 25 s. (D) Virtual representation of the breathing zone (orange box) around the healthcare worker.

environment. When analysing the air flow within the SGCG, it can be hypothesized that increasing the air suction rate of its negative pressure suction system could lead to improved extraction of airborne particles within the SGCG and a lower concentration in the room.

Discussion

Despite the use of PPE and the SGCG, HCWs are susceptible to contamination by viruses, given their continuous presence in the environment, as demonstrated by the viral detection analysis developed, and regardless of the use or not of the SGCG. From this, the aerosolization simulation of the airborne particles aimed to delineate the spread of the virus in the room and identify measures that could be effective in reducing the risk of contamination. This showed that: (1) reducing the gap between the plastic film and the Plexiglas box may decrease the number of particles remaining in the room air significantly (70% less after 100 s); and (2) depending on the room architecture and ventilation design, the position of the HCW could be important in reducing exposure to airborne pathogens.

Despite the adaptations developed in the SGCG, the presence of particles in the environment was observed by viral analysis and by simulation with a common SGCG configuration (gap of 140 mm). From the 3D simulation, it was observed that in the presence of an SGCG with a 140-mm gap, over half (58%) of the particles shed by the patient escape the SGCG and go into the room. In comparison, with a gap of 20 mm, only 10% of particles go into the room air and 72% remain airborne inside the SGCG, showing that reducing the gap seems to be important to improve the protective efficiency of the SGCG. It should also be emphasized that there is a high concentration of particles inside the SGCG, so their removal/movement from the room must be done carefully to avoid spreading them in room air.

CFD simulation has been widely employed as a fast, reliable and cost-effective technique to support decision making and predict mitigation protocols. Its combination with clinical data has optimal applicability, and this was proposed in this study. Physical measurements (phage or gas tracer) to correlate with the CFD analysis were not performed and would add value. Based on this, it was possible to verify that the traditional positioning of the HCW, facing the door and therefore facing

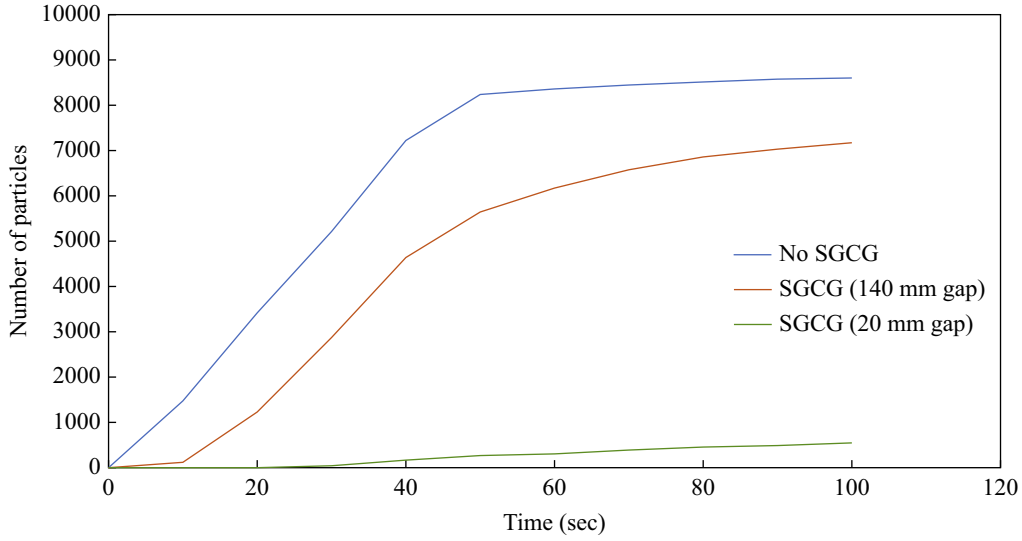

Figure 5. Evolution of the cumulative number of particles passing through the healthcare worker's breathing zone over time depending on the SplashGuard Caregiver (SGCG) configuration.

the air stream, could expose them to a larger amount of virus and possible contamination. However, with the HCW's back turned towards the door, this exposure could be reduced, even if this higher exposure was not reflected in contamination levels through the sampling, as none of the HCWs evaluated were infected by SARS-CoV-2. This is due to the fact that it is not only the presence of airborne virus which determines infection. The use of PPE, the type of AGP performed (e.g. intubation and positive pressure ventilation seem to be riskier), the duration of exposure of the HCW to the pathogen, their immune status, the clinical condition of the patient and the virulence of the strain can also have an impact [28—30].

Over the course of the pandemic, the science around the modes of transmission of SARS-CoV-2 has evolved, with increasing recognition that transmission occurs through multiple modes of contact with particles of varying sizes. However, the relative contribution of each mode of transmission, and how it may vary according to the environment and circumstances is not well delineated [29,31]. In the present study, the use of PPE probably explains the lack of contamination of the HCWs. However, at the beginning of the pandemic, shortages in PPE were observed at some centres, and HCW positioning combined with SGCG use could have been an option to limit HCW exposure to viral particles. It is important to note that

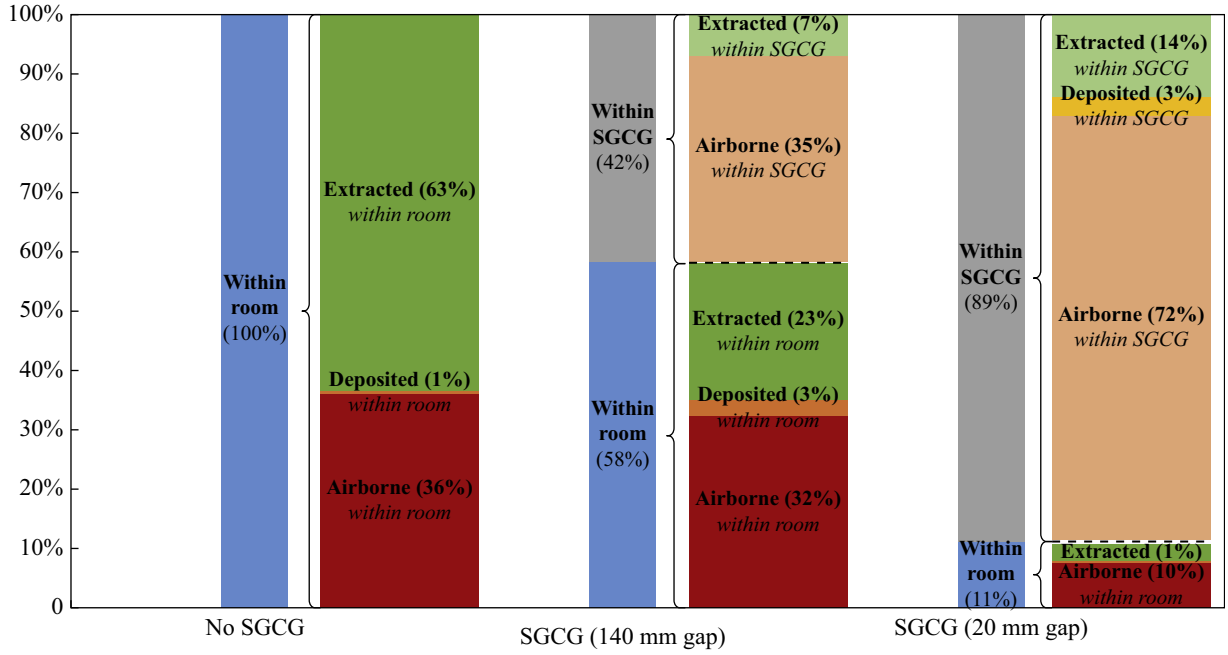

Figure 6. Breakdown of extracted, deposited and airborne particles within the room and the SplashGuard Caregiver (SGCG) for each configuration after 100 s of physical time.

patients' needs were assessed carefully before the device was implemented, and a user manual was drawn up to prevent any misuse, including management of the device in emergency situations (available at https://rsr-qc.ca/Splashguard-cg/ with English and French versions). No side effects were recorded during the use of the device.

The COVID-19 pandemic resulted in the implementation of several public health and social measures to mitigate spread, which have likely contributed to the significant reduction in seasonal respiratory viruses such as influenza and respiratory syncytial virus in Canada [32], the USA [28] and Europe [33]. Therefore, while these measures were evaluated in the context of SARS-COV-2, they are certainly transposable to other aetiological agents. For example, since the decline of the SARS-COV-2 pandemic, there has been a major increase in respiratory syncytial infection in paediatrics, and use of the same virus containment measures adopted during the COVID-2 pandemic could be explored [34,35].

The strengths of this study include its prospective design and a pragmatic approach to viral spread, from detection of the virus by accurate methods to the simulation of aerosolized particles within a patient room. In addition, the use of a single room for both virus collection and simulation, addressing all details of its architecture and ventilation, helped to reduce evaluation biases.

Limitations of this study include the single-centre design, the lack of characterization of the strain's virulence, and the small number of patients and AGPs included. Furthermore, based on the viral PCR results, as well as the CFD simulation method (experimental), it was not fully demonstrated that the SGCG offered additional protection over standard PPE. However, by adjusting the device in the CFD (narrowing the gap), the authors were able to identify recommendations for making better use of the SGCG.

In conclusion, this study documented the presence of SARS-CoV-2 in the environment of infected patients without HCW contamination. This indicates that other variables are associated with contamination, as well as the presence of the virus in the air. Furthermore, the simulation showed that reducing the gap between the plastic film and the Plexiglas box, and modifying the suction port design would make the SGCG more effective. Finally, the position of the HCW within the room can have an impact on their exposure to airborne pathogens.

Acknowledgements

The authors wish to thank the HCWs and research assistants who participated in the study during a very stressful period. In addition, the authors wish to thank Quebec Respiratory Health Research Network for their support in promoting the SGCG via the website.

Conflict of interest statement
None declared.

Funding sources
Philippe Jouvet receives a salary from the Fonds de Recherdche Quebec Santé, and received funding from institute TransMedTech, Ministry of Health of Quebec and Sainte-Justine Hospital to conduct the study. Arul Ammaiyappan, Emmanuel Vanoli and Cyril Crawford receive a salary from Dassault Systèmes, which received funding from Institut TransMedTech to conduct the study.

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