# Effectiveness of Extra- oral Suction Comparing to Other Suction in Reducing Particles Matter and Bioaerosol in Dental Clinic, Randomized Clinical Trial.

NCT05848245

September 15, 2022

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# Content table

## 1. Abstract in English

Aerosol particles generated when using dental instrument such as ultrasonic and high air driven handpieces, this aerosol is mixture of blood, saliva, infectious agents, and dental materials. Inhaler dust that range between $PM_{2.5}$ to $PM_{10}$ could transferred to the human lung's terminal bronchioles and alveoli that cause a harm effect.

The aim of this study to assess the effectiveness of different dental suction devices that could be contributed to decrease risk of particles count, Bacterial and fungal that arising from patient mouth to indoor air dental clinic

This is a randomized clinical trial will be conducted in three different places: educational hospital, public hospital, and private clinic. In each place 40 subject will be recruited. Measurement including particles count and microorganism will be taken before 15 minutes and during of scaling and prophylaxis procedure to measure particles count, oral bacteria, fungus, and microbial air. In this study will be compared between four intervention groups; Group A with high and low suction only, Group B using dry shield suction and low section, Group C using extra-oral suction with high and low suction, and Group D using dry shield suction and extra-oral suction and low section. Difference between each categorical groups and particle, oral bacterial, fungus, and microbial air concentration will be tested using two-way ANOVA test or one way ANOVA test. Statistical analysis will be carried using STATA version 13.

## 2. Introduction

### 2.1 Background

Aerosols described as any fluid and solid particles dropped in the air. Any particles less than 50 micrometer in diameter could be suspended into air for extended period before rest on environmental surfaces or enter respiratory tract(1). Bioaerosol Are a complex mixture of airborne particles of biological origin such as bacteria, viruses, and fungus.

In dental clinic, dental team are exposed to infectious droplet through a direct contact with body fluid of patient, contact with environmental surfaces or instrument(2). Dental aerosol might be not easily to measure. However, many studies assess the amount of bacteria using bacteria growth media such as blood agar culture(1). In addition, particle number concentrations are considered to more closely indicate the health exposure risk to characterize cleanroom. Particles in the range of 0.5–10 μm diameter can be inhaled and held on the human lung's terminal bronchioles and alveoli(3). Dental instruments and procedure generate varies air-borne contamination amount, the highest bacterial growth was produced by ultra-sonic scaler, followed by the air-driven high-speed handpiece, the air polisher and various other instruments such as the airwater syringe and prophylaxis angles(4-6). In addition, one of study in vitro was found the high amount of aerosol and spatter generated from ultrasonic scalar if used without cooling and presence of small amounts of liquid placed at the operative site to mimic blood and saliva (7)

Using personal protective barrier would be prevented spatter droplets but particles which is less than 50 micrometer that consist of infectious agent has the potential to enter the respiratory tract through leaks in masks (8). The exact hazard effects of dental aerosol not possible to recognize currently however the probable spread of infection should be minimized and eliminated (1).

Nowadays in the market we have new devices might reduce the amount of particles in air such as extra-oral suction (EOS). There is some study evaluate the influence of EOS, they found EOS is effective in reducing droplets (9-15). However, most of these study(9-11, 14-16) was perform in vitro on Manikin head and measure particles concentration, that give us some indication of effectiveness of EOS but still it is not precise due to different factors that present in patient mouth such as saliva, blood and infectious agent.

Other study that were done in vitro using Zirc suction -that work as dryshield suction- show efficiency of reduction in aerosol by 88% comparing to other groups(17).

The aim of this study to assess the effectiveness of different dental suction devices that could be contributed to decrease risk of particles count, Bacterial and fungal that arising from patient mouth to indoor air dental clinic

### 2.2 Rational of research

Most of the previous studies used a low numbers of sample size and the majority of them were conducted in vitro. In addition, they assessed either amount of bacteria or particles comparing EOS to baseline.

In this study, we will analyze particles count and microorganisms comparing EOS to dryshield, combined group and standard group.

### 2.3 Objective

1. Measure particles, bacteria and fungus that arising from patient's mouth in each group.

2. Evaluate health exposure risk for each group to baseline reading (pre-test).

3. Compare health exposure risk for each group to standard group ( Group A)

4. Compare health exposure risk between each of the following groups A, B , C and D.

## 3. MATERIAL AND METHODS

### 3.1 Study design

Randomize clinical trial

### 3.2 Intervention devices

1. Extra oral suction

EOS is used to remove aerosol and droplet that arising from patient mouth and filtering the air.

2. All in one system (dryshield suction)

Dryshied suction is unites of high volume suction and saliva ejection with a bite block, tongue, and oral pathway protection.

### 3.3 Intervention groups

Group A with high and low suction only ( standard care),

Group B using dry shield suction and low section

Group C using extra-oral suction with high and low suction

Group D using dry shield suction and extra-oral suction and low section.

### 3.4 Study area and setting

1. This study will be conducted in close rooms at educational hospital, public hospital and private dental clinic. Humidity and temperature will be recorded at the beginning, measuring particles oral bacteria and fungus will be performed 15 minutes before and approximately 15 minutes during scaling and prophylaxes procedure in two opposite quadrants in left side. Additionally 5 minutes will require between two interval to allow cleaning process of filter in Digital dust monitor. Microbial sampler devices will be distributed at several locations in room, three microbial air sampler devices around patient, at 8 o'clock position, 1 o'clock position and 4 o'clock. Another device that will be placed near to air condition and one ~~a~~gar media on the floor to control another microbial agents that could be arising from A.C.. Intervention devices that will be used is EOS where being place on left side of patent to allow comfortable movement of hygienist and suction cone will be away from patient mouth from 10 -15 cm based on manufacture instruction.

### 3.5 Assessment

<u>Risk</u>

Noise that will be caused by dental suction and other measurement devices.

patient could spend additional time in dental clinic before procedure starting

<u>Benefit</u>

Experience more comfortable treatment setting than routine setting

Alternative

Subjects have all rights to withdraw from study at any time for any reasons. In addition, scaling and prophylaxis treatment will be completed as usual.

### 3.6 Study participants

Patients from King Abdulaziz dental hospital, dental private office, and King Fahad hospital

### 3.7 Sample size

Total sample will be 120 subjects.

### 3.8 Sampling technique

Multiple stage stratified random sampling at place level then subject randomly assign from schedule appointment using simple random sampling. Last stage, Simple random sampling of 40 subject at each 4 groups using computer-generated random numbers.

### 3.9 Inclusion and exclusion criteria

Inclusion criteria

Adult patient above 18 years of age, who has schedule appointment in dental hygienist clinic for scaling and prophylaxis procedure.

Exclusion criteria

Any room have additional mechanical ventilation rather than air conditioner and orthodontic patient will be excluded.

### 3.10 Variables and Data collection

Measurement devices

2. Digital dust monitor

Particles matter will be measured using Digital dust monitor (model 3443, KANOMAX.USA INC., made in Japan). This device measure particle size that range from 0.1 to 10 Mm using light scattering method (semiconductor laser radiation light source ) with flow rate 1 L/min. air is collect through a filter which is built-in in order to eliminate coarse particles. Filter is reusable and it needs approximately 5 minutes cleaning time depending on environment. Minimum, maximum, and average concentration result show among measurement time. Calibration of device will be performed according to manufacture instruction.

3. Microbial air sampler device (sampl'air ASE)

Is considered as active air sampler method which used to collect microorganism onto solid media with flow rate 100 L/ min. Positive hole conversion table should be used in order to counting colony; colony forming units per volume of air (CFU m−3).

In this study a specific agar media will be used to collect oral bacteria and fungus.

Outcome variable

Particle count level (difference in PN count[ ΔPN ;post-test – pre-test , counts/ m3]) (continuous variable)

Average of oral bacterial concentration before and during procedure

Average of fungus concentration before and during procedure

Microbial air concentration including bacteria and fungus before and during procedure (floor and near to A.C)

Explanatory variable

Categorical variable

Place ,intervention groups, order of patient ,gender and supragingival calculus (mild, moderate, heavy) ,

Continuous variable

time of procedure that staring from the beginning of scaling until finishing of scaling (in minutes), time on day (morning, afternoon), age, year experience of hygienist, distance of room, humidity, and room temperature.

### 3.11 Statistical consideration

All continuous variables will be express as mean and stander deviation

All categorical variables will be described as frequency and percentage

Difference between baseline and during of procedure measurement intended for particle, oral bacteria, fungus and microbial air concentration will be calculating using pairwise t test.

Difference between each categorical groups and particle, oral bacterial, fungus, and microbial air concentration will be tested using two way ANOVA test or one way ANOVA test

Strength and direction of association between particle count levels and time of procedure will be tested using correlation test

Multiple linear regression model will be built to predict particles count level with entrance value of 0.01 and exit value 0.101. Confidence level of 95% will be computed and p-value less than 0.05 will be considered as significant.

### 3.12 Ethical consideration

Ethical approval will be provided from institutional ethics review. Consent form would be presented by investigator for each subject before experimental trial. Subject will require reading and signing.

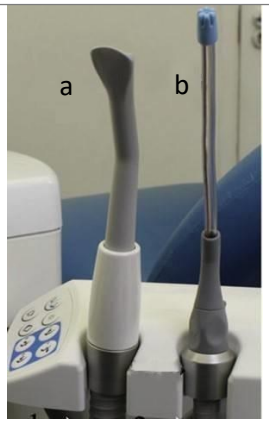
To confirm confidentiality of participant information, each participant will get a unique alphanumeric code. The information will only be shared between the researchers.

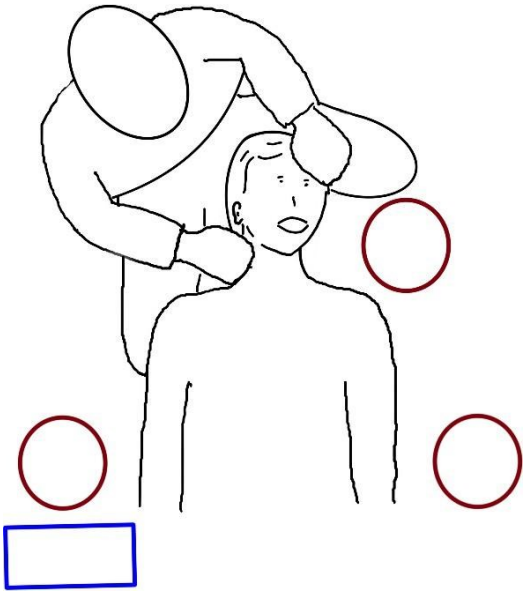
There is no payment and transportation provide to participants.

### 3.13 Limitation and strength

Randomly involved of subject into intervention groups is one of strength in our study. One of limitation is subject and observer could not be blind.

**4. Devices and setting figure**

| Name | Picture |
|---|---|
| a) High volume suction<br>b) Low volume suction |  |
| All in one system (dry-shield) |  |
| Extra oral suction |  |
| Microbial air sampler device (sampl'air ASE) |  |
| | |

| | |
|---|---|
| **Digital dust monitor , KANOMAX , model 3443,** |  |
| **Circles represent location of microbial air sampler device**<br>**Square represents digital dust monitor device** |  |

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