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The FEES box: A novel barrier to contain particles during aerosol-generating procedures

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ABSTRACT

Purpose: Due to the COVID-19 pandemic, aerosol-generating procedures (AGPs) such as flexible endoscopic evaluation of swallowing (FEES) have been deemed high-risk and in some cases restricted, indicating the need for additional personal protective equipment. The aim of this study was to erect and study a protective barrier for FEES.

Materials and methods: A PVC cube was constructed to fit over a patient while allowing for upright endoscopy. A plastic drape was fitted over the cube, and the protective barrier was subsequently named the "FEES Box." Three different particulate-generating tasks were carried out: sneezing, coughing, and spraying water from an atomizer bottle. Each task was completed within and without the FEES Box, and particulate was measured with a particle counter. The average particles/L detected during the three tasks, and baseline measurements, were statistically compared.

Results: Without the FEES Box in place, the sneezing and spraying tasks resulted in a statistically significant increase in particles above baseline ($p < 0.001$ and $p = 0.004$, respectively); coughing particulate never reached levels significantly higher than baseline ($p = 0.230$). With use of the FEES Box, there was no statistically significant increase in particles above baseline in any of the three tasks.

Conclusion: The FEES Box effectively contained particles generated during sneezes and an atomizer spray. It would also likely mitigate coughing particulate, but coughing did not generate a significant increase in particles above baseline. Further research is warranted to test the efficacy of the FEES Box in containing particulate matter during a complete FEES procedure.

1. Introduction

The COVID-19 pandemic has brought about a dramatic shift in the way specific medical procedures are conducted in healthcare settings, especially for speech-language pathologists (SLPs) who must routinely evaluate patients' swallowing function while being in close proximity to the patient for an extended period of time during droplet-generating and aerosolizing tasks: a high-risk situation. Recent studies have demonstrated that droplets are able to carry the COVID-19 virus when an individual coughs or sneezes [1–3] and that any aerosolized particles generated by speech may remain suspended in the air for several hours and travel over a range of distances depending on the ambient conditions [4–7].

International organizations such as the Dysphagia Research Society have proposed guidelines specifying which assessments specific to SLPs are high-risk for potentially aerosolizing COVID particles from aerosol-generating procedures (AGPs) [8]: laryngoscopy, stroboscopy, transnasal esophagoscopy, cough reflex testing, and flexible endoscopic evaluations of swallowing (FEES). During FEES, after insertion of the nasal endoscope, the patient is given food and liquid while the endoscopist visualizes the laryngopharynx. FEES is of particular interest to SLPs in this context, as it is routinely used to evaluate the swallowing function of acutely ill patients, including those with COVID, to determine swallowing physiology and safety [9,10]. FEES could put clinicians at risk in more than one way: the endoscopy procedure itself, the extended amount of time in close proximity to the patient – more so than

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other endoscopy exams, and a higher chance of the patient speaking, coughing, or sneezing [11]. Further, given that complications from COVID-19 typically present with cough, respiratory distress, in addition to potential laryngeal dysfunction from intubation, COVID patients are likely to present with oropharyngeal swallowing dysfunction and aspiration [12]. Being able to effectively evaluate and manage swallowing difficulties in this population has proven difficult given the recommended precautions for personal protective equipment, but FEES would be the preferred instrumental evaluation. In fact, the Centers for Medicare &Medicaid Services do not recommend delaying endoscopic procedures in those with COVID-19 [13].

To reduce the risk of COVID-19 spread, guidelines have been established regarding the proper personal protective equipment (PPE) during swallowing evaluations [14] but to date, no published methods could be found that provided increased protection to a clinician during a swallowing evaluation. A need has arisen for a barrier that is able to limit the droplets and aerosol generated during a dysphagia evaluation without compromising the need for an instrumental exam. The purpose of this study was to propose a novel device termed the FEES Box that can reduce the spread of particles during a FEES exam. We aimed to answer the question: Does the FEES Box sufficiently contain particulate matter during three common particulate-generating tasks? Three clinical scenarios were tested: sneezing, coughing, and atomizer spraying. We hypothesized that the FEES Box would significantly reduce the number of particles detected by a particle counter in all three particulate-generating scenarios.

2. Materials and methods

2.1. Equipment

In order to quantify the aerosols, a PCE-PCO 1 particle counter was used (Fig. 1) [15]. This device can detect particles ranging in size from 0.3 to 25 μm utilizing a laser and optical sensor to count how many particles are collected inside by an internal pump. Each measurement sample lasted 21 s, which is equivalent to 1 L of air sampled and delivered into the device.

For each condition tested, the counter was placed on a tripod at mouth level of the seated subject (55 cm off the ground) and 15 cm in front of the mouth to resemble a realistic distance between provider and patient (Figs. 2, 3A, B).

The FEES Box (Fig. 4A, B, C) is a 23 × 26 × 25 inch cube frame made of ¾ inch PVC pipe and covered with a plastic equipment bag. This plastic cover serves as the barrier. Four, 6-in. arm slits were created on opposite sides of the FEES Box cover and secured with Tegaderm. These slits allow the SLP and an assistant to insert their arms into the slits with increased stability at the slits and better closure around the wrists.

Fig. 1. PCE-PCO 1 particle counter.

2.2. Study design

All experiments in this study were performed in a dedicated clinic examination room (80 ft^2) equipped with one standard hospital ventilation system that exchanged the air on average six times each hour. The door to the clinic room was kept closed during the experiments and the number of people and movement of people inside the room was kept to a minimum and not changed throughout the protocols. Three study clinicians were in the room, one of whom operated the particle counter and collected data. The FEES Box was placed over the participant who was seated in the clinic examination chair (Fig. 3A, B). The FEES Box rested on the armrests of the chair and was secured to the headrest of the chair using an attachable PVC hook (Fig. 2). The participant maintained a seated position with the particle counter 15 cm from the participant's mouth.

The particle counter was used to take 8 baseline measurements of the room before any scenarios were tested. The baseline measurements were completed just once at the beginning of the entire experiment. The particle counter functions via a pump that intakes air in a sample that was programmed to last 21 s, and there was a 6-s delay between successive samples.

When collecting data, the general sequence of data collection taken proceeded as follows:

1. 4 pre-test samples
2. 1 sample with the scenario performed with the FEES Box
3. 4 pre-test samples
4. 1 sample with the scenario performed without the FEES Box

For the sneezing and atomizer spraying scenarios, the above sequence was repeated 8 times. The sneeze task was carried out in the same way for each sample: a large inhale followed by a forceful, singular sneeze. The spray task was a single pulse from the atomizer spray. For the coughing task, the above sequence was repeated a total of 12 times: four samples were taken from three different healthy female participants to assess if cough variability from person to person would yield different results. The coughing task was carried out in the same way across each of the three participants: a large inhale followed by a "strong" series of

Fig. 2. FEES Box set up on clinic chair for experimental design.

Fig. 3. A, Participant set-up without FEES Box. B, Participant set-up with FEES Box.

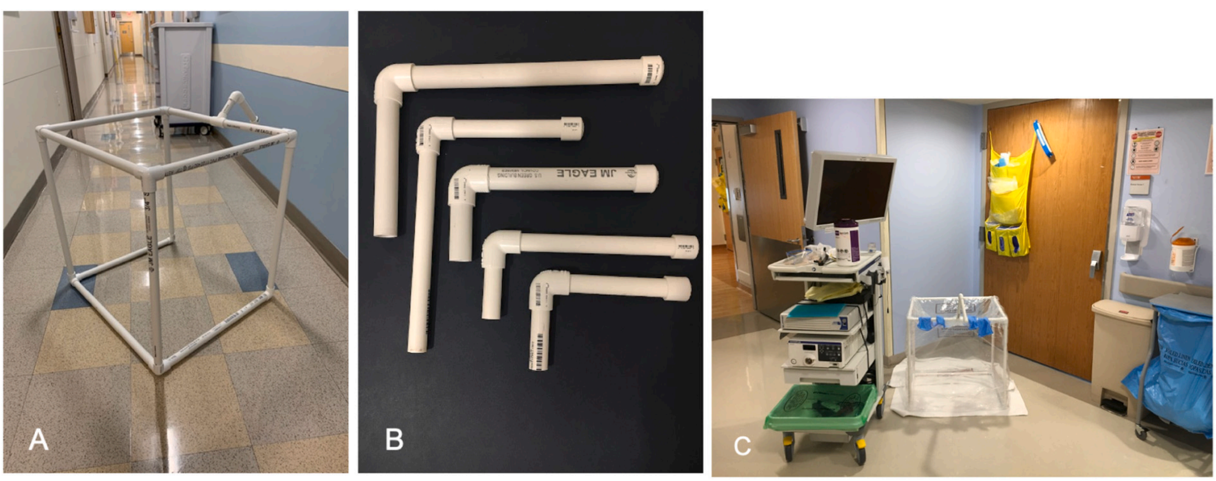

Fig. 4. A, FEES Box frame. B, Various hook attachments for different bed and chair types. C, FEES Box frame with cover and hook, next to FEES cart on hospital unit.

three forceful coughs, one immediately after the other. A very small sip of water was taken prior to each coughing series as a means to moisten the mouth, prevent drying out, and maintain the same level of oral moisture prior to each coughing series. Following the completion of all tasks, the FEES box was lifted off of the participant and placed on the floor. The plastic was then pulled off of the PVC piping from the top and center, in an umbrella-like pulling fashion.

2.3. Statistics

The average particles/L detected was calculated during the various clinical scenarios as well as baseline measurements. The averages of each clinical scenario were then compared to the respective baseline averages using two sample *T*-Tests. A 2-way ANOVA test was used to test for any significant differences between the three different participants in the two test conditions for the coughing samples. Additionally, a 95% confidence interval was calculated using Microsoft Excel.

3. Results

3.1. Sneezing

For the scenarios involving simulated sneezing, a total of 80 measurements were collected using the particle counter. The 0.3uM particle counts were recorded and the average baseline level was 422 particles/L (Fig. 5). When the subject sneezed within the FEES box, an average of 421 particles/L were recorded but this was not statistically significant from baseline ($p = 0.951$). When the subject sneezed without the FEES box, an average of 4251 particles/L were recorded, and this did constitute a significant increase above baseline ($p < 0.001$).

3.2. Coughing

For the scenarios involving simulated coughing, a total of 120 measurements were collected using the particle counter, 40 from each participant. Table 1 displays the average particles for each participant.

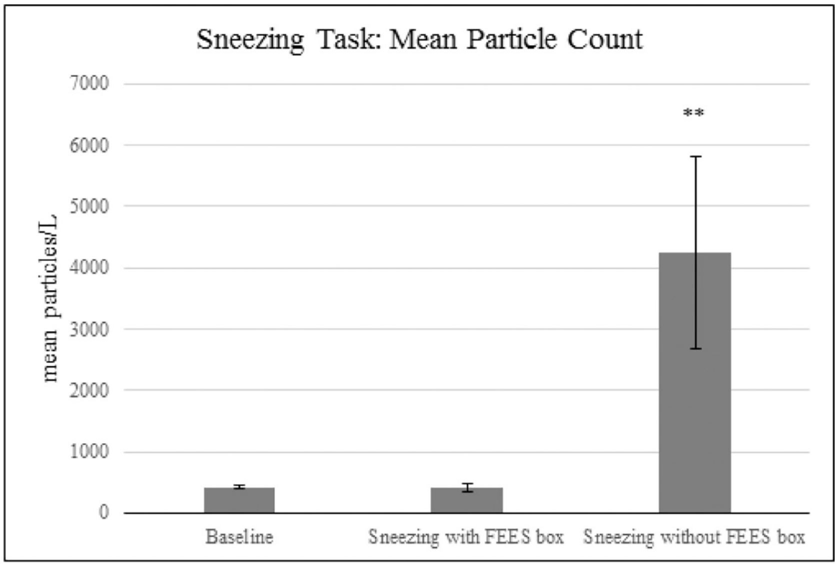

Fig. 5. The mean particle count during simulated sneezing with and without the FEES box. ** Indicates a statistically significant difference from baseline at the 5% level. Error bars represent a 95% confidence interval.

Table 1
Particles from the four-cough series with and without the FEES Box in place.

	Coughing within FEES Box (average particles/L)	Min	Max	Coughing without FEES Box (average particles/L)	Min	Max
Participant 1	298.75	145	476	495.75	281	813
Participant 2	408.25	316	496	388.25	177	577
Participant 3	185	95	252	335	125	480
Average	*297.33*	*185.3*	*408*	*406.33*	*194*	*623*

The 0.3uM particle counts were recorded and the average baseline level was 335 particles/L (Fig. 6).

When the subject coughed within the FEES box, an average of 297 particles/L were recorded but this was not statistically significant from baseline ($p = 0.368$). When the subject coughed without the FEES box, an average of 406.3 particles/L were recorded, and this too did not constitute a significant increase above baseline ($p = 0.230$). The ANOVA comparing the three participants ($p = 0.102$) in the two test conditions ($p = 0.151$) was not significant and neither was their interaction ($p = 0.359$).

3.3. *Spraying*

For the scenarios involving spraying with an atomizing spray bottle, a total of 80 measurements were taken using the particle counter. The 0.3uM particle counts were recorded and the average baseline level was 371 particles/L (Fig. 7). When the subject sprayed the spray within the FEES box, an average of 384 particles/L were recorded but this was not statistically significant from baseline ($p = 0.817$). When the subject sprayed the spray without the FEES box, an average of 24,991 particles/L were recorded, and this did constitute a significant increase above baseline ($p = 0.004$).

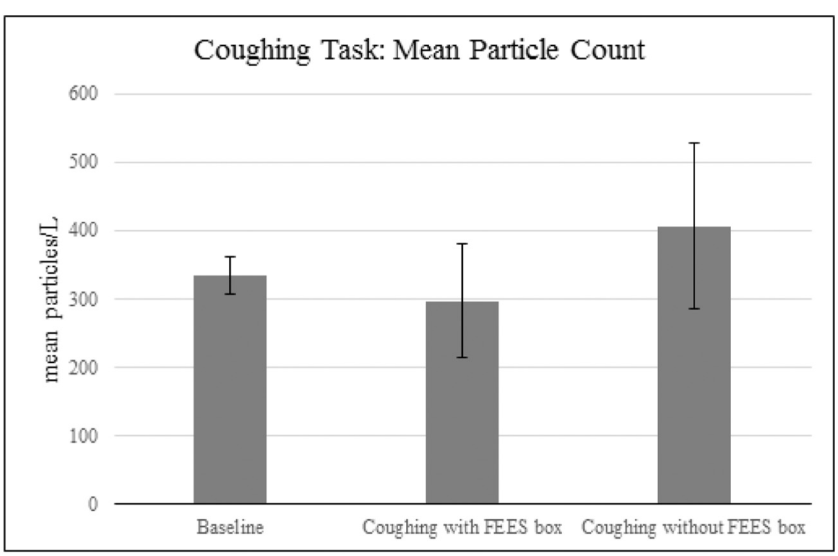

Fig. 6. The mean particle counts during simulated coughing with and without the FEES box. There was no statistically significant difference in either condition from baseline at the 5% level. Error bars represent a 95% confidence interval.

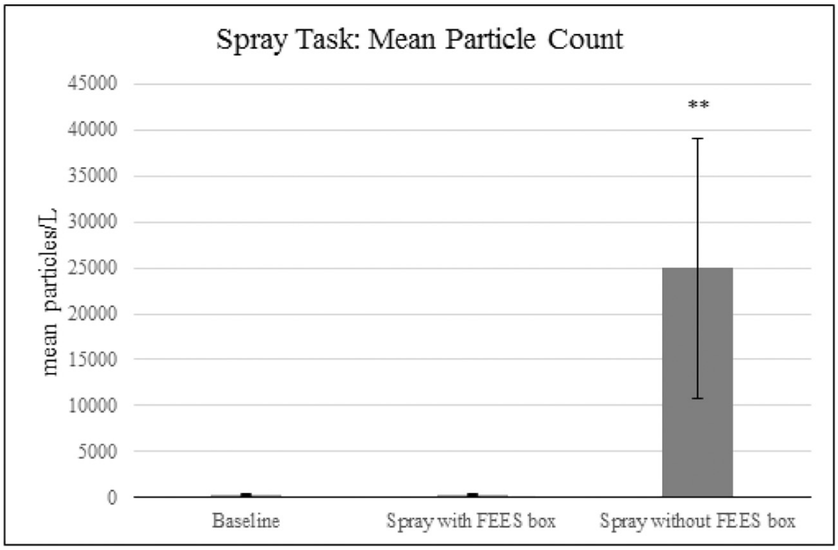

Fig. 7. The mean particle counts during simulated coughing with and without the FEES box. ** Indicates a statistically significant difference from baseline at the 5% level. Error bars represent a 95% confidence interval.

4. Discussion

In the setting of the COVID-19 pandemic, the need has arisen to emphasize personal protective equipment and barriers for AGPs [16–19]. This is particularly salient for SLPs who must perform FEES to assess the swallowing ability of COVID patients. The results of this proof of concept study reveal that the FEES Box can serve as an effective protective barrier to reduce the spread of particulate matter under three particulate-generating conditions: sneezing, coughing, and spraying with an atomizer.

A cough was believed to be a particular concern for spreading particulate matter [11,12,14,20,21] and was of notable clinical relevance to the present study given that dysphagia evaluations may involve frequent spontaneous or cued coughing. In this study, however, no statistically significant increase in particulate matter from baseline was generated during the cough tasks, regardless of the presence of the FEES Box. While coughing did not significantly increase particle counts from baseline, it would be erroneous to dismiss coughing as a potential contaminating action that could put providers at risk. After all, COVID-19 has been shown to transmit via tasks much lesser than a strong cough such as singing [7,20]. Further, coughing is one of the main symptoms of COVID-19, and dysphagia evaluations nearly always involve some form of coughing; the Part 1 speech tasks of a traditional FEES exams [22] include a volitional cough to assess overall strength and glottic closure, during which increased particulate will be produced. If the patient is sensate to aspiration, they may produce a strong spontaneous cough and potentially eject a myriad of droplets and aerosols.

Other studies have found that sneezing, as compared to risk from an endoscopic exam itself, increases risk of particulate spread [23,24]. In this study, the sneeze tasks did result in a statistically significant increase in particles counted from baseline. This finding is consistent with studies that report that sneezes travel farther, are more powerful and produce a larger number of droplets (approximately 40,000) than a cough (approximately 3000) [25–28]. The FEES Box effectively prevented the significant increase in particles counted. While sneezing is not an elicited task during FEES, some patients may sneeze in response to scope insertion or removal. Sneezing could also be a symptom of a viral infection and therefore protection for the clinician would be necessary. Newer literature in the advent of COVID-19 has assessed the protective nature of various forms of mask PPE and not all apparent forms of masks effectively contain a sneeze: thin masks made of T-shirt material less than 300 threads per inch reduced the sneeze projection from roughly 8 ft to only 4 ft [29,30] and, more concerning, Plocienniczak et al. [31] found that sneezing with an N95 in place still produced a significant number of particles above baseline levels. The FEES Box would protect a clinician and others in the room from excess particulate produced from a sneeze.

Numerous studies have focused on particles generated from breathing, which are smaller in size, fewer in amount, and projected at lower velocities than a sneeze or cough. Contested debate is ongoing about whether COVID-19 is transmitted via the very small particles that are aerosolized [32]. The present study was not able to assess the number of particles smaller than 0.3 μm, due to limitations of the particle counter. However, it is notable that COVID-19 is estimated to be around 0.125 μm and these virion particles themselves tend to attach to larger particles ranging from 0.5–10 μm, which we could accurately measure in this study.

The topical nasal anesthetic or decongestant that is commonly used for a FEES was one of the testing scenarios and while the spray produces tiny particles that remain airborne, we could only measure the larger droplet particles. It could be assumed that should this topical spray be applied to the nasal mucosa of a COVID-19-infected person, the risk for aerosolization of the virus would be great. However, this was not directly studied. The FEES Box appears to be effective at containing larger droplets classified as >10 μm, that would be expected to be produced from any nasal spray or from in dysphagia-related tasks like chewing or coughing, large projections of sputum or food or drink.

The FEES Box proved to be an effective tool in containing the spread of particulate matter. These results should be taken into account when conducting endoscopy procedures that have the potential for generating aerosol or particulate, particularly Speech-Language Pathologists who may need a protective barrier when performing a FEES evaluation. However, our study contains several limitations warranting mention. First, during our investigation, we were not able to elicit a spontaneous cough to replicate the robust coughing that could be produced from an aspiration event or account for different types severities of cough to mimic the variability within patients.

Despite our efforts, the coughs produced in our study may not represent the range of coughing patients might exhibit during FEES. Further, we did not study flow rate or flow direction of the coughs produced or measure the area of mouth opening during a coughing process. Analysis of cough dynamics in future FEES Box trials could provide information used to help control the spread of infected aerosolized particles.

We used the particle counter to measure a *single series* of particle counts, or the amount of particulate generated for a single task: pre-test scenarios or FEES Box scenarios. We did not use the particle counter to measure the amount of particulate generated for the entire duration of the tasks. Cumulative particle counts could give an indication of the density of particle accumulation within the FEES Box, or essentially, the concentration of the viral load if the particles measured were assumed to be infected particles. Additionally, the increase in familywise error rate across the reported statistical analysis was not controlled.

The testing conducted with the FEES Box was primarily designed to show proof of concept that such a barrier type could be effective. However, the specific clinical scenarios tested in this study were controlled and may not be generalizable to all real-world presentations; for example, a patient's severe coughing episode may vary from a series of typical coughs from a healthy person). Further, while the intention in developing this box was to use it as a barrier for FEES, the findings of this study were for specific tasks only and not for an entire FEES exam.

Furthermore, the FEES Box was designed and tested in an outpatient clinic environment. The hooks that were designed to attach to the FEES Box held the box in place when the participant was seated in a clinic examination chair. While hooks of various sizes were created for the FEES Box to accommodate different examination chairs or mattress depths (Fig. 4B), testing within an inpatient hospital room was not conducted in this study. The FEES Box also has not yet been designed or tested for use with patients who are wheelchair bound. We also did not test the particulate spread after doffing the box. However, each task contained a pre-test air sample, which would have contained any particulate from the prior tasks' doffing effect. None of the pre-test values were significantly higher than baseline, suggesting that doffing did not disperse a significant amount of measurable particulate into the air.

Future research should assess the efficacy of the FEES Box in containing particulate matter when conducting a complete FEES evaluation, including speech tasks, swallowing of food and liquid as well as potential coughing and gagging, and insertion and removal of the nasal endoscope.

5. Conclusions

The innovative protective barrier called the FEES Box is effective in reducing the spread of particulate and could reduce risk of spread of potentially infectious particulate matter during endoscopy. Utilization of the FEES Box would improve safety for the endoscopist and others while continuing to provide a high level of dysphagia care under strict droplet precautions. The FEES Box is an inexpensive and effective way to achieve those goals.

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None.

Declaration of competing interest

All authors declare they have no financial, consultant, institutional, or other relationships that may lead to a bias or conflict of interest.

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