SPECIAL ARTICLE

A Novel Negative Pressure Isolation Device for Aerosol Transmissible COVID-19

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The coronavirus disease 2019 (COVID-19) pandemic creates a need to protect health care workers (HCWs) from patients undergoing aerosol-generating procedures which may transmit the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). Existing personal containment devices (PCDs) may protect HCWs from respiratory droplets but not from potentially dangerous respiratory-generated aerosols. We describe a new PCD and its aerosol containment capabilities. The device ships flat and folds into a chamber. With its torso drape and protective arm sleeves mounted, it provides contact, droplet, and aerosol isolation during intubation and cardiopulmonary resuscitation (CPR). Significantly improved ergonomics, single-use workflow, and ease of removal distinguish this device from previously published designs. (Anesth Analg XXX;XXX:00–00)

GLOSSARY

BIPAP = bilevel positive airway pressure; **COVID-19** = coronavirus disease 2019; **CPR** = cardiopulmonary resuscitation; **HCW** = health care workers; **IFU** = instruction for use; **LLD** = left lateral decubitus; **OR** = operating room; **PCD** = personal containment device; **SARS-CoV-2** = severe acute respiratory syndrome coronavirus-2; **SLACC** = suction-assisted local aerosol containment chamber; **UV** = ultraviolet

The coronavirus disease 2019 (COVID-19) pandemic has created new challenges for health care workers (HCWs) performing droplet and aerosol-generating procedures including endotracheal intubation and cardiopulmonary resuscitation (CPR).[1–3] Evolving data suggest that the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) responsible for COVID-19 is highly transmissible and can spread throughout clinical care environments via both mixed-size droplets and cloud-like aerosols, that can remain airborne for prolonged time periods.[4–7] To mitigate the possibility of HCW infection, several groups have developed and shared designs for personal containment devices (PCDs) to be utilized during these high-risk procedures.[8–10] These recently published concepts share the common form of a rigid plastic barrier between HCW and patient that traps potentially infectious respiratory aerosols.

However, all current designs lack 3 main features that we feel are prerequisite for a successful aerosol containment device: (1) complete contact barrier between HCWs and patient, (2) flexibility and freedom of movement for the provider's arms, (3) containment and safe elimination of generated aerosols. With these and other goals in mind, our resident-led design team developed a novel containment device to protect HCWs from contact with infectious respiratory aerosols during airway management of patients with COVID-19. The major concepts of our design and relevant usability testing are hereby presented.

METHODS

Our group undertook an iterative development and prototyping process resulting in the design of the suction-assisted local aerosol containment chamber (SLACC) device, discussed below. This process began with a goal of addressing the shortcomings of existing PCDs (noted above) and included the following additional requirements. First, the device should be low cost and simple to manufacture. Second, the device should be light and compact for ease of shipping and deployment in crisis conditions. Third, it must not

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Accepted for publication June 4, 2020.

Funding: S.U. is supported by a K08 grant (1K08 HL141995 01A1) from the National Institutes of Health, Bethesda, MD.

The authors declare no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (www.anesthesia-analgesia.org).

Reprints will not be available from the authors.

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DOI: 10.1213/ANE.0000000000005052

only protect against droplets but also successfully contain aerosols. Finally, we targeted a disposable single-use design to eliminate the need for time consuming and potentially risky decontamination for reuse.

Prototypes were initially tested in a high-fidelity simulation center (UCLA Simulation Center, Los Angeles, CA). Specifically, we focused on (1) ease of airway management including endotracheal intubation, (2) containment of droplets generated during simulated intubation, (3) containment and evacuation of aerosols generated during airway management and/or CPR. Ease of intubation was assessed by several anesthesiologists (residents and faculty with varying experience) using a full-sized mannequin (SimMan, Laerdal Medical, Stavenger, Norway) and video laryngoscope (Glidescope VL, Verathon Medical, Bothell, WA). All required instruments and accessories (videolaryngoscope blade, suction, anesthesia circuit, etc) were introduced into the containment chamber before simulated induction.

Droplet containment was tested using fluorescent dye spray (Glo Germ Co, Moab, UT) to simulate exhaled respiratory droplets as previously reported.[9] The solution was delivered every 3–5 seconds using a manual spray bottle placed near the oral cavity and aimed at the clinician throughout laryngoscopy. Photos were then taken under ultraviolet (UV) light to assess for contamination of the mannequin, equipment, environment, and clinician.

Aerosol containment was simulated using a theatrical smoke machine (Co-Z 400w mini fog smoke effect generator, China) rigged to emit a buoyant water vapor from near the simulation mannequin's oral cavity during intubation and chest compressions (simulated CPR). For each of the aforementioned tests, we compared our new device to a previously described rigid PCD (Dr Lai Box).[8,9] After emitting smoke for 6 seconds, both simulated high-flow operating theater suction (1000 L/min, <1 psi; Air Boss 120 v by Fine Expectations) and wall suction (–300 mm Hg, variable flow) were tested for their ability to rapidly clear the smoke from the chamber while also preventing its efflux into the environment. Photographic evidence of smoke clearance and leakage at 30 and 60 seconds were recorded. Of note, we used a dedicated suction system for the SLACC to preserve ready access to standard wall suction Yankauer catheter for airway management.

We tested the ability to rapidly remove the SLACC, as could be required during failed airway management, episode of emesis, or other emergent scenario, via simulation to determine ease and speed of removal and possible cross-contamination. During simulation of a failed intubation, fluorescent dye was sprayed as described above. Once the intubator requested removal of the device, an uninvolved observer started a timer and observed the workflow. Time to full removal was recorded, ease of removal was observed and queried, and photos were taken under UV light to assess contamination of the involved HCWs and nearby environment.

Finally, we simulated patient position change from supine to the left lateral decubitus (LLD) position without removal of the SLACC, as could be required during management of regurgitation of gastric contents. A human volunteer who lay supine under the device was turned LLD by the intubator, a second assistant holding the torso, and a third assistant holding the legs. An uninvolved observer was again utilized to time and grade the process.

RESULTS

Our development process culminated with the development and testing of the SLACC device. Its construction consists of a clear and flexible plastic sheet cut to a prespecified shape that is subsequently folded into a 3-dimensional construct. Peel-and-stick adhesive tabs with overlapping seams allow easy assembly and ensure structural integrity while also securing the device to the simulated patient's bed. Flexible thin-walled plastic sleeves and a torso drape are added using simple tape adhesive to enable complete barrier separation between HCW and patient, and to effectively seal the chamber along the patient's upper torso. Operator arms are introduced through sleeves incorporated into the device. Finally, suction is connected to a port integrated into the device to create a negative pressure microenvironment surrounding and enclosing the patient's head and upper torso (Figure, panel A). The aforementioned assembly and positioning of the SLACC were easily achieved in <2 minutes by experienced operators who followed a simple instruction for use (IFU) page (to be included with the device).

During development of the SLACC, all providers found previously described rigid plastic devices somewhat difficult to use because their precut arm holes limited positioning of the anesthesiologist's arm and restricted 3-dimensional arm motion. In contrast, the SLACC's structural flexibility enabled providers to flex and warp the box with their arms, allowing for full range of motion needed to successfully manage the airway (Figure, panel A). All providers using SLACC were able to easily intubate the mannequin on the first try in <30 seconds. The device includes 2 additional access ports to allow assistants to perform important support tasks including applying cricoid pressure or changing head position. A small port on the top of the box allowed for easy access of a bronchoscope as would be required for awake intubations. All required instruments and accessories were easily introduced into the containment chamber by passing them under

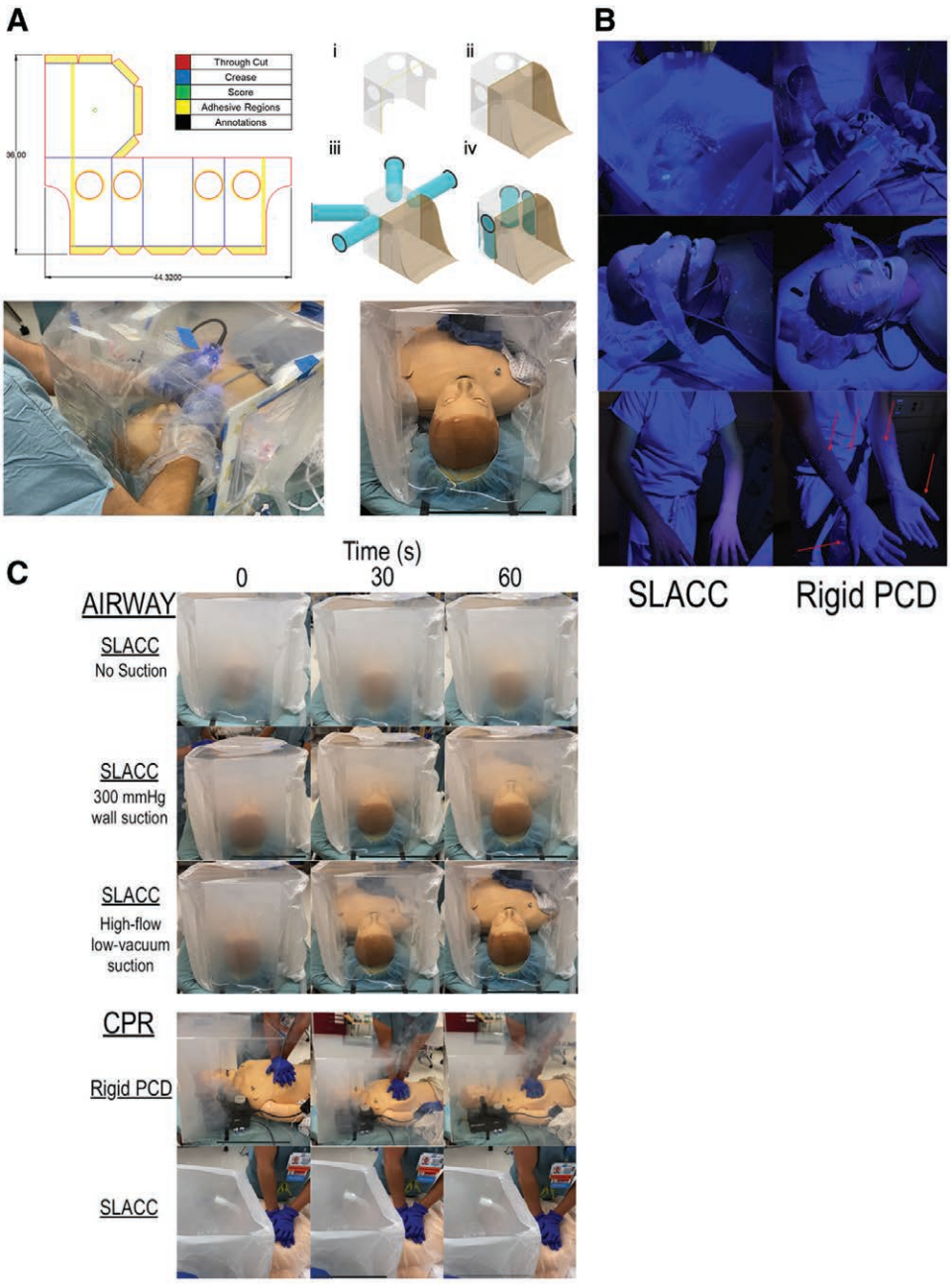

Figure. The SLACC. A, Top: Assembled SLACC computer model, showing torso drape (brown) and arm sleeves (blue). Bottom: Intubation using the SLACC. B, Droplet testing with fluorescent dye during simulated laryngoscopy. Note forearm contamination with rigid PCD. C, Aerosol containment and clearance testing using smoke as a simulant. Top: Comparison of the SLACC used with no, low-flow, and high-flow suction. Images taken at 30 s intervals after 6 s of smoke production. Bottom: Simulated aerosol exposure during CPR. Images taken at 30 s intervals with continuous smoke production. CPR indicates cardiopulmonary resuscitation; PCD, personal containment device; SLACC, suction-assisted local aerosol containment chamber.

the patient drape near the shoulder or inserting them through a sealable access port (Supplemental Digital Content, Video, http://links.lww.com/AA/D138).

VIDEO+

In droplet containment testing, the rigid box contained the majority of the spray within the enclosure as has previously been demonstrated.[9] However, the provider's hands and arms were circumferentially contaminated (Figure, panel B). In comparison, the SLACC contained all of the sprayed dye in the chamber and no tracer was noted on the provider's hands or arms due to the protective sleeves built into the SLACC (Figure, panel B; Supplemental Digital Content, Video, http://links.lww.com/AA/D138).

In aerosol containment testing, the majority of simulated aerosols escaped the rigid PCD within the first 30 seconds of the test, even with high-flow suction applied. The SLACC contained the smoke within the enclosure, allowing only wisps of vapor to escape when

no suction was utilized (Figure, panel C). High-flow suction (intended to simulate the use of a surgical smoke evacuator) rapidly evacuated all the smoke (<1 minute), whereas wall suction only partially cleared the smoke from the enclosure (Figure, panel C). In CPR simulation with continuous smoke production and suctioning during the delivery of chest compressions, no smoke was noted escaping the SLACC. In contrast, the rigid PCD allowed sufficient smoke escape to trigger the simulation center's smoke alarms, demonstrating wide environmental spread of simulated aerosols (Figure, panel C; Supplemental Digital Content, Video, http://links.lww.com/AA/D138).

To test the ability of clinicians to remove the SLACC device, we simulated emergent removal from the manikin. The entire device was removed and disposed in 10 seconds by a single provider (Supplemental Digital Content, Video, http://links.lww.com/AA/D138). Both the operator and observer rated the operation as very easy. Removal of the device did not result in any fluorescent dye beyond the simulated patient's neck, head, and upper shoulders (all areas contained within the SLACC). In addition, 3 providers were able to place the volunteer in the LLD position in 2 seconds without dislodging the SLACC from the operating room (OR) table.

DISCUSSION

In this report, we describe the development and testing of a disposable containment chamber that protects HCWs from contact with droplets and dispersed aerosols released by a patient during airway management. The SLACC device is easily portable, light, completely isolates the patient from the provider, and was easy to deploy and remove. During simulated testing, the device prevented contamination with both droplet and aerosol, allowed ready positioning in the lateral position, and was easily removable to allow unfettered access to the patient airway.

Our device has several advantages over previously published versions. Although current PCDs are heavy and bulky, SLACC is light and easy to bring to most intubation venues. The flexible nature of the components allows for full range of motion of the providers' arms and hands, compared to noted limitations of previous models.[7] The device is not only quick to assemble but can also be broken down and discarded in a matter of seconds, an important feature during an unexpected airway emergency. In simulated testing, the SLACC was quickly and easily removed from the patient in an emergency without contaminating personnel or the environment. Although heavier plastic boxes can possibly injure the patient or provider if dislodged or removed in an emergency, the SLACC is designed for use even in extreme patient and OR table positions (LLD, Trendelenburg, airplane rotation, etc) due to its light weight and adhesive table mounts. The device's flexible walls minimally restricts operator hand position, facilitating intubation and allowing for quick patient repositioning as may be required in an emergency (ie, lateral positioning for suspected aspiration). Furthermore, this single-use disposable product eliminates the need for time consuming and possibly dangerous decontamination of a contaminated, bulky item. Finally, SLACC can be used in other aerosol-generating procedures besides endotracheal intubation such as CPR and bronchoscopy, whereas rigid PCDs cannot.

Our device does have potential limitations. First, to act as a negative pressure enclosure, the device requires dedicated high-flow suction (available in most modern ORs). Although wall suction can be used, it is unlikely to produce adequate clearance, and if the airway suction is used, it may prevent prompt response to emesis or other events requiring suction. Second, the device has not yet been tested in clinical care and still requires in-vivo and real-world testing, especially in difficult airway and emergency scenarios. Although we demonstrated protection from simulated droplets and aerosols, we did not test the effect on HCW infection rates. Third, the device size may prove inadequate for morbidly obese patients or those with bulky head gear such as bilevel positive airway pressure (BIPAP) masks. Fourth, patient conditions such as claustrophobia or delirium could make deployment of the device difficult. We were unable to directly test our device in our hospital due to a limited number of patients with severe COVID-19 who required intubation. Finally, we did not evaluate the ability of the device to clear aerosols using negative pressure when high-flow nasal cannula or other high-flow oxygen devices are used. It is possible that aerosol clearance is less effective due to the interaction between high-flow oxygen and suction.

Our device is simple, cost effective, and overcomes the shortcomings of previously described designs and thus merits further investigation. Even if COVID-19 were to suddenly disappear from the earth, the presence of other diseases requiring isolation (Ebola, *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, carbapenem-resistant Enterobacteriaceae, vancomycin-resistant enterococci, tuberculosis, measles, etc) suggests that the need for a protective device during airway management may remain. Further study is needed to identify aspects of PCD design optimal for airway management in high-risk patients.

ACKNOWLEDGMENTS

We salute our friends and colleagues fighting the early COVID-19 surges as we prepare and learn from their battle. The authors thank David Tebon, Phil Macnamara,

Beth Payne, and Maverick Concepts for their assistance with the material selection and prototyping of the system. The authors also thank Jeremy Gaudin, CRNA, for his observations on this topic, and UCLA Simulation Center.

DISCLOSURES

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This manuscript was handled by: Avery Tung, MD, FCCM.

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