





ORIGINAL RESEARCH

# Aerosol generation during cadaveric simulation of otologic surgery and live cochlear implantation

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## Abstract

**Objective:** The risk of SARS-CoV-2 transmission to healthcare workers through airborne aerosolization during otologic surgery has not been characterized. The objective of this study was to describe and quantify the aerosol generation during common otologic procedures in both cadaveric surgical simulation and live patient surgery.

**Methods:** The number concentrations of generated aerosols in the particle size range of 0.30 to 10.0  $\mu\text{m}$  were quantified using an optical particle sizer during both a cadaveric simulation of routine otologic procedures as well as cochlear implant surgery on live patients in the operating room.

**Results:** In the cadaveric simulation, temporalis fascia graft harvest using cold techniques (without electrocautery) ( $n = 4$ ) did not generate aerosols above baseline concentrations. Tympanoplasty ( $n = 3$ ) and mastoidectomy ( $n = 3$ ) both produced statistically significant increases in concentrations of aerosols ( $P < 0.05$ ), predominantly submicron particles ( $< 1.0 \mu\text{m}$ ). High-speed, powered drilling of the temporal bone during mastoidectomy with a Multi Flute cutting burr resulted in higher peak concentrations and greater number of spikes in aerosols than with a diamond burr. In the operating room, spikes in aerosols occurred during both cochlear implant surgeries.

**Conclusion:** In the cadaveric simulation, temporalis fascia graft harvest without electrocautery did not generate aerosol levels above baseline, while significant aerosol levels were generated during mastoidectomy and to a much less degree during tympanoplasty. Aerosol spikes were appreciated during cochlear implantation surgery in live patients.

**Level of Evidence:** 2.

## KEYWORDS

Aerosol-Generating Procedure, COVID-19, Mastoidectomy, Otologic Surgery, Tympanoplasty

Dhruv Sharma and Vincent J. Campiti contributed equally to this work.

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## 1 | INTRODUCTION

Decisions regarding appropriate healthcare worker protections in the COVID-19 era, including use of personal protective equipment (PPE), have been made with an incomplete understanding of the risk of transmission. These decisions have been influenced by the potential for aerosol generation, as this determines whether airborne isolation or droplet precautions are more appropriate. The National Institute for Occupational Safety and Health recommends allowing time for air clearance after aerosolization of potentially harmful substances, with the exact wait time influenced by the number of air changes per hour.<sup>1</sup> Implementation of prolonged wait times between surgeries or outpatient clinical encounters, as recommended after performing aerosol generating procedures (AGP), has important implications for practice management and the ability to deliver clinical care efficiently. Thus, it is critical to determine which procedures are AGPs. This information will allow us to make informed choices as we navigate the delicate balance between practice efficiency and safety without compromising care. In addition, use of N95 or an equivalent respirator is warranted when infectious particles are aerosolized, and understanding which procedures warrant use of enhanced PPE will enable us to be good stewards of this resource.

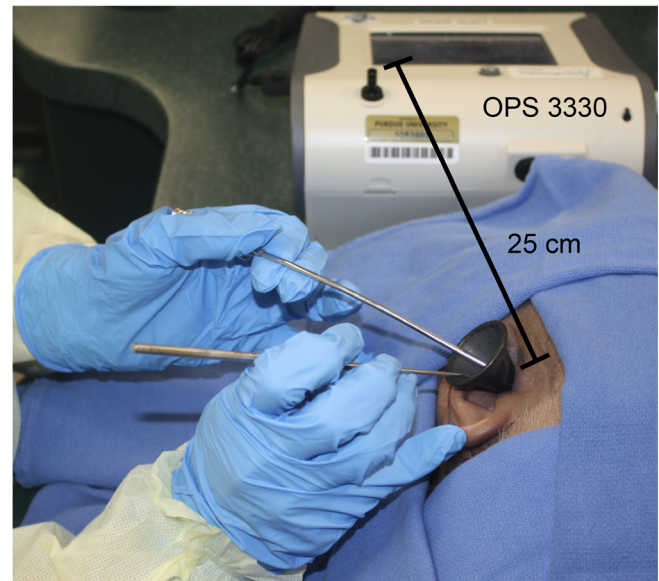
Aerosols are particles suspended in a gas, and infectious aerosols are defined by particles smaller than 100  $\mu\text{m}$  in diameter.<sup>2-4</sup> The Infectious Disease Society of America defines "respirable particles" as less than 10  $\mu\text{m}$ ,<sup>5</sup> and such aerosols are known to be capable of both short- and long-range viral transmission with an ability to penetrate into the lower airway.<sup>3</sup> These strict size criteria should be interpreted with caution as larger particles have been found to desiccate into smaller ones under certain environmental conditions.<sup>3,6</sup> SARS-CoV-2 virions range from 60 to 140 nm (0.060-0.140  $\mu\text{m}$ ) in size, allowing for potential aerosolization of the infectious viral particles.<sup>7,8</sup> However, the risk of viral transmission via aerosols, the threshold particle concentrations, and the duration of exposure necessary for transmission have not been well characterized.

While relevant data demonstrate an increased risk of airborne transmission of acute respiratory infections during intubation and tracheostomy, there is a dearth of objective data regarding the potential for aerosolization of viral particles during routine otologic procedures.<sup>9</sup> This is particularly important in light of the recent recovery of SARS-CoV-2 RNA from the middle ear and mastoid of deceased COVID-19 patients. This is an important but expected finding, as the middle ear and mastoid have previously been shown to harbor other respiratory viruses.<sup>10,11</sup> In this investigation, we devised a cadaveric simulation to quantify aerosol generation during routine otologic procedures including temporalis fascia graft harvest (TFGH), tympanoplasty, and mastoidectomy. We then evaluated aerosol levels generated during cochlear implantation in a live surgery setting.

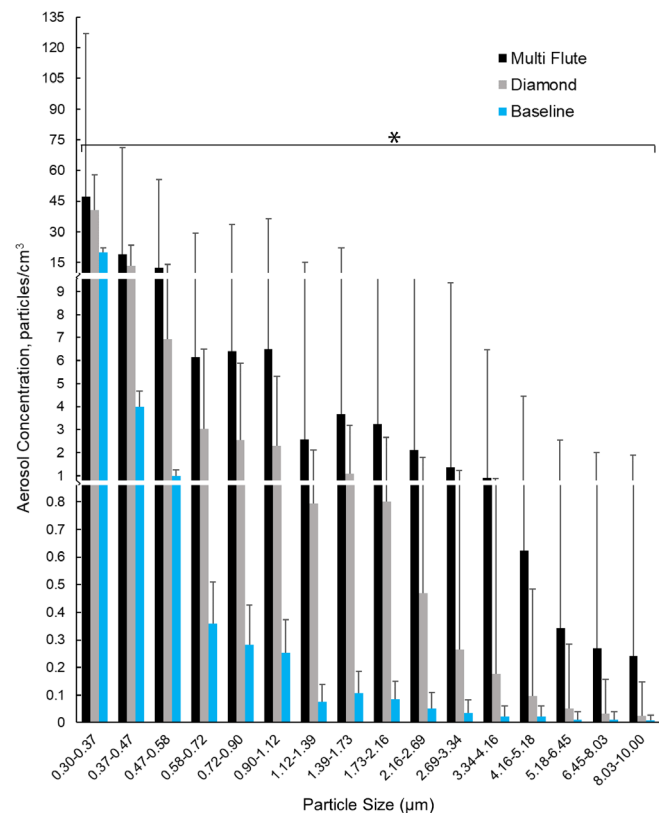
## 2 | MATERIALS AND METHODS

### 2.1 | Supplies and equipment

This study was deemed exempt by the Indiana University School of Medicine (IUSOM) institutional review board (IRB) because it involved



**FIGURE 1** This photograph shows the experimental set-up, in which the optical particle sizer's port was measured to be 25 cm from the external auditory canal

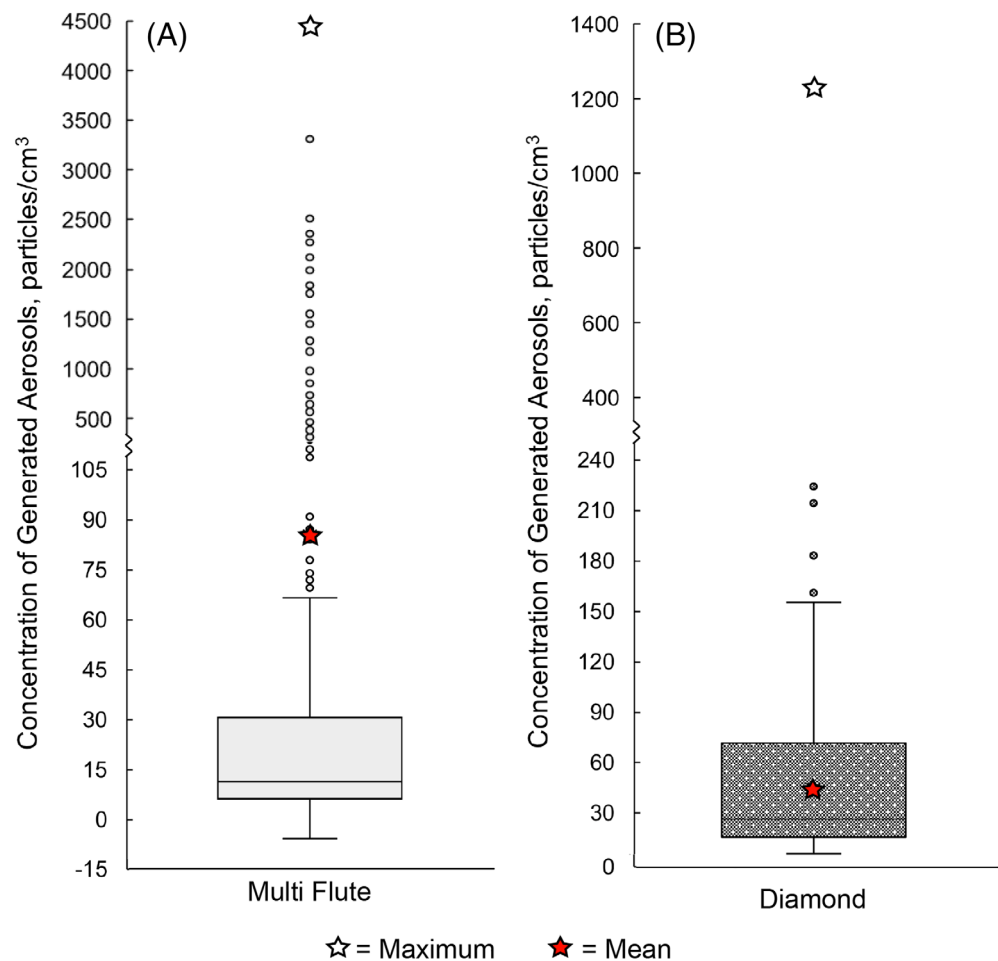


**FIGURE 2** Mean concentrations of aerosols during mastoidectomy with Multi Flute cutting and diamond burrs compared to baseline levels. Error bars represent one SD. Asterisk represents particle size ranges for which the mean concentrations were significantly above baseline with  $P < 0.001$

the use of nonliving deidentified human cadaveric tissue specimens for the cadaveric portion (IRB protocol # 2004100753) and because no patient protected health information was collected for the live portion (IRB protocol #2005714775). Therefore, no informed consent was necessary for this study as deemed by the IUSOM IRB. Sampling of aerosols was performed using an optical particle sizer (OPS) 3330 (TSI Inc., Shoreview, MN), which detects aerosol particles from 0.30 to 10.0  $\mu\text{m}$  (up to 16 channels per decade) with <5% resolution at 0.5  $\mu\text{m}$ . Therefore, the OPS 3330 accurately measures submicron larger than 0.30  $\mu\text{m}$  and micron particles from 1.0 to 10.0  $\mu\text{m}$ . The sampling flow rate through the OPS 3330's 3-mm inlet port was 1.0 L/min. Number concentration of aerosols was measured once every second for the duration of each procedure. The cadaveric experiments in this study were all conducted in a dedicated surgical laboratory using two fresh-frozen cadaver head specimens (2 left ears, 1 right ear) thawed to room temperature. The surgical laboratory was equipped with a high efficiency particulate air (HEPA) filtration system, which was employed between experimental conditions to return aerosols back to baseline levels. Cochlear implantation on live patients was performed in an operating room.

## 2.2 | Experimental setup and aerosol sampling during the cadaveric simulation

Each cadaver head was placed in the standard otologic position for an operating room procedure with a microscope. All procedures were performed by the senior author (S.J.B.), who is a right-handed surgeon. The OPS 3330 was positioned on the left side of the cadaver head (surgeon's left; Figure 1) with the inlet port 25 cm from the nearest edge of the EAC (the inferior edge of the EAC for a left-sided procedure and the superior edge for a right-sided procedure). Baseline aerosol concentrations were measured for 60 seconds before each experimental trial. Number concentration of aerosols was then measured each second for the duration of each procedure. The following surgical procedures were performed systematically on the first cadaver head: 1) left-sided tympanoplasty 2) left-sided mastoidectomy 3) right-sided tympanoplasty 4) right-sided mastoidectomy. The following surgical procedures were performed systematically on the second cadaver head: 5) left-sided tympanoplasty 6) left-sided mastoidectomy. 7) left TFGH 8) right TFGH 9) a second left TFGH 10) a second right TFGH. The HEPA filtration system ran for at least 3 minutes followed by background sampling of the baseline aerosol levels prior to each surgical simulation, and suction was utilized to evacuate any retained particulates following each experimental trial.

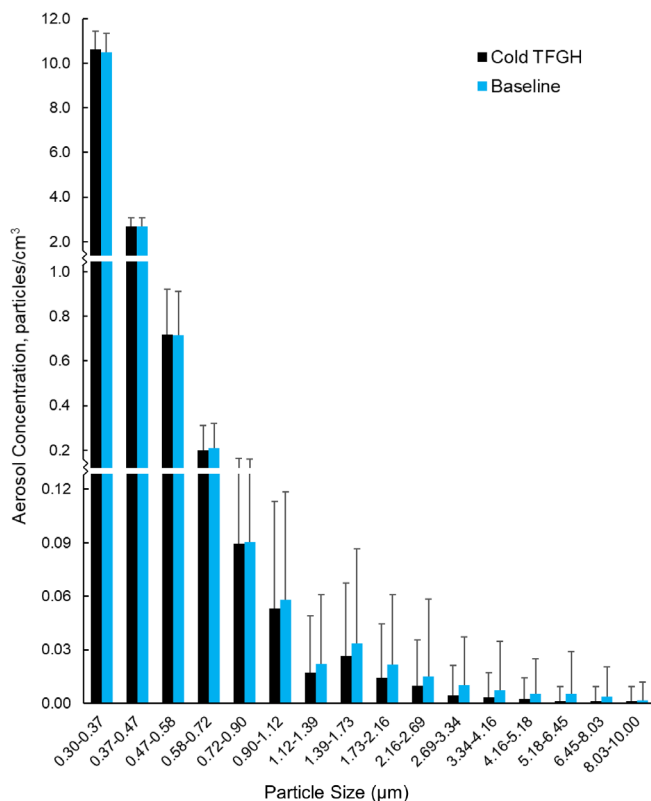


**FIGURE 3** Spread of 0.30 to 10.0  $\mu\text{m}$  aerosol concentrations above baseline levels during mastoidectomy with Multi Flute and diamond drill bits: (A) Multi Flute drill bit with y-axis scaled to show all outliers; (B) Multi Flute drill bit with y-axis scaled to show median and quartiles; (C) Diamond drill bit with y-axis scaled to show all outliers; (D) Diamond drill bit with y-axis scaled to show median and quartiles

Each mastoidectomy was performed with high-speed powered drilling at 75000 rpm (Stryker S2  $\pi$ Drive Drill) for a total of 10 minutes: first with a 6-mm Multi Flute cutting burr for 5 minutes and then a 6-mm diamond burr for 5 minutes. The Multi Flute cutting burr was utilized on the outer thick cortical bone followed by the mastoid air cells with entry into the mastoid antrum, while the diamond burr was used to blue line critical structures in a systematic fashion with delineation of tegmen, sigmoid sinus, and lateral semi-circular canal. While drilling, irrigation through an 8-French suction irrigator was performed in the standard fashion for a mastoidectomy. In performing a TFGH, no electrocautery was utilized. For tympanoplasty, a perforation was created in the tympanic membrane with a rosen, followed by transcanal approach for elevation of a tympanomeatal flap. Next, the previously harvested (separate condition) temporalis fascia graft was placed using a medial (underlay) grafting technique.

### 2.3 | Experimental setup and aerosol sampling during live cochlear implant surgery

To measure aerosols during cochlear implantation, the OPS 3330 was positioned directly behind the surgeon at the height of the surgeon's shoulder with the inlet port 90 cm from the patient's ipsilateral external auditory canal. Baseline aerosol concentrations were measured for 60 seconds prior to the start of each case. Aerosol concentrations were



**FIGURE 4** Mean concentrations of aerosols during TFGH without electrocautery compared to baseline levels. Error bars represent one SD. There were no particle size ranges with a statistically significant increase in aerosols above baseline. TFGH, temporalis fascia graft harvest

then measured each second for the duration of each surgery. Two total cochlear implant surgeries were included (1 right ear and 1 left ear). In both cases, the cortical mastoidectomy was started by a left-handed resident surgeon and then completed by the attending surgeon (R.F.N.).

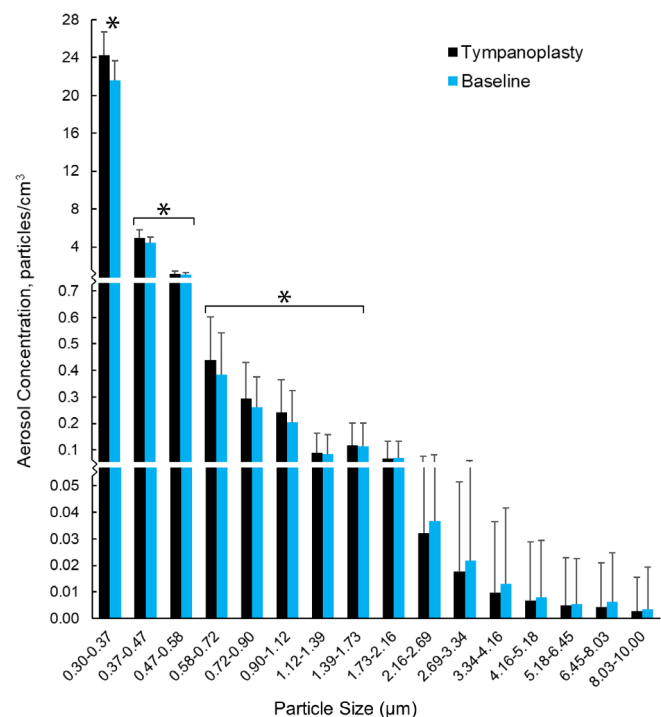
### 2.4 | Statistical analysis

All statistical analyses were performed using the Statistical Package for Social Sciences (IBM SPSS Statistics for Windows, Version 20.0; IBM Corp., Armonk, NY). Mann-Whitney U tests were used to evaluate the differences between baseline aerosol concentrations and aerosol concentrations generated during simulated surgical conditions. Statistical significance was set at  $P < 0.05$ .

## 3 | RESULTS

### 3.1 | Aerosol generation during cadaveric mastoid cortical and air cell drilling

Each mastoidectomy ( $n = 3$ ) was performed with high-speed, powered drilling of the temporal bone utilizing a Multi Flute cutting burr (MFCB) for 5 minutes followed by a diamond burr (DB) for 5 minutes. The MFCB generated high concentrations of aerosols with a mean total aerosol concentration (AC) of  $86.5 \pm 331$  particles/cm<sup>3</sup> above baseline ( $P < 0.001$ ). The DB also generated highly significant



**FIGURE 5** Mean concentrations of aerosols during tympanoplasty compared to baseline levels. Error bars represent one SD. Asterisk represents particle size ranges for which the mean concentrations were significantly above baseline with  $P < 0.01$

concentrations with a mean total AC of  $46.5 \pm 51.9$  particles/cm<sup>3</sup> above baseline ( $P < 0.001$ ). Concentrations of all 16 tested size channels were significantly higher than baseline levels for each condition (all  $P < 0.001$ ), and the highest concentrations observed were among the smallest particle sizes (Figure 2). In addition, the MFCB produced more spikes in aerosol concentrations compared to the diamond drill bit, shown as outliers in Figure 3, with maximum total aerosol concentrations of 4434 particles/cm<sup>3</sup> and 1231 particles/cm<sup>3</sup> generated while using MFCB and DB, respectively.

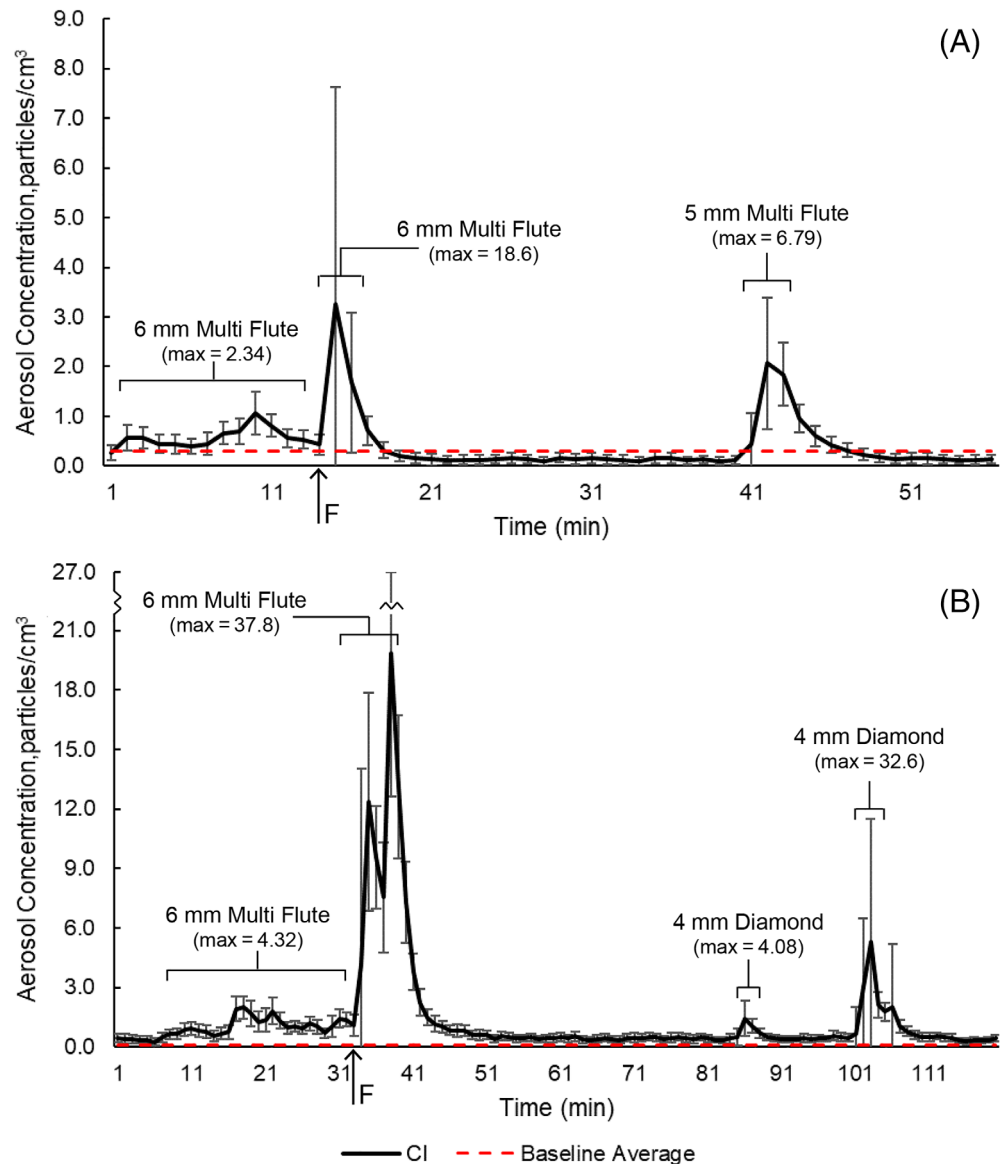
### 3.2 | Aerosol generation during cadaveric temporalis fascia graft harvest and tympanoplasty

Four trials of TFGH were completed in a mean duration of  $253 \pm 17$  seconds. The total AC was not significantly elevated compared to baseline. Figure 4 shows concentrations for particles of all

tested size channels compared to baseline levels. Three trials of tympanoplasty were performed in a mean duration of  $412 \pm 38$  seconds, generating a mean total AC of  $3.48 \pm 3.12$  particles/cm<sup>3</sup>. Generated aerosols were predominantly submicron ( $< 1 \mu\text{m}$ ) particles (Figure 5).

### 3.3 | Aerosol concentrations during live cochlear implant surgery

Aerosols were measured during two cochlear implantation surgeries. Given the duration of the surgeries with aerosol measurements every second, the mean total AC for each minute of the procedures are shown in Figure 6. Spikes in aerosols occurred during both cases, and all spikes were associated with mastoid drilling. Use of the Multi Flute burr was responsible for aerosol spikes with a maximum concentration of 37.8 particles/cm<sup>3</sup>.



**FIGURE 6** Aerosol concentrations during cochlear implantation on live patients in the operating room (A) Case 1: Right Ear. (B) Case 2: Left Ear. Arrow with the letter “F” corresponds to timing of transition from left-handed resident to right-handed faculty surgeon

## 4 | DISCUSSION

While the primary mode of infectious spread of SARS-CoV-2 is believed to be through respiratory droplets, the risk of aerosolization and airborne transmission continues to be a significant concern for the field of otolaryngology.<sup>6</sup> As the middle ear and mastoid serve as a repository for upper respiratory pathogens, including SARS-CoV-2, aerosol generation during otologic surgeries is a potential source of spread.<sup>11,12</sup> High-speed powered drilling has been of particular concern, resulting in gross droplet contamination in recent cadaveric simulations.<sup>12,13</sup> However, limited literature assessing aerosol generation and aerosolization during otologic procedures exists,<sup>14</sup> and this study is the first in multiple regards.

In the cadaveric simulation, routine otologic procedures were performed including TFGH, tympanoplasty, and mastoidectomy. The cold techniques used in TFGH did not generate aerosols above baseline levels. Tympanoplasty utilizing standard cold techniques generated statistically significant increases in aerosols in the size channels from 0.30-1.73  $\mu\text{m}$  but not among larger particle sizes, while mastoidectomy generated an increase in particles of all sizes. Nonetheless, the magnitude of aerosol generation during mastoidectomy was largest for smaller particles. Therefore, tympanoplasty and mastoidectomy, but not cold TFGH, were shown to generate aerosols over background levels with a predominance of submicron (< 1.0  $\mu\text{m}$ ) particles. This is a novel finding in the field of otolaryngology with regards to otologic procedures. Submicron aerosols are of particular interest, as penetration of N95 masks increases as particle size decreases.<sup>15</sup> Previously, Qian et al. reported that N95 masks were at least 95% efficient for filtering the most penetrating particle sizes ranging from 0.10 to 0.30  $\mu\text{m}$ , and that the filtration efficiency of particles at a size of 0.75  $\mu\text{m}$  is 99.5% or higher. With a good N95 seal, they reported an approximate 1.8% mask penetration with particles less than 1  $\mu\text{m}$ .<sup>16</sup> Therefore based on the results of their study, 98.2% of submicron aerosols should be blocked by an N95 respirator worn appropriately.

In the present simulation, the use of powered drilling also led to more overall aerosolization with significant increases in the larger particles from 1.0-10.0  $\mu\text{m}$  compared to nonpowered techniques. This is consistent with recent findings in the endonasal setting that powered drilling has the greatest risk of aerosol generation.<sup>17,18</sup>

When comparing our results to two recent cadaveric simulations which also utilized the OPS 3330 for data collection, we found that high-speed, powered drilling of the temporal bone had more variation than endonasal drilling.<sup>17,18</sup> Considering the purpose of using MFCB vs DB in the otologic setting, the higher peak AC and the increased number and magnitude of spikes in aerosols seen with the utilization of the MFDB is likely secondary to both the shape and nature of the burr as well as the greater thickness of the cortical bone being drilled.<sup>19</sup> There is likely also some portion of aerosols that are blocked by the soft tissue boundaries of the nose with endonasal procedures compared to open temporal bone drilling. A comparative analysis between the two types of burrs was not performed because baseline aerosol levels were not measured before transitioning directly from MFCB to DB.

We saw similar variability with multiple spikes in aerosols in our live patient data evaluating aerosol generation during cochlear implantation, which includes drilling of both cortical mastoidectomy and facial recess. Interestingly, Figure 6 shows a large spike in aerosols during both cases occurred right after an attending surgeon took over drilling from a resident surgeon, which likely reflects the increased intensity and speed with which a more experienced surgeon drills. We believe that this data likely underestimates surgeon exposure to aerosols, as the OPS was positioned directly behind the primary surgeon. Despite positioning the OPS at the height of the surgeon's shoulder, there is almost certainly a shadow effect in which particles are blocked by the surgeon themselves. However, given the limitations of utilizing a nonsterile aerosol sampler during an implant surgery, we utilized this position to approximate levels of aerosol without disrupting patient care. To our knowledge, this represents the first report of aerosol generation during live otologic surgery.

In a study of cortical mastoidectomy performed on cadaveric temporal bones, Norris et al previously demonstrated that the total suspended particulate matter generated during mastoidectomy was below the OSHA threshold for respirator use, though this threshold is based on dust exposure rather than the risk of viable infectious particles.<sup>20</sup> It is important to note that in their study, the authors employed a different methodology utilizing a gravimetric method to measure mass concentration of aerosols. This makes it difficult to analyze the smaller particles in detail since mass concentration can be dominated by larger particles. By contrast, we measured number concentration by size utilizing the OPS 3330, which accurately measures aerosols from 0.30 to 10.0  $\mu\text{m}$  with excellent resolution.

Other studies evaluating potential infectious risk to the surgical team during mastoidectomy have focused on droplet spread, particularly transconjunctival risk. In a simulation study evaluating corneal penetration by bone spicules during mastoidectomy, fish corneas up to one meter away were noted to be violated by bone spicules, highlighting the potential for transcorneal transmission of infectious agents.<sup>21</sup> This is in agreement with our prior analysis of droplet spread during mastoidectomy, in which cadaveric tissue was detected 6 ft from the surgical site.<sup>12</sup> In a separate study, the spread of particulates generated during mastoidectomy was noted at a maximum of 41 cm away.<sup>22</sup> Together with the current study, there is evidence of both droplet spread and aerosol generation during mastoidectomy, but no direct evidence for SARS-CoV-2 transmission. We did not assess for bioaerosols in the current study, as the type and quantity of bacteria and viruses present in a cadaver did not seem immediately clinically relevant.

To our knowledge, this study is the first to evaluate aerosol generation during tympanoplasty. Figure 5 shows statistically significant increases in concentrations of 0.30 to 1.73  $\mu\text{m}$  aerosols during tympanoplasty compared to baseline levels, though the error bars (representing 1 SD) do overlap. It is important to note that the data did not follow a normal distribution, which likely explains this overlap. However, despite statistical significance, the overlap could suggest that this difference may not be clinically significant.

Further studies with a greater number of trials are certainly warranted to elucidate whether there is a clinically meaningful difference or not.

As aerosols may be produced by air flow over a liquid surface, the mechanism of aerosol generation from tympanoplasty is possibly due to the high air flow from the use of suction across the external auditory canal and middle ear mucosa.<sup>8</sup> The small volume within these spaces may cause greater pooling of fluids, especially in a cadaveric setting. Moreover, the suction used during tympanoplasty is often applied in a dynamic fashion to suction fluids directly around the tympanomeatal flap for visualization. This dynamic motion of the suction during tympanoplasty potentially allows for aerosol escape around the suction.

Furthermore, while the use of suction during a simulation of endoscopic endonasal procedures and the use of barrier drapes with and without a second suction during a simulation of otologic procedures have demonstrated mitigation of aerosols, it is important to note that these studies only measured aerosols 1.0 to 10.0  $\mu\text{m}$  in diameter.<sup>14,17</sup> Our study used the same aerosol sampling machine but also included submicron aerosols from 0.30 to 1.00  $\mu\text{m}$  in diameter. The significance in aerosol generation during tympanoplasty was largely secondary to aerosols  $\leq 0.90$   $\mu\text{m}$ . The results presented here do not contradict the prior findings given that important technical difference. Furthermore, it is important to note that the second study simulating endonasal procedures showed that although passive and active suctioning significantly reduced particles, aerosols were still present above baseline levels in some cases, predominantly in the submicron particle size range.<sup>17</sup>

A number of limitations in this study warrant discussion. Only aerosols in the 0.30 to 10.0  $\mu\text{m}$  range were measured, so there was potential to not measure all aerosols that may have been present. The composition of aerosols and their capacity to harbor viral DNA/RNA or viable viral particles was not measured, and the infectious potential of these aerosols remains unknown. Aerosols were only measured at a fixed distance 25 cm away from the EAC for cadaveric simulations. As a result, these measurements likely reflect only aerosol exposure risk to the surgeon and surgical technologist. Therefore, future directions of study could be measuring aerosol levels at the average distance of the anesthesia and circulating staff. Moreover, aerosol levels during tympanoplasty in live patients should be measured to determine if the statistically significant difference found in our cadaveric simulation data is clinically meaningful.

Our live surgery data is limited due to increased distance from the surgical field and shadow effect from the surgeon. Differences in the mean particle number concentration when comparing cadaveric simulation to live surgery are attributable to not only these differences in measurement but also differences in air flow, humidity, and temperature in the different environments, as well as differences in body temperature, blood flow, and middle ear and mastoid secretions. The numeric data presented represent the mean across the entire surgery, during which a combination of cold techniques, electrocautery, and the powered drill were used.

## 5 | CONCLUSION

We demonstrate here that significant aerosols are generated above baseline levels in a cadaveric simulation of mastoidectomy, and to a much less degree during tympanoplasty. Similar increases in aerosols were not seen during cold TFGH in a cadaveric simulation. Moreover, there were multiple spikes in aerosols during cochlear implantation in live patients. The majority of aerosols were produced in the submicron ( $< 1.0$   $\mu\text{m}$ ) particle range. High-speed drilling of the temporal bone generates the highest amounts of aerosols, confirming that mastoidectomy poses the greatest risk in terms of otologic procedures.

## CONFLICT OF INTEREST

The authors have no conflict of interests to disclose. This work has not been submitted for publication elsewhere.

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