Title: Aerosol dispersion during mastoidectomy and custom mitigation strategies for otologic surgery in the COVID-19 era

Short title: Mitigation of aerosols during mastoidectomy

Key words: mastoidectomy, COVID-19, severe acute respiratory syndrome coronavirus-2, SARS-CoV-2, virus transmission, aerosol, aerosol generating procedure, aerosolization, airborne, otology, neurotology, barrier drape, personal protective equipment, healthcare providers, safety, OtoTent

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Abstract (Word count 250)

Objective: To investigate small particle aerosolization from mastoidectomy relevant to potential viral transmission and to test source control mitigation strategies.

Study Design: Cadaveric simulation.

Setting: Surgical simulation laboratory.

Subjects and methods: An optical particle size spectrometer was used to quantify 1-10um size aerosols 30cm from mastoid cortex drilling. Two barrier drapes were evaluated: (1) OtoTent1–a drape affixed to the microscope; (2) OtoTent2–a custom, structured drape which enclosed the surgical field with specialized ports.

Results: Mastoid drilling without a barrier drape, with or without an aerosol scavenging second suction (SS), generated large amounts of 1-10um particulate. With OtoTent1, drilling generated a high particle density compared to baseline environmental levels ($p<0.001$, $U=107$), but mean particle density remained at baseline when a SS was added. With OtoTent2, mean particle density remained at baseline when drilling, with or without a SS. For OtoTent1 and OtoTent2, particle density significantly increased compared to baseline upon removal of the drape ($p<0.001, U=0$ and $p<0.001, U=2$, respectively). For both drapes, particle density did not increase above baseline when both a SS *and* a one-minute delay were employed for drape removal.

Conclusions: Mastoidectomy without a barrier, even when SS was added, generated substantial 1-10um aerosols. During drilling, OtoTent2 (with or without a SS) was effective in mitigating airborne aerosol dispersion, while OtoTent1 was only effective when a SS was added. The combination of a SS and delaying removal effectively mitigated aerosol dispersion during removal of either drape.

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Introduction

During the acute phase of the COVID-19 pandemic, major disruptions occurred in the healthcare sector.[1] The initial closure of clinics and cancellations of non-urgent operations significantly impacted otolaryngology practices.[2,3] As COVID-19 infection rates plateau and begin to decline globally, clinicians require strategies to safely re-open practices, particularly in the setting of persistent shortages of widely available testing,[4] personal protective equipment (PPE),[5] and a lack of contact tracing in the community as has been attempted in other countries.[6,7]

Otolaryngologists may be at increased risk for occupational exposure as studies show that the use of a high-powered drill is associated with aerosol generation.[8–12] The Centers for Disease Control (CDC) and World Health Organization (WHO) have recommended higher levels of PPE for aerosol generating procedures.[13,14] Local source control may be an effective adjunctive strategy to mitigate viral transmission risk; however, there are currently no standardized local source control strategies for otologic surgery. In a recent study, we illustrated the plume of aerosolized debris generated by mastoidectomy, quantified particulate (≥100um) dispersion in a 360-degree field around the surgical site, and demonstrated the effectiveness of a simple barrier drape attached to the microscope (previously termed "OtoTent", and referred to as "OtoTent1" in this study) for reducing large particulate dispersion.[8]

Herein, we investigate the generation of aerosols during mastoidectomy in human cadaveric specimens for droplets and particulates 1-10um in size, which includes the size range commonly associated with airborne disease spread[15]. Furthermore, we evaluate the efficacy of two barrier drapes to decrease exposure to these aerosols, including OtoTent1 and a novel prototype customized for otologic surgery, OtoTent2. Additionally, we evaluate the effect of adding a second suction to the field, with or without barrier drapes.

Methods

Preparation of Specimens and Surgical Simulation

The protocol was deemed exempt by the Institutional Review Board (protocol number 2020P001151). Surgical simulation was performed on six ears from three thawed, fresh-frozen cadaveric head specimens. All experiments were performed in a surgical laboratory set at 72°F, equipped with air exchangers operating at a rate of six air changes in the room per hour. Specimens were prepared with a C-shaped postauricular skin incision. A single, right-handed surgeon completed all surgical conditions. The surgeon performed a cortical mastoidectomy and drilled for one minute for each condition. The microscope was a wall-mounted Zeiss OPMI Pico (Carl Zeiss, Meditec AG, Jena, Germany) with an objective lens focal distance of 250 mm. The Midas Rex© Legend Stylus otologic drill with a compatible Xomed© 6 mm round fluted bur and 5 mm diamond bur (Medtronic, Inc., Minneapolis, MN, USA) was used at 70,000 RPM for drilling. The otologic drill had an attached irrigation port set to 10 mL/ min. A 12-French (Fr) suction was used in the surgeon's non-dominant hand, with the suction tip maintained approximately 1 cm from the drill bur, in all conditions except the "no suction" and "suction irrigator" conditions. The 12-Fr suction connected to wall suction in the laboratory which applied 538 mmHg suction pressure (measured by a digital pressure gauge, Cole-Parmer, Vernon Hills, IL, USA) and resulted in 32 L/min air flow rate (measured by a variable area flowmeter, Cole-Parmer, Vernon Hills, IL, USA). The suction irrigator used in one test condition had a 12-Fr suction port and a 10-Fr irrigation port.

Aerosol Sampling

An optical particle sizer (OPS 3330, TSI Inc., Shoreview, MN) placed 30 cm from the ear canal (**Figure 1A**) measured particle number and size distribution. Single particle counting technology was used to measure particles 1-10um in size. The optical particle sizer had a flow rate of 1.0 Liters/min through a 3 mm port. Particle size distribution was measured in 16 channels. Total particle counts by size were collected in 10 second intervals for the duration of each experiment with replicates performed for each test condition. Background measurements were taken before each experiment for 60 seconds and experiments proceeded only if the aerosol concentration was at baseline.

Barrier Drapes

Two types of barrier drapes were fashioned. "OtoTent1" was created with a 1060 Steri-drape (3M, St. Paul, MN) that enclosed the microscope lens, cadaveric head specimen, and immediate surrounding 30 cm surgical field (**Figure 1B**) as previously described.[8] A circle with a 6 cm diameter was cut into the incise film (which has an adhesive backing) to secure the drape to the outer perimeter of the microscope lens. OtoTent1 was draped over the surgical field and secured in three cardinal locations. The surgeon's hands and instruments were passed under the drape to access the surgical field.

"OtoTent2" was a custom prototype design based on a modified Zeiss OPMI microscope drape (Carl Zeiss, Meditec AG, Jena, Germany; **Figure 1C**) created by Grace Medical (Memphis, TN). It was attached to the outer perimeter of the microscope lens with a 9 cm opening and secured with an elastic cinch cord. OtoTent2 contained two arm ports to accommodate the surgeon's hands, with reinforced stiffened entry points to facilitate arm placement. The arm ports were *not* sealed around the surgeon's arms. A third port accommodated the suction and otologic drill, sealed circumferentially with a piece of Velcro. OtoTent2 created a 3-dimensional enclosed space with a plastic drape that formed the "floor." A 12 cm diameter hole was cut into the "floor" and loosely adhered (but not sealed) to the cadaveric head around the surgical site. Neither OtoTent1 nor OtoTent2 was a sealed system, and potential sources of air leak are illustrated in **Figure 2**. Volumes for OtoTent1 and OtoTent2 were calculated based on a truncated cone shape and pyramidal shape, respectively, and found to be 40 Liters(L) and 37L, respectively.

Second Suction Set-up

Where indicated, the open end of a second suction (SS) tubing (Cardinal Health, 3/16" x 6', Dublin, OH, USA) was secured 3 cm from the mastoid cortex to continuously scavenge aerosolized particles from the air near the surgical site (**Figure 3**). (Of note, it was not used to suction liquid runoff.) The SS was connected to a second wall suction (separate from that with the 12-Fr suction), with measured air flow rate of 65 L/min. The noise level from the second suction was measured with Decibel X, a sound level meter (SkyPaw Co., Ltd, Hanoi, Vietnam) and found to be 53 dB. In contrast, the noise level of the 12F suction was 73 dB.

Test Conditions

A cortical mastoidectomy was performed under the microscope (with no barrier drape) while drilling for 1-minute. All procedures were performed with a 6 mm round fluted ("cutting") otologic bur. To assess the two barrier drapes, the following conditions were tested with simulated cortical mastoidectomy: 1) no barrier drape; 2) OtoTent1; 3) OtoTent2 (**Figure 1**). Each condition was tested with and without the use of a SS fixed in the surgical field to continuously evacuate particles. The SS was turned on at the start of drilling and left on during barrier removal and subsequent particulate measurements. The drape was removed either immediately upon cessation of drilling or after a 60 second rest period. The surgeon's arms were removed from the field at the conclusion of drilling regardless of whether the drape was removed in an immediate or delayed fashion.

Statistical analysis

Stata version 13 (StataCorp, College Station, TX) software was used for statistical analysis to assess differences in airborne aerosol generation above matched, specific pre-replicate baseline values for all test conditions. Non-parametric statistical techniques were utilized due to small sample sizes, with Bonferroni correction for multiple comparisons. Prism Version 8 (GraphPad Software, La Jolla, CA, USA) was used to graph data. All values are reported as means with standard error.

Results

Mastoidectomy (no barrier) with and without second suction

The average particle density across time is shown for mastoidectomy without a barrier drape in two drilling conditions: (1) cutting bur and (2) cutting bur with SS (**Figure 4**). The average particle (1-10um) density during 60 seconds of drilling detected 30 cm away from the surgical site in an open field without a barrier drape using a cutting bur with and without SS was 61,500 ±19,200 and 42,500±17,700 particles/L, respectively.

The background level of particle detection was low prior to drilling in both conditions. The peak particle density occurred in a delayed fashion in both conditions, with maximum particle density noted at 30 seconds after drilling for the no SS condition and at 40 seconds after drilling for the SS condition. No statistical difference was found between the two conditions for particle density over a 60 second drilling period.

Mastoidectomy with barrier drapes with and without second suction

Comparison of particle density generated in the mastoidectomy without a barrier drape condition and the two barrier strategies, OtoTent1 and OtoTent2, with and without the use of SS is shown in **Figure 5**. Three of the conditions (mastoidectomy without barrier drape [$p<0.001$, $U=57$], mastoidectomy without barrier drape but with SS [$p<0.001$, $U=95$], and OtoTent1 without SS [$p<0.001$, $U=107$]), showed high rates of particle generation during drilling compared to background levels of particle density ($n=24$ per condition, Mann-Whitney U Test, Bonferroni correction for multiple comparisons). The remaining conditions (OtoTent1 with SS, OtoTent2 without SS, and OtoTent2 with SS) showed lower levels of particle generation during drilling, and the number of particles generated was not found to be statistically different from that in background levels for each of these three conditions (**Figure 6a**).

Effect of arm removal from drape

During surgeon arm removal, OtoTent1 and OtoTent2 resulted in significant aerosol dispersion above background ($p<0.001$, $U=0$ and $p<0.05$, $U=24.5$, respectively **Figure 6b**), but when the SS was used, the levels were not significantly different from background.

Effect of delaying barrier removal

The effect of delaying barrier removal by 60 seconds following completion of drilling is shown in **Figure 6c**. Delaying barrier removal when using OtoTent1 without SS still demonstrated significant aerosol dispersion compared to background levels ($p<0.001$, $U=0$, $n=10,12$). Although delaying barrier removal when using OtoTent2 without SS marginally reduced aerosol generation compared to immediate removal, significant aerosol was still generated compared to background levels ($p<0.001$, $U=2$, $n=12,12$). However, delaying barrier removal when using OtoTent1 with SS or OtoTent2 with SS mitigated aerosol dispersion to levels not significantly different from baseline.

Discussion

Concerns that COVID-19 may be spread through otologic and neurotologic surgery have arisen,[16] as the fluid and mucosa of the middle ear and mastoid are contiguous with that of the upper respiratory tract where the viral load is high.[2] Other respiratory viruses, such as human coronavirus, rhinovirus, respiratory syncytial virus, influenza, parainfluenza, enterovirus and adenovirus, have been identified in middle ear fluid samples from children with upper respiratory illnesses.[17,18] Although we are unaware of studies showing SARS-CoV-2 in the middle ear, it is prudent to assume a potential risk of otologic transmission. While SARS-CoV-2 is primarily spread via droplet transmission,[19] it can act as an opportunistic airborne infection, particularly in the setting of aerosolizing procedures.[11,20] Typically, airborne aerosol particles are less than 5um, while droplet spread occurs through particles greater than 5um.[15]

This study demonstrates that mastoid drilling generates large quantities of 1–10um size aerosolized particles, complementing existing research of larger particles generated during mastoidectomy.[8,12] Within the limits of comparison given differences in experimental techniques and conditions, mastoidectomy appears to generate far more aerosol dispersion than speech, cough, sneeze, and intubation, as well as more than intranasal cautery and anterior skull base drilling.[21,22] There is a paucity of experimental data for small particulate mastoidectomy aerosolization and our data could not be compared to a prior study with a gravitational spectrometer[9], due to differences in mass-based rather than optical particle size quantification. Risks from aerosol generating procedures (AGP) may be further stratified into a "high risk" category, which denotes increased risk based on (1) viral load at that site, (2) degree of aerosolization, and (3) exposure time.[23] While viral load in the mastoid/ middle ear is unknown for SARS-CoV-2, this study suggests a high degree of aerosolization and exposure time may be long with otologic and neurotologic cases.

We investigated the use of two barrier strategies to mitigate aerosols produced during mastoidectomy. Both could be attached to any microscope and some exoscopes. OtoTent1 was created from a commercially available, low cost, opaque drape, and the design is described in a prior study.[8] Carron et al. proposed implementation of two similar barrier drape concepts that used either a 1015 Steri-drape (3M, St. Paul, MN) or a C-Armor drape (Tidi, Neenah, WI), and Hellier et al. recommended that a second microscope drape be used to reduce droplet spray.[24,25] These innovations suggest that otolaryngologists are interested in identifying techniques to mitigate aerosol and large droplet dispersion. Unfortunately, these simple barrier drapes can be inconvenient to use, preventing instruments from being easily passed between the surgical scrub technician and the surgeon and intermittently obscuring the surgical field.

Thus, we sought to create a customized drape, OtoTent2, to address usability issues and potentially improve airborne aerosol containment. OtoTent2 was designed with clear plastic, with specialized ports for the surgeon's arms, and instrument ports to accommodate easy transfer of instruments between the surgical scrub technician and the surgeon. OtoTent2 formed a semi-enclosed space over the surgical site, including a partial "floor" with a central hole to access the surgical site. OtoTent2 is *not* sealed around the surgical site and can be lifted off the field without dripping any pooled irrigation fluid. Irrigation runoff can be managed as per the surgeon's current preferred typical set-up (i.e. with a separate irrigation collection bag or with towels placed around the drilling site). OtoTent2 included a rigid frame to keep the operating space unobstructed by drape material. Surgeons who trialed OtoTent2 in the laboratory noted that it was comfortable to use and did not obstruct the view of the surgical site.

OtoTent2 without second suction successfully contained aerosol during short 1-minute drilling trials, such that the mean particle density was not significantly different from background levels. In OtoTent2, the "floor" and the use of arm and instrument ports likely accounted for improved aerosol containment, but the individual design elements were not evaluated separately to determine which feature(s) were effective. When using the OtoTent1 without second suction, high aerosol levels were measured compared to background, which may have been from aerosol escape from under the open edge of OtoTent1 and escape with small arm movements. Thus, while OtoTent1 may successfully mitigate large droplet splatter,[8] it does not appear to successfully decrease small particle spread.

Placement of the second suction within the drape is critical for decreasing particle dispersion, likely due to increased volume of air turnover within the drape. The volume of the OtoTent1 and OtoTent2 barrier drapes were approximately 40L and 37L, respectively. The flow rate of the second suction was 65 L/min, such that volume within the drape could potentially be exchanged during drilling. In contrast, the flow rate of the 12-Fr suction was 32 L/min.

Use of the SS within OtoTent1 reduced aerosol dispersion, such that *on average,* aerosol density was not significantly greater than baseline. There was, however, some variability in aerosol dispersion in the trials with OtoTent1 with SS, which accounts for the small elevation in particle density seen in Figure 5 for this condition. These variable results may be attributed to inconsistencies in the OtoTent1 "seal" at the bottom edge of the open drape or around the arms, depending upon positioning. Both use of the second suction and delaying removal of the drape appear to be important for minimizing aerosol escape during surgeon arm removal and drape removal. Overall, simultaneous application of multiple strategies including (1) use of the barrier drape, (2) increased air turn over via the second suction, and (3) delaying drape removal were important.

Potential concerns with using a barrier drape include added time for set-up, difficulty in passing instruments, concerns with the drape obstructing the view, particulate accumulating on the drape/lens, and interference with management of an unexpected adverse event (such as from injury to the sigmoid sinus). Both OtoTent1 and OtoTent2 take about one minute to set up. OtoTent2 improves ease of passing instruments with use of ports; however, both drapes present sufficient inconvenience that we expect surgeons will use drapes only during aerosol generating procedures (i.e. drilling). Subjectively, the scaffold on the OtoTent2 provides adequate rigidity such that the drape does not obstruct the surgical view. In our clinical experience with OtoTent1, the drape can temporarily obstruct the view when instruments are passed, requiring repositioning of the drape. Particulate accumulation on the drape does not appear to interfere with surgery and debris on the lens can be wiped clean as needed. In case of an adverse event, such as hemorrhage, instruments may be passed through the ports, the microscope with the attached drape may be moved away to access the surgical site, or either drape may be removed in a matter of seconds.

Overall, surgeons and operating room staff will need to balance concerns with potential risks of inhaling biomaterials, which at the time of this writing includes the potential risk of contracting SARS-CoV-2, with the inconveniences from using a drape. As testing availability and accuracy improves for COVID-19, the immediate threat of contracting the virus is reduced. However, the COVID-19 era has already led to heightened awareness of biomaterial dispersion from aerosol generating procedures,[8,12,21,22] which may lead to long-term changes in practice patterns despite a lack of proven nosocomial infections.

The limitations of this study stem from the use of static methods for aerosol assessment, cadaveric models, and the natural variability in aerosol generation from high speed drilling. This study measured optical particle size without the use an aerodynamic particle sizer or dynamic assessment techniques, and did not account for change in droplet size, desiccation, or formation of droplet nuclei over time. Particulate density was measured at only one location in the surgical field and particulates >10μm in size were not assessed. Small droplets and bone dust particulate could not be distinguished. The presence of infectious pathogens, including virus or bacteria, in the aerosol were not assessed. Air exchange in the laboratory setting occurred at a rate of 6 turnovers per hour, whereas most operating rooms in the United States have around 15-20 air changes per hour, depending on the type of operating room.[26] Longer drilling times were not included given the limited cadaveric resources, and only mastoid cortical bone was drilled in this study in order to limit variance from differences in surgical site bone. Further research is needed to determine the optimal length of the rest period prior to drape removal and instrument exchange, as it will depend on duration of drilling, leakage rate of barrier design, and suction air flow rate. Drilling in cadaveric bones may not be analogous to drilling in living patients as the bones have different composition and lack viable mucosa and mucous. Additionally, measuring aerosol dispersion when passing instruments, such as to change burs or suction sizes, would be valuable. Despite the apparent success of the barrier strategies, PPE should not be reduced as this study has not been replicated in a clinical setting.

Conclusions

Mastoidectomy using a high-speed drill is a highly aerosolizing procedure with the potential to disperse particles smaller than 10um. Barrier drapes can be an effective way to mitigate aerosol dispersion, but this depends on the drape design. Use of OtoTent2 (with or without a second suction) was an effective strategy to mitigate dispersion of aerosols during drilling, but OtoTent1 was only effective when a second suction was added. Use of a second suction and delayed removal of the drape after drilling should be used in conjunction with either barrier drape to decrease particle dispersion. These three strategies (barrier drape, second suction, and delayed drape removal) may be used as an adjunct to appropriate PPE during the COVID-19 era.

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Figure Legends:

Figure 1: Experimental setup. (A) No barrier. Optical particle sizer, 30 cm from surgical field. (B) OtoTent1. (C) OtoTent2. Arm ports (green arrows), instruments/suction ports (yellow arrows), and collapsible frame (orange arrows).

Figure 2: Experimental set-up of second suction. Suction tubing was attached to the cadaver 3 cm from the mastoid cortex to continuously evacuate particles.

Figure 3: Barrier drape schematic. (A) OtoTent1. No floor, surgeon's hands and instruments pass under the drape. (B) OtoTent2. Specialized drape with floor, arm ports for surgeon's hands and port for instruments/suction.

Figure 4: Average particle density across time for mastoidectomy without a barrier in two conditions: cutting bur and cutting bur with a second suction.

Figure 5: Comparison of particle density generated in mastoidectomy without a barrier and with the OtoTent1 and OtoTent2, across time, and with and without a second suction.

Figure 6: Particle density generated (A) during one minute of drilling and (B) following barrier removal either immediately or after one minute had elapsed after drilling.

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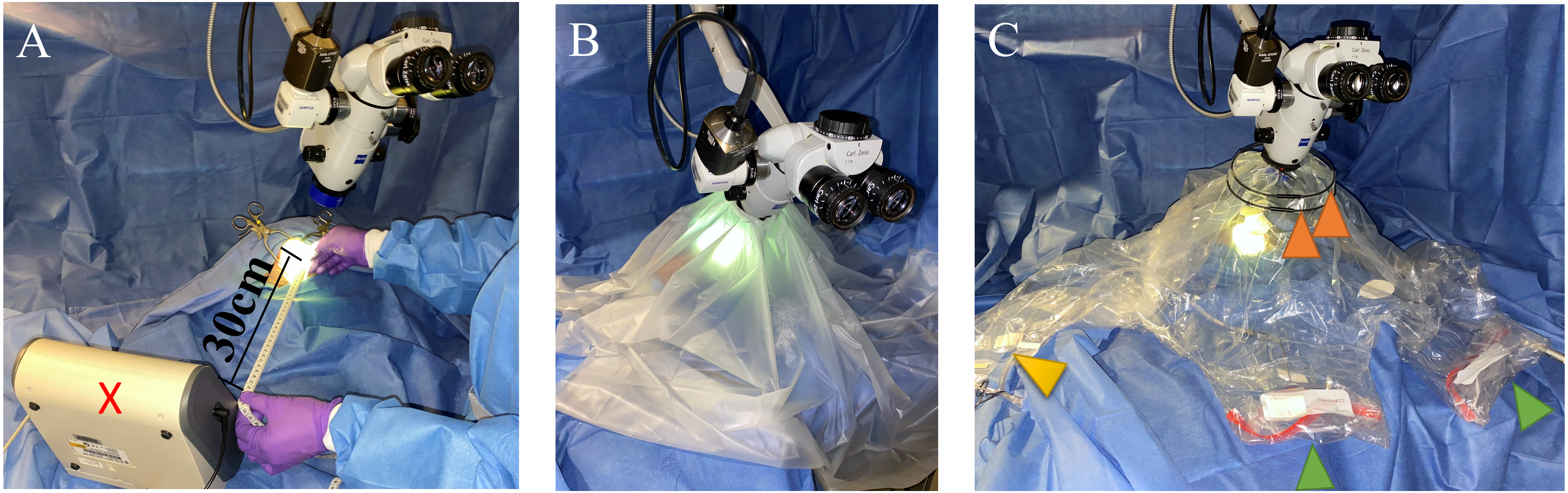

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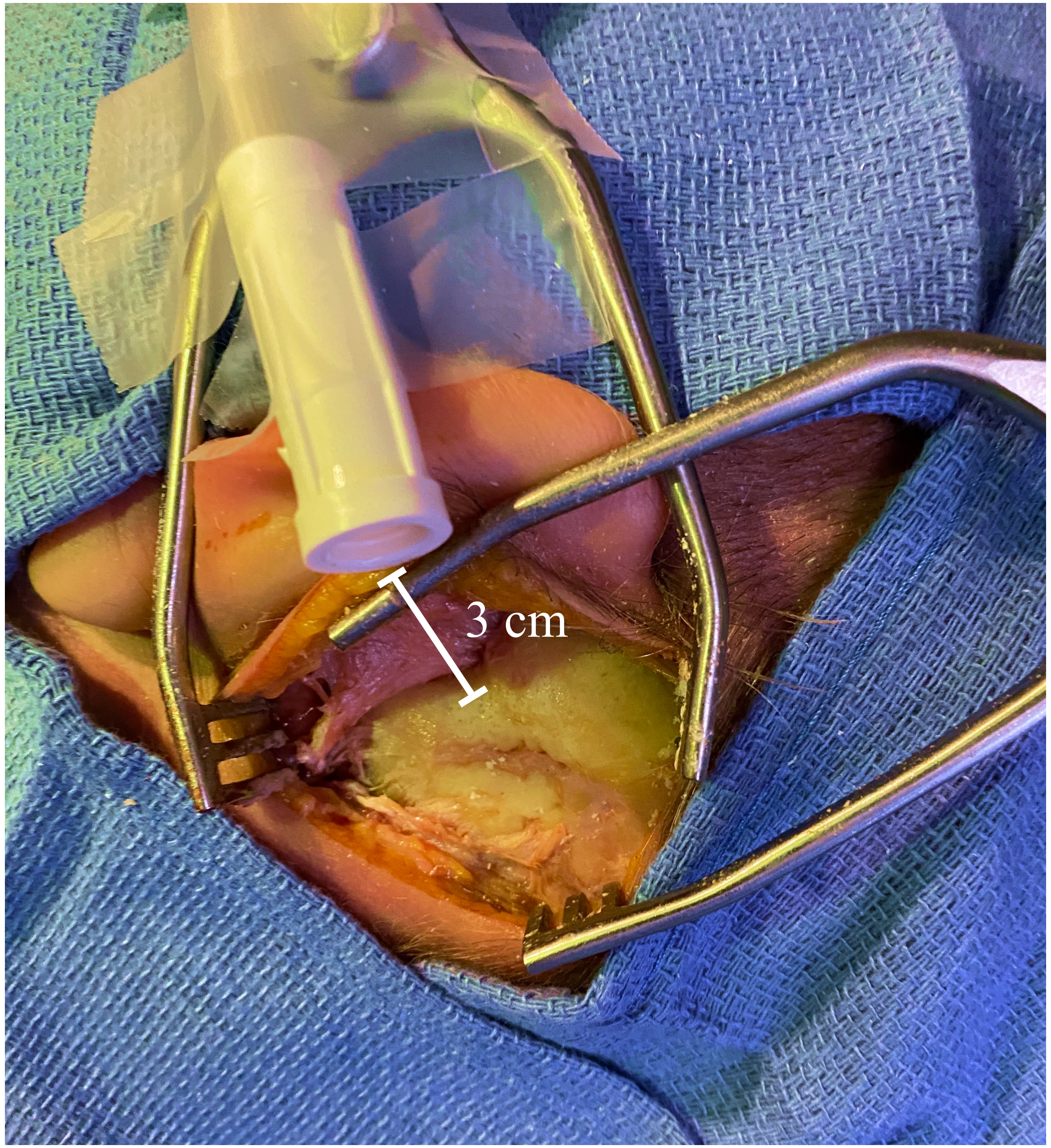

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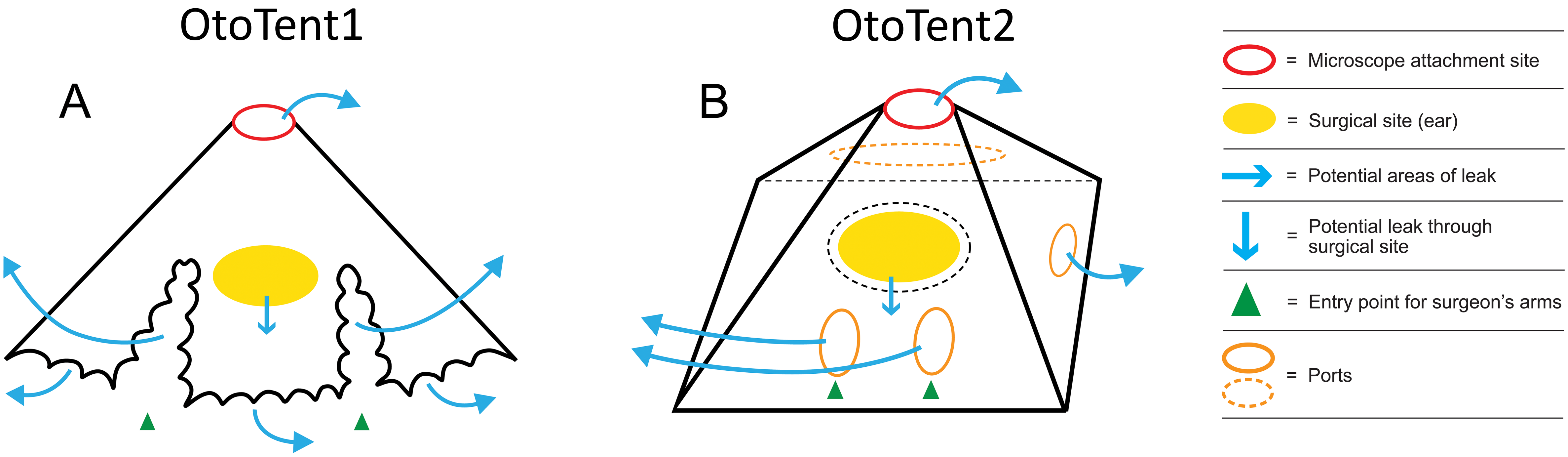
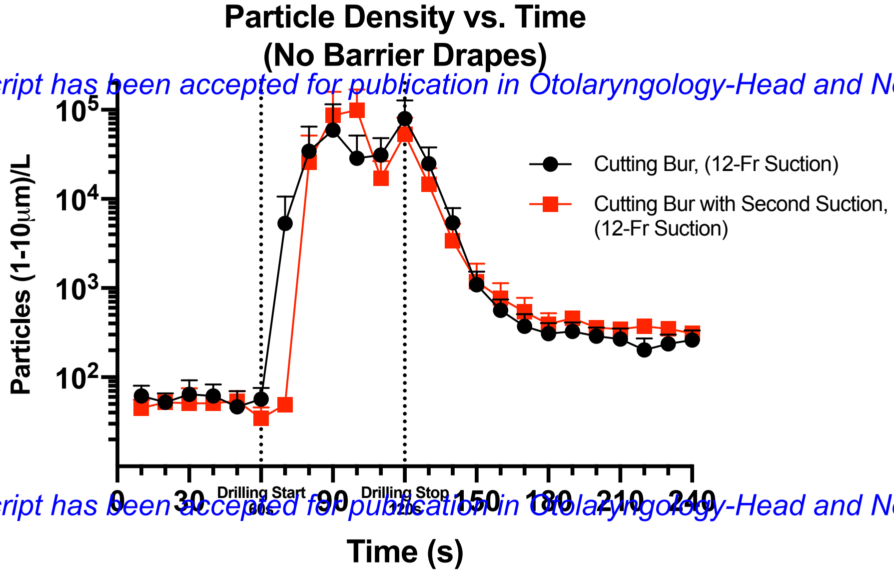

OtoTent1
A
OtoTent2
B
= Microscope attachment site
= Surgical site (ear)
= Potential areas of leak
= Potential leak through surgical site
= Entry point for surgeon's arms
= Ports



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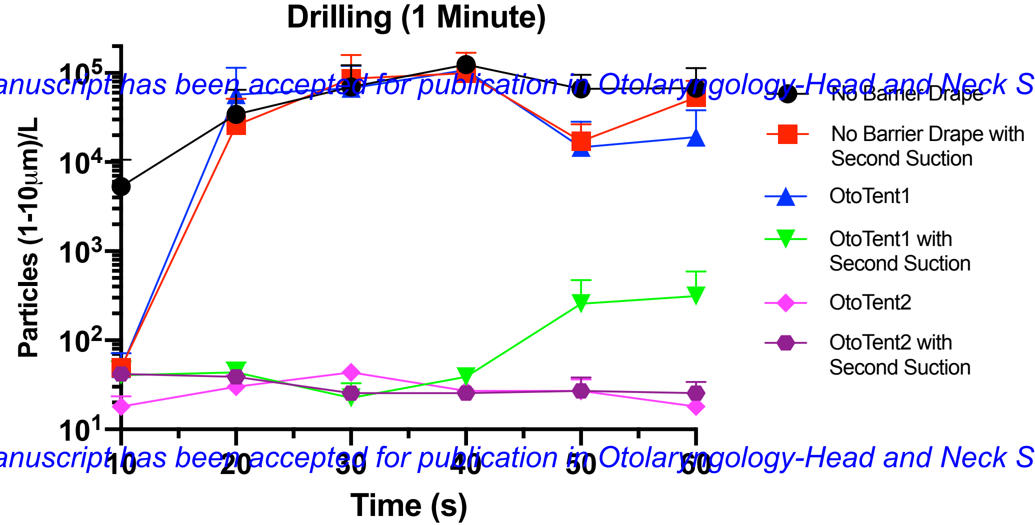

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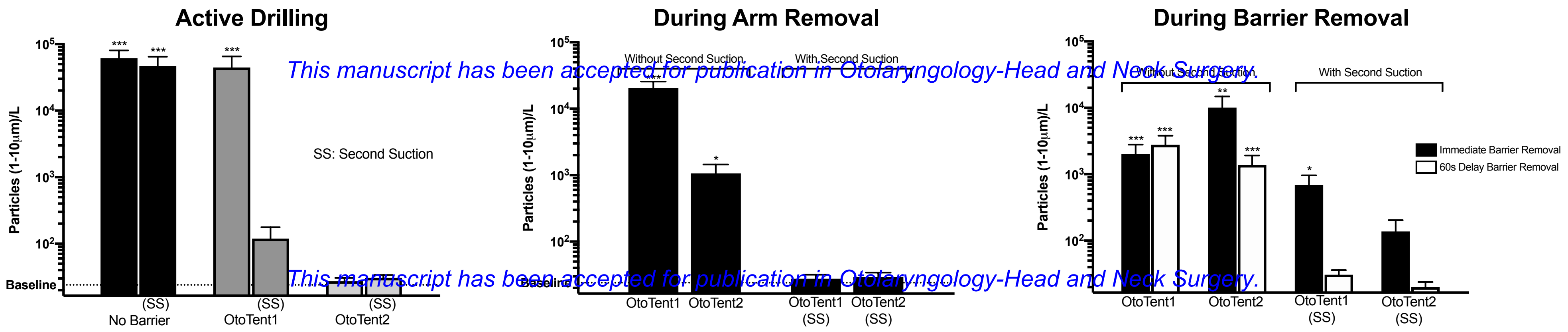

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