Evaluation of Aerosol Composition in Dental Settings

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A Introduction

A1 Study Abstract

SARS-CoV-2, the virus responsible for COVID-19, is thought to be primarily transmitted via large respiratory droplets. However, contact and aerosol transmission can also occur according to the US Centers for Disease Control and Prevention. Our research team is in the process of determining which dental procedures generate aerosols. Our preliminary data suggest that several common dental procedures generate aerosols in the immediate vicinity of dental healthcare personnel. These data suggest that dental healthcare personnel would be at high risk of developing COVID-19 while caring for patients. However, from an epidemiologic standpoint, we have not seen any substantial outbreak of COVID-19 within dental settings. There may be a variety of reasons for this low rate of infections, including appropriate use of PPE, care screening of patients for symptoms, and the elective nature of most dental procedures. However, our research team believes the main reason is that dental aerosols may be different from those in medical settings. In particular, a substantial quantity of the aerosols may water from water cooled devices, rather than saliva.

A2 Purpose of the Study Protocol

The purpose of this grant is to evaluate the 1) microbiologic and 2) inorganic composition of dental aerosols. Our team proposes to place a cart with several sensors in a dental clinic to record both particle size and composition during routine dental care. We propose to collect data on low, medium, and high risk aerosol generating procedures in pediatric dentistry, periodontic, endodontic, and orthodontic clinics at an academic dental center. We believe that these data will help us better quantify the risk of aerosol generating procedures in dental settings.

B Background

B1 Prior Literature and Studies

Prior studies have suggested that bacteria are present in dental aerosols, generating “bioaerosols”. These studies have largely used primitive techniques, such as settle plates and fluorescent markers in dental settings. According to the authors of a recent systematic review on dental aerosols, the studies were of poor quality and lacked controls, including baseline data measurement. To our knowledge, no studies have paired aerosol size and composition together. Furthermore, no studies have evaluated the inorganic composition of dental aerosols. Fine dental aerosols generated during drilling dental cement, crowns, and amalgam may lead to deposition of metals and other inorganic particles deep into the lung alveoli. The occupational risks of aerosolized amalgam to dentists remains a significant research gap. However, indirect data suggests that dental office staff have higher exposure to mercury than a control population.[

B2 Rationale for this Study

SARS-CoV-2, the virus responsible for COVID-19, is primarily transmitted via large respiratory droplets. However, under certain circumstances, SARS-CoV-2 can be transmitted via fine respiratory aerosols. Dentistry is one of the highest risk occupations for exposure to aerosols. Dentists routinely use high speed drills, ultrasonic scalers, and other devices that are thought to generate aerosols in the oropharynx. Indeed, our preliminary data from a recent X01 reveal a substantial quantity of aerosols generated during routine dental procedures. Our work also revealed that common aerosol mitigation interventions, including intraoral suction, dramatically the quantity of aerosols in the environment. However, despite these interventions, dentists remain

exposed to a substantial quantity of aerosols. However, the relevance of these aerosols remains unclear. Many dental tools are water cooled, which generated a substantial quantity of benign water droplets. These water droplets may have the dual effect of 1) potentially being the primary source of dental aerosols identified in our preliminary data; and 2) likely diluting out viral and bacterial pathogens that would otherwise be present in non-dental respiratory droplets and aerosols. Further research is needed to describe the composition of dental aerosols in order to better understanding the actual risks to dentists of COVID-19 and potentially future pathogens.

C Study Objectives

C1 Specific Aims

1. Evaluate the organic composition of dental aerosols
    a. Aim 1a: Evaluate bacterial burden of dental aerosols
    b. Aim 1b: Evaluate viral composition of dental aerosolsEvaluate and quantify the level of aerosol generation in common dental procedures.
2. Evaluate the inorganic composition of dental aerosols

D Study Design

D1 Overview or Design Summary

We propose to 1) Evaluate the organic composition of dental aerosols, including bacterial and viral composition of dental aerosols; and 2) Evaluate the inorganic composition of dental aerosols, including chemical analysis of all aerosol materials. We will accomplish this by placing a suite of sensors on a mobile cart that can be transported into a dental operatory at St. Louis University (SLU) Center for Advanced Dental Education (CADE). The sensors will include the P-Trak Ultrafine Particle Counter (TSI, Inc.), which measures particle number concentration (number/cm3); the SidePak AM520 Personal Aerosol Mobility Spectrometer (TSI, Inc.), which measures particle mass concentration (PM2.5; mg/cm3); the AeroTrak Portable Particle Counter (TSI, Inc.), which estimates the particle surface area (microm2/m3) that would deposit in the alveolar region of the human lung; the Aerodynamic Particle Sizer (APS), which measures the size distribution of aerosolized particles ranging from 0.5 to 20 micrometers. We will capture bacterial and viral data using a SKC BioSampler, which uses an impinger-based sampling methodology that attaches to a Viable Virus Aerosol Sampler (VIVAS). Impingers are recognized as the most sensitive recovery method for biological aerosol testing, and the method with the highest likelihood of retaining pathogen viability.

D2 Subject Selection and Withdrawal

2.a Inclusion Criteria

A subset of high-and low-risk dental procedures.

2.a Exclusion Criteria

We will also exclude any cases where our equipment cart cannot be transported into the dental operatory.

2.b Subject Recruitment Plans and Consent Process

Not applicable

2.c Risks and Benefits

This study will pose little risk to patients and staff. Only environmental specimens will be collected for analysis, which requires no physical contact with patients and will not interfere with patient care. The risk of loss of confidentiality is also small because no identifiable patient information will be collected. We will record only the type of dental procedure and clinic.

The only potential risk is a breach of confidentiality. As with any research, there is a potential risk of loss of privacy and inadvertent release of protected health information, and this can lead to psychological, social, or legal distress. The study team will protect against this risk by storing paper forms in locked file cabinets in locked offices. Electronic data will be stored in password-proteted databases on secure network servers to which only select members of the study team have access. Data will be stripped of all identifiers before being shared with the NIH or National Dental Practice-Based Research Network. Any manuscripts that result from this study will be written in such a way that individual participants cannot be identified.

There are no direct benefits to patients and healthcare providers associated with this study. This research will benefit others/society by providing important data about the risk of SARS-CoV-2 transmission during aerosol-generating procedures in dental care settings. This information is urgently needed to inform guidelines and recommendations related to the use of personal protective equipment (PPE) during these procedures, infection prevention, and dental clinic design.

2.d Early Withdrawal of Subjects

Not applicable

2.e Data Collection and Follow-up for Withdrawn Subjects

Not applicable

E Study Procedures

We will place the cart of sensors at SLU CADE and Case Dental, which includes pediatric dentistry, orthodontics, endodontics, and periodontics specialties. The research team will meet to select a subset of high- and low-risk aerosol generating dental procedures to study for pilot testing. The team will consist of all study investigators and 2 dental content experts Drs. Lockhart and Thornhill. We will then develop a standardized case report form for procedure documentation. This form will include information on the procedure performed and the types of aerosol mitigation procedures performed. A research coordinator and the dental staff will then capture the data on each preselected dental procedure using a standardized case report form. We will collect a total of 20 samples for organic and inorganic analyses, including preprocedural data. No patient information will be collected.

On the day prior to visit, the research team will collect all necessary sterilized bacterial and viral specimen collection impingers from the microbiology lab.

On the day of the visit, the research coordinator and engineering staff will wheel the cart into a designated patient area for passive data collection. The research coordinator will document the planned procedure type based on discussion with the dentist. The engineering staff will calibrate and turn on the machines. The research coordinator will document the date, time, and procedure type in a spreadsheet. The research coordinator will label the specimens to allow linkage of the aerosol data with the biologic and chemical

analyses at a later date. Once the specimens have been collected, they will be stored on ice until they can be analyzed at WUSM. Each specimen will be labelled and logged in the spreadsheet to link procedures with specimens.

We will repeat this process between 3 and 5 times for high and low risk aerosol generating procedures. We will collect a total of at least 20 samples.

Once we have an adequate number of specimens, our microbiology tech will reconstitute and run the samples using commercial laboratory equipment.

F Statistical Plan

F1 Sample Size Determination and Power

As no previous aerosol data exists in dental settings, it is not possible to perform standard power and sample size calculations. However, we anticipate collecting a minimum total of 20 samples from at least 10 procedures based on our previous experience.

F2 Data Management

Data will be recorded on standardized data collection forms and entered into a secure database to which only the select members of the study team will have access. Names will not be included on the paper data collection forms.

F3 Statistical Methods

For aim 1, pooled statistical analyses will be compared between the three groups using analysis of variance testing. As the sensors on our cart will also capture particle size, our team should also be able to characterize air particle sizes associated with viable bacteria.

For aim 2, each polyethrahluoroethylene filter will be weighed and baked at 550 degrees Celsius for 4 hours prior to sampling. After specimen collection, the filters will be re-weighed and analyzed. We will use a coupled plasma-mass spectrometry to evaluate the samples. We will analyze carbon composition using a thermal optical carbon analyzer and an ion chromatograph. The samples will be analyzed by x-ray fluorescence to obtain elemental concentrations of 72 elements; and also verified by ICP-MS. This methodology is analogous to that used for ambient aerosol samples. Some of our methodologies may also use a diffusion dryer sampling system to dry the particles in flight to then collect the dry residue which will also give us the relative concentrations.

G Data Handling and Record Keeping

G1 Confidentiality and Security

To protect against loss of confidentiality, all electronic data will be stored in a password-protected electronic database on the password-protected, HIPAA-compliant server maintained and operated by Washington University Information Technology (WUIT). Data access in REDCap will be restricted to key study personnel. Participant name will be kept in a separate file from the remainder of the study data and will be linked by a unique identification number. Study data will never be transferred electronically via e-mail or protocols.

Shredders will be used on any printed material containing PHI. Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, e-mail, texting, and electronic FTP. PHI will be available only to the PI, Dr. Durkin, and his direct research team. Only aggregate data will be reported in any abstracts or publications that result from this study.

G2 Training

Study personnel will receive training in how to operate the aerosol equipment used in this study.

G3 Case Report Forms and Source Documents

Case report forms and source documents will be stored in locked file cabinets in locked offices to which only select members of the study team have access.

G4 Records Retention

Records will be retained for 7 years after the closure of the study IRB.

H Study Administration

H1 Organization and Participating Centers

The lead site for this study is Washington University School of Medicine. The participating sites include:

1. St. Louis University Center for Advanced Dental Education: endodontics, orthodontics, periodontics, and pediatric dentistry
2. Case Dental Practice

H2 Funding Source and Conflicts of Interest

This study is funded by the National Institutes of Health: National Institute of Dental and Craniofacial Research.

H3 Subject Stipends or Payments

Subjects will not receive any stipends or payments for participation in this study.

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