Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Mitigating the spread of COVID-19 during extubation: Assessing the impact of a barrier device

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ABSTRACT

COVID-19 is a novel virus spread via airborne particles. Given the inherent risk to the anesthesia provider, intubation and airway management guidelines have been recently established. Various studies have been published advocating and detailing the results of different intubation devices designed to decrease the number of airborne particles. Currently, little literature exists regarding devices designed to mitigate the spread of COVID-19 airborne particles during extubation. The purpose of this prospective *in situ* simulated manikin study was to measure the effectiveness of an aerosolized containment device during passive (deep) and forced (simulated coughing) extubation. Airborne particles were measured at the 0.3, 0.5, 1, 2, 5, 10-micron level. Statistically significant decreases were seen with the use of a barrier device during both passive and forced extubation.

1. Introduction

The risk of spreading COVID-19 via aerosolization has been well documented.[1–5] Published studies have identified high concentrations of the COVID-19 virus in airborne particulate samples of 1–4 microns.[6,7] Additionally, COVID-19 has been discovered in airborne particles of > 5 μm which quickly "settle" on surfaces due to their size.[6,7] Biological aerosolized droplets produced during sneezing or coughing measure approximately 1 to 5 μm in size and can travel 3 to 6 feet from its source.[6]

Recommendations related to intubation and anesthetic management of COVID-19 patients have recently been established.[8] Most clinical guidelines focus primarily on mitigating these dangers during the intubation procedure by advocating for the avoidance of coughing on induction prior to manipulation of the patient's airway.[9–11] The majority of literature focuses on techniques, materials, and innovative devices aimed at decreasing exposure to aerosolized particles during intubation.[12–16]

Extubation is also associated with coughing and is an aerosol generating procedure.[10,17] However, consensus guidelines surrounding extubation of COVID-19 patients have yet to be established.[17] Current recommendations include extubating a patient in a negative pressure room, limiting orotracheal suctioning, and placing a sealed mask over the patient's face during and after the extubation.[17–19] Barrier devices aimed at reducing exposure to aerosolized particles during extubation seem to mimic those devices used during intubation. Plastic drapes, extubation "boxes," and plexi-glass hoods have been described with varying degrees of impact.[20–23] To date, there are a limited number of studies aimed at measuring the effectiveness of an aerosol containment device specifically designed for extubation of a COVID-19 patient.

The SAM Guard (RTM Medical LLC, Huntingdon Valley, Pennsylvania) is an airway device designed to capture airborne particles upon removal of an endotracheal tube or laryngeal mask airway. Designed as a single use, disposable, non-invasive device, the SAM Guard is a sanitary endotracheal tube cover consisting of a patient mouth cover as well as a continuous sleeve.

2. Methods and design

This was a single-center, prospective non-blinded *in-situ* manikin simulation study performed at a community hospital in Huntingdon Valley, Pennsylvania. The purpose of this study was to measure the effectiveness of an aerosolized containment device during passive (deep) and forced (simulated coughing) extubation. The use of one aerosol barrier device, specifically the SAM Guard, was compared to a lack of aerosol barrier devices.

The simulation was performed in a self-contained, operating room (OR) measuring 21 feet by 21 feet by 9 feet high. The room was pressure-equilibrated at positive pressure, with an air rate exchange of 40 air changes per hour. Operating room doors were closed for the duration of the study with volunteers enclosed inside the OR room.

A Laerdal Airway Management trainer (Laerdal Medical, Stavanger,

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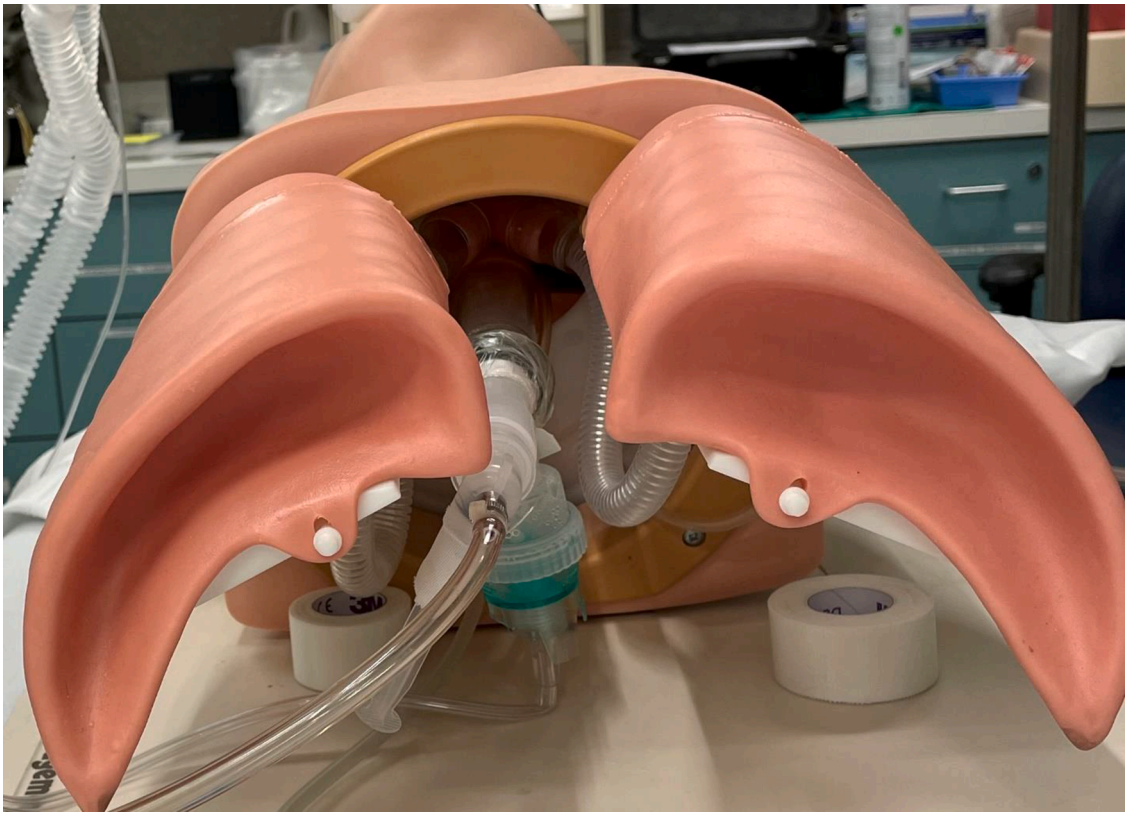

Image 1. Initial setup.

Norway) was used to simulate endotracheal extubation. To simulate aerosolization, 5 ml of saline was nebulized at 6 liters/min using a standard Hudson RCI 'Micro Mist' Small Volume Nebulizer (Teleflex, Wayne, PA) was attached to the base of the manikin (Image 1).

To simulate passive extubation, oxygen was delivered via the nebulizer at a rate of 6 L/min. Given the wide range of outcomes and lack of definitive quantification regarding the true force of a human cough, coughing during extubation was simulated at 5 psi via use of a jet ventilator "Safety Blow Gun" (Coilhose Pneumatics, Middlesex, NJ).[24–26] The simulated coughs were delivered at a rate of 5 psi every 2 s for the first 10 s.

To measure the number of airborne particles in the environment, a Fluke 985 airborne particle counter (Fluke Corporation, Everett, WA) was positioned on a Mayo stand with a pre-set height of 48 inches. The Fluke 985 was measured to be 14.5 inches above the simulated patient's head, for a total operating height of 62.5 inches (Image 2). This height was maintained throughout the duration of the experiment.

The airborne particle counter, typically used for indoor and outdoor air quality testing in HVAC/R, cell sorting analysis, as well as facilities management, uses an isokinetic probe sample inlet and measures air particles via a laser diode and photo detector.[27–30] This device counts airborne particles of 0.3, 0.5, 1.0, 2.0, 5.0, and 10 μm respectively.[27–30] Per the manufacturer, the device has a 50% accuracy for particles at 0.3 μm, but 100% accuracy for particles measuring 0.45 μm or higher.[31] The Fluke 985 was zeroed per manufacturer guidelines prior to conducting the study and a baseline airborne particle reading of the OR was obtained.

The experiment was divided into two groups: Group 1 (passive extubation) and Group 2 (forced extubation). Each group was then subdivided into (A) extubation without SAM barrier device and (B) extubation with SAM barrier device. Each subgroup underwent 10 separate 1 min simulated extubation trials, for a total of 40 experimental trials. The nebulization was paused between each trial and particle count was allowed to passively return to its baseline reading. Particle count for each 1 min interval was recorded. To limit cross contamination and allow for accurate airborne particle measurement, personnel flow was kept to a minimum as volunteers were not allowed to leave the operating room while the experiment was being conducted. All volunteers were required to wear N95 masks and were instructed to remain silent during the experiment.

For all subgroups, prior to the start of nebulization and subsequent particle measurement, the Laerdal Airway Management trainer was intubated via a MAC 3 blade with a 7.0 cuffed Shiley oral endotracheal tube (Covidien LLC, Mansfield, Massachusetts) and the cuff was inflated with a volume of 5 ml of air. The endotracheal tube was then secured with paper tape at 21 cm at the mannikin's lips and connected to the Drager Fabius GS premium anesthesia machine (Draeger Inc, Telford, Pennsylvania). The Fluke 985 airborne particle counter was then turned on, followed by the nebulizer prior to removal of the endotracheal tube. Standardized extubation for all subgroups occurred 15 s after the initiation of the nebulizer and consisted of deflating the endotracheal tube cuff and removing the endotracheal tube.

For groups 1 and 2A, the anesthesia mask and circuit was applied 10 s after the manikin was extubated. These stayed in place for the remainder of the 1 min trial and were then subsequently removed.

For groups 1 and 2B, the SAM Guard barrier device was left in place resting over the manikin's nose and mouth with the endotracheal tube contained in the sleeve for 10 s following extubation. The barrier device was then removed and discarded, in exchange for the anesthesia mask and circuit which remained for the duration of the 1 min trial (Image 3).

The expected outcome was a reduction in passive and forced post extubation particle rates following the implementation of SAM Guard. Categorical data was summarized using percentages and counts. Measurement data was analyzed via the one tailed t-test two sample assuming unequal variances to determine statistical differences between the preintervention (Groups 1 and 2A) and postintervention (Groups 1 and 2B).

Both a null and alternative hypothesis was created. The null

Image 2. Position of FLUKE monitor.

hypothesis stated that application of the SAM Guard barrier device during simulated extubation (either passive or forced) will not cause a decrease in airborne particles. The alternative hypothesis stated that SAM Guard application will result in a decrease in airborne particles. All raw data were checked for errors and analyzed using a spreadsheet (Excel, Microsoft) with significance determined as $P < 0.05$. To help decrease the likelihood of a type 1 error, a 5% level of significance (an α of 0.05 was selected) and 95% confidence intervals was used.

3. Results

Results from each group were analyzed based on particle size pre-and post-intervention (Table 1).

Based on the information from Table 1, application of the SAM Guard in Group 1B resulted in an overall decrease of 95% of all airborne particles when compared to Group 1A. Respectively a 93% decrease in 0.3 μm particle counts, a 96% reduction in 0.5 μm particle counts, a 98% drop in 1.0 μm particle counts, a 99% decrease in 2.0 μm particle counts, a 99% decline in 5.0 μm particle counts, and a 50% decrease in 10.0 μm particles was also seen.

Application of the SAM Guard in Group 2B resulted in an overall decrease of 97% of all airborne particles when compared to Group 2A. Additionally a 95% decrease in 0.3 μm particle counts, a 97% reduction in 0.5 μm particle counts, a 99% drop in 1.0 μm particle counts, a 99% decrease in 2.0 μm particle counts, an 81% decline in 5.0 μm particle counts, and an 3.5% increase in 10.0 μm particles was observed.

Figs. 1 and 2 display the measurement of airborne particles measured during Groups 1A and 1B Baseline measurements of airborne particles measured during Group 2A and Group 2B can be seen in Figs. 3 and 4 respectively.

When compared with Group 1A, Group 1B showed a statistically significant decrease in particle count at the 0.3 ($p = 0.000004$), 0.5 ($p = 0.00002$), 1 ($p = 0.00005$), 2 ($p = 0.0002$), 5 ($p = 0.02$) micron measurements. No statistically significant decrease was determined at the 10 ($p = 0.2$) micron range. Based on the resultant p values, we rejected the null hypothesis and accepted the alternate hypothesis for the 0.3 um, 0.5 um, 1 um, 2 um and 5 um values. With a p value of 0.2 for the 10 um measurement, we are not able to reject the null hypothesis.

When compared to Group 2A, Group 2B showed a statistically significant decrease in airborne particles at the 0.3 ($p = 0.0000008$), 0.5 ($p = 0.000001$), 1 ($p = 0.000003$), 2 ($p = 0.0001$), 5 ($p = 0.006$), and 10 ($p = 0.02$) micron measurements. Based on the resultant p values, the null hypothesis was rejected and the alternative hypothesis was accepted for all particle results. Table 2 provides the p values for both post-intervention groups.

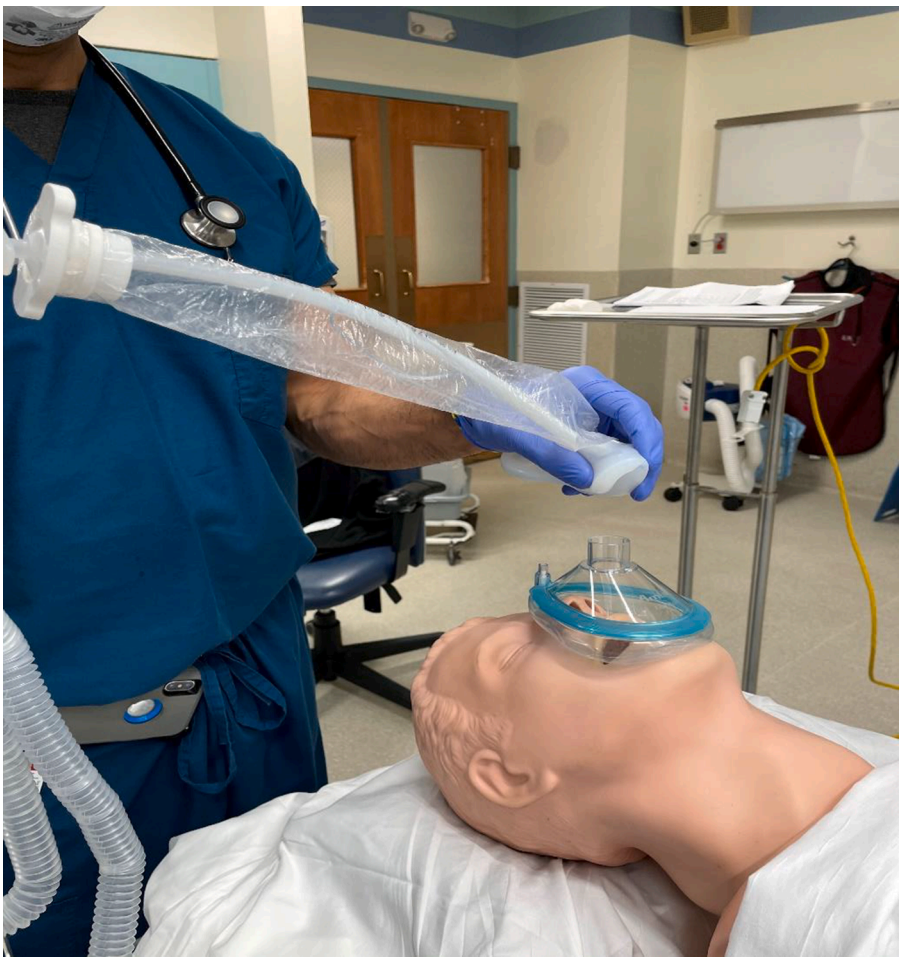

Image 3. Extubation and removal of SAM guard.

Table 1
Subgroups passive and forced particle count.

Particle size(microns)	Group 1A	Group 1B	Group 2A	Group 2B
0.3	431,243	29,678	195,002	9187
0.5	279,003	12,289	106,969	2729
1.0	147,269	3091	41,445	459
2.0	74,753	700	15,169	95
5.0	1092	15	63	12
10.0	16	8	2	9

4. Discussion and limitations

The SAM Guard was designed to be a single use, disposable, non-invasive device, to help mitigate the spread of airborne particles during extubation. Application of the SAM Guard in Group 1B resulted in a 97% (1.0 um), 98% (2.0 um), and 99% (5.0 um) decrease in theoretical COVID-19 airborne carrier particulate counts. By comparison, Group 2B displayed a 93% (1.0 um), 93% (2.0 um), and 65% (5.0 um) decline.

Although the presence of the SAM guard in Group 1B resulted in a 50% reduction of 10 um particles, the resultant p value of 0.2 leads us to accept the null hypothesis. Theories as to why this occurred include lack of a forced extubation or cough, which would in turn generate more 10 um particles as evidenced by Group 2B's 3.5% increase in 10 um particles. This increase is consistent with research documenting the force of a human cough and the subsequent generation of larger airborne particle sizes.[27,28] Despite Group 2B's relatively small increase in 10 um particle size, the resultant p value of 0.02 is statistically significant.

Currently, there is no consensus regarding the actual pressure of a human cough. While literature does exist regarding the velocity and size of particles a human cough can produce, there is a paucity of studies that have been able to objectively quantify the intensity of a cough.[24–26] Even amongst those studies, a wide range of pressure readings have been reported as high as 3 psi for a voluntary cough.[24–26]Other studies infer that a reflexive involuntary cough may produce a greater pressure.[24–26] Given the lack of a "baseline" quantifiable pressure for a human cough, as well as the complex factors involved in coughing, use of a jet ventilator may have generated pressures potentially greater than an average human cough. As the design of the SAM Guard allows for use while the patient is still actively coughing, the lack of volunteer human subjects to intubate and extubate may also be considered a limitation.

Other limiting factors include the use of a positive pressure operating room, specifically one with a high room cycle flow rate. The American Society of Anesthesiologists recommends that procedures on COVID-19 positive patients be performed in a negative pressure room.[32] However the site where the study was conducted only had one negative pressure room that was being actively used to treat COVID-19 patients.

While the evidence suggests a possible significant reduction in the overall potential COVID-19 airborne particle carriers, further research is needed to determine the clinical impact of the SAM Guard in mitigating the spread of COVID-19 or other aerosolized diseases.

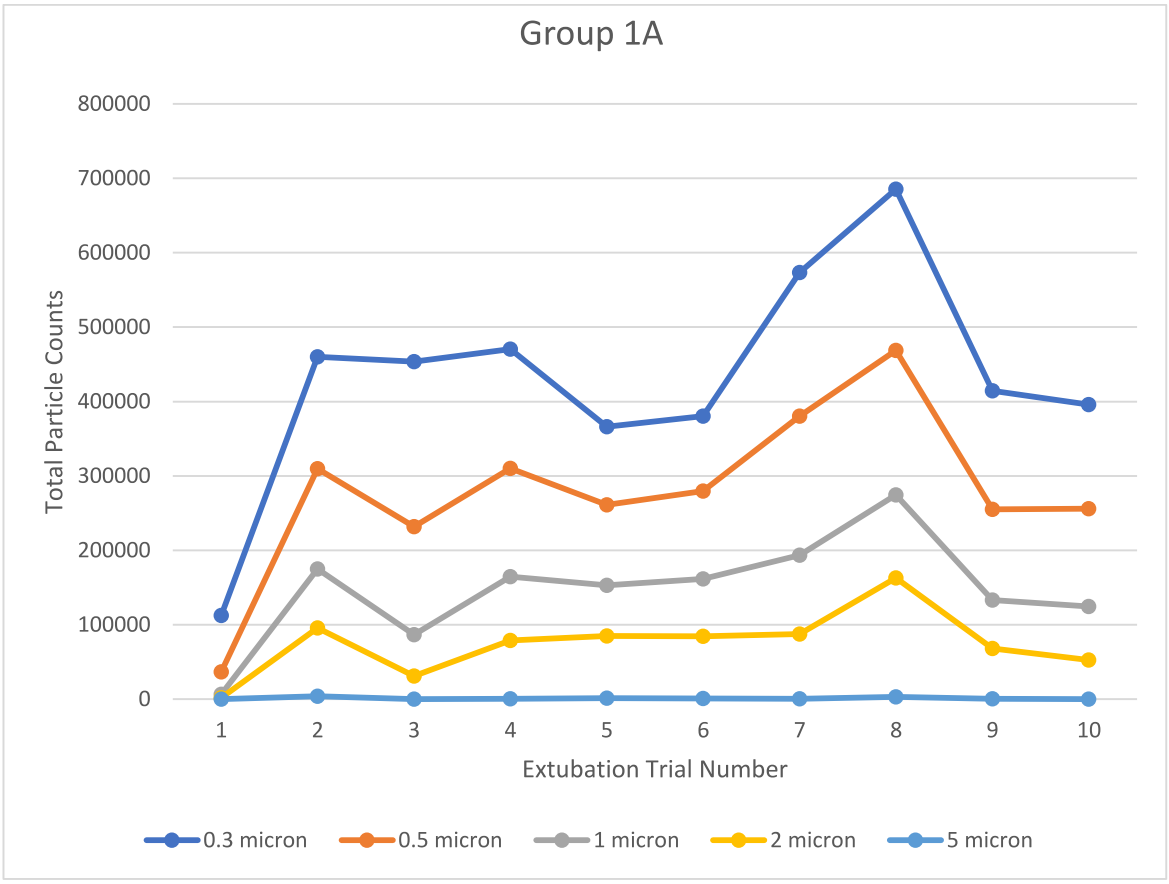

Fig. 1. Airborne particles measured during group 1A.

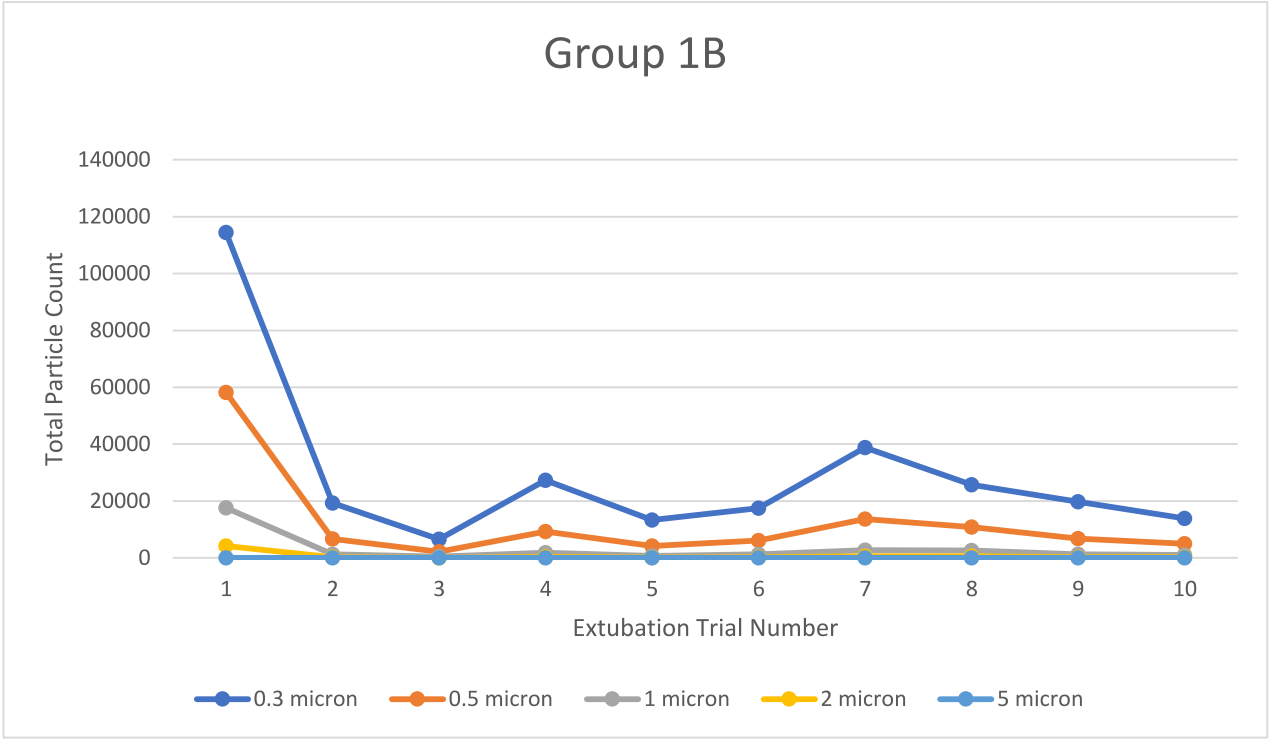

Fig. 2. Airborne particles measured during group 1B.

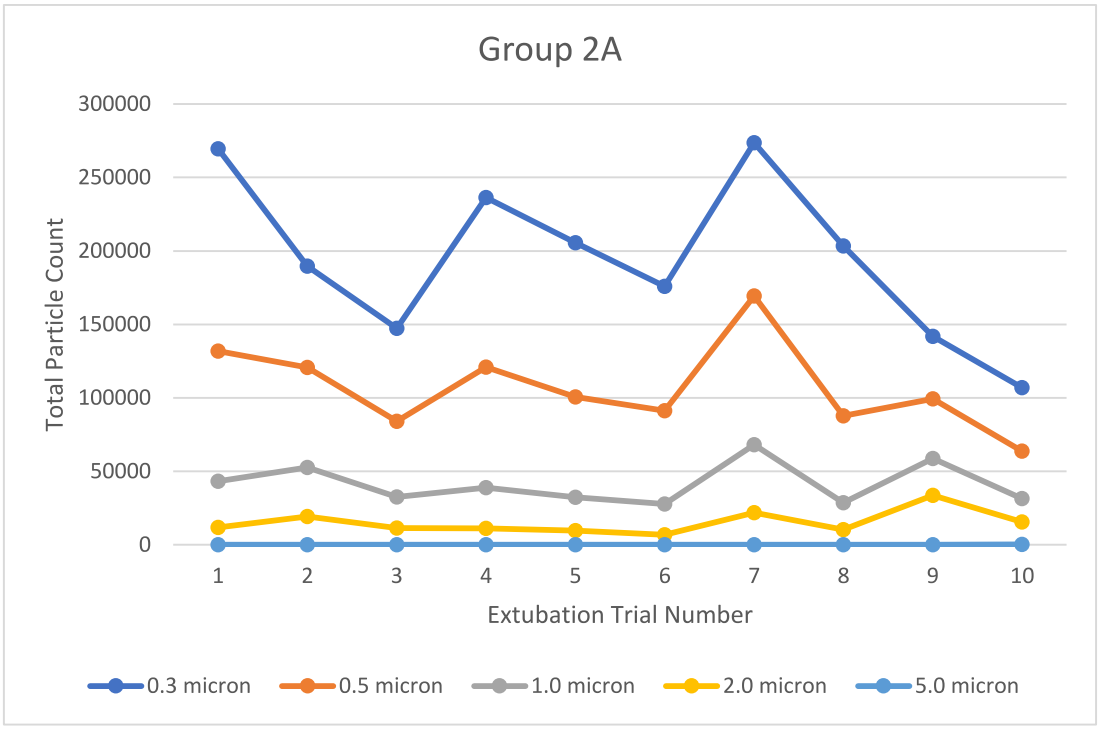

Fig. 3. Airborne particles measured during group 2A.

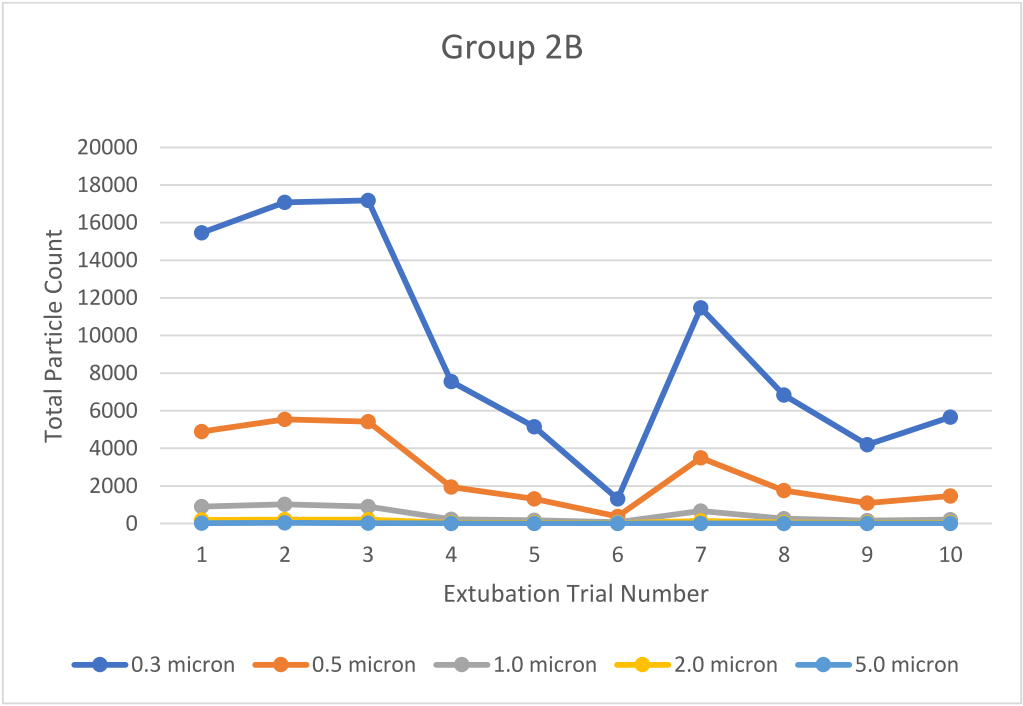

Fig. 4. Airborne particles measured during group 2B.

Table 2
Comparison of p values between groups 1B and 2B.

Particle Size (Microns)	Group 1B p value	Group 2B p value
0.3	0.000004	0.0000008
0.5	0.00002	0.000001
1	0.00005	0.000003
2	0.0002	0.0001
5	0.02	0.006
10	0.2	0.02

CRediT authorship contribution statement

Robert W. Simon: Conceptualization, Methodology, Software, Data curation, Writing – original draft, Visualization, Investigation, Supervision, Validation, Writing – review & editing.

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.

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