

Modelling effectiveness of PPE on aerosol exposure for healthcare workers during typical ENT procedures*

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Rhinology Online, Vol 4: 24 - 29, 2021

<http://doi.org/10.4193/RHINOL/20.087>

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***Received for publication:**

November 19, 2020

Accepted: January 26, 2021

Published: February 4, 2021

Abstract

Background: Previous studies report environmental aerosolization with various endonasal procedures, but do not specifically measure intranasal levels of inhaled aerosolized particles in healthcare providers (HCP) performing such procedures. The purpose of this study is to measure the impact of various types of personal protective equipment (PPE) worn by HCP during a variety of office-based endonasal procedures.

Methodology: Simulated sneeze and office-based procedures were performed in a test model and aerosol levels were quantified in the middle meatus of a simulated HCP model wearing various forms of PPE by using a laser diode-based particle counter. Endoscopic exam, balloon sinus dilation, suction and irrigation, simulated tissue resection with a microdebrider, and routine debridement procedures were evaluated. The aerosol levels were evaluated with and without the use of PPE to assess HCP aerosol exposure.

Results: A simulated sneeze represents a worst-case aerosol generating event when compared to other common office-based procedures (approximately 1,000 times greater than baseline particle count). Common endoscopic procedures did not generate significantly greater particle counts above baseline. When compared to no mask, a surgical mask reduces particle counts experienced by HCP in the middle meatus by 69%, while an N95 mask significantly reduced particles by 93%.

Conclusions: The levels of aerosols generated during common office-based procedures are consistent with the background aerosol levels measured at baseline. Masks are effective, with the N95 mask most effective at reducing HCP exposure to aerosols generated during a simulated sneeze.

Key words: COVID-19, personal protective equipment, aerosolization, balloon sinus dilation, aerosol generating procedure

Introduction

The COVID 19 pandemic has placed a high level of focus on aerosols as a potential mode of transmission for the SARS-CoV-2 virus. Patel et al. published a letter related to surgical staff in Wuhan becoming infected with COVID-19⁽¹⁾. The team were involved with the care of a COVID-19 patient undergoing transnasal surgery and it was reported that multiple members of the care team contracted COVID-19. Subsequent publications have clarified the initial reports, stating that the COVID-19 cases reported among the medical staff were deemed postoperative

rather than intraoperative and attributed to not applying sufficient personal airway protection⁽²⁾. However, there remains a need for additional study of the effectiveness of personal protective equipment (PPE) in minimizing aerosol exposure to health care providers (HCPs) and differentiating between procedures by levels of aerosol generation.

In July 2020, the World Health Organization updated its guidance on transmission of SARS-CoV-2 to affirm the risk of airborne transmission and flagged a heightened risk profile for HCPs in environments where aerosol generating procedures

(AGPs) are performed⁽³⁾. Workman et al. explored the aerosol generation within the exam room during a range of nasal interventions using typical ENT instrumentation in an OR environment, as well as typical clinical interactions between a patient and HCP and the role of PPE in limiting HCP exposure^(4,5). Office-based procedures using surgical instrumentation are increasingly commonplace, affirming the need to evaluate aerosol exposure and the impact of PPE in this site of care. According to the CDC there is currently neither expert consensus, nor a sufficient body of data to create a definitive list of AGPs in different healthcare settings⁽⁶⁾.

To contribute to the available data on aerosol generation during common otolaryngologic in-office procedures and the impact of PPE, we evaluated intranasal HCP exposure to aerosols during common office interactions. The purpose of this simulation was to measure aerosolization of a variety of endonasal procedures in the office microenvironment to provide a relative comparison between procedures, and to evaluate the effects of PPE as potential mitigation to aerosol exposure.

Materials and methods

Supplies and equipment

The simulations were performed in an enclosed chamber (Figure 1), which provided isolation while testing was in process and was equipped with gloves mounted to the side panel to allow the tester to maneuver devices inside of the chamber while closed. The test chamber was also equipped with a ventilation system to evacuate residual particles between tests to return the chamber to baseline levels. Patient and HCP models were placed inside the chamber. Each model contained a sinus cavity insert that replicated typical nasal anatomy. Prior to each test, the sinus cavity of the patient model was coated with 2 mL of a simulated mucous solution created using a 1:1 mixture of saline and glycerin that was dispensed from an atomizer bottle. To simulate exhalation of an awake patient, plastic tubing was attached to the opening at the base of the sinus insert and then connected to an air source with a flow rate of 15 L/min. This is approximately twice the normal respiratory rate and was intended to represent a worst-case scenario⁽⁷⁾. A laser diode-based particle counter (Particles Plus 8306, Particles Plus, Inc., Stoughton, MA) was inserted through an opening on the back of the HCP model and the collection cone was placed into the middle meatus of the HCP sinus cavity to measure total particle counts (size range 0.3 to 25.0 microns). To simulate HCP inhalation, plastic tubing was inserted into the base of the sinus insert and connected to a vacuum pump with a flow rate of 15 L/min.

The instruments tested include a 3-mm x 30° endoscope (Entellus Medical, Plymouth, MN), a 6-mm sinus balloon dilation system (XprESS LoProfile 6x20, Stryker ENT, Plymouth, MN), a sinonasal suction and irrigation system (Cyclone, Stryker ENT, Plymouth, MN), resorbable nasal packing and a 9 Fr Frasier

suction (NasoPore Firm, Stryker, Kalamazoo, MI), and a powered microdebrider with suction (Entellus Medical Shaver System with 4-mm straight, double serrated blade at 5,000 oscillations/min, Entellus Medical, Plymouth, MN). The sneeze was generated using an atomizer (MADomizer atomizer, Teleflex, Wayne, PA) filled with the 1:1 saline and glycerin mixture.

Test setup

To simulate typical in-office procedures, the patient model was placed in a reclined position at a 45° angle. The HCP model was placed facing the patient model at 16 inches away to represent a worst-case scenario of close contact during a procedure. Testing was performed both with and without PPE installed on the HCP model. A baseline particle count was established before each test by recording the particle count for a total of 5 consecutive test intervals of 30 seconds each. Prior to each test run, the test device was placed inside the chamber and the chamber was closed. The test technician used the gloves mounted on the side of the test chamber to maneuver the devices within the chamber. For each test run, the test device was placed into the patient model and a simulated procedure was performed with particle counts recorded for a 30-second interval. A total of 5 30-second test runs were completed for each test device. The chamber was evacuated between each test until the particle count returned to baseline levels. The simulated sneeze was generated by dispensing 2 sprays (0.1 mL) of the saline/glycerin mixture in quick succession.

Test protocol for simulated sneeze

The tip of the atomizer bottle was placed alongside the nose of the patient model at the nasal base and positioned parallel to the direction of air flow. At the start of the test interval, the simulated sneeze was generated by dispensing 2 sprays (0.1 mL) of the saline/glycerin mixture in quick succession.

Test protocol for endoscopic exam

At the start of the test interval, the endoscope was inserted into the patient model. The simulated endoscopic exam consisted of manipulation of the middle turbinate, visualization of the frontal recess, visualization of the sphenoid ostium, visualization of the Eustachian tube, and removal of the endoscope.

Test protocol for balloon dilation

At the start of the test interval, the endoscope and the balloon dilation device were inserted into the patient model. Each balloon dilation test consisted of visualizing the target sinus opening with the endoscope, tracking the tip of the balloon dilation device into the target sinus opening, advancing the balloon along the catheter until fully deployed into the target sinus opening, inflating the balloon for 5 seconds, deflating the balloon, retracting the balloon along the catheter, and removing

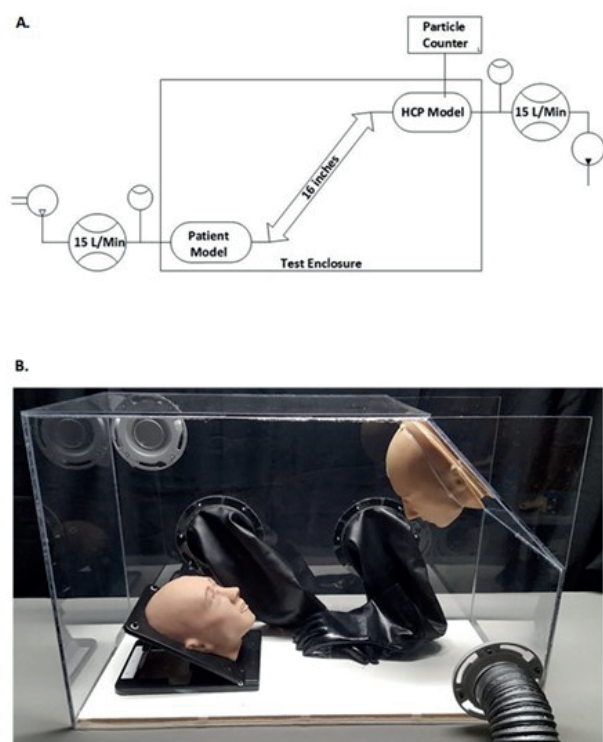


Figure 1. (A) Schematic diagram for the test fixture. (B) Test enclosure with patient and HCP models.

the balloon dilation device and endoscope from the patient model.

Test protocol for sinonasal suction and irrigation

At the start of the test interval, the endoscope and the sinonasal suction/irrigation device were inserted into the patient model. The tip of the device was placed into the frontal recess and the suction tube advanced up to the frontal recess to capture the effluent. The frontal sinus was irrigated with 30 mL of saline, adjusting the location of the suction tube to capture as much saline as possible. Upon completion of the irrigation, the device and the endoscope were removed from the patient model.

Test protocol for microdebrider

At the start of the test interval, the endoscope and the microdebrider blade were inserted into the patient model. The microdebrider test sample was visualized in the middle meatus of the patient model. The microdebrider was activated so that the blade removed material from the test sample. At the end of the 30-second test period, the endoscope and microdebrider were removed from the patient model.

Test protocol for simulated debridement

Simulated debridement consists of removing pieces of hydrated resorbable nasal packing from the patient model with a 9 Fr suc-

tion. Prior to establishing the baseline particle measurements, the model is prepared by inserting 5 pieces of nasal packing (5 mm x 5 mm x 5 mm in size) hydrated with 1 mL of saline into the middle meatus.

At the start of the test interval, the endoscope and the 9 Fr suction were inserted into the patient model. The suction was used to remove the nasal packing from the model. If necessary, the nasal packing was removed from the tip of the suction by hand after removing the suction from the patient model. Upon completion of the test, the endoscope and suction were removed from the patient model.

Statistical methods

The data were compiled in a Microsoft Excel spreadsheet. The mean change in particle count for each test group was calculated by subtracting the mean baseline count from the mean test particle count. Minitab 17 (Minitab, LLC, State College, PA) was used to calculate mean and the standard deviation for each device, which was graphed along with the mean change in particle count over baseline. Two-sample t-tests with a 95% confidence interval (CI) were conducted in Minitab 17 and used to determine statistical differences between the simulated sneeze, simulated sneeze with surgical mask, simulated sneeze with N95 respirator, and the procedures as well as between procedures and baseline.

Results

The simulated sneeze is the highest aerosol generating event with a mean change in particle count over baseline of 130,097 particles (Figure 2). The mean change in particle count over baseline across all the procedures was 2,094 particles, indicating that there is a statistically significant difference between the simulated sneeze and the procedures tested ($p=0.002$). The mean particle count for the procedure baseline measurements was 2,079 particles. Data analysis shows that there is no statistical difference between particle counts at baseline and those measured during the procedures ($p=0.64$).

Figure 3 shows that during a simulated sneeze, application of a surgical mask to the HCP model reduced the mean change in particle count over baseline to 45,246, a 69% reduction in aerosol exposure. Similarly, the application of an N95 mask reduced the mean change in particle count over baseline to 4,089, which is a 93% reduction in aerosol exposure for the HCP model. The data indicate that there are statistically significant differences between the mean change in particle count over baseline of a simulated sneeze and that of the simulated sneeze with surgical mask ($p=0.012$) and the simulated sneeze with N95 mask ($p=0.003$).

Discussion

The role of aerosols in the airborne spread of the SARS-CoV-2

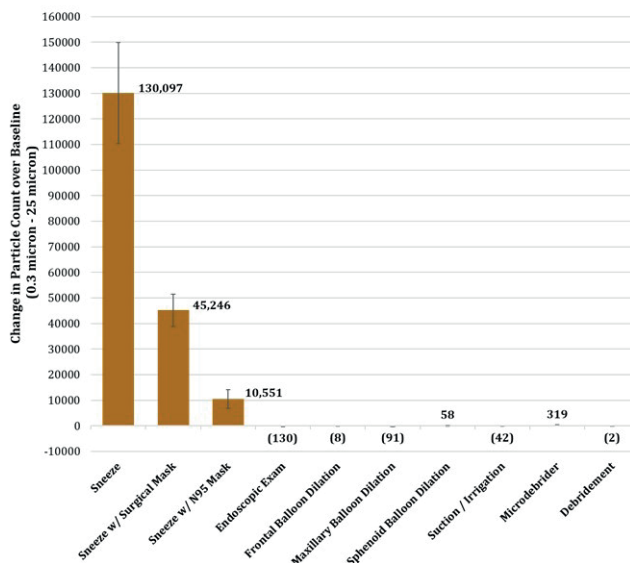


Figure 2. Particle count from common ENT office procedures. Mean change in particle count from baseline measurements for each procedure. Negative numbers are shown in brackets. Error bars represent the standard deviation for each test.

virus is of concern. Aerosol particles, particularly those smaller than 10 microns, are capable of staying suspended in the air for extended periods and can penetrate deep into the lungs when inhaled⁽⁸⁾. In order to model clinically relevant and potentially infectious HCP exposure, this test measured particle counts in the middle meatus of a simulated HCP model with and without PPE. The simulated sneeze generated the highest aerosol levels in this test. These results are similar to those of Workman et al. in that the simulated sneeze generated a significant increase in aerosols over baseline⁽⁵⁾. Use of PPE on the HCP model showed a significant reduction in the aerosol levels measured. While a surgical mask provides 69% reduction in aerosol exposure, a N95 mask provides the best protection from aerosol exposure with a calculated reduction of 93%. The multilayer construction of the HCP model and lack of a fit test of the N95 mask to the model may account for this value falling below the expected 95% reduction of an N95 mask. However, these data highlight the need to minimize the occurrence of sneezes and coughs during office-based procedures in conjunction with the use of PPE per the CDC and WHO guidances^(9,10).

A secondary goal of the test was to examine the relative differences in aerosol generation between common office-based procedures. We observed that aerosol levels of the procedures were consistent with the aerosol levels measured at baseline (increased by <1% over the mean baseline levels). The data analyses show that there are no statistical differences between baseline and the procedures tested. These results support the findings of Workman et al. that cold instrumentation and micro-

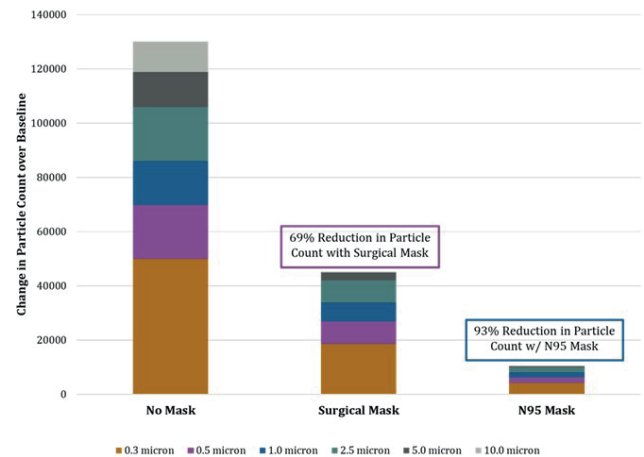


Figure 3. Effect of PPE on Simulated Sneeze. Mean change in particle count from baseline for simulated sneeze with and without PPE. The breakdown of particle size is shown within each test. The surgical mask reduces HCP aerosol exposure by 69% ($p=0.012$) and the N95 mask reduces aerosol exposure by 93% ($p=0.003$).

debridement do not produce significant detectable aerosols⁽⁵⁾. Murr et al. also found no increase in aerosol concentrations during diagnostic nasal endoscopy in the office environment⁽¹¹⁾. However, they did observe an increase in aerosol levels for patients who required debridement compared with those not requiring debridement. This is contrary to our findings in the simulated patient model that found no increase in aerosol levels over baseline for endoscopic exam. Testing within the simulated model does not account for factors such as differences in nasal anatomy, inflammation, or nasal crusting which may account for the observed differences in aerosol levels. This underscores the complexity of the problem with clinically relevant aerosol generation in the office environment and highlights the need for use of the appropriate PPE and taking additional precautions such as those outlined in Van Gerven et al.⁽¹²⁾.

It is important to note that the change in particle count over baseline for all procedures evaluated (mean=2,094 particles) was less than the change in particle count over baseline of the simulated sneeze (mean=130,097 particles), simulated sneeze with surgical mask (mean=45,246 particles), and the simulated sneeze with N95 mask (mean=4,089 particles) on the physician model.

The model used in this study was designed to create a controlled test environment to minimize the impact of external factors such as room air exchange rates. A synthetic anatomical model was chosen to provide a consistent test subject across all procedures. The internal anatomy of the model was coated with a simulated mucous solution of a 1:1 mixture of saline and glycerin which aided in demonstrating the creation and spread of aerosols. This simulated mucous solution does not account for

varying degrees of viral loading in the mucous of a live patient, but does allow the measurement of overall aerosol production and the effect of PPE. The aerosol particle counts were collected inside of the nasal airway of the HCP model, a clinically relevant location that also allowed us to assess the aerosol exposure of the HCP model both with and without PPE. Both a surgical mask and an N95 mask were tested to demonstrate the relative reductions in aerosol exposure to the HCP with different types of PPE. The change in particle count over baseline was used to compare common office-based procedures to baseline levels and to provide a comparison of aerosol levels between different types of procedures. This differs from other published studies that measured aerosol levels generated using cadaveric specimens or patient volunteers in ambient clinic and operating room settings.

Conclusions

This study demonstrates the relative aerosol generation of common office-based interactions and the impact of PPE on HCP exposure. The data show that a sneeze may be considered a worst-case aerosol producing event in the otolaryngology office environment, while routine office procedures produce aerosol levels consistent with background levels. The infectious dose of viable SARS-CoV-2 required to cause infection is unknown and, therefore, no definitive conclusion can be reached on the level of safety offered by PPE at present. However, in combination with other risk mitigation efforts such as testing and screening, confidence can be derived from the relatively low levels of aerosols created by typical in-office procedures and the effectiveness of an N95 mask in significantly reducing the exposure of HCPs.

Acknowledgments

We thank the following Stryker ENT staff: Aaron Pidde for the

design and fabrication of the test model, performing the testing, and data acquisition; Tony Hanson for fabricating the test enclosure and the simulated head models, and for providing technical support; Jason Barvels for developing the test protocols and methods and for providing the statistical analysis; Damian Curtin and Paul Unglaub for their contributions to the study design, review of this manuscript, and support of the study; and Ellen M. O'Malley, MS for review and editing of the manuscript.

Funding

The study was funded and conducted by Stryker ENT.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Authorship contribution

BS, RS, and PL contributed to the design of the experiment. PL gathered the data and performed the data analysis. BS, RS, and PL wrote the manuscript, edited the manuscript, and approved the final version for publication.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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