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Airborne Aerosol Generation During Endonasal Procedures in the Era of COVID-19: Risks and Recommendations

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Conflict of Interest Statement: Dr. Benjamin S. Bleier has consultant relationships with Olympus, Medtronic, Karl Storz, Sinopsys, Baxter, and 3D Matrix and receives royalties from Theime. He holds patents for “Treatment of Sinusitis Through Modulation of Cell Membrane Pumps” (Non-provisional USP assigned to MEEI), “Inhibition of Cystatins for the treatment of Chronic Rhinosinusitis” (Non-provisional USP), and “Methods of delivery pharmaceutical agents” (US 13/561,998). Dr. Bleier is working with industry to develop source control solutions for endoscopic procedures which may include an equity position in the future.

Key-words: COVID-19, Airborne, Aerosolization, Endoscopy, Nasal Endoscopy, Aerosol Generating Surgery, Aerosol Generating Procedure

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Objective: In the era of SARS-CoV-2, the risk of infectious airborne aerosol generation during otolaryngologic procedures has been an area of increasing concern. The objective of this investigation was to quantify airborne aerosol production under clinical and surgical conditions and examine efficacy of mask mitigation strategies.

Study Design: Prospective quantification of airborne aerosol generation during surgical and clinical simulation.

Setting: Cadaver laboratory and clinical examination room.

Subjects and Methods: Airborne aerosol quantification with an optical particle sizer was performed in real-time during cadaveric simulated endoscopic surgical conditions, including hand instrumentation, microdebrider use, high-speed drilling, and cautery. Aerosol sampling was additionally performed in simulated clinical and diagnostic settings. All clinical and surgical procedures were evaluated for propensity for significant airborne aerosol generation.

Results: Hand instrumentation and microdebridement did not produce detectable airborne aerosols in the 1-10μm range. Suction drilling at 12,000rpm, high speed drilling (4mm diamond or cutting burs) at 70,000rpm, and transnasal cautery generated significant airborne aerosols ($p<0.001$). In clinical simulations, nasal endoscopy ($p<0.05$), speech($p<0.01$), and sneezing ($p<0.01$) generated 1-10μm airborne aerosols. Significant aerosol escape was seen even with utilization of a standard surgical mask ($p<0.05$). Intact and VENT-modified N95 respirator use prevented significant airborne aerosol spread.

Conclusion: Transnasal drill and cautery use are associated with significant airborne particulate matter production in the 1-10μm range under surgical conditions. During simulated clinical activity, airborne aerosol generation was seen during nasal endoscopy, speech, and sneezing. Intact or VENT-modified N95 respirators mitigated airborne aerosol transmission while standard surgical masks did not.

Introduction

The COVID-19 pandemic has catalyzed an unparalleled disruption in the provision of health care around the world. Following its detection in December 2019, health policy shifted from an initial strategy of containment to mitigation[1]. These efforts have been largely successful at preventing hospital resources from becoming overwhelmed within the United States. However, it has required the delay or cancellation of almost all elective patient visits and procedures. Fortunately, infection and case fatality rates have begun to plateau in even the most severely impacted regions. Clinicians and hospitals now face challenging decisions as to how to safely allow elective patients back into the clinics and operating rooms. This difficulty in planning is further compounded by a persistent lack of personal protective equipment (PPE), effective treatments for COVID-19, COVID-19 testing capacity and turnaround time, and clarity regarding sensitivity and specificity of the currently available tests for COVID-19[2].

Rhinologic patients are of unique concern in this reopening phase. Delays in elective care do appear to be associated with worse outcomes[3] and higher costs[4]. However, endoscopic procedures have been shown to carry a risk of respiratory droplet formation in both diagnostic and surgical settings [5]. While these risks can be mitigated using low level personal protection equipment, the potential of airborne aerosol generation during endoscopic procedures has not been studied. An evidence-based analysis of this potential is essential as it bears directly on the status of endonasal instrumentation as an Aerosol Generating Procedure (AGP) with its attendant heightened requirements for PPE, air handling, and environmental controls.

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90 The purpose of this study was to therefore 1) quantify airborne aerosol production
91 following endonasal instrumentation during cadaveric surgical and clinical diagnostic
92 conditions and 2) determine the relative efficacy of source control solutions.

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Methods

Study Design

The surgical simulation was IRB approved through a formal excess tissue protocol. The clinical simulation was reviewed by the Partner's Human Research Committee director and performed under the Quality Improvement Initiative at Massachusetts Eye and Ear and as such was not required to be formally supervised by the IRB per their policies. All cadaver experiments in this study were performed in a dedicated surgical laboratory using two fresh-frozen cadaver head specimens at room temperature. Both the clinical examination room (111 sq ft) and surgical laboratory (726 sq feet) were equipped with air exchangers operating at a rate of 6 total air changes per hour.

Aerosol Sampling

Aerosol sampling was performed using an optical particle sizer (OPS 3330, TSI Inc, Shoreview, MN), which measures particle number, concentration, and size distribution using single particle counting technology up to a size of 10μm. Flow rate through the OPS 3330 is a constant 1.0L/min through a 3mm port. Particle size distribution is measured in 16 user-adjustable channels. Total particle counts by size over a period of timed data were collected.

Surgical Simulation

The cadaver head was placed in a supine position with the nostril situated 15cm from the optical particle sizer (OPS) intake port (Figure 1A). Five ml of saline was irrigated into the nose using a syringe prior to each surgical condition. For surgical visualization,

a high definition endoscopic camera was attached to a 4mm 0° endoscope (Karl Storz, Tuttlingen, Germany). Background samplings were obtained prior to surgical conditions and at least two minutes elapsed between each experiment to allow for verification of return to baseline aerosol concentrations at the intake port. Suction was utilized to evacuate any retained intranasal particulates following all drilling and cautery conditions. Experiments were conducted in 30-second durations with sequential replicates performed for a total duration of 2 to 5 minutes. The surgical conditions included: 1) nasal suctioning using a 10Fr Frazier suction; 2) hand actuated instrumentation using a through cutting forceps of the middle turbinate; 3) powered suction microdebridement (4mm Tricut® blade at 5,000 oscillations/min, Medtronic, Jacksonville, Fl) of the posterior nasal septum; 4) powered high-speed drilling of the sphenoid rostrum using a 4mm diamond reverse taper suction drill at 12,000rpm (Medtronic); 5) powered high-speed drilling of the sphenoid rostrum using a Midas Rex Legend Stylus with 4mm diamond bur at 70,000rpm, (Medtronic); 6) powered high-speed drilling of the sphenoid rostrum using a Midas Rex Legend Stylus with 4mm cutting bur at 70,000rpm; and 7) battery-powered endonasal cautery of the inferior turbinate (Acu-Tip, Practicon, Greenville, NC). Each intervention was performed in duplicate on two separate cadaver heads.

Clinical Simulation

Subjects were seated upright in a clinical room examination chair with the nare placed 15cm from the OPS intake port (Figure 2A). Background samplings were obtained in an empty clinic room, and at least 2 minutes elapsed between experiments to allow for

return to baseline aerosol concentrations at the intake port. Each experiment was conducted in 30-second durations with sequential replicates performed for a total duration of 1 minute. The clinical conditions included: 1) simulated heavy mouth breathing (e.g. panting) with breaths every 3 seconds; 2) simulated coughing every 5 seconds; 3) speech by reading of the "Rainbow Passage" a standardized vocalization paradigm (Voice and Articulation Drillbook, Harper and Row); 4) simulated sneezing every 10 seconds; 5) simulated nasal endoscopy by the intranasal placement of a 2.7mm 0° rigid and 3.5mm flexible endoscope (Karl Storz) for 20 seconds followed by removal; and 6) simulated topical spray of a 1:1 1% lidocaine and oxymetazoline 0.05% solution (MADomizer, Teleflex, Wayne, PA) 15cm away from the OPS intake port every 10 seconds. Subjects took a sip of water in between each condition to ensure adequate and consistent hydration. Each intervention was performed in duplicate on two separate subjects.

Following behavioral simulation, subjects then performed additional simulated sneezing every 10 seconds for 30 second replicates with the opening of their mouth positioned 15cm from the OPS intake port, while wearing 1) a Standard Level 1 surgical mask (Halyard Health, Alpharetta, GA), 2) N95 Health Care Particulate Respirator and Surgical Mask (3M 1860, Saint Paul, MN), and 3) modified N95 VENT respirator as previously described [5] to allow passage of an endoscope through the mask while maintaining a tight seal. An additional trial was performed by doffing of the N95 respirator for 30 seconds following sneezing to measure airborne aerosol release following mask removal.

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Statistical Analysis

Stata version 13 (StataCorp, College Station, TX) software was used for statistical analysis to assess differences between background particle concentration and particles generated during simulated clinical and surgical activities. Non-parametric statistical techniques were utilized due to small sample sizes, with Bonferroni correction for multiple comparisons. Average background particle concentration (separate for clinical encounter and surgical laboratory encounter) was subtracted from each condition prior to data visualization as previously described[6]. Prism Version 8 (GraphPad Software, La Jolla, CA, USA) was used for visualization of data.

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Results

Surgical Simulation

Airborne Aerosol Generation During Cold Instrumentation and Microdebridement

All sampling periods were 30 seconds in duration, and conditions were performed in duplicate with two separate cadaver heads. Sixteen background samples were obtained spaced between experiments and minimal variability in background was observed. Nasal suctioning with a 10Fr Frazier suction for four sampling periods and endoscopic through biting of the middle turbinate (hand actuated) for 10 sampling periods did not produce significant detectable airborne aerosols in the 1-10 μm range (Figure 1B). Application of a microdebrider to the posterior septum with debridement of tissue and declogging external to the nare did not produce 1-10 μm airborne aerosols over 10 sampling periods (5 minutes). The cutting edge of the microdebrider was open upon introduction and removal.

Airborne Aerosol Generation During High Speed Drilling Conditions

With the cadaver head in surgical position, three separate drilling conditions were performed: (1) a suction drill at 12,000rpm for 10 30-second samples (2) a powered high-speed drill at 70,000rpm with a 4mm diamond bur for 4 30-second samples, and (3) a powered high-speed drill at 70,000rpm with a 4mm cutting bur for 4 30-second samples. The drill was used to remove bone at the sphenoid rostrum. In all three conditions, significant airborne aerosol generation in the 1-10 μm range was observed (Figure 1B; suction drill $p<0.001$, $U=15$, $n=20$; diamond drill $p<0.001$, $U=0$, $n=8$; cutting drill $p<0.001$, $U=1.5$, $n=8$, Mann-Whitney U test). Particle generation was observed to

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increase throughout the duration of the drilling with increased particle generation during the latter portion of drilling periods. Particle number decreased with increasing particle diameter across the 1-10 μm range (Figure 1C). Finally, an additional experiment was performed demonstrating increased particle generation in the absence of suction using the suction drill at 12,000rpm over the first 120 seconds of drilling (Figure 1D).

Airborne Aerosol Generation During Transnasal Cautery

Transnasal cautery of the inferior turbinate demonstrated significant particle generation in the 1-10 μm range over background in 4 30-second samples (Figure 1B, $p<0.001$, $U=0$, $n=8$, Mann-Whitney U test). Particles generated were on average smaller than those observed in the drilling conditions (Figure 1C).

Clinical Simulation

Airborne Aerosol Generation During Simulated Patient Activities

Subjects were positioned sitting upright with the nose and mouth 15 cm from the aperture of the optical particle sizer air intake valve. All samples were collected over a period of 30 seconds and performed with two different subjects and at least two replicates per subject (n=4-10). Panting and coughing generated detectable 1-10 μm aerosols which were not significantly greater than background (Figure 2B). Both nasal endoscopy and speech conditions generated significant airborne aerosols (nasal endoscopy, $p<0.05$, $U=10$, $n=8$; speech, $p<0.01$, $U=6.5$, $n=10$, Mann-Whitney U test). Simulated sneezing generated the most airborne particles per minute by an order of magnitude ($p<0.01$, $U=0$, $n=4$, Mann-Whitney U test). Simulated topical spraying of

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lidocaine and oxymetazoline generated airborne aerosols comparable to those generated with sneezing (Figure 2C, $p<0.01$, $U=0$, $n=4$, Mann-Whitney U test).

Airborne Aerosol Detection During Simulated Sneeze Under Masked Conditions

As simulated sneezing generated the largest number of 1-10 μm airborne aerosols, several sneezing conditions were performed using different source control mask solutions. The surgical mask alone attenuated airborne aerosol generation (Figure 2C), however statistically significant aerosol escape was still detected ($p<0.05$, $U=2$, $n=4$, Mann-Whitney U test). Both an N95 respirator and a modified N95 VENT respirator ameliorated airborne particle generation to background levels. N95 doffing following simulated sneezing over a 30 second period demonstrated an increase in airborne particle generation that did not reach significance above background.

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Discussion

While droplet and contact infectious transmission in SARS-CoV-2 have been largely accepted, the role of airborne transmission remains unclear. This mode is of particular concern in the healthcare setting given the propensity for AGPs to produce particles less than 10μm[7]. The size of the SARS-CoV-2 virus is approximately 60-140nm, based on electron micrographs[8]. Since the advent of COVID-19, the field of Otolaryngology has found itself grappling with potential aerosolization risk of endoscopic procedures despite a distinct lack of quantitative evidence to guide best practices. In an effort to address this unmet need, our team previously reported on a semi-quantitative method to determine the risk of droplet aerosol production during both outpatient diagnostic and surgical endonasal procedures[5]. The purpose of the current study was to extend those findings into the range of airborne aerosols.

Our surgical simulation conditions were designed to test a variety of endonasal instruments from suction and through cutting forceps through powered devices and thermal cautery. Our findings were generally consistent with our prior study in that use of a surgical drill carried the greatest risk of generating detectable aerosols. The concomitant use of suction appeared to provide some benefit in reducing aerosol concentration however the lower speed of the suction drill is a confounding variable. Similarly, the microdebrider with distal tip suction did not produce detectable aerosols even when requiring removal and active unclogging adjacent to the detector. Conversely, thermal cautery produced significant and particularly fine aerosols which is consistent with the previous literature[9]. These findings serve to provide further evidence

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that the use of drills and cautery remain the endonasal surgical procedures of greatest risk.

With regards to the clinical diagnostic conditions, our findings demonstrated that detectable airborne aerosols are generated even during limited periods of speech, panting, cough, and sneeze. However, talking and sneezing were the only behaviors associated with a significant increase over background. Unfortunately, the most common method used to reduce sneezing, namely topical nasal anesthesia and decongestion spray, also produced a significant number of aerosols. While the lack of significance in the other behavioral conditions could be attributed to the short testing duration and use of healthy volunteers, these results are consistent with prior physiologic reports confirming the differential risk of speech and sneeze conditions[10–13]. Of particular importance, unlike our prior droplet data[5], nasal endoscopy was found to be associated with airborne aerosol production irrespective of whether a rigid or flexible scope was utilized. AGPs are defined by the CDC as “commonly performed medical procedures…that create uncontrolled respiratory secretions.” Insofar as endoscopic examinations 1) require prolonged close proximity to the patient, 2) produce detectable airborne aerosols, and 3) carry a distinct yet unpredictable risk of triggering sneeze events, our findings suggest that nasal endoscopy carries a similar risk profile as currently recognized AGPs [7–14].

Our tested mask conditions focused on the ability to mitigate sneeze associated aerosol production as this was clearly the behavior of greatest risk. The existing literature

regarding the utility of masks is complex as studies tend to focus on discreet attributes such as filtration efficiency, performance under steady and episodic conditions, or the relationship between mask use and infectious transmission. Epidemiologic and virologic studies have suggested that surgical masks may be equivalent to N95 respirators at protecting healthcare workers from infectious respiratory viruses[15,16]. Similarly, some virologic reports have shown that surgical masks alone are adequate to prevent coronavirus aerosol spread in both the droplet and airborne ranges during talk and cough conditions[17]. Conversely, studies employing episodic stresses such as sneeze have shown that surgical masks are vulnerable to leakage from dynamic changes in pressure and air velocity[16,18,19] This is perhaps not surprising as sneezing may produce thousands of airborne droplet nuclei at high speeds [12,13]. The evident discrepancies between mask efficacy readouts highlights the importance of context dependent testing as a basis for the creation of subspecialty specific safety guidelines. Our results were consistent with previous findings [16,18,19] in that an intact surgical mask was incapable of controlling the spread of sneeze associated airborne aerosols. This result stands in contrast to our prior findings in which a surgical mask did prevent simulated respiratory droplet contamination[5]. Conversely, the N95 respirator in both the intact and VENT modification conditions appeared to effectively contain aerosol spread. Though not statistically significant, we did observe some contamination after N95 respirator removal suggesting that when used as source control, masks should not be doffed within the clinical space.

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As we apply this data to infection prevention and control recommendations in the outpatient Otolaryngology setting, it is useful to conceptualize the protection needs of the three “Ps”, namely the patient, the provider team (including both administrative and medical staff), and the physical plant (including the clinic/waiting room surfaces and air supply). Comprehensive adherence to “standard precautions” as defined by the CDC[14] will tend to simultaneously address each of these groups and should integrate source, engineering, and environmental control strategies. Our results suggest that the proper use of a fit-tested N95 or equivalent VENT respirator is effective at mitigating sneezing, the behavior associated with the highest number of aerosols at the highest velocities. Consequently, these latter barrier strategies may be considered 1) a source control by protecting the provider/physical plant from the patient and 2) an engineering control by protecting the patient from the providers and one another.

There are several limitations to this study which bear discussion. As the surgical simulation was performed in a cadaver head, it is possible that the lack of pulsatile blood supply at body temperature and physiologic mucus secretion may alter the propensity for aerosol production in the 1-10μm range. Consequently, further studies during active surgery are warranted. With regards to the testing of the clinical diagnostic conditions, we must stress that our methodology was sensitive only to the generation of airborne droplet nuclei. The study was not designed to detect the presence of virus within these particles nor their infectious transmissibility. However, in the absence of clear data on the minimum infectious dose of SARS-CoV-2, we believe our findings

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should be interpreted in the most conservative context possible with respect to infectious control recommendations.

Conclusion

Our study represents a systematic effort to quantify the degree of airborne aerosol production associated with a variety of endonasal procedures. The surgical simulation data confirm that the use of high speed drills and cautery produce the largest number of particles. The clinical conditions revealed that endoscopic instrumentation, speech, and sneezing all produced significant detectable airborne aerosols within only 30 seconds of measurement. An intact surgical mask failed to fully protect against sneeze associated contamination. Therefore, surgical VENT masks, as previously described by our group, may not be sufficient when considering sub-10 µm particles. However, when applied to an N95 respirator, the VENT modification retained the ability contain airborne aerosols. These results suggest that while nasal endoscopy carries a risk profile similar to established AGPs, barrier mask solutions offer the potential of effective source and engineering controls.

Figure Legends

Figure 1: Surgical Simulation: A) Experimental setup (arrow denotes intake port). B) Aerosol generation after 2-5 minutes (*** $p<0.001$). C) Particles separated by size (1-10μm). D) Aerosols in the presence and absence of distal tip suction.

Figure 2: Clinical Simulation: A) Experimental setup (arrow denotes intake port). B) Airborne aerosol generation during simulated clinical conditions. C) Airborne particle generation under sneeze conditions with various source controls. (* $p<0.05$, ** $p<0.01$).

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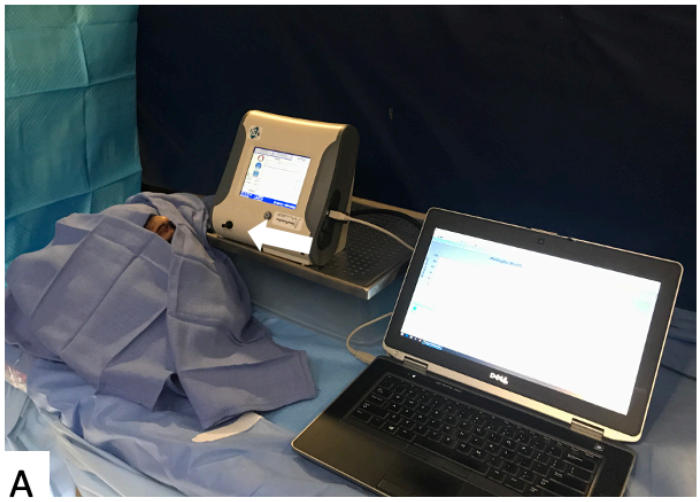

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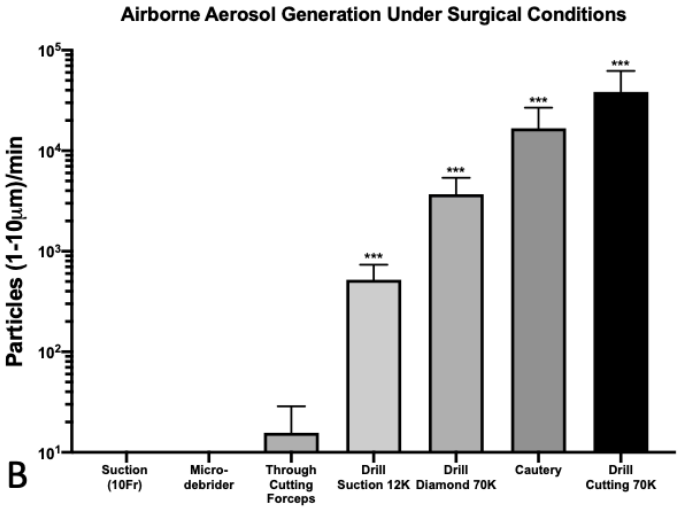
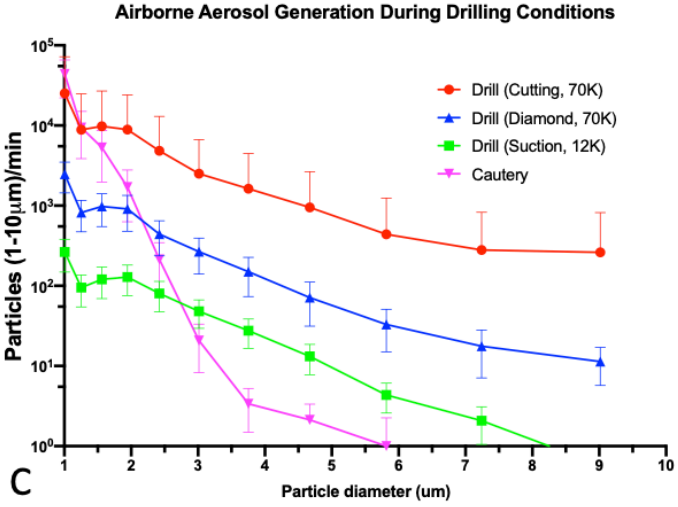
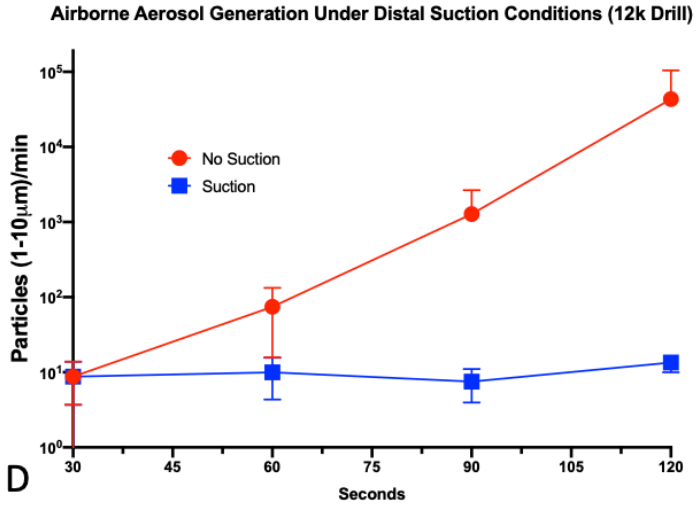

Airborne Aerosol Generation Under Surgical Conditions
Particles (1-10μm)/min
10^5
10^4
10^3
10^2
10^1
***
Suction (10Fr)
Micro-debrider
Through Cutting Forceps
Drill Suction 12K
Drill Diamond 70K
Cautery
Drill Cutting 70K

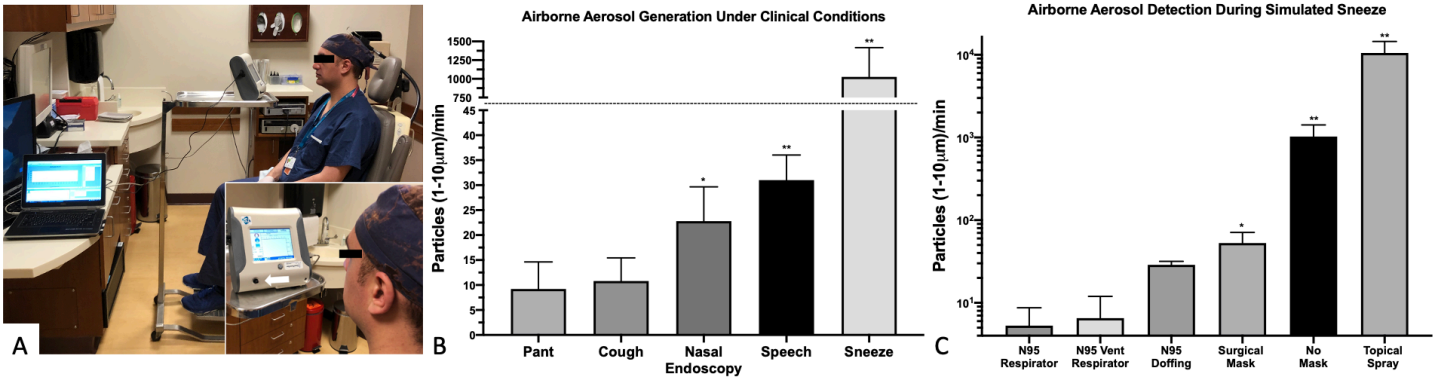
B


Airborne Aerosol Generation During Drilling Conditions
Drill (Cutting, 70K)
Drill (Diamond, 70K)
Drill (Suction, 12K)
Cautery
Particles (1-10μm)/min
10^5
10^4
10^3
10^2
10^1
10^0
1
2
3
4
5
6
7
8
9
10
Particle diameter (um)

C


Airborne Aerosol Generation Under Distal Suction Conditions (12k Drill)
No Suction
Suction
Particles (1-10μm)/min
10^5
10^4
10^3
10^2
10^1
10^0
30
45
60
75
90
105
120
Seconds

D


A
B
Airborne Aerosol Generation Under Clinical Conditions
Particles (1-10μm)/min
1500
1250
1000
750
45
40
35
30
25
20
15
10
5
0
**
*
**
Pant
Cough
Nasal Endoscopy
Speech
Sneeze
C
Airborne Aerosol Detection During Simulated Sneeze
Particles (1-10μm)/min
10^4
10^3
10^2
10^1
**
*
**
N95 Respirator
N95 Vent Respirator
N95 Doffing
Surgical Mask
No Mask
Topical Spray