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Original Article

A novel negative pressure isolation device reduces aerosol exposure: A randomized controlled trial

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ABSTRACT

Background and aim: The COVID-19 pandemic has led to a proliferation of intubation barriers designed to protect healthcare workers from infection. We developed the Suction-Assisted Local Aerosol Containment Chamber (SLACC) and tested it in the operating room. The primary objectives were to determine the ease and safety of airway management with SLACC, and to measure its efficacy of aerosol containment to determine if it significantly reduces exposure to health care workers.

Methods: In this randomized clinical trial, adult patients scheduled to undergo elective surgery with general endotracheal anesthesia were screened and informed consent obtained from those willing to participate. Patients were randomized to airway management either with or without the SLACC device. Patients inhaled nebulized saline before and during anesthesia induction to simulate the size and concentration of particles seen with severe symptomatic SARS-CoV-2 infection.

Results: 79 patients were enrolled and randomized. Particle number concentration (PNC) at the patients' and healthcare workers' locations were measured and compared between the SLACC vs. control groups during airway management. Ease and success of tracheal intubation were recorded for each patient. All intubations were successful and time to intubation was similar between the two groups. Healthcare workers were exposed to significantly lower particle number concentrations (#/cm3) during airway management when SLACC was utilized vs. control. The particle count outside SLACC was reduced by 97% compared to that inside the device.

Conclusions: The SLACC device does not interfere with airway management and significantly reduces healthcare worker exposure to aerosolized particles during airway management.

1. Introduction

Airborne transmission is a major mode of SARS-CoV2 virus infection, and respiratory particle inoculum plays a role in determining probability and severity of viral infection [1,2]. Clinicians worldwide introduced several novel intubation shields in early 2020 with the goal of protecting health care workers during aerosol generating procedures including tracheal intubation [3–6]. Published data on these devices consisted mostly of simulation-based and case report series, and questions of the devices' efficacy and safety have been raised [7–12].

As the Covid-19 pandemic wore on, clinicians questioned the need for such devices given that controlled intubation in paralyzed patients may not generate large aerosol plumes in all patients. However, deep breathing and coughing that occur immediately before induction and intubation of patients with respiratory illness can produce large concentrations of infectious aerosols. Others have questioned the need for containment chambers given the high efficacy of standard personal protective equipment at protecting health care workers from Covid-19 disease. While endemic infection combined with effective vaccines and treatments have reduced the morbidity of Covid-19 infection, clinicians must nevertheless learn lessons from this experience and prepare for future, perhaps deadlier pandemics.

Our research group developed the Suction-Assisted Local Aerosol Containment Chamber (SLACC) with these design goals: 1)

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low cost, 2) quick and easy assembly, 3) flat storage and shipping, 4) excellent ergonomics for tracheal intubation, 5) effective airborne isolation of patients from health care workers. Early prototype devices tested in a simulation setting showed promising results but lacked real world credibility [13].

This study aims to: 1) test a production-quality intubation shield in actual patient intubations to determine the ease and safety of airway management, 2) measure the efficacy of aerosol containment by the device to determine if it significantly reduces exposure to health care workers.

2. Materials and methods

This study was approved by the University's Institutional Review Board (IRB #21–000022) and written informed consent was obtained from all subjects participating in the trial. The trial was registered prior to patient enrollment at clinicaltrials.gov (NCT 04864236, https://clinicaltrials.gov/ct2/show/NCT04864236, Principal investigator: John Shin, Date of registration: April 28, 2021). This was a single-center randomized controlled trial in the operating room of a major university hospital system. Adult patients scheduled to undergo elective surgery with general endotracheal anesthesia were interviewed and written informed consent obtained from those willing to participate (Fig. 1). Patients expected to be a difficult mask ventilation or intubation, or those with a body mass index greater than 40 kg/m2, were excluded from participation.

The SLACC device consisted of the flexible plastic shell, four inverted arm sleeves, a lower body drape, and a suction hose that connected the internal environment of the device to the high-power smoke evacuation suction port of a surgical suction machine (Fig. 2). The device was applied to all patients randomized to the SLACC group after arrival to the operating room and placement of standard ASA monitors. Automated airborne particle counters deployed in the operating room continuously measured air particle number concentrations at the following three locations: 1) head of the table at the physician's face, 2) side of the table where the assistant stood, 3) patient's face (Fig. 3). Saline was then nebulized near the patient's face to generate high concentrations of particles 1–5 μm in size. Clinicians would be expected to encounter similar aerosol particle sizes and numbers during airway management of patients with severe symptomatic SARS-CoV-2 respiratory illness [14].

To determine the safety and utility of the SLACC device during airway management, patients were randomized to intubation either with or without the device. A randomization list was generated using R V 3.6.1 (www.r-project.org Vienna, AU) using the "blockrand" package [15], with block sizes were specified to 4 to ensure that the study would be relatively balanced between groups over time. Patients assigned to the SLACC device group underwent preoxygenation, induction, mask ventilation, and intubation with the device fully deployed.

Patients allocated to the control group underwent standard airway management without SLACC. Ease of mask ventilation, grade of laryngoscopic view, time to successful intubation, number of attempts required to successfully intubate, and intubation failure were compared between the two groups. Choice of anesthetic agents, neuromuscular blockade, and other decisions related to airway management were left to the discretion of the attending anesthesiologist providing care to the patient. Mask ventilation and intubation were performed by members of the study team (5 attending anesthesiologists) utilizing a video laryngoscope (Glidescope, Verathon Inc, Bothell, WA, USA). Protocol dictated that the SLACC device be removed at the discretion of the physician when difficult airway management was encountered.

To measure the SLACC device's aerosol containment ability, two separate comparisons were made. First, the particle number concentration near the patient's face was compared to those at the physician's and assistant's positions when SLACC was deployed. Second, particle number concentrations at the patient, physician,

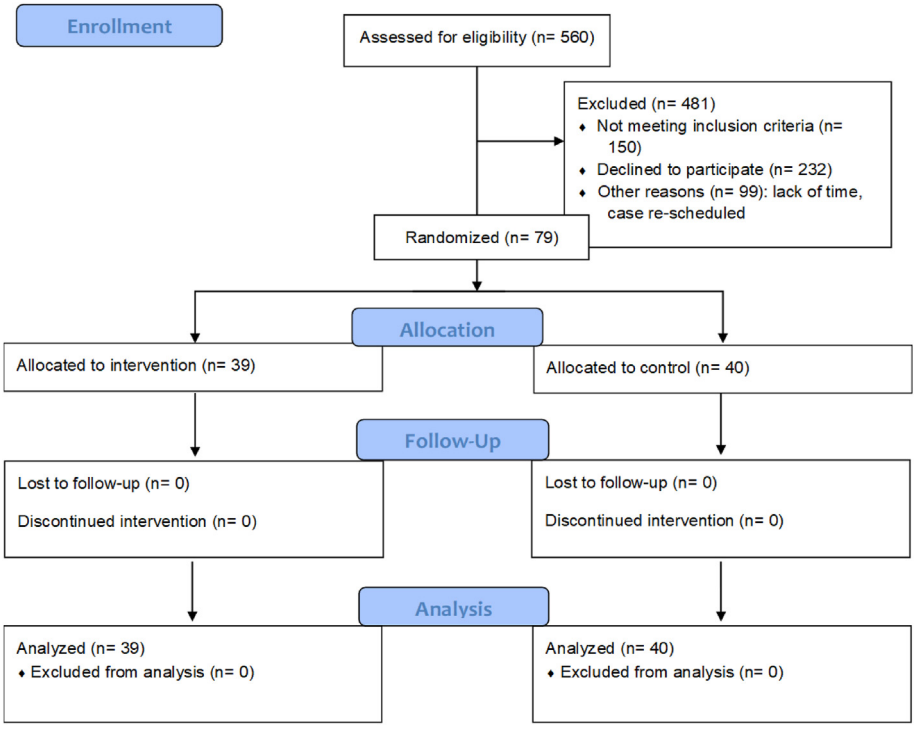

Fig. 1. Consolidated Standards of Reporting Trials flow diagram.

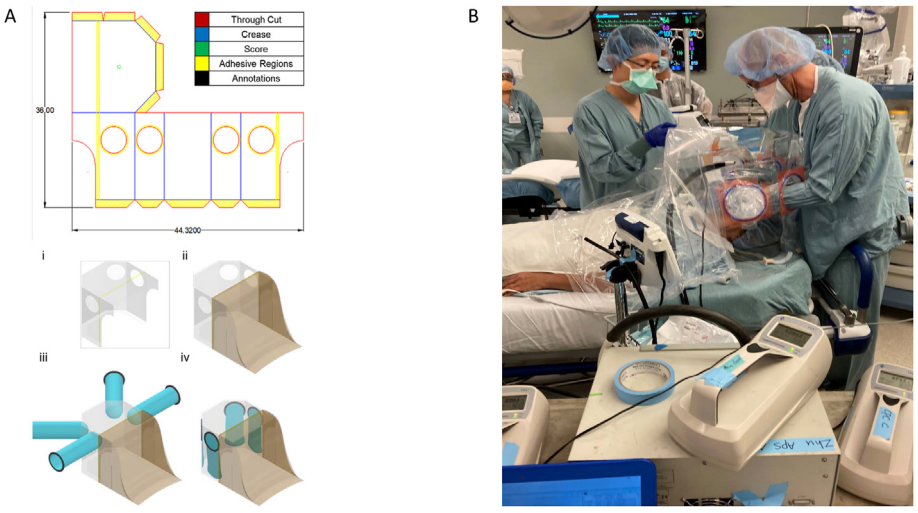

Fig. 2. A) SLACC device 2-D and 3-D schematic B) SLACC being used in the operating room.

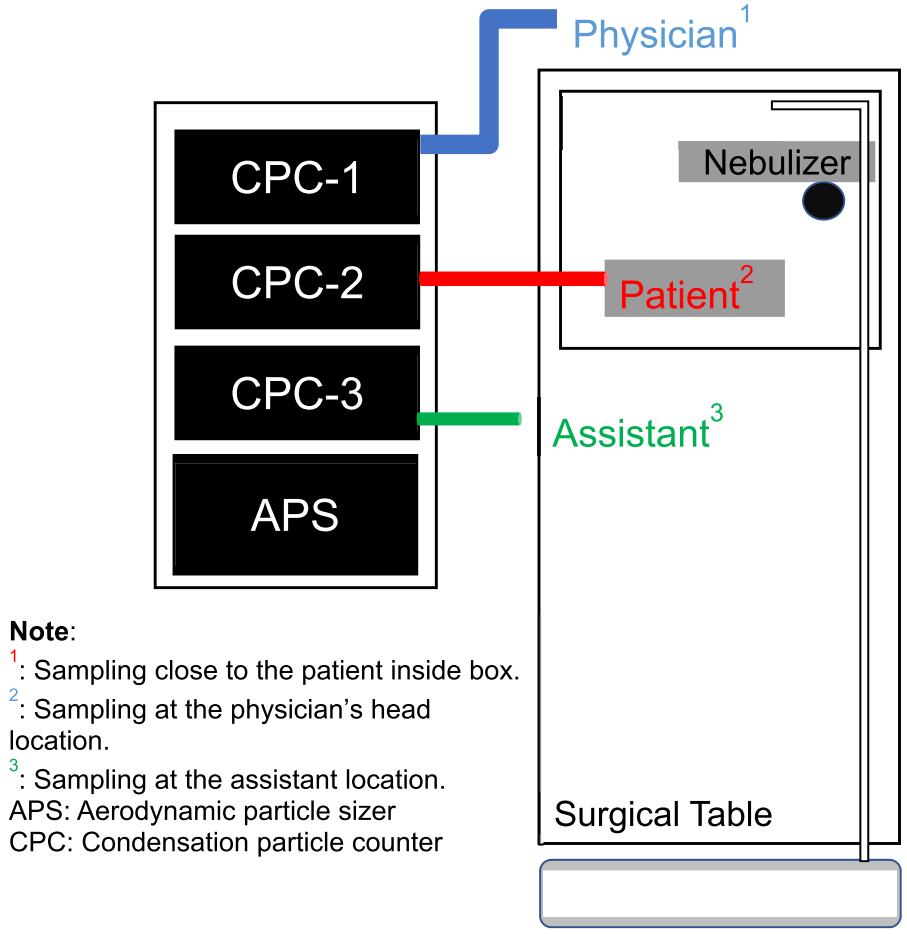

Fig. 3. Experimental setup in the operating room.

and assistant locations were compared between cases randomized to SLACC vs. control groups.

Particle number concentrations were sampled at the previously defined locations irrespective of group randomization, and quantified during the following sequential time periods with patients in the supine position.

1) Pre anesthesia Baseline #1: 2 min of quiet breathing before saline nebulizer activation.
2) Pre anesthesia Baseline #2: 2 min of quiet breathing after saline nebulizer activation.
3) Pre anesthesia deep breathing/coughing: 30 s of deep breathing followed by 30 s of coughing, repeated once (total 2 min).

4) Initiation of anesthesia with airway management: preoxygenation, induction, mask ventilation, tracheal intubation, connection to the anesthesia circuit, mechanical ventilation.
5) Post intubation: after initiation of mechanical ventilation the nebulizer was discontinued, and particle number concentrations recorded for 2 min. In the SLACC group, the device was removed and we collected data for 2 additional minutes to measure particle decay.

We decided to include periods of coughing and deep breathing before induction of anesthesia, as well as periods of mask ventilation and tracheal intubation after induction, to measure aerosol concentrations during these activities. Given the difference of opinion among clinicians as to whether controlled intubations generate aerosol particles, we chose to include all these distinct activities in the final analysis. A consecutive 60 s of particle count data was selected out of the 2-min sampling period for each session for statistical analysis.

2.1. Technical details of the experiment

Aerosol generation: A small volume nebulizer (Airlife en-Misty Fast, Vyaire Medical Inc, Chicago, IL, USA) filled with 5 mL normal saline was connected to wall source oxygen flowing at a rate of approximately 2.8 L per minute. This optimal oxygen flow rate consistently produced around 10^5 particles per cubic centimeter inside the SLACC chamber when suction was active, simulating a highly contagious super spreader event [16].

Aerosol Measurements and Instrumentation: Real-time particle number concentration was measured at each sampling location using a Condensation Particle Counter (CPC 3007, TSI Inc., Shoreview, MN, USA), with a sampling size ranging from 10 nm to > 1 μm. Particle size distribution was characterized using an aerodynamic particle sizer (APS 3321, TSI Inc.), measuring particle size range of 0.5–19.8 μm. Size information was only collected at the patient location as other locations had negligible number of particles detected within the size range of the aerodynamic particle sizer due to the operating rooms' high air exchange rate. An indoor air quality monitor (Q-Trak 7575, TSI Inc.) was used to measure temperature, relative humidity, and CO_2 concentration in the operating room. We tracked the oxygen flow rate through the saline nebulizer using a Mass Flow Meter (4100 series, TSI Inc.). The data logging intervals for both the condensation particle counter and aerodynamic particle sizer were set to 1 s, while the data logging interval for the indoor air quality monitor was set to 1 min.

Quality Control and Quality Assurance: Condensation particle counters were cross calibrated and collocated before the test to ensure that data from different devices were comparable. Condensation particle counters and aerodynamic particle sizer were zero-checked and warmed up for more than 5 min before each test. All devices were carefully monitored by the researcher throughout the entire process of the test to ensure proper function. Activities that could affect proper data collection such as patient talking, SLACC drape movement, and blocking of sampling inlet were recorded. Minor adjustments to the oxygen flow meter were made to maintain a measured gas flow of 2.8 L per minute.

Suction and particle removal: The SLACC device's internal airspace was directly connected to the Neptune 3 Waste Management System's (Stryker Corp, Kalamazoo, MI, USA) Ultra Low Particulate Air (ULPA) smoke evacuation filter via the manufacturer supplied tubing (22 mm diameter, 3.1 m length). The smoke evacuation setting was dialed to 100% suction, correlating to a suction flow rate of 320 L per minute. The Ultra Low Particulate Air filter is described as at least 99.999% efficient at the most penetrating particle size and 100% efficient at 0.01 μm.

Data correction for exogenous particle contamination: the Neptune 3 system's smoke evacuation exhaust plume generated varying quantities of airborne particles <0.5 μm in diameter. This quantity of particle noise varied from experiment to experiment and was not consistent among specific machines, necessitating the subtraction of this particular artifact from the total measured particle number concentrations. Failure to subtract this artifact would skew the results given that no Neptune suction was used in the control arm. In order to remain conservative and not risk overcorrection of data noise, we measured the average background particle count during periods when Neptune suction was activated but the nebulizer was not (Baseline #1). Particles generated at this timeframe were defined as background artifact generated solely from the Neptune, and this value was subtracted from the total particle number concentrations measured during the experiment periods when the SLACC and Neptune were in use.

3. Statistical analysis

Patient characteristics and study variables were summarized between groups using mean (SD) or frequency (%) and formally compared using the *t*-test or chi-square test, as appropriate (Table 1). Each patient had a series of data where aerosol particle counts were measured every second across different settings (see methods above for details). From each patient/setting/condition combination, we computed the median particle number concentrations. Next, we presented the median (IQR) and compared these particle number concentrations between groups using the Wilcoxon test (Table 2). Analyses were conducted using IBM SPSS V28 (Armonk, NY) and p-values <0.05 were considered statistically significant.

Power and sample size: A sample size of 17 per group would allow us to detect an effect size as small as 1.00 between groups (using a *t*-test, >80% power, two sided alpha 0.05). A similar study exploring the effectiveness of several different containment devices on airborne particles in similar settings mentioned an effect size of 1.0 (20,000 particles vs 12,000, SD of 8000) [5]. We hypothesize that our device will be more effective than any device tested in this previous study at reducing airborne contamination so this is a conservative estimate of what we expect to see with our device. Ultimately, we decided on 39 per group to better assess both efficacy of the primary outcome as well as increase reliability in our secondary outcomes. This sample size will allow us to detect effect sizes as small as 0.65 between groups (using a *t*-test, >80% power, two sided alpha 0.05) and gives us a measure of precision of a confidence interval for the mean on our primary outcome of within ± 2510 particles assuming the box group is 12,000 with a standard deviation of 8000 [5].

4. Results

A total of 79 patients were recruited and randomized: 39 to the SLACC group and 40 to the control group (Fig. 1). Gender, height, weight, and body mass index (BMI) were not statistically different among the two groups and every patient completed the trial. The SLACC device did not significantly interfere with airway management. Ease of mask ventilation and grade of laryngoscopic view were similar in both groups, and there were no failed intubations necessitating rescue airway management in either group. Number of intubation attempts were not different between two the groups ($p = 0.670$, average difference 0 attempts, 95% CI -0.1, 0.1), and time to intubation with SLACC was not significantly longer compared to the control group ($p = 0.073$, average difference 9.8 s, 95% CI -0.9, 20.6) (Table 1).

During the deep breathing and coughing period, the SLACC

Table 1
Baseline demographic and airway characteristics.

Baseline characteristic	Control (n = 40)	SLACC (n = 39)	p-value
Age (years)	54.1 (19.3)	51.7 (16.0)	0.566
Gender (Male%)	20 (50.0%)	16 (41.0%)	0.423
Height (meters)	1.72 (0.10)	1.68 (0.11)	0.109
Weight (kilograms)	77.3 (16.5)	76.7 (17.8)	0.870
BMI (kilograms/meters^2)	26.1 (4.8)	27.2 (5.9)	0.399
Time to Intubation (seconds)	41.8 (25.7)	51.6 (22.2)	0.073
Intubation Attempts	1.08 (0.27)	1.05 (0.22)	0.670
Pre-Op Mallampati Score	1.53 (0.72)	1.74 (0.68)	0.167
Pre-Op Thyromental Distance (finger breadths)	3.18 (0.45)	3.10 (0.38)	0.442
Laryngoscopy Grade View (Cormack-Lehane grade)	1.10 (0.30)	1.21 (0.41)	0.198
Oral Airway Used	13 (32.5%)	15 (38.5%)	0.580
Facial Hair	9 (22.5%)	9 (23.1%)	0.951

Table 2
Median particle number concentration (PNC) for each time period and location for SLACC and control groups. Median particle number concentration (Quartile 1 – Quartile 3).

Experiment Phase	Location	Median PNC (/cm^3) Control (n = 40)	Median PNC (/cm^3) SLACC (n = 39)	p-value
Breathing/Coughing	Patient	411 (211–987)	4026 (1778–7616)	<0.001
	Anesthesiologist	392 (207–1259)	105 (37–232)	<0.001
	Assistant	185 (98–302)	74 (18–211)	0.004
Intubation	Patient	490 (235–1394)	1560 (728–3093)	<0.001
	Anesthesiologist	556 (297–1579)	48 (15–145)	<0.001
	Assistant	218 (158–436)	27 (5–80)	<0.001

device reduced the median particle number concentration from 4026/cm^3 at the patient's face to 105/cm^3 at the physician's position, a 97% reduction. During the tracheal intubation period, the SLACC device reduced the median particle number concentration from 1560/cm^3 at the patient's face to 48/cm^3 at the physician's position, a 97% reduction (Table 2).

The median particle number concentration was significantly lower in the SLACC vs. control group at both the physician and assistant locations. This was consistent during deep breathing/coughing (physician 105 vs. 392/cm^3, $p < 0.001$, assistant 74 vs. 185/cm^3, $P < 0.004$) and intubation (physician 48 vs. 556/cm^3, $p < 0.001$, assistant 27 vs. 218/cm^3, $p < 0.001$) (Fig. 4). Furthermore, physician exposure to extremely high concentrations of particles (aerosol spikes with >10,000 particles/cm3), which were commonly seen during airway management in the control group (Fig. 5A), were totally eliminated when SLACC was utilized (Fig. 5B).

5. Discussion

This randomized clinical trial was first to test a commercially manufactured single-use intubation barrier designed to be inexpensive, easy to assemble and use, while retaining a flat configuration for storage and transport. Our team had forgone intellectual property rights protection and can provide design blueprints to enable widespread adoption of this technology. While the device is designed to isolate the health care worker from both contact and airborne pathogen sources, we only tested its airborne isolation efficacy in this trial.

No statistically or clinically significant differences were observed during the entire airway management period, from preoxygenation, through induction, mask ventilation, and tracheal intubation. This was likely due to the SLACC's flexible materials which allowed the health care worker to flex and warp the box to suit his or her intubation stance. Many protective enclosures introduced early in the pandemic were rigid plastic boxes that

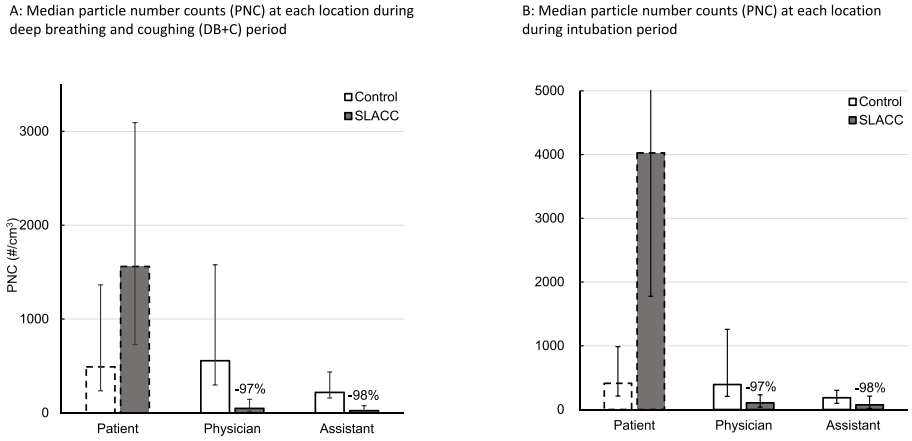

Fig. 4. A) Median particle number concentration (PNC) at each location during deep breathing and coughing (DB + C) period B) Median particle number concentration (PNC) at each location during intubation period.

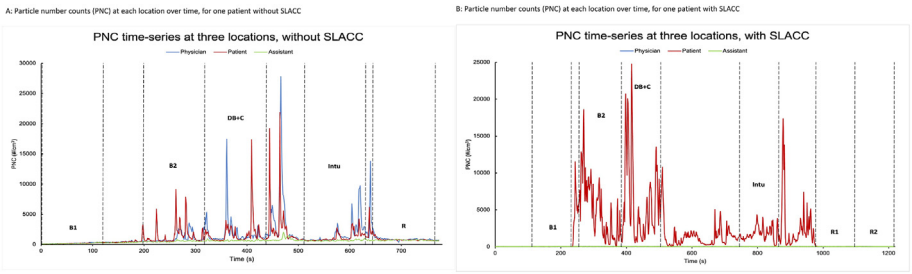

Fig. 5. A) Particle number concentration (PNC) at each location over time, for one patient without SLACC B) Particle number concentration (PNC) at each location over time, for one patient with SLACC.

restricted degrees of freedom and made intubation more challenging; SLACC's design seems to have solved those initial problems. In order to minimize clinical inexperience as a potential confounding variable, all intubations were performed by experienced anesthesiologists who previously practiced a handful of times on a simulator. Furthermore, video laryngoscopy was utilized in every intubation as recommended by most Covid-19 intubation protocols [7]. Although compatibility of the SLACC device with direct laryngoscopy was not tested, its transparency should not obstruct direct viewing of the larynx. Patients with claustrophobia, morbid obesity or suspected difficult airways were excluded, which reduces the study results' generalizability to those patient populations. However, SLACC's compatibility with video laryngoscopy suggests that these patients could also be successfully intubated, though more research is needed to confirm these assumptions. While SLACC was designed for all aspects of airway management, ease of extubation under the enclosure was not specifically studied in this trial. Finally, airway management occurred in a controlled operating room setting on optimally positioned patients. Further studies in other locations and scenarios should be conducted before generalizing these findings to all clinical settings.

The SLACC device demonstrated a 97% reduction in particle concentration between the patient location and physician location during both coughing/breathing as well as intubation periods. This demonstrated that large and potentially hazardous plumes of aerosolized particles, which were generated both preinduction as well as during mask ventilation and intubation, can be effectively contained within a thin flexible plastic box when combined with high power suction. The device was effective in every patient and no failures were observed during any of the measured phases. Given the SLACC's small size and non-airtight construct, Neptune high power suction was vital for both minimizing aerosol particle leakage and enabling ultra-filtration of contaminated air. Our results may not be generalized to other smoke evacuation devices or suction set-ups.

Particle number concentration at the health care worker (physician or assistant) position was 2.5–10 times lower when SLACC was used compared to the control cases without SLACC. Of perhaps greater significance, short-lived particle spikes exceeding tens of thousands particles/cm3, commonly seen throughout the control group, were completely eliminated in every SLACC case. It is believed that the inhaled inoculum of virus particles may impact both probability of infection and severity of disease, highlighting the importance of infectious respiratory particle count reduction during airway management [17]. Operating rooms have very high air turnover (up to 20 times per hour) to reduce airborne contaminants and concomitant infection rates. In theory, operating rooms are considered safer environments for airway management than other locations with inferior airflow such as emergency departments and intensive care units. We therefore expect SLACC to be even more effective at reducing health care worker exposure in such alternative venues where overall airflow is reduced, although further studies in alternative locations should be conducted.

Removal of SLACC after 2 min of continuous suction eliminated any detectable particle number concentration increase at the health care worker locations, demonstrating its safe removal soon after completion of intubation when Neptune suction and filtration is used. Different suction or filtration, or lack thereof, may negatively impact this observed margin of safety. In an airway emergency, the device can be removed from the patient's head/body and discarded in less than 5 s. However, doing so would most likely result in spread of aerosol particles.

Nebulized saline was used to replicate highly infectious conditions in which patients exhale high concentrations of respiratory particles. No live virus particles were used in our experiment. Although our measured particle size and counts were identical to those generated by the respiratory system, unanticipated differences between natural and replicated scenarios could exist. This trial was not designed or powered to detect differences in infection prevention, and patients with suspected or confirmed SARS-CoV-2 infection were excluded. Further research is warranted before SLACC is certified as protective; currently such devices are not cleared by the United States Food and Drug Administration for clinical use. The device should only supplement, rather than replace, personal protective equipment during airway management.

SLACC can be manufactured and shipped as a single flat sheet of plastic. Final assembly and preparation for clinical use takes about 5–10 min. If prepared ahead of time and stored in a “ready for use state” it can be applied to patients in a matter of seconds. All one needs to do is place it over the head and shoulders of the patients and attach the suction source. The cost for the device varies by country of manufacture. Our cost was about $30 per device, but that was during the height of the pandemic when the plastic was in extremely short supply as well as our low volume of manufacture. At higher volumes of manufacture and with the current plastic supply, it should be less than half ($15) in the United States and perhaps much lower in other countries. The authors are happy to share the blueprints with any interested readers.

The need for devices like SLACC has been questioned as the SARS-CoV2 virus becomes endemic and the Covid-19 pandemic comes to an end. Yet we feel now is exactly the time to conduct research and development of novel protective equipment. While the timing of the next major viral outbreak is difficult to predict, we clinicians must perfect our tools for self-defense while there is still time.

In conclusion, the SLACC device is a simple, inexpensive, and effective device that may protect health care workers from dangerous airborne pathogens encountered during airway management and tracheal intubation.

Trial registration

ClinicalTrials.gov, NCT 04864236, registered on April 28, 2021

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CRediT authorship contribution statement

John S. Shin: designed the study, and, Writing – review & editing, screened and enrolled patients, and performed airway management for all patients, Data curation, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Muchuan Niu:** designed the study, and, Writing – review & editing, Data curation, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Haoxuan Chen:** designed the study, and, Writing – review & editing, Data curation, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Tristan Grogan:** performed the randomization and, Formal analysis, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Jason S. Lee:** screened and enrolled patients, and performed airway management for all patients, Data curation, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Elaine C. Liew:** screened and enrolled patients, and performed airway management for all patients, Data curation, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Soban Umar:** screened and enrolled patients, and performed airway management for all patients, Data curation, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Dong Ho Shin:** provided logistical support, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Yifang Zhu:** designed the study, and, Writing – review & editing, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication. **Nir N. Hoftman:** designed the study, and, Writing – review & editing, screened and enrolled patients, and performed airway management for all patients, Data curation, All authors had full access to all the data in the study, edited the manuscript, and had final responsibility for the decision to submit for publication.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tacc.2023.101229.

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