Evaluation of Aerosol in a Dental Clinic

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Protocol Title:	Evaluation of Aerosol in a Dental Clinic
Principal Investigator:	Claudia Ruiz Brisuela, DDS, Clinical Assistant Professor, Department of Restorative Dentistry and Prosthodontics, School of Dentistry, UTHealth, Houston, TX.
Co-Investigators:	Maria A. Loza, DMD, MS, Professor and Chair, Department of Restorative Dentistry and Prosthodontics, School of Dentistry, UTHealth, Houston, TX. Aaron Glick, DDS, Clinical Assistant Professor, Department of General Practice and Dental Public Health, School of Dentistry, UTHealth, Houston, TX. Gena Tribble, PhD, Associate Professor, Department of Periodontics and Dental Hygiene, School of Dentistry, UTHealth, Houston, TX. PhanThanh Saint John, Certified Dental Assistant, Department of Restorative Dentistry and Prosthodontics, School of Dentistry, UTHealth, Houston, TX.
Population:	Approximately 40 participants, 18 years of older, patients of the Advanced Education in Prosthodontics Program Clinic, UTHealth School of Dentistry, Houston, TX.
Number of Sites:	1 UTHealth, School of Dentistry, Houston, TX.
Study Duration:	4 Years
Subject Duration:	1 Appointment

General Information

- This research project will evaluate aerosols in a dental clinic. We will investigate safety measures that can be used to potentially minimize the risk to the dental practitioners during patient encounters.

Background Information

SARS-CoV-2, the virus responsible for the COVID-19 pandemic, has a particle size of .25μm to 2.5 μm (Liu 2020). At such a small particle size the virus has the potential to remain in the air for long periods, have increased pathogenicity (can penetrate lower airways), and travel further from the infection source (Anderson 2020). Infection with SARS-CoV-2 can be serious and fatal with a mortality rate of 2-4.4% reported in a recent meta-analysis (Hu 2020).

Routine dental procedures produce splatter and aerosols that can contain bacteria, viruses, and other potentially harmful pathogens to the provider and others within the operating environment. Individuals with active COVID-19 can remain asymptomatic and potentially spread the virus to dental workers and others within the dental office through aerosols. New products exist claiming to

Objectives

UTHealth Houston
IRB NUMBER: HSC-DB-20-1017
IRB APPROVAL DATE: 04/04/2025

– The primary objective is to evaluate the effectiveness of hydrogen peroxide mouth rinse and evacuation units during aerosol generating procedures in a dental clinic.

– The secondary objective is to determine the risk level for dental practitioners during aerosol generating procedures.

Study Design

– The study will be a randomized control trial. Groups will be compared as follows:

1. Hydrogen Peroxide + High volume evacuation (HP-HVE)
2. Hydrogen Peroxide + HVE + Extraoral vacuum aspirator (HP- EVA)
3. No Hydrogen Peroxide + High volume evacuation (No HP- HVE)
4. No Hydrogen Peroxide + HVE + Extraoral vacuum aspirator (No HP- EVA)

– Bacterial aerosols generated during dental procedures will serve as a proxy for viral aerosols. Bacterial colony forming units (CFUs) will be captured before and during the dental treatment by placing large format petri dishes containing bacterial culture media in the dental operatory with open lids at four specific positions from the patient's head. Once aerosol capture is complete, the petri dishes will be incubated and quantified after the 72 hours, under BSL-2 safety conditions in the microbiology laboratory.

– The patients will randomly receive a 1.5 % hydrogen peroxide mouth rinse or a placebo (plain water). This part will be blind, neither the patient nor the dentist will know if the participant is receiving hydrogen peroxide mouth rinse or placebo, as both will look the same.

– The expected duration of the study is 4 years with approximately 40 patients aged 18 years or older. The duration of the study is 4 years to accommodate for enrollment of an adequate number of subjects. Study will be conducted concurrently with their routine care and the study will take place on onevisit.

– Aim 1: Primary aim is to quantify the effectiveness of hydrogen peroxide mouthwash and evacuation units during a natural tooth preparation procedure in the dental clinic to reduce potentially harmful aerosols. Primary outcomes will be the number of bacterial colonies forming units (CFUs) during the procedure compared to the baseline results.

– Aim 2: Secondary aim is to quantify the risk to the dental providers during a tooth preparation procedure on natural teeth in the dental clinic. Secondary outcomes will be based on the CFUs changes (baseline vs. procedure) of the five different positions of the collecting tools.

Study Population

Forty participants will be randomly selected from the Advanced Education Prosthodontic Program clinic EHR scheduler.

– Inclusion criteria: 18 years or older, prepping natural teeth at the appointment, at least an hour-long procedure, the procedure will be the first one in the morning.

Study Procedures

– The participant will be only seen once, and the appointment should last at least an hour to allow enough time to collect the samples. It must be the first appointment in the morning to avoid cross contamination

UTHealth Houston
IRB NUMBER: HSC-DB-20-1017
IRB APPROVAL DATE: 04/04/2025

from other procedures. There will be no direct intervention with the participant besides the assignment of the evacuation device and/or the mouth rinse (either a solution of peroxide and water or a placebo). A consent form will be discussed and signed by the patient before proceeding with the aerosol collection.

- The participants will be randomly assigned to one of the experimental groups:

1. Hydrogen Peroxide + High volume evacuation (HP-HVE)
2. Hydrogen Peroxide + HVE + Extraoral vacuum aspirator (HP- EVA)
3. No Hydrogen Peroxide + High volume evacuation (No HP- HVE)
4. No Hydrogen Peroxide + HVE + Extraoral vacuum aspirator (No HP- EVA)

– Four (4) agar-petri dishes will be placed by the investigator. The petri dishes will be placed at four standardized locations (1', 2', 3' & 6' from the patient's head) in the dental operating room at: baseline (during 1 hour before the patient enters the chair side) and treatment (during 1 hour from the start of the procedure). An Impinger (REF) will be placed at each interval, 1' from the patient's head. Ten (10) petri dishes will be needed per patient, including two extras to collect solution from impingers.

– The petri dishes will be incubated at 37 degrees Celsius for 72 hours. Storage of bacterial specimens will be consistent with previously approved protocol IBC-16-059.

– CFUs will be counted, type of mouthwash given, type of intervention (evacuation devices used), the time and location of the petri dish will be recorded on an Excel spreadsheet

– CFUs will be quantified and compared among the four groups and between baseline and treatment.

– A separate linking log will be used and kept separate from the data collection spreadsheet. No PHI will be stored or collected.

Data and Safety Monitoring

– Adverse events are not expected.

– Plans to report unanticipated problems include the routine standard of care informing patients if they develop COVID-19 within 2 weeks of the dental visit, for the patient to contact the school. In addition, CFUs data will be continually monitored to assess the safety of dental providers in all conditions. Should an adverse event occur, the event will be documented and sent to PI.

– No patient information will be gathered for the study except for the procedures performed.

Statistics

– Based on power calculations, the number of subjects planned to be enrolled is 40.

– The level of significance to be used is $p = 0.05$.

– Descriptive analysis and nonparametric statistics will be used to compare between the colony forming units (CFUs) at the petri dishes from the four different groups of evacuation devices and mouth

rinses will be evaluated and analyzed.

Ethics

– IRB approval will be sought from the Committee for the Protection of Human Subjects of The University of Texas Health Science Center at Houston.

– Patients who are eligible and willing to participate in the study will be provided with informed consent forms which explain the possible adverse events of treatment and the use of patient data for research.

Data handling and record keeping

– No information will be collected from the patient except the procedure performed. Therefore, no health protected information will be involved in this study.

Quality control and assurance

– The PIs will provide oversight and monitoring to ensure the validity and integrity of the data.

– All the data will be stored in two different password-protected computers.

Publication Plan

– We plan to publish the results in a peer-reviewed journal in dentistry or health fields that would be available for dental and/or medical providers. In addition, these data could be presented at dental/medical meetings to allow health providers to transfer the results of our study to aid in protecting other healthcare workers. We could also present this research at table clinics to provide student involvement.

– Results will not be returned to research subjects.

ATTACHMENTS

1. Consent Document

2. Data Collection Form

3. Linking Log

4. Data Sheet NovelClear Tubing

References

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