A Novel Negative Pressure, Face-Mounted Antechamber to Minimize Aerosolization of Particles During Endoscopic Skull Base Surgery

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BACKGROUND: The COVID-19 pandemic has revealed deficiencies in the adequacy of personal protective equipment (PPE) for healthcare workers. Endoscopic endonasal skull base surgery is thought to be among the highest-risk aerosol-generating procedures for surgeons and operating room personnel.

OBJECTIVE: To validate the efficacy and clinical feasibility of a novel surgical device.

METHODS: A low-cost, modifiable, and easily producible negative pressure, face-mounted antechamber was developed utilizing 3D printing and silicone molding. Efficacy was evaluated using an optical particle sizer to quantify aerosols generated during both cadaver and intraoperative human use with high-speed drilling.

RESULTS: Particle counts in the cadaver showed that drilling led to a 2.49-fold increase in particles 0.3 to 5 μm ($P = .001$) and that the chamber was effective at reducing particles to levels not significantly different than baseline. In humans, drilling led to a 37-fold increase in particles 0.3 to 5 μm ($P < .001$), and the chamber was effective at reducing particles to a level not significantly different than baseline. Use of the antechamber in 6 complex cases did not interfere with the ability to perform surgery. Patients did not report any facial discomfort after surgery related to antechamber use.

CONCLUSION: The use of a negative pressure facial antechamber can effectively reduce aerosolization from endoscopic drilling without disturbing the flow of the operation. The antechamber, in conjunction with appropriate PPE, will be useful during the COVID-19 pandemic, as well as during flu season and any future viral outbreaks.

KEY WORDS: COVID-19, SARS-CoV-2, Endoscopic skull base surgery, Endoscopic endonasal surgery, Aerosol-generating procedure, Negative pressure, Antechamber

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The COVID-19 pandemic has exposed significant insufficiencies in personal protective equipment (PPE), among other failures of the healthcare system. One of the lessons from this recent pandemic is that aerosol-generating procedures (AGPs) put healthcare workers at high risk of infection without adequate protection. Endoscopic skull base surgery (ESBS) involves the use of high-speed, powered instruments in the nasal cavity and nasopharynx, sites of viral colonization by most respiratory pathogens that may become aerosolized at an astonishingly high rate.[1-6]

Early commentary about SARS-CoV-2 and skull base surgery highlighted these risks and offered a practical set of guidelines.[1] Although the dangers of ESBS may have been overestimated initially, concerns about procedural risk persist due to inexperience in the face of a novel pandemic.[6-9] Moreover, the lack of adequate PPE, both in quantity and quality, has driven enterprising physicians to devise novel solutions for protecting healthcare workers, including barriers designed to contain the aerosols produced by patients during AGPs.[10-12]

In this paper, we present an original strategy for reducing the viral exposure of surgeons and operating room personnel using a face-mounted, negative pressure antechamber. The device can

ABBREVIATONS:: **AGP,** aerosol-generating procedure; **ESBS,** endonasal skull base surgery; **OPS,** optical particle sizer; **PPE,** personal protective equipment

FIGURE 1. *Front view of device showing 3D-printed polylactic acid (PLA) frame, transparent acrylic shield, and semicircular instrument port with silicone diaphragm.*

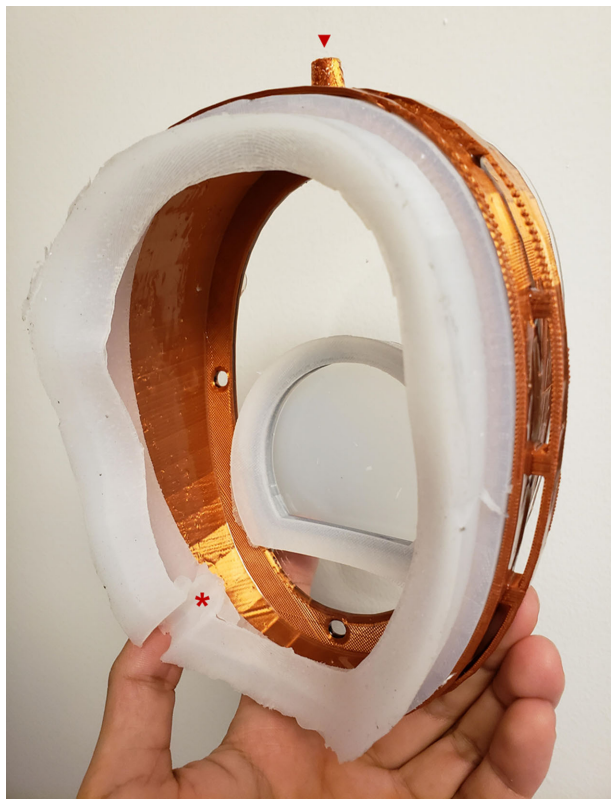

FIGURE 2. *Back view demonstrating suction port (arrowhead) and mold-casted silicone gasket featuring groove for endotracheal tube (asterisk).*

be produced via 3D printing within a few hours, and its efficacy at reducing aerosols has been validated in laboratory studies using an ovine rib model with optical particle counting and high-speed videography/shadowography.[13] In this paper, we extend our validation of this device utilizing particle counting in a cadaver model, as well as particle counting and surgeon assessment in a small group of patients undergoing ESBS.

METHODS

The antechamber (provisional patent EFS ID 39386708, application #63021722 submitted on May 8, 2020) was originally modeled after a biological safety cabinet in a portable format that could be adapted for use in the operating room. The design process and specifications of the antechamber are extensively detailed in our prior publication.[13] Negative pressure is achieved by attaching the assembly to a suction source, and the flexible silicone rim features a cutout for the endotracheal tube to minimize disruption of the negative pressure seal (Figures 1 and 2). The device is attached to the face using elastic hooks, which are secured against a Mayfield headrest.

Iterative changes were made in the design of the antechamber based on surgeon feedback. The first version featured a triangular cutout in the acrylic shield at the level of the nares. The second version improved upon this with a rectangular cutout situated further inferiorly and covered by a silicone diaphragm to maximize aerosol containment. The third prototype included a rounded top to the diaphragm to accommodate larger noses found in acromegaly and a tapered design with a lower profile near the chin to bring instruments closer to the face and nares (Figures 1 and 2). Vertical slits were created in the diaphragm with a surgical blade at the start of surgery to allow for passage of instruments. These were widened during the course of surgery as needed.

Efficacy of the device was assessed utilizing an optical particle sizer (OPS) (AeroTrak 9306, TSI Incorporated; Shoreview, Minnesota) to quantify the production of particles during endonasal surgery under various conditions. This assay was modeled after previously published methods[14] and performed first in a human cadaver and then in the operating room after obtaining Institutional Review Board approval. In the cadaver model, a complete sphenoethmoidectomy, bilateral middle turbinectomy, and posterior septectomy were performed in a fixed, latex-injected human cadaver head. Next, the rostrum of the sphenoid was drilled under controlled conditions utilizing a 4-mm cutting burr at 75 000 rpm. The isokinetic inlet of the OPS was placed approximately 15 cm away from the head, and particle counts were collected every 30 s. Counts were obtained in absence of drilling (baseline), during drilling without the antechamber, and during drilling with the antechamber, with and without the silicone diaphragm. Drilling

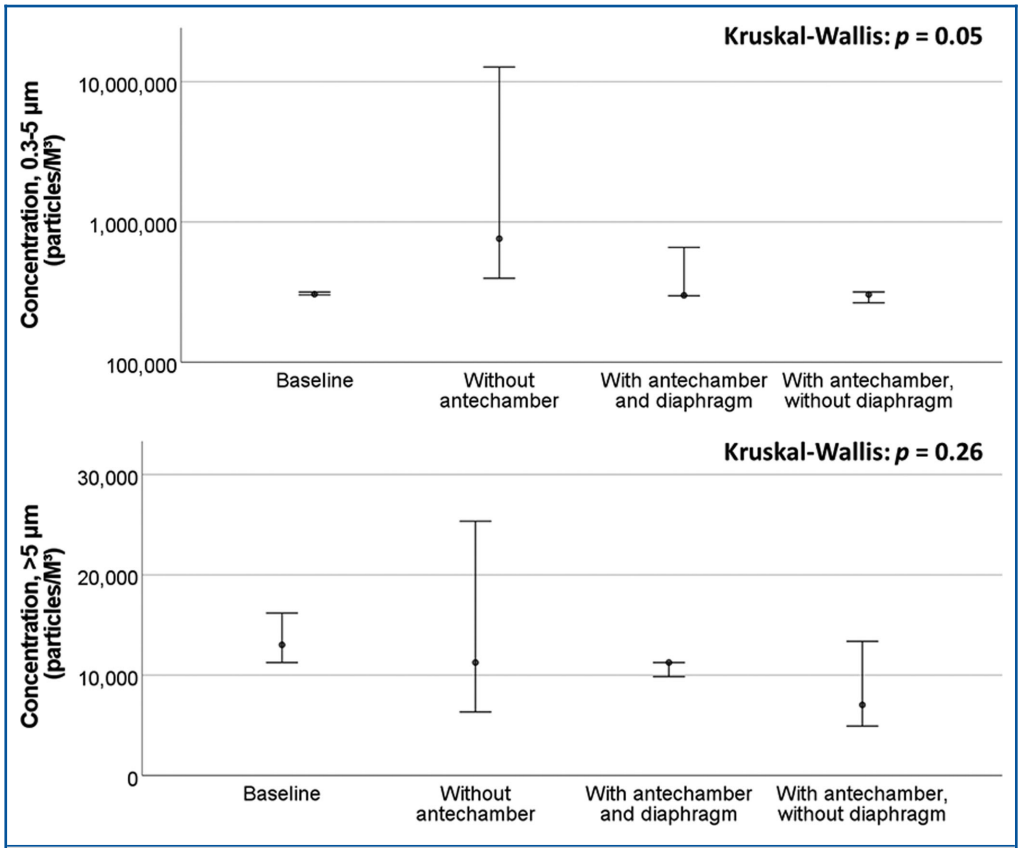

FIGURE 3. *Whisker plot depicting median particle counts during cadaver experiments. Kruskal-Wallis 1-way analysis of variance performed for each particle stratum.*

commenced for 30 s, with a 2-min washout period between measurements, which were repeated in triplicate. For data analysis, particles were stratified by size: 0.3 to 5 μm and >5 μm.

Clinical feasibility and efficacy of the antechamber were then assessed in 6 endoscopic endonasal skull base procedures. All surgeries were scheduled electively and approved by a panel tasked with balancing clinical necessity against the risks of SARS-CoV-2 exposure. Preoperative workup includes screening for COVID-19 symptoms, nasopharyngeal swab testing (if possible, twice within 72 h of surgery), and a temperature check the morning of surgery. None of the patients in this series reported symptoms or had a positive test result prior to surgery. Despite these precautions, full PPE was implemented, including N95 masks and face shields, given the possibility of a false negative test.

The operative setup for endoscopic skull base surgery at our institution has previously been described[15] and includes fixation of the head in pins on a Mayfield head holder, slight flexion of the neck and extension of the head ("sniffing position") and rotation of the head with the chin toward the surgeon, dynamic endoscopy during the approach to the skull base, static endoscopy with an endoscope holder and irrigation sheath for intracranial work, and line-of-sight intraoperative navigation utilizing the Brainlab system (Munich, Germany). Particle counts were collected during endoscopic drilling with a 15°, 4-mm coarse diamond skull base burr for the latter 3 cases. Readings were taken every 30 s to 1 min, and the isokinetic inlet of the OPS was placed as closed to the surgical field as possible without breaking sterility. Drilling was deliberately performed in absence of an intranasal suction to maximize the aerosols propagated and potentially captured by the OPS. Electronic medical records were accessed retrospectively to collect demographic details, operative time, and pathological diagnosis. Patients were also contacted by telephone or directly during office visits between 1 to 2 wk after surgery and queried about potential complications related to use of the antechamber, including facial deformity or discomfort.

Express consent was obtained from patients for intraoperative photography and use of the images for research purposes, along with consent to participate in the study and standard surgical consent. Statistical analysis, including Kruskal-Wallis 1-way analysis of variance with post hoc Mann-Whitney pairwise comparison, was performed using SPSS 26 (IBM, Armonk, New York).

RESULTS

Cadaver Studies

Kruskal-Wallis testing revealed a statistically significant difference ($P = .05$) in the median number of particles 0.3 to 5 μm between the experimental conditions (Figure 3). Drilling of the sphenoid bone resulted in a statistically significant 2.49-fold

TABLE 1. Median Particle Counts During Cadaver Drilling Under Experimental Conditions

		0.3-5 μm		>5 μm	
	N	Median concentration (particles/m^3)	*P* value	Median concentration (particles/m^3)	*P* value
Baseline	20	305 634		13 028	
Without antechamber	3	760 563	**.001**[a]	11 268	.763
Antechamber with diaphragm	3	300 000	1.000	11 268	.196
Antechamber without diaphragm	3	304 225	.514	7042	.094

[a]Statistically significant change compared to baseline.
Mann-Whitney pairwise testing performed for each condition compared to baseline.

TABLE 2. Summary of Clinical Cases

Case	Age	Gender	ASA class	Location	Pathology	Operative time (min)
1	61	F	3	Clival	Keratinizing SCCa	218
2	68	F	2	Sellar/suprasellar	Pituitary adenoma	172
3	51	F	3	Sellar	Chiasmal descent and empty sella	168
4	69	M	2	Petrous apex	Chordoma	328
5	60	F	2	Sellar/cavernous sinus	Pituitary adenoma	296
6	53	M	2	Sellar	Rathke's cleft cyst	219

TABLE 3. Median Particle Counts During Endoscopic Skull Base Surgery

		0.3-5 μm		>5 μm	
	N	Median concentration (particles/m^3)	*P* value	Median concentration (particles/m^3)	*P* value
Baseline	20	15 548		1413	
Without antechamber	3	577 739	**<.001**[a]	2297	**.027**[a]
Antechamber with diaphragm	3	22 261	.133	1060	.671
Antechamber without diaphragm	3	17 667	.368	0	.007

[a]Statistically significant change compared to baseline.
Mann-Whitney pairwise testing performed for each operative scenario compared to baseline.

increase ($P = .001$) in particles 0.3 to 5 μm compared to baseline on post hoc testing (Table 1). Use of the antechamber led to return of counts to baseline, both with and without the presence of the silicone diaphragm (Table 1). In contrast, there was no statistically significant difference in the number of particles >5 μm ($P = .255$) under the same set of conditions.

Human Studies

Based on its efficacy in the cadaver model, the antechamber was utilized for ESBS in 6 live patient cases. Table 2 summarizes pertinent clinical details and operative data. None of the 4 surgeons reported significant disruptions by the antechamber in their ability to perform surgery, and none of the patients reported any complications related to use of the device. Summary data from intraoperative particle counts are displayed in Table 3 and Figure 4. There was a statistically significant ($P < .001$) difference in median particle counts between baseline and various drilling conditions. Compared to baseline, endoscopic drilling with the face uncovered led to a 37-fold increase in the number of particles 0.3-5 μm ($P < .001$). Use of the antechamber led to a return in the number of detected particles down to levels not significantly different from baseline counts, both with and without the use of the diaphragm ($P = .13$ and .37). For particles >5 μm, compared to baseline, endoscopic drilling with the face uncovered led to a 1.6-fold increase in the number of particles ($P = .03$). Use of the antechamber was associated with a decrease in the number of detected particles down to baseline ($P = .67$) with the diaphragm and to levels significantly lower than baseline without the use of the diaphragm ($P = .007$).

DISCUSSION

The COVID-19 pandemic has exposed the heretofore underappreciated risks of viral aerosolization during ESBS, not to

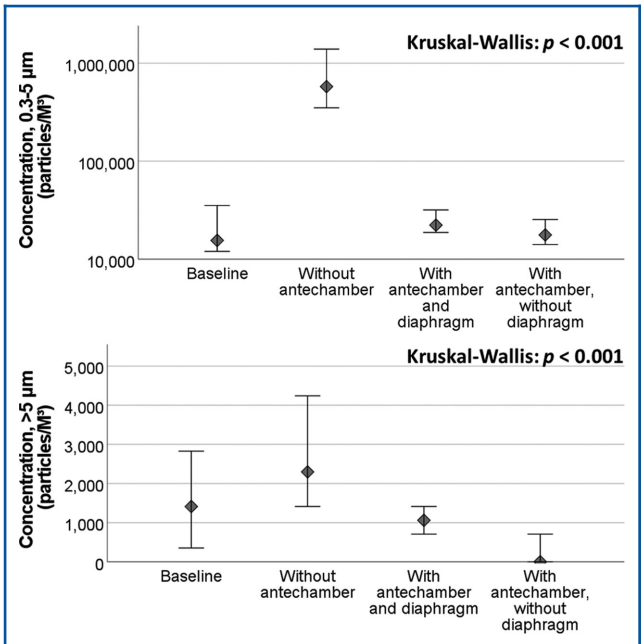

FIGURE 4. *Whisker plot depicting median particle counts during endoscopic skull base surgery. Kruskal-Wallis 1-way analysis of variance performed for each particle stratum.*

mention other AGPs including intubation, tracheotomy, and sinus surgery. In this paper, we provide additional laboratory and, finally, clinical validation for a device that can be utilized to effectively reduce the aerosolization of particles during ESBS with high-speed drilling. This study furthers our initial publication on the device's conception and laboratory validation.[13] Its universal implementation, in conjunction with appropriate PPE, could have a dramatic impact on iatrogenic contagion of healthcare workers during highly aerosolizing procedures not only during viral pandemics but also during seasonal influenza outbreaks.

Our work builds on recent research[10,14] demonstrating that use of a high-speed drill corresponded to the greatest elaboration of aerosols. To mitigate viral transmission risk, some have proposed the application of povidone-iodine to decrease the viral load in the nasal cavity and nasopharynx[16] and the use of negative pressure rooms to limit spread in the hospital setting.[4,8,17] Other devices that have been developed include intubation covers[12] or boxes[11] and modified surgical and N95 masks[10,14] with a flexible port to allow passage of an endoscope. These share the strategy of physically shielding the healthcare provider from the aerosols generated during intubation or endoscopy. Our antechamber, in contrast, is a compact, portable solution that actively removes virus-containing aerosols from circulation and, thereby, also reduces the risk of secondary transmission, including fomite transmission. Furthermore, as demonstrated in our clinical cases, it is feasible for use during surgery and does not interfere with line-of-sight image guidance systems or surgical instrumentation. Its design consists of components that are easily reproducible, modifiable, and affordable, translating to rapid implementation, adaptability, and cost savings. A similar device in publication requires additional components, including a laparoscopic trocar, which may limit the reach of certain instruments and has not been validated in live patient use.[18] Finally, placement of a suction device in the nasal cavity or in the nasopharynx has been shown in Vitro to be an effective mitigation strategy for aerosols generated during endonasal surgery.[19] However, this strategy is prone to failure if the suction is not actively maintained in appropriate position, specifically away from tissue that could potentially occlude the tip.

The antechamber was effective in Vitro and in Vivo at reducing the number of aerosolized particles, particularly in the sub-5-μm range. Interestingly, the open-face instrument port did not correspond to a greater number of particles detected, suggesting that negative pressure, in the strict sense, is not responsible for the effectiveness of the antechamber. This is supported by intraoperative measurements demonstrating negative flow within the antechamber in absence of measurable negative pressure. Active diversion of particles out of the antechamber may be chiefly responsible for the reduction in particles detected externally, similar to the mode of action of biosafety cabinets. Based on our data, aerosols elaborated during endoscopic drilling were primarily between 0.3 and 5 μm, and use of the antechamber led to a reduction of particles detected in this size range. The predominance of particles generated and detected within the sub-5-μm range may explain the seemingly disparate results for particles >5 μm between the cadaver and live patients. Other possible explanations include differences between the sterile environment of the operating room and the comparatively particulate-rich setting of cadaver dissection lab, as reflected in the dramatic discrepancy in baseline counts, as well as inherent variability in aerosolization potential of formalin-fixed vs live tissue. Overall, endoscopic drilling appeared to generate few particles >5 μm, which simply may have limited our ability to detect meaningful differences in this range.

The instrument used to quantify particle size and number in our study has a reported detection range spanning particles 0.3 to 25 μm in size. The SARS-CoV-2 virus measures 0.07 to 0.09 μm, raising the theoretical possibility that particles smaller than the minimum threshold for detection in our study could have been generated and leaked by the antechamber. However, the primary mode of transmission for SARS-CoV-2 and other respiratory viruses is via droplets and aerosols. Indeed, one study[20] detected SARS-CoV-2 RNA copies in both aerosols in 2 size ranges (0.25-1 μm and >2.5 μm). Another[21] estimated the minimum aerosol size for conveying the virus to range from 0.4 to 42 μm, with size inversely proportional to aerosol suspension time. Moreover, efficacy of our device in reducing aerosols smaller than 5 to 10 μm could have implications for mitigating the transmission risk for influenza, which may be propagated in

aerosols $<2.5\ \mu$m,[22] as well as future pandemic viruses as yet unencountered.

Limitations

Because of the quantitative nature of our study and presumably COVID-negative cohort, we are unable to verify that particles generated during ESBS and measured by the OPS are in fact capable of transmitting SARS-CoV-2. Another limitation of our research is the inclusion of a small number of patients. Although we did not encounter any ergonomic or practical barriers to use of the device in our 6 cases, utilizing the chamber in a larger number of patients and clinical contexts will more rigorously reveal any deficiencies in design and opportunities for improvement. As noted in our methods, the device was not tested during dynamic endoscopy with 2 surgeons operating simultaneously.

CONCLUSION

ESBS in the time of COVID-19 can be performed more safely with strategies to eliminate aerosols that may spread SARS-CoV-2. We demonstrate efficacy and clinical feasibility of a portable, negative pressure antechamber designed to decrease viral propagation at the source during AGPs. This novel device is not intended to obviate the need for PPE, but rather represents an additional line of defense for surgeons and healthcare providers during the current pandemic. Universal use of this device may also reduce transmission of influenza or other heretofore undescribed viruses.

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Disclosures

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article.

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