

**Assessment of Effectiveness of Three Aerosol Mitigation Methods for
Orthodontic Debonding**

by

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Abstract

Background: The COVID-19 pandemic has shown us that our infection prevention and control (IPC) knowledge has some glaring gaps on what best ways to treat dental patients, leading to a flurry of research to understand the best mitigation strategies to reduce aerosols. One of these strategies was the addition of a Local Exhaust Ventilation System (LEV), similar to the ones used in other fields as construction, soldering and chemical engineering. **Hypothesis:** In this manuscript, we investigated the additional effect of adding aerosol capture methods during orthodontic debonding to investigate their added effect to high-volume evacuator (the golden standard). **Materials and Methods:** We investigated three mitigation methods during orthodontic debonding: 1) HVE, 2) HVE and saliva ejector, 3) HVE, saliva ejector and a LEV device, BriteHive, which shares the dental chair's HVE connector. We have used a randomized clinical trial approach to investigate whether the three methods are statistically equivalent from each other (effect size of 0.2 standard deviations ~ 16% from each other). And measured the aerosols generated from the three mitigation strategies using two devices, Optical Particle Sizer (OPS) which measures particle concentration across 13 different particle sizes, and DustTrak, which measures mass concentration across different particle matter, PM sizes. **Results:** Mass concentration showed that HVE and Saliva Ejector strategy had the lowest number of statistically significant PM sizes, with only the total PM size being statistically significant. **Conclusion:** The addition of Saliva Ejector to HVE should supersede both HVE, and HVE, Saliva Ejector and BriteHive as the gold standard.

Preface

This thesis is an original work by Ramon Souza Carvalho. The research project, of which this thesis is a part, received research ethics approval from the University of Alberta Research Ethics Board, No. PRO00103510, on August 23rd of 2021.

The sample collection for this study was done in collaboration with the students, assistants, and professors at the University of Alberta Orthodontics Clinic. The study design is by my supervisor(s) and mentors: Dr. Khaled Altabtbaei, Dr Carlos Flores-Mir, Dr Bernadette Quemerais and Dr Monica Gibson. Data collection and analysis for the entirety of this work was done by me, Ramon Carvalho with Dr. Altabtbaei's supervision.

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Thank you to my friends, especially Dr. Raisa Catunda, your friendship, warmth, worry, and love made it seem like I've never left my home. Finally, thank you to my whole family, for the never-ending love, emotional support, understanding and long FaceTime calls. You might be watching me from a distance but that will never grow us apart, as you are the best part of me.

“No person is sent to you by accident.”

I am truly blessed to have so many wonderful people around me.

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Chapter 1 – Introduction

Dental healthcare professionals are exposed to numerous risk factors in a dental office, including exposure to infectious organisms. An example of this hazardous exposure at the dental clinic is a report of an Odontogenic *Mycobacterium Abscessus* (MAB) outbreak that was traced back to a dental clinic where in a span of 9 months in 2016, twenty-two patients contracted the bacteria which was present in the dental unit waterline ^[1]. Another issue that came into light during the SARS-CoV-2 pandemic is the possibility of infections from patients they are treating or from patients' presence in the various dental clinic areas.

This cross-contamination can occur through direct contact with an infected person, through particles, or fomites (contaminated surfaces and objects). One type of infecting agent that has gained considerable attention is aerosols. Aerosols are any volume of air containing solid or liquid particles in suspension. Depending on their size, these particles can remain floating for a short or long period, varying between 0.001 and 100 µm. Aerosol particles with diameters greater than 100 µm are called splashes and, due to the gravitational force, settle more quickly than smaller particles ^[2].

Even though we are at the trailing end of the pandemic, with the World Health Organization downgrading COVID-19 from a global emergency^[3], the World Health Organization warns that there is always the potential for other pathogenic threats with higher deadlier potentials ^[3]. For example, the MPox virus caused several outbreaks worldwide in 2022. Therefore, developing clinical protocols is a consequential and active health issue that aims to stop the spread of disease by limiting the exposure of providers, assistants, and staff to pathogens. Occupational health advances brought to the practice of dentistry throughout the past century, such as using gloves and masks, and disinfecting surfaces, have decreased cross-infections in the field; cross-infection by way of aerosols is still present in dentistry, and knowledge of the best ways to mitigate them is equivocal. Understandably, the interest in investigating this niche subject emerges during epidemics/pandemics. However, some questions should be investigated now so that we are better prepared in the future.

The story about aerosols in dentistry

Aerosols are a conglomerate of liquid or solid particles suspended in air or a gaseous ambient. Aerosols are, by definition, a colloidal system. In which fine particles, liquid or solid, are dispersed throughout another substance. Depending on their function in the colloid, they could either be a Dispersed Substance (DS) or a Dispersion Medium (DM), where the substance is spread out within the dispersion medium (Figure 1)^[4]. One simple example of those definitions can be seen in a fog, where the DM is the air, and the DS are the water droplets floating within the medium.

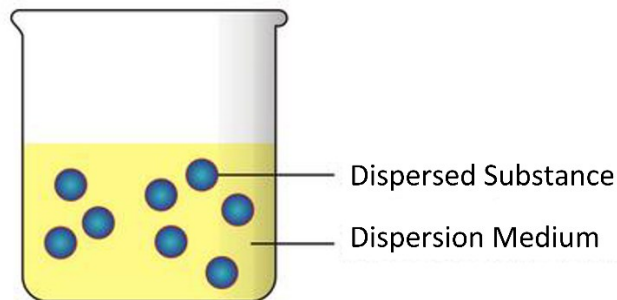


Figure 1 – Representation of a Colloid

Understanding the main components of a colloid is a primordial step in categorizing it, determining its dynamic and spatial behaviour, and estimating its hazardous potential to workers. The categorization of each colloid depends on what the DM and DS are. In an aerosol, the DM is always in a gaseous state; the DS could be solid or liquid (Table 1).

Dispersed Substance	Dispersion Medium	Colloid Type	Examples
Liquid	Gas	Aerosol	Fog, mist, disinfectant spray
Solid	Gas	Aerosol	Smoke, dust in the air

Table 1 - Types of Colloids – Aerosols

In preventive Medicine, the dispersed substance is often called Particulate Matter (PM). The size of these particles is measured in micrometers (μm), ranging from $0.001\mu\text{m}$ to $100\mu\text{m}$, where one μm is equivalent to 10^{-6} m. To measure the airborne PMs, four particle sizes are often used; PM0.1, PM1, PM2.5 and PM10. According to the US Environmental Protection Agency (EPA), particulate matter (PM) is a mixture of particles of various materials, solid or liquid [5]. This material can be about five times thinner than a strand of hair (Figure 2). The spatial behaviour of a PM is precisely the same as any DS, where the material is suspended in the air. In this case, the residue varies in pathogenicity depending on what it is: bacterial, viral, organic, or inorganic particle.

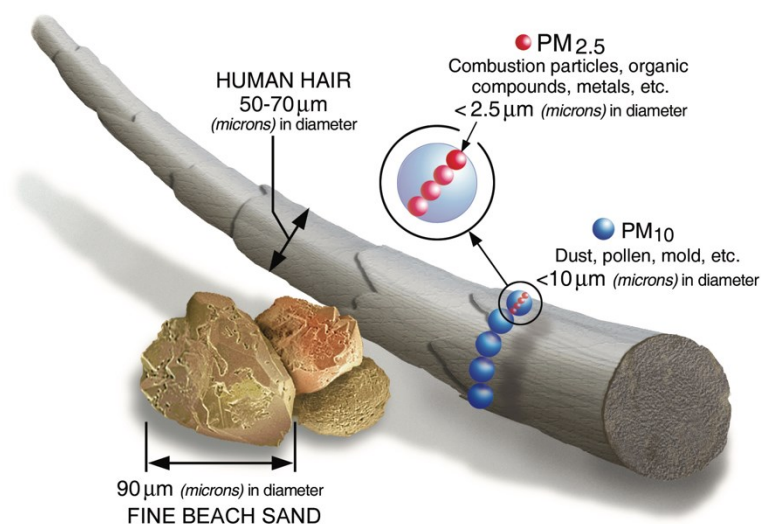


Figure 2 – Representation and size comparison of PMs [5]

The EPA states that the main sources of PM_{2.5} are, in descending order, dust, fuel combustion and motor vehicles. The same can be said for the sources of PM₁₀, with the addition of agriculture^[6]. The dispersed substance (DS) present in PM, mainly in PM_{2.5}, is responsible for several health problems. Studies point to several diseases caused by DS, such as heart attacks and cardiac arrhythmias^[7, 8]. There are also reports of developing asthma in children and other respiratory systems problems, such as airways irritation, coughing, and difficulty breathing^[9]. Another study by the Paul Scherrer Institute showed that particles with high oxidative potential in PMs intensify the inflammatory reaction of cells. In addition, they found that the material from urban areas has a greater oxidative potential than that from rural areas and thus is more harmful to health^[10]. This is because the PM size is directly related to the depth by which these PMs can penetrate the pulmonary system, with the smaller particles capable of penetrating deeper into the system and even passing through the alveolar sacs into the blood circulation^[7, 9]

Similarly, dental personnel face a similar situation in which they are exposed to various DS through their daily dental therapy. The sources of DM could be the patient's saliva or the mist from the dental unit waterline whenever a dispersed instrument is used, such as a high-speed turbine, ultrasonic scalers, or air-water syringe^[11-21]. The DS could either originate from the patient's enamel, residue from the burs, restoration materials, and appliances, the material carried from saliva, or the nose, including pathogens that reside in these areas^[19]. Pathogenic microorganisms that are eventually present in the blood and saliva of patients can be transported by the PM and infect other people, causing diseases such as flu, common cold, tuberculosis, and COVID.

This correlation between PM sources and health issues helps our understanding of the true hazardous potential of aerosols generated in dentistry. Especially after studies during the recent COVID-19 pandemic time stated that the dental field is not exempt from this harm^[11, 13, 22]. The average microbial load suspended in the air increases by more than three times during dental care compared to the period before the beginning of care^[23]. As such, these suspended particles have the potential to penetrate through the respiratory tract of dental healthcare workers and patients who are treated in the same area.

The pathogenic potential of a procedure does not end at the end of the treatment as many particles can remain suspended in the air for long periods. These suspended particles need time to settle down, a concept known as Fallow Time (FT). In the context of dental treatment, FT is the amount of time that an operatory should, in theory, be left empty to allow either the clearance of the aerosols by the air extraction systems or the settlement of the particles to the ground. Historically, this technique has been crucial in preventing highly contagious diseases such as Measles, whose virus can persist in the air for hours after a person infected with measles leaves the room^[24].

Fallow time requires that the room where the dental therapy was performed be closed and empty; the only resource to assist the air change per hour (ACH) is a source exhaust system. Studies designed to investigate FT in dental clinics do not consider that many operatories have multiple dental chairs; they are “open concept” dental operatories, where emptying all operatories once one procedure is completed is not feasible. Recently, a study determined the influence of human walking on the resuspension of the PM and its different sizes. Benabed et al. found that simply walking around the area caused significant increases in the concentration of PM_{0.1} particles^[25]. In addition, they found that the resuspension rate is related to the size of the particles, as the rate of resuspension of PM₁₀ is several orders of magnitude higher than that of PM_{2.5}, PM₁ and PM_{0.1} ^[25]. It is, therefore, best if the dental procedures are accompanied by appropriate suctioning methods that would reduce the particles, leaving the minimum levels possible to escape to the surrounding areas.

Dental mitigation strategies have been implemented for several decades to reduce aerosol exposure by dental personnel, such as saliva ejectors and high-volume evacuators. These instruments have one purpose; to reduce exposure directly by capturing the particles generated as close to the source as possible. During the SARS-CoV-2 pandemic, several new strategies have been introduced to reduce aerosols escaping the treatment area, such as local exhaust ventilation (LEV) systems.

LEV equipment is also called “extraction” or “fume-control” in other areas such as construction, soldering and chemical engineering. These different jobs across different industries involve work processes that create dust and fumes that, if not controlled properly, could cause diseases if inhaled, such as asthma, lung scarring and cancer.

One common way to control the dust and fumes is by an LEV system. All ventilation systems on LEVs work similarly; the air extraction hose is connected to an isolation chamber or a funnel to facilitate particle capture. The right type of LEV hood is critical; if the hood design is right for the process, it is possible to control the dust and fume. After the particles or fumes are captured, the contaminated air goes through a filtering process to be ventilated back to the outer part of the facility where it came from. (Figure 3).

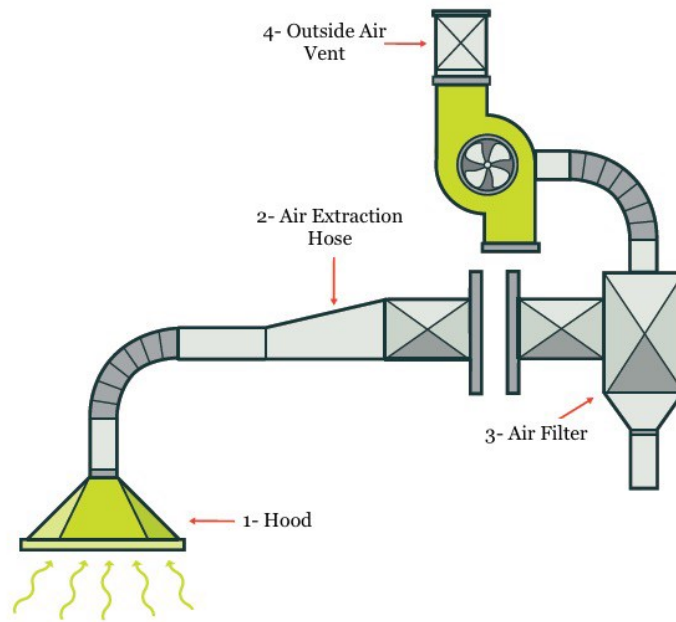


Figure 3 – Local Evacuation Ventilation Schematics

Enclosures can be very effective, but in practice, LEV hoods come in all shapes and sizes, from ones which are large enough to stand in, to others that are small enough to be built into tools (Figure 4).

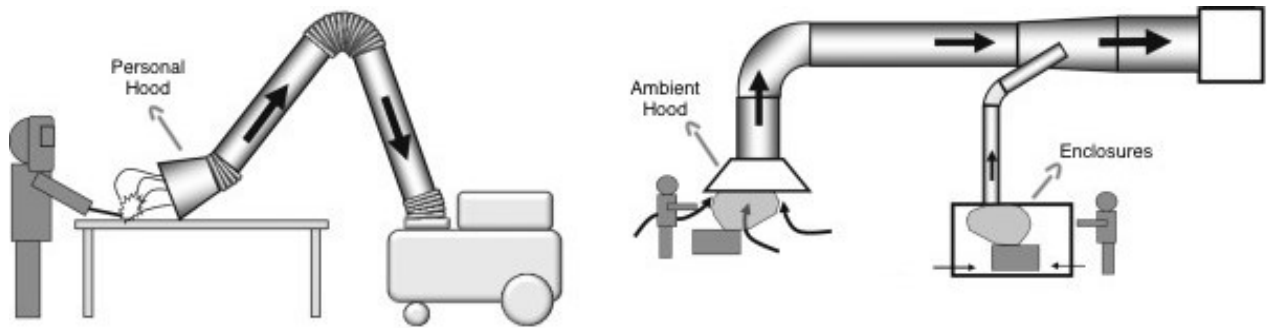


Figure 4 - LEV Hood Types

In dentistry, examples of such systems are as follows: VODEX DentalAIR UVC®, Ventilation Arms from Systech Design, and the Genius Shield by BriteHive Solutions, which uses a movable funnel-shaped hood that is placed between the patient and the dental personnel which contains a clear surface that allows a physical blockage of the particles while providing a clear view for the operator and the assistant, and also a clear path for the operatory chair's light. The BriteHive system is attached to the dental chair with one of the high-volume adapters on it. That is, it does not require an external machine to provide the suctioning capacity, therefore making it a very convenient option to dental clinics. Once attached to the chair, the assistant or operator can control the air ventilation on the chair's control panel or manually on the adaptor's switch.



Figure 5 – BriteHive's LEV System

Past Studies

Previous studies have tried to identify the best aerosol mitigation strategy for reducing aerosol emissions in dentistry using various techniques. We will attempt to summarize them below.

Vernon et al. examined the effect of utilizing high-volume suction^[26]. This pilot study used a viral vector (sigma-6 bacteriophage) as a surrogate virus for SARS-CoV-2 in an artificial saliva system in a mannequin. The study used Agar plates around the operator and by the mannequin's mouth. Air Turbine and High-speed contra-angle handpieces were used to test for the aerosolization of the artificial saliva. One group used either a high-volume evacuator, a local exhaust ventilation (Aspi Jet 25 aerosol extraction device with a flute-shaped end piece – Cattani Air Technology) or a rubber dam. In contrast, the control did not use any mitigation devices. Each test was repeated at least three times. Interestingly, they found that prolonged fallow time was unnecessary when the contra-angle handpiece was used with evacuation systems (HVE or local exhaust systems) or rubber dams.

Piela et al. simulated crown preparation and scaling in a laboratory to characterize aerosols and determine their best mitigation method^[27]. Two categories were created for the mitigation methods: static and dynamic, and the aerosols were measured using two laser dust sensors (Plantower PMS5003). Saliva Ejector, and Dry-Shields were placed in one spot throughout the procedures, and as such they are considered static mitigation methods. The assistants were able to move as desired the HVE and the Purevac tips freely to provide the best suctioning capability, and hence they were considered "Dynamic". Piela et al found that the Dynamic group performed better than the Static methods in reducing the aerosols generated in both procedure types, which sometimes measured indistinguishable level of aerosols as the ambient background before the procedures. Another study also looked at the same dynamic and static categorization system. Suprono et al. examined the two methods while performing dental prophylaxis on students^[28]. Thirty-one dental students were recruited for this split-mouth study to assess the use of High-Volume Evacuators using blood agar plates for aerosols capture. The first half of the prophylaxis procedure used a static method as

follows: an HVE hose was attached to a bite block with an orifice that would allow saliva evacuation. The second half of the prophylaxis also included a regular HVE tip and the aforementioned static equipment. The authors concluded that combining both HVE methods was more effective than just the static method when reducing the bacterial load of the aerosols.

Ou et al. conducted a study that compares the efficacy of Local Exhaust Systems by adding it to either a Saliva Ejector or a High Volume Evacuator^[18]. They used 1) LEV only at High Setting (LEV-H), 2) LEV only at Low Setting (LEV-L), 3) HVE only, 4) Saliva Ejector only, 5) HVE and LEV-H, and 6) Saliva Ejector and LEV-H. The six groups' efficiency in reducing a simulated ultrasonic cleaning were compared. The digital inline holographic and laser sheet measurements showed that LEV can positively respond to aerosol reduction when used in the Highest setting in clinical settings. The use of HVE generally requires an additional person to assist the hygienist, whereas an LEV can be operated hands-free when a dental hygienist is performing ultrasonic scaling and other operations.

At a university's clinic, Choudhary et al., looked at different procedures that were categorized according to the specialty (that is, that were not pre-selected)^[29]. Two real-time sizing equipment were used in the study, a MINIMATM wearable particle sensor and an Optical Aerosol Spectrometer (Model 11C, GRIMM). By the aerosol sizes found in the different specialty clinics, they categorized the generated aerosols and the most effective method to use in all these clinics as a "universal method". In their results, the most effective HVE tip is the ISOVAC HVE, mostly used in ultrasonic scaling and in periodontics as a field. Another interesting finding from these authors corroborates our previous study finding (Rafiee et al^[19]), the use of High-Speed handpieces in Orthodontics produced the highest concentration of particles when compared to pediatrics, endodontics, and ultrasonic scaling in periodontics.

Alisson et al. tested the effectiveness of a local exhaust device by performing two different procedures in two different clinical settings^[30]. The procedures were: 1) a single anterior crown preparation (approx. 10min). In all experiments in this setting, an assistant-operated dental suction with an 8.3-mm internal diameter suction tip at a flow rate of 133 L/min of air measured using a flow meter (Ramvac Flowcheck; DentalEZ);

this equates to "medium-volume suction" according to UK guidelines^[31]. The second procedure was an ultrasonic scaling (approx. 10min) where an assistant had a High-Volume Suction in some sessions. In those, an assistant operated dental suction with a 14.0-mm internal diameter suction tip at a flow rate of 251 L/min of air; this equates to "high-volume suction"^[31]. Three replicates were conducted for each experiment and for a negative control condition for the ultrasonic scaling. The clinical setting were as follows: 1) ultrasonic scaling was performed in an open-setting setup and 2) the tooth preparation was performed in a single room operatory. A fluorescein tracer was placed in the water reservoir for both procedure types. The study demonstrated that Local Exhaust Ventilation reduced the aerosols from dental procedures by 90% within 0.5m.

Based on the studies above and their limitations, our current study aims to determine the profile of the aerosols lingering in the air during orthodontic debonding performed in-vivo, using three mitigation strategies: 1) Use of high-volume evacuator 2) use of high-volume evacuator and saliva ejector 3) use of high-volume evacuator, saliva ejector and local exhaust ventilation (LEV) that is attached to the HVE line in the chair (BriteHive). This study specifically looks at the additional level of aerosol reduction provided by adding further suctioning devices.

Chapter 2 – Materials and Methods

Study Design and Ethical Approval

The Health Research Ethics Board-Health Panel of the University of Alberta reviewed the study protocol and ethical approval (PRO00103510). The purpose, procedure, and possible risks, discomforts, and benefits of this study were explained to the patient and their parents/guardians when the patient was a minor. Consent was obtained from patients and all parents/guardians of eligible children before being recruited for the study.

Settings and Participants

The study participants were recruited from the Kaye Edmonton Clinic in Edmonton, Alberta – Canada. At the University's clinic, the Orthodontics Program takes place on the 8th floor of Kaye Clinic, an open-concept clinic where dental therapy is provided collectively and simultaneously among their 14 dental chairs without distinction of procedures performed.

The following inclusion criteria were used to recruit patients:

- a) Patients who had their Orthodontics Fixed Appliances, commonly called braces, bonded at the University of Alberta Orthodontics Clinic, following its protocol.
- b) Patients who have the same resin composite material used for bonding.
- c) The braces had to be present on both arches, upper and lower.
- d) The brackets systems were not considered for the inclusion criteria.
- e) All brackets had to be present in time for the Debond, a minimum of 26 in mouth.

Patients from the Orthodontics Graduate Program were approached during their treatment's final phase, just before the removal of their fixed appliance. A group of 3-4 patients with debonding were included in the same area, to reduce exposure from other procedures in the background. This setup was used in a larger study design where the sources of the exposure was measured in all of the patients, however, this manuscript presents only part of the study. As such,

despite the 3-4 patients having their debonding done simultaneously, the particles of one patient at a time was measured in this study. As such, the exclusion criteria for this study included the following:

- a) Patients who refused to sign the consent form.
- b) Patients who cannot attend at the designated time or place for debonding to occur in the dedicated debonding area.
- c) Patients who were deemed to require further adjustment and therefore are not ready to proceed with orthodontic debonding.

Orthodontics Debonding Protocol

Fixed orthodontics appliances, or brackets, at the University of Alberta (UofA) Clinic, are bonded to the patient's teeth with a resin composite material. The 3M™ Transbond™ XT Light Cure Adhesive is the resin used at the school's clinic.

Depending on the case and desired movements, some adjustments are necessary. Those adjustments could include a different type of bracket system, repositioning one or multiple brackets, and using other fixed appliances (buttons). However, one constant in its protocol is the use of the same resin for the fixation of those above.

After the desired result is met and agreed upon between the clinical personnel and the patient, or legal guardian, the fixed appliance removal occurs. The removal, or Orthodontic Debonding, follows a clinical protocol established by the clinical supervisors. Debonding starts with the physical separation of the bracket/button from the tooth surface. With a bracket removal Plier, the graduate student removes the brackets sequentially until all brackets are removed (Figure 6A). This leaves the resin composite used for bonding those brackets on the teeth. At this point, composite removal is only possible through a High-Speed Hand-piece and a Carbide Bur attached to it (Figure 6b).

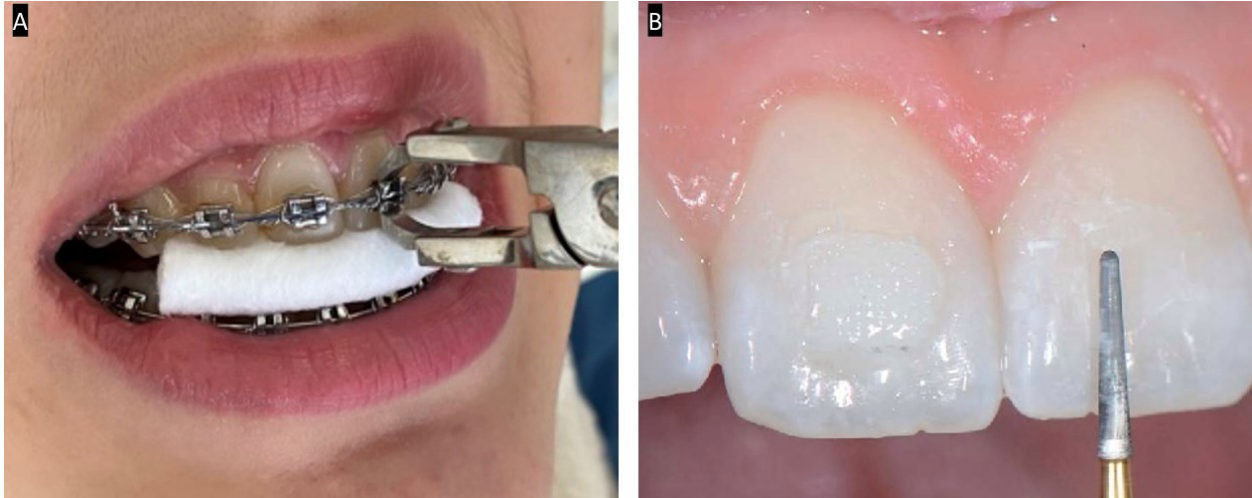


Figure 6 – A) Representation of brackets removal using a plier. B) Removal of the bracket adhesive with a carbide bur at high speed, without water coolant.

High-Speed Handpiece can rotate its bur up to 400,000 rpm (rotations per minute). This can vary upon contact with surfaces (tooth, metal, or resin) from 180,000 to 350,000rpm. Such high rotations are hazardous to the tooth structure as they can increase the internal temperature of the tooth beyond what the tooth pulp is capable of handling, leading to pulp necrosis if done for extended periods of time. Therefore, it is highly recommended to use water to cool down the bur during drilling, polishing, or removing dental materials from the surface of the tooth. This thermal stress can sometimes be overlooked by some professionals, especially when a dry field is needed to distinguish between tooth surfaces and tooth-surface coloured composite materials. This is because the composite material colour is chosen while the tooth is “wet”, and the drying of the tooth makes the two materials easier to distinguish (figure 6B). As such, the use of water in bracket removal can make the process more difficult. While the clinic procedure states that water coolant should be used to remove the bulk of the composite, and only be turned off at the end when the practitioner needs more visual acuity to distinguish between the two, we did not standardize the debonding procedure with these practitioners, and allowed each to determine when that point is.

Mitigation Methods

As we have previously shown, orthodontic debonding is considered an aerosol generating procedure with one of the highest production of particles [19]. These particles carry constituents from the patients' nasal and salivary secretions [19]. This increases the risk of the dental professional to get sick from the patient's exposure, especially since dental therapy cannot utilize masks to cover the patient's nose/mouth. As such, mitigation strategies are necessary.

We utilized three methods in this study. The first method is the use of a single intraoral aspiration device, a High-Volume Evacuation (HVE) tip, attached to the dental chair evacuation adapters (Figure 7). This first method is seen by the dental community as a gold standard of care and is not only used in Orthodontics but in other specialties too. The second method considers the habitual use of a low-potency aspiration called Saliva Ejectors (SE), also attached to one of the aspirations switches on the chair (Figure 7). This low-volume evacuator is often used as the primary and only source of aspiration in non-aerosol-generating procedures, as teeth whitening, or simultaneously with the HVE to enhance the patient's comfort during procedures that require water coolant.

The use of local exhaust systems (LEV) in dentistry is a recent phenomenon due to the increased awareness of bioaerosol exposure during the COVID-19 pandemic. As such, the last mitigation strategy was to use an LEV in addition to HVE and saliva ejector. We used the BriteHive system. It has a clear umbrella-shaped hood to allow the practitioner to place the hood between themselves and the patient, as such allowing the practitioner to have a physical barrier before the patient.

To summarize, the first method consists of one device (HVE), the second of two devices (HVE and SE), and the third of three devices (HVE, SE, and BriteHive) (figure 7). In the manuscript below, we sometimes refer to the third mitigation strategy as BriteHive for simplicity. This still implies the stacked usage of HVE, Saliva ejector and BriteHive.

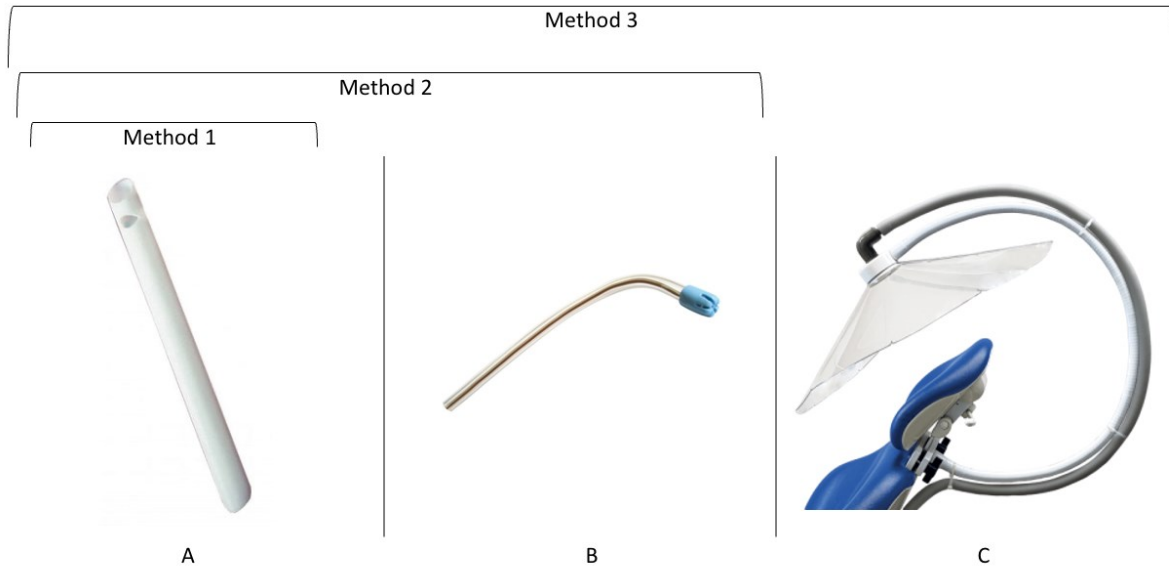


Figure 7 – A) High Volume Evacuation Tip. B) Saliva ejector. C) Local exhaust ventilation device. Methods are sectioned on the top part of the image.

Measuring Equipment

We have used two devices to measure two properties of the aerosols, mass concentration, and particle concentration. This is done based on the diameter of the particle. Note that particles are amorphous (figure 8), however, they are still measured based on their equivalent spherical size as they both have similar spatial behaviour. This is because their devices sort the particles prior to measurement based on the calibration of standardized aerodynamic spherical particles, with known diameters. Therefore, the diameter of amorphous particles is based on its aerodynamic diameter, thus how it behaves in an aerodynamic system, not its actual physical diameter.

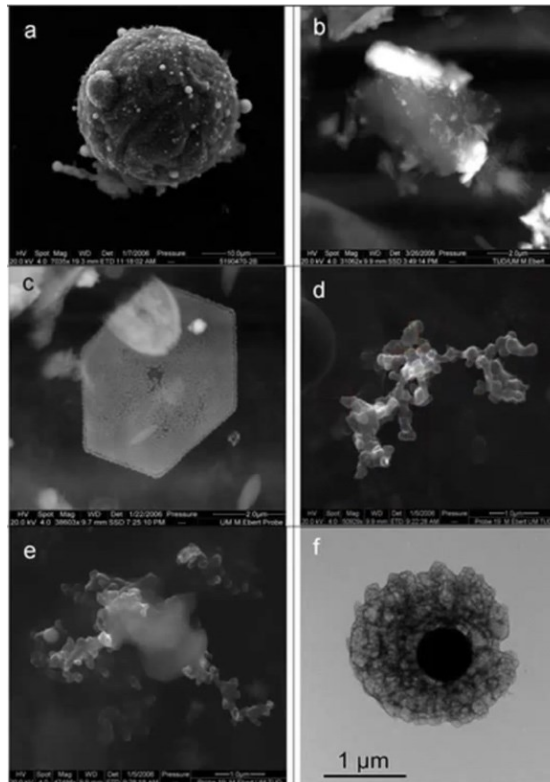


Figure 8 - Microscopic view of different aerosols' shapes.

Optical Particle Sizer 3330

The Optical Particle Sizer (OPS) Model 3330 measures the number of particles in a given volume of air (that is, particle concentration). It provides particle concentration based on their aerodynamic diameter. The methodology works as follows: a stream of particles goes through the equipment and an in-built laser system detects any disturbance on the laser stream (figure 9). As the stream of particles can be fixed, the concentration can be measured by the OPS, giving it in quantity over cm^3 .

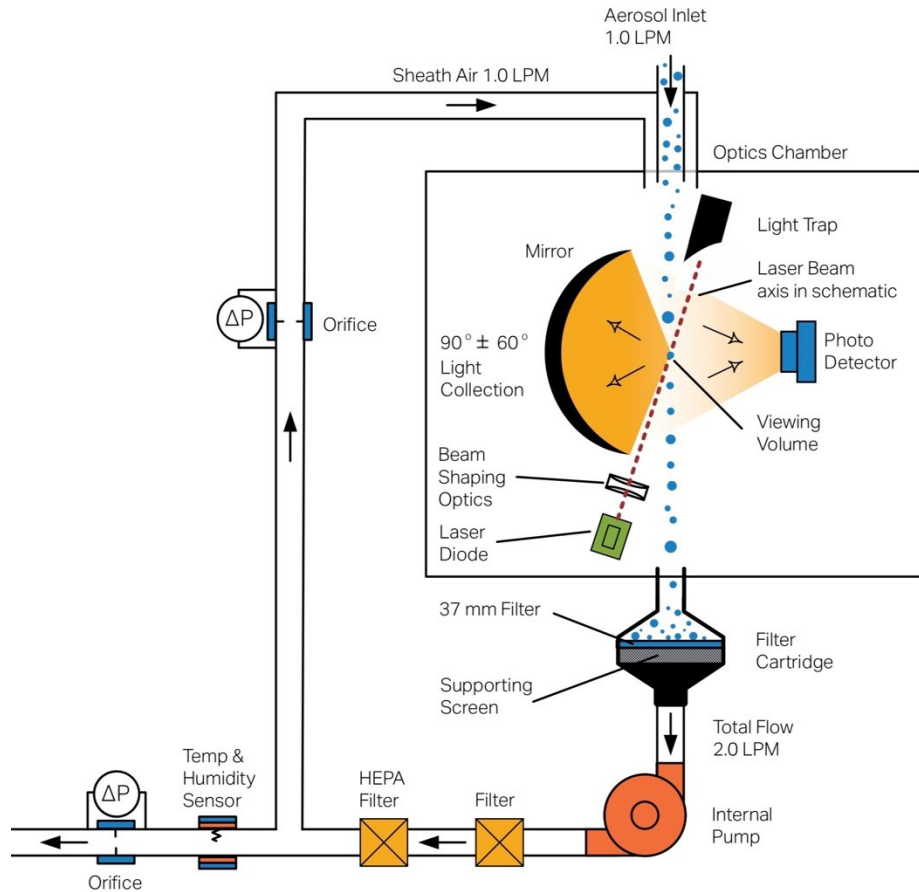


Figure 9 - Aerosols Inflow in an OPS [32]

The results are reported in “bins”, based on their aerodynamic diameter. OPS separates the particles based on thirteen different aerodynamic diameters, with each bin represents the maximum aerodynamic diameter that it can measure. Each particle is only counted once. That is, for example, one 0.2µm particle in bin 1 does not get counted again in the next bins even though the next bins’ cut points are higher than that particle. The thirteen bins and their respective cut-off points can be seen in the Table 2 below.

Optical Particle Sizer Bins Cut Points

Bin 1	Bin 2	Bin 3	Bin 4	Bin 5	Bin 6	Bin 7	Bin 8	Bin 9	Bin 10	Bin 11	Bin 12	Bin 13
0.3	0.4	0.55	0.7	1	1.3	1.6	2.2	3	4	5.5	7	10

Table 2 - Cut points for the OPS Bins, measured in µm.

Dust-Trak 8534

As no two particles carry the exact same dispersion substance (DS), understanding the weight of DS in the particles is important, as a particle with no contaminant carries minimal risk while a heavier particle can potentially carry inhalational hazards such as composite shavings or pathogens. The Dust-Trak 8534 machine measures the weight of particles expressed as mass concentration. Similar to the OPS Bins System, the measurement is categorized in particle sizes, termed Particulate Matter (PM) Size.

Dust-Trak (DT) Model 8534 has an in-built photometer that weighs the particles. Mass photometry is done by analyzing molecules once they land on a glass slide. Once the molecule lands on the glass, it can scatter light that was previously directed through the slide. This process of scattered light observation happens multiple times in different time points as the particle moves through the device. The machine itself examines when the particle provides the maximum light deflection, that is, maximum contrast. Based on the maximum contrast, the device determines the mass needed to give such contrast and interaction with the light (Figure 10).

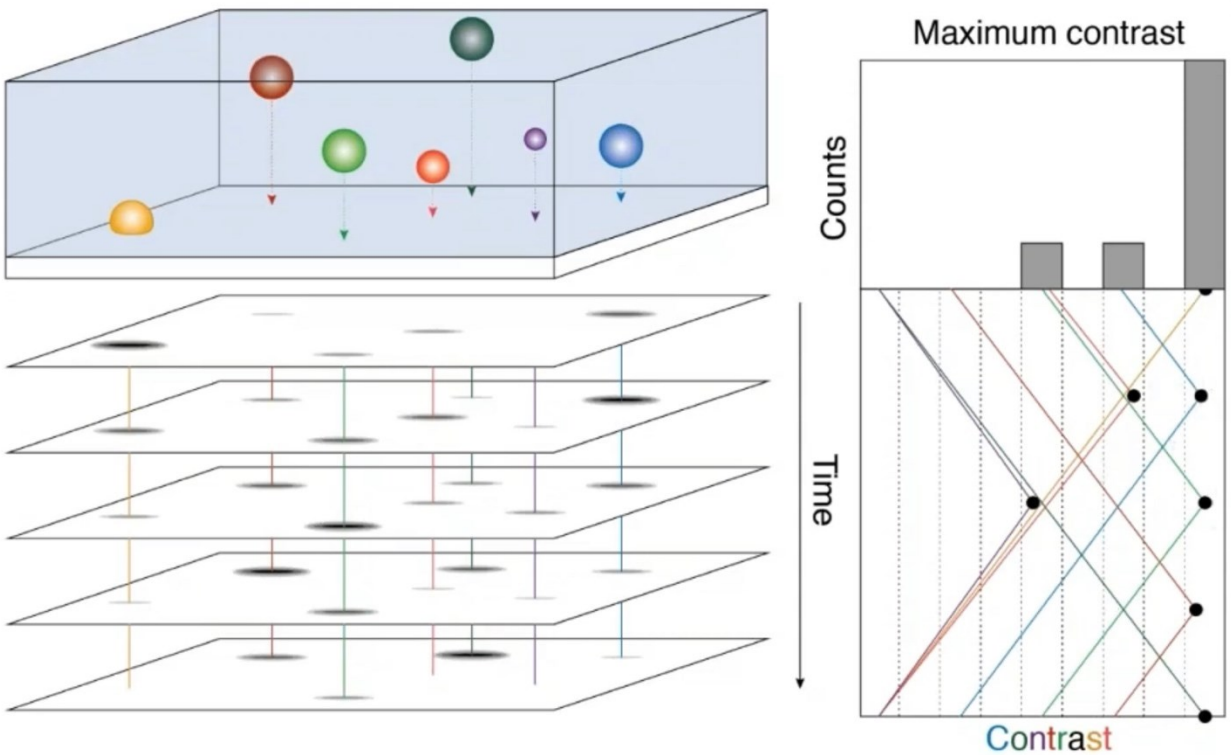


Figure 10 - Mass Photometry. On the left side, the representation of the particles landing on the glass surface, and below the glass the contrast representation throughout time. On the right side the count of maximum contrast for each, for later conversion into their respective mass.

Equipment Positioning

All equipment were used concomitantly, and within the patients' breathable area (figure 11). This position was previously found to provide a comparable of exposure closer to the patient's mouth and the operator's breathing area, without being a physical barrier between the two. OPS and DustTrak air sampling occurred in three different stages: 1) Pre-procedural – collection of air samples for 30 min where treatment with AGP would take place before any patients are brought to the area; 2) Procedural, air sample after the patient's arrival and instructions, during treatment; 3) Post-procedural, sampling of air for 30 min, after the dismissal of the patient.



Figure 11 - OPS and Dust-Trak positioning in a Sampling Session.

Statistical Tests

All statistical tests were performed in RStudio, a computer software that uses R as its primary language. Additional libraries allow RStudio to perform tests as the ones used in this study. The additional libraries used in this study were: 'toster', 'tidyverse', 'chisq.posthoc.test', 'coin', 'multcomp', 'colorspace', 'rstatix', 'ggpubr' and 'plyr'.

The first test performed after data collection was the Shapiro-Wilk test, to test the normality among the spreadsheets. In which it was concluded that the data was not normally distributed, culminating in the use of non-parametric tests, Friedman Test and Two One-Sided Test (TOST).

Comparison between pre-, during- and post-procedural air – Friedman test

The study examined particle and mass concentrations across three-time periods: pre-procedural, during-procedure, and post-procedural air. As such, the data is paired in

nature. As our data does not meet the assumptions of normality, Friedman's test provides a method to investigate this type of dataset in a similar manner as a repeated measure ANOVA, which requires normally distributed data. Like paired non-parametric tests such as Wilcoxon's signed rank sum test, Friedman's test is based on ranks, not data's actual value, and assesses whether there are structural differences between the groups or not.

The null hypothesis of the Friedman test is that there is no difference between the groups (HVE only, HVE + saliva ejector, HVE + saliva ejector + BriteHive) on the measured variable. The alternative hypothesis is that there is a difference between the groups on the measured variable. If the p-value is less than 0.05, the null hypothesis is rejected, and it is concluded that there is a significant difference between the groups, meaning that the aerosol generated during the procedure was enough to alter the sample air profile across the different timepoints.

H₀: No difference is seen in between the group across the time points.

H_a: There is a difference in the group's response across the time points.

Since sampling time provides multiple values in each time period, we took the median value to represent that time period. For example, when BriteHive patient 1 was sampled during the pre-procedural air with DustTrak, the device recorded 190 values each for PM₁, PM_{2.5}, PM_{Resp}, PM₁₀, PM_{Total}. For each of these PM sizes, the median value of the 190 recordings was used to represent the level of particles in that pre-procedural air session.

Comparison between the different mitigation methods – Student’s t-test, and Two One-Sided Test (TOST)

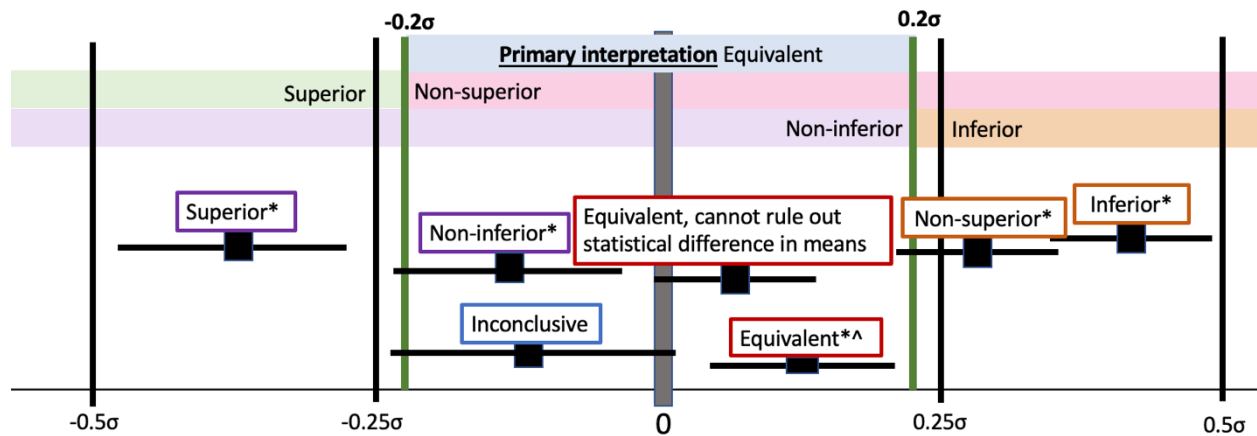


Figure 12 - Explanation of interpretation of the 95% confidence interval of the second group with the equivalence bounds (vertical green lines) after centering the mean of the gold standard at zero. Each 95% confidence interval is illustrated as a whisker plot with the box in the middle at the mean of group 2. For the two groups to be considered statistically equivalent, the 95% confidence interval of group 2 needs to lie between the two equivalence bounds. Note that multiple scenarios exist where the classical statistical test of the difference between two means was statistically significant (indicated with *) that have different interpretations concerning the equivalence bounds. Note that the equivalence designation is the strictest therefore, we are considering it as a primary interpretation. Only if the device was not equivalent, where we test to see if the device is superior, inferior, non-superior or non-inferior. Note that the classical interpretation of superiority and inferiority tests the significance line starts from zero, giving us the ability for a device to be both equivalent and inferior (for example the interval indicated with ^ above). We chose to move the lines so that each group can be exclusively interpreted with one interpretation, where superior or inferior takes on a clinical interpretation of higher or lower than the designated equivalence bounds.

We wanted to examine the effect of different mitigation strategies on aerosol particle mass and particle concentrations. This can be done using various statistical methods to compare different groups. However, it must be noted that the differences between mitigation strategies can simultaneously be statistically significant while falling within a margin where this difference is considered clinically inconsequential. This represents a situation where one may argue that adding more mitigation methods is incommensurate with the complications of adding more mitigation methods, such as adding support staff or slower procedures due to manipulating multiple suction methods.

As such, we used a statistical method that examines the differences between groups while accounting for a desired effect size beyond which the difference is considered clinically valuable. While we can simply compare the differences in the two means to see if it falls within the desired effect size, we pursued a more rigorous statistical method to examine the same question while considering the variance within and between each group. As such, we used a commonly used test in pharmaceutical research called the Two One-Sided Test (TOST).

TOST is commonly used in pharmacological testing as a statistical analysis to compare brand name drugs (first in the market, and therefore the gold standard) with newly produced generic drugs, where generic needs to be compared in efficacy to the golden standard. TOST performs two one-sided tests using the reference/golden standard group – High-Volume Evacuator (HVE) in our case – is the baseline where we test whether the difference in the gold standard and the compared group falls within a specified range of values (known as equivalence bounds) that the researcher deems inconsequential with the two equivalence bounds surround the mean of the golden standard (Figure 11). More formally, the two one-sided tests examine whether the second group's 95% confidence interval of the mean (the range of values likely to contain the true population parameter with a 95% confidence) is either lower or higher than the researcher-provided equivalence bounds. Suppose the two one-sided tests are statistically significant; the compared group's 95% confidence interval of the mean is simultaneously higher than the lower equivalence bound and lower than the higher equivalence bound. This signifies that the compared group's 95% confidence interval is within the range of the two equivalence bounds. Therefore, the two means can be considered equivalent.

The equivalence bounds of TOST vary depending on the data type being used; for example, in parametric tests, the equivalence bounds are expressed as standard deviations from the mean of the golden standard, and in non-parametric tests, any user-defined measurements can be used. However, parametric tests provide an intuitive way to define the equivalence bounds as standard deviations from the mean, which can also be expressed as percentage variation away from the mean. Despite our data being non-parametric in nature, a technique can be used to allow for more accurate estimates

called Bootstrapping. Bootstrapping is a statistical technique that has become increasingly popular in clinical research due to its ability to provide reliable estimates of uncertainty and improve the accuracy of statistical inference. By randomly generating many resamples from the original data, you can generate normally distributed data that estimate the non-parametric relationships as a normally distributed population, allowing us to use well-understood statistical parameters such as standard deviations and confidence intervals. Therefore, we used bootstrapping in our non-parametric data and the parametric version of TOST to attempt an intuitive interpretation of the data that uses means and standard deviations as the equivalence bounds.

Although the equivalence bounds in the pharmaceutical industry are well established through US FDA regulations, we could not find a similar type of effect size for aerosol mitigation. Therefore, we relied on a purely statistical bound established by Cohen, where an effect size of 0.2 standard deviations is considered small, 0.5 is medium, and 0.8 is a large effect size [33]. For the second group to be considered equivalent to the gold standard at an equivalence bound of 0.2 standard deviations, its 95% confidence interval must fall within 15.86% of the values away from the mean of the golden standard, HVE. Failure to reject the two one-sided tests means we do not have evidence to say they are equivalent. However, from a statistical point of view, failure to reject either one of the two tests provides valuable insight into the relationship between the two methods (Figure 11). For example, if either the upper or the lower bounds of the second group overlaps with the equivalence bounds failing to reject the one-sided test, then this the second test is either inferior or superior, based on whether the equivalence bounds of the 95% confidence interval overlaps with the negative or the positive equivalence bounds, respectively.

In summary, the Two One-Sided Test (TOST) is a specialized statistical test that tests the following statistical hypothesis:

H₀: The treatments, or methods proposed are not equivalent.

H_a: The treatments or methods proposed are equivalent.

To put these concepts in perspective of our study, we are primarily examining HVE usage, the most used method for aerosol mitigation, and testing whether adding saliva ejector and LEV results in equivalent amounts of aerosol reduction; that is, they provide inconsequential additional reduction in particle exposure. If the equivalence test is not statistically significant, we examined the confidence intervals to test if the device is superior (the particles captured have a lower mean, indicating superior suctioning by the device) or inferior.

Comparison between time-points with active Aerosol Generation and Inactivity – Chi-Square Test.

A chi-square test is a statistical test for categorical data that can be used to test whether the observed frequency distribution of a variable is significantly different from the expected frequency distribution. In our case, the expected frequency distribution in the Aerosol Generation while the procedure was happening. We also tested the distribution of those particles among their Bin Size or PM Size according to the equipment pre-sets. In our tests we accounted for time-points where no particles were detected compared to time-points where they were not.

H₀: the proportions of time points without detectable particles to time points with detectable particles is proportional across all bin/PM sizes and mitigation methods.

H_a: proportions are different in the observed bins and mitigation methods

Chapter 3 – Results

We started by examining whether there is any statistical difference in particle concentrations between pre-procedural, procedural and post-procedural air ($p < 0.05$, Friedman's test – table 3). Particle concentration in HVE was statistically different between these three-time points in all particle sizes ($p < 0.05$, Friedman's test), except the $10\mu\text{m}$.

The BriteHive group showed the second highest amount of statistically significant bins, with particle concentrations being statistically different between these three time-points in particle sizes $0.55\mu\text{m}$, $0.7\mu\text{m}$, $1\mu\text{m}$, $1.3\mu\text{m}$, $4\mu\text{m}$, $5.5\mu\text{m}$, $7\mu\text{m}$, $10\mu\text{m}$ ($p < 0.05$, Friedman's test).

Finally, particle concentration in HVE and saliva ejector was statistically different in these three-time points in particle sizes $1\mu\text{m}$, $1.3\mu\text{m}$, $3\mu\text{m}$ and $7\mu\text{m}$ ($p < 0.05$, Friedman's test).

Mitigation Strategy	PM sizes	Friedman's test	P-values after False Discovery Rate		
			Pre- vs during procedural air	Pre- vs post-procedural air	During vs post-procedural air
HVE	0.3µm	0.022	0.094	0.625	0.094
	0.4µm	0.007	0.063	0.063	0.063
	0.55µm	0.007	0.063	0.063	0.063
	0.7µm	0.015	0.094	0.125	0.094
	1µm	0.015	0.094	0.136	0.094
	1.3µm	0.015	0.094	0.188	0.094
	1.6µm	0.015	0.094	0.125	0.094
	2.2µm	0.015	0.094	0.136	0.094
	3µm	0.007	0.063	0.063	0.063
	4µm	0.016	0.094	0.197	0.094
	5.5µm	0.007	0.063	0.063	0.063
	7µm	0.021	0.125	0.125	0.125
	10µm	0.291	NA		
	TOTAL	0.015	0.062	0.187	0.062
HVE/SE	0.3µm	0.717	NA		
	0.4µm	0.264	NA		
	0.55µm	0.097	NA		
	0.7µm	0.097	NA		
	1µm	0.049	0.25	0.25	0.25
	1.3µm	0.049	0.25	0.25	0.25
	1.6µm	0.06	NA		
	2.2µm	0.097	NA		
	3µm	0.049	0.25	0.25	0.25
	4µm	0.06	NA		
	5.5µm	0.061	NA		
	7µm	0.049	0.25	0.25	0.25
	10µm	0.148	NA		
	TOTAL	0.716	NA		
HVE/SE/BriteHive	0.3µm	0.091	NA		
	0.4µm	0.074	NA		
	0.55µm	0.016	0.094	0.201	0.094
	0.7µm	0.021	0.125	0.125	0.125
	1µm	0.041	0.188	0.313	0.188
	1.3µm	0.041	0.188	0.313	0.188
	1.6µm	0.091	NA		
	2.2µm	0.076	NA		
	3µm	0.091	NA		
	4µm	0.022	0.094	0.684	0.094
5.5µm	0.016	0.087	0.424	0.087	

7µm	0.016	0.094	0.461	0.094
10µm	0.037	0.272	0.346	0.272
TOTAL	0.090	NA		

Table 3 – OPS’s Friedman Test – Performed in all patients across all three time points; Pre- Procedural, Procedural and Post-Procedure, to determine changes in Air Profile. HVE = High volume evacuator. HVE/SE = High volume evacuator and saliva ejector. BriteHive = High volume evacuator, saliva ejector and BriteHive local exhaust ventilation (LEV). N0= no difference in air across the 3 different time points. Statistically significant p-values were highlighted. Wilcoxon signed rank sum test was done to each pairwise sessions, then the raw p-values were corrected with False Discovery Rate (FDR).

The results of Dust-Trak followed that of OPS, where the HVE group showed the highest amount of statistically significant air profile difference ($p < 0.05$, Friedman’s test – Table 4), followed by the BriteHive group and finally HVE+SE, with only the “TOTAL” being statistically significant ($p < 0.05$, Friedman’s test – Table 4).

Mitigation strategy	PM sizes	Friedman's test	p-values after False Discovery Rate		
			Pre- vs during procedural air	Pre- vs post-procedural air	During vs post-procedural air
HVE	1	0.009	0.087	1	0.087
	2.5	0.009	0.087	1	0.087
	Resp	0.028	0.151	0.773	0.151
	10	0.015	0.089	1	0.089
	Total	0.03	0.151	0.269	0.094
HVE/SE	1	0.116	NA		
	2.5	0.116	NA		
	Resp	0.062	NA		
	10	0.071	NA		
	Total	0.037	0.181	0.181	0.181
HVE/SE/ BriteHive	1	0.023	0.142	1	0.142
	2.5	0.023	0.142	1	0.142
	Resp	0.009	0.08	1	0.08
	10	0.025	0.146	0.773	0.146
	Total	0.076	NA		

Table 4 – Dust-Trak’s Friedman Test– Performed in all patients across all three time points, Pre, During and Post Procedural, to determine changes in their Air Profile, with PM sizes as references
N0= no difference in air. HVE = High volume evacuator. HVE/SE = High volume evacuator and saliva ejector. BriteHive = High volume evacuator, saliva ejector and BriteHive local exhaust volume (LEV). Statistically significant p-values were highlighted. Wilcoxon signed rank-sum test

was done to each pairwise sessions, then the raw p-values were corrected with False Discovery Rate (FDR).

Using TOST to compare the particle concentration in procedural air between HVE and HVE and saliva ejector, HVE and saliva ejector was non-inferior in controlling particles in the 0.3 μm range compared to HVE (table 5). Moreover, BriteHive was non-superior in controlling particles in the 0.3 μm range compared to HVE (table 5). When mass concentration compared across the three mitigation strategies, they were equivalent across all PM sizes ($p < 0.05$, equivalency test – table 6).

OPS					
HVE x HVE and Saliva Ejector					
Bin Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation
Cut Point	Lower test p-value	Upper test p-value	Equivalency test p-value		
0.3 μm	1	<0.001	1	<0.001	Non-inferior
0.4 μm	0.683	0.317	0.683	0.634	Inconclusive
0.55 μm	0.47	0.529	0.529	0.941	Inconclusive
0.7 μm	0.333	0.666	0.666	0.667	Inconclusive
1 μm	0.283	0.716	0.716	0.568	Inconclusive
1.3 μm	0.267	0.732	0.732	0.534	Inconclusive
1.6 μm	0.271	0.729	0.729	0.542	Inconclusive
2.2 μm	0.253	0.746	0.746	0.507	Inconclusive
3 μm	0.213	0.787	0.787	0.426	Inconclusive
4 μm	0.193	0.804	0.804	0.389	Inconclusive
5.5 μm	0.17	0.822	0.822	0.348	Inconclusive
7 μm	0.185	0.809	0.809	0.376	Inconclusive
10 μm	0.096	0.895	0.895	0.2	Inconclusive
TOTAL	0.204	0.796	0.795	0.411	Inconclusive
HVE x BriteHive					
Bin Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation
Cut Point	Lower test p-value	Upper test p-value	Equivalency test p-value		
0.3 μm	0.046	0.954	0.954	0.091	Non-superior
0.4 μm	0.091	0.908	0.908	0.183	Inconclusive
0.55 μm	0.14	0.86	0.86	0.279	Inconclusive
0.7 μm	0.236	0.764	0.764	0.472	Inconclusive
1 μm	0.261	0.738	0.738	0.523	Inconclusive
1.3 μm	0.277	0.722	0.722	0.554	Inconclusive

1.6µm	0.316	0.684	0.684	0.633	Inconclusive
2.2µm	0.326	0.673	0.673	0.653	Inconclusive
3µm	0.291	0.708	0.708	0.583	Inconclusive
4µm	0.276	0.724	0.724	0.552	Inconclusive
5.5µm	0.259	0.735	0.735	0.524	Inconclusive
7µm	0.268	0.725	0.725	0.543	Inconclusive
10µm	0.241	0.747	0.747	0.494	Inconclusive
TOTAL	0.837	0.163	0.837	0.326	Inconclusive

Table 5 - Equivalency test for particle concentration between the gold standard procedure HVE, and HVE and saliva ejector, and HVE saliva ejector and BriteHive. Statistical test performed using Two One-Sided Test (TOST). HVE = High volume evacuator. HVE/SE = High volume evacuator and saliva ejector. BriteHive = High volume evacuator, saliva ejector and BriteHive local exhaust volume (LEV). Statistically significant p-values are highlighted.

Dust-Trak					
HVE x HVE and Saliva Ejector					
PM Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation
	Lower test p-value	Upper test p-value	Equivalency test p-value		
PM 1	<0.001	<0.001	<0.001	0.901	Equivalent
PM 2.5	<0.001	<0.001	<0.001	0.914	Equivalent
RESPIRABLE	<0.001	<0.001	<0.001	0.997	Equivalent
PM 10	<0.001	<0.001	<0.001	0.759	Equivalent
TOTAL	<0.001	<0.001	<0.001	0.611	Equivalent
HVE x BriteHive					
PM Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation
	Lower test p-value	Upper test p-value	Equivalency test p-value		
PM 1	<0.001	<0.001	<0.001	<0.001	Equivalent
PM 2.5	<0.001	<0.001	<0.001	<0.001	Equivalent
RESPIRABLE	<0.001	<0.001	<0.001	<0.001	Equivalent
PM 10	<0.001	<0.001	<0.001	<0.001	Equivalent
TOTAL	<0.001	<0.001	<0.001	<0.001	Equivalent

Table 6 - Equivalency test for mass concentration between the gold standard procedure HVE, and HVE and saliva ejector, and HVE saliva ejector and BriteHive. Statistical test performed using Two One-Sided Test (TOST). HVE = High volume evacuator. HVE/SE = High volume evacuator and saliva ejector. BriteHive = High volume evacuator, saliva ejector and BriteHive local exhaust volume (LEV). Statistically significant p-values are highlighted.

Chi-square was performed on the frequencies where the measurement devices were not able to detect any particles compared to the time points where particles were detected, with the rationale that it would show us any unexpected deviation in the way the three devices perform based on particle sizes. The results of the particle concentration are in table 7. Across all mitigation methods, most time points had detectable particles across all different bin sizes, with moments without detectable particles ranging from 0-5.5%. Notable exceptions are as follows. HVE only group had 12.2% and 8.3% of its time points without detectable particles in 5.5µm and 7µm bins, respectively, while the addition of saliva ejector to HVE resulted in the increase in particle-absent proportions to 13.9% and 8.5%, respectively ($p < 0.05$, Chi-square). The BriteHive group demonstrated the highest particle absent time-points, with 15%, 9%, and 5.8% of exposure being particle free in the 5.5µm, 7µm and 10µm bins, respectively ($p < 0.05$, Chi-square).

Mitigation Strategy	Bin Cut-off point	# timepoints without detectable particles/# time points with detectable particles (Proportion)	p values
HVE	0.3µm	0/156 (0.000)	0.227
	0.4µm	0/156 (0.000)	0.227
	0.55µm	0/156 (0.000)	0.227
	0.7µm	0/156 (0.000)	0.227
	1µm	0/156 (0.000)	0.227
	1.3µm	0/156 (0.000)	0.227
	1.6µm	0/156 (0.000)	0.227
	2.2µm	0/156 (0.000)	0.227
	3µm	0/156 (0.000)	0.227
	4µm	3/153 (0.020)	1.000
	5.5µm	17/139 (0.122)	<0.001
	7µm	12/144 (0.083)	<0.001
	10µm	5/151 (0.033)	0.762
	TOTAL	0/156 (0.000)	0.227
HVE + Saliva Ejector	0.3µm	0/115 (0.000)	0.282
	0.4µm	0/115 (0.000)	0.282
	0.55µm	0/115 (0.000)	0.282
	0.7µm	0/115 (0.000)	0.282

	1µm	1/114 (0.009)	0.762
	1.3µm	1/114 (0.009)	0.762
	1.6µm	0/115 (0.000)	0.282
	2.2µm	0/115 (0.000)	0.282
	3µm	1/114 (0.009)	0.762
	4µm	2/113 (0.018)	1.000
	5.5µm	14/101 (0.139)	<0.001
	7µm	9/106 (0.085)	<0.001
	10µm	6/109 (0.055)	0.182
	TOTAL	0/115 (0.000)	0.282
HVE + Saliva Ejector + BriteHive	0.3µm	0/146 (0.000)	0.227
	0.4µm	0/146 (0.000)	0.227
	0.55µm	0/146 (0.000)	0.227
	0.7µm	0/146 (0.000)	0.227
	1µm	0/146 (0.000)	0.227
	1.3µm	1/145 (0.007)	0.551
	1.6µm	0/146 (0.000)	0.227
	2.2µm	0/146 (0.000)	0.227
	3µm	0/146 (0.000)	0.227
	4µm	3/143 (0.021)	1.000
	5.5µm	19/127 (0.150)	<0.001
	7µm	12/134 (0.090)	<0.001
	10µm	8/138 (0.058)	0.044
	TOTAL	0/146 (0.000)	0.227

Table 7 – Chi-Square comparison across the Bin Sizes, with respective p values and the time points where aerosols were not generated through the procedure in relation to the time points where they were generated, and in parenthesis their frequency.

Dust-Trak, Mitigation Strategy and PM Sizes were also checked for proportion without detectable mass concentrations via Chi-Square test of proportions. The results can be found in Table 8. The baseline (that is, the proportions with $p > 0.05$) were PM1 Resp and PM10 of HVE, which showed percentages without detectable concentrations of 5.3%, 4.9% and 4.2%, respectively. All PM sizes of the HVE, saliva ejector and BriteHive performed below this level, with PM1 (1%), PM2.5 (0.2%), Resp (0.6%), PM10 (0.2%) and PMTotal (0.2%) having percentage without detectable particles ($p < 0.05$, Chi-square). Similarly, the use of HVE only had statistically lower proportion of time points

without detectable mass concentrations in the PM2.5 (1.8%) and PMTotal (2.2%) ranges. On the other hand, HVE and saliva ejector had statistically higher proportions of time without detectable particles in the PM1 (12.1%), PM2.5 (6.8%), Resp (10.8%), PM10 (9.6%) and PMTotal (5.9%) ranges.

Mitigation Strategy	PM Sizes	# timepoints with not detectable particles/# time points with detectable particles (Proportion)	p values
HVE	1	54/1026 (0.053)	0.220
	2.5	23/1057 (0.022)	0.003
	Resp	50/1030 (0.049)	0.654
	10	44/1036 (0.042)	1.000
	Total	19/1061 (0.018)	<0.001
HVE + Saliva Ejector	1	96/796 (0.121)	<0.001
	2.5	57/835 (0.068)	<0.001
	Resp	87/805 (0.108)	<0.001
	10	78/814 (0.096)	<0.001
	Total	50/842 (0.059)	0.035
HVE + Saliva Ejector + BriteHive	1	9/881 (0.010)	<0.001
	2.5	2/888 (0.002)	<0.001
	Resp	5/885 (0.006)	<0.001
	10	2/888 (0.002)	<0.001
	Total	2/888 (0.002)	<0.001

Table 8 - Chi-Square comparison across the PM Sizes, with respective p values and the time points where aerosols were not generated through the procedure in relation to the time points where they were generated, and in parenthesis their frequency.

Chapter 4 – Discussion

This current study examined mitigation strategies using three-time points: pre-, during- and post-procedural aerosol levels. We tested these three-time points because we wanted to see if the aerosol mitigation method would maintain the same level of aerosolization as seen in the pre-procedural background.

We have previously demonstrated that some procedures maintain a level comparable to pre-background levels, corroborated with DNA bacterial analysis from the patient's nose and saliva^[19]. That is, they maintained a low level of aerosolization across all time points. This was used as a starting point for the current analysis. With that in mind, we examined the mitigation strategies to see if they provide a similar mitigation pattern.

When comparing the particle size concentration results between the three methods, the aerosol mitigation strategy with the largest number of statistically significant bins between the three-time points was the HVE-only group, followed by the HVE+SE+BriteHive group and, finally, the group that had the HVE+SE mitigation method. This indicates that the HVE-only group is the least sufficient in maintaining aerosols at their pre-procedural levels. BriteHive mitigation strategy were statistically significant in the 0.55-1.3 μm and 4-10 μm particle concentration ranges.

We have previously shown an inverse relationship between the particles and the quantity produced in dental procedures, with particles $\leq 0.7 \mu\text{m}$ being significantly more abundant than those $\geq 1 \mu\text{m}$ ranges. As such, BriteHive can capture the most prevalent particles being produced. However, computer modelling has shown that the smaller the particle size, the less chance it is that the particle would carry a pathogenic virus such as SARS-CoV-2, with particles three μm from the saliva having the associated probability of carrying a viral particle of 0.01% ^[34]. As such, BriteHive can reduce exposure in general while missing larger particles that are potentially more pathogenic to the host.

Furthermore, as measured by DustTrak, mass concentration showed that HVE and saliva ejector strategy had the lowest number of statistically significant PM sizes, with only the total PM size being statistically significant. Therefore, the addition of saliva

ejector to HVE should supersede both HVE, and HVE, saliva ejector and BriteHive as the gold standard, and policies should consider it as the standard when aerosol production needs to be reduced as much as possible, such as in the case of working on patients with higher levels of risk of aerosol-mediated infections. However, there is still a gap in mitigation strategy knowledge in how to maintain particle concentrations at the same level as their pre-procedural levels across all particle sizes that should be addressed in future research. Such strategies would most likely need to use of local exhaust ventilation with external suction mechanisms that does not depend on retrofitting the suction on the chair's HVE line.

The suction capability of the various mitigation strategies was, surprisingly, equivalent in mass concentration. The differences in particle concentration were too large across the different mitigation strategy to show any statistical relationship, clinical interpretation of the situation is still possible. Particles produced by dental debonding have the potential to carry a variety of particles, such as composite particles, organic and non-organic material from the host's nasal and salivary cavity, and pathogenic microbiota.

Water coolant tends to increase the weight of particles [35], leading to faster sedimentation, therefore leading to only those that have escaped this sedimentation process to reach the DustTrak device. These particles tend to show equivalent mass concentration, with equivalent mass across devices. Our previous study enhanced our operators' awareness of the importance of using the water coolant during debonding, with stopping water coolant being done only in the later stages of debonding. Moreover, the operators and assistants are likely more aware of the importance of suctioning in reducing aerosol escape to the surrounding areas, and as such, has resulted in fewer particles escaping from the oral cavity, and only those light enough to escape before capturing reaching the device. Nonetheless, this further demonstrates the importance of water coolant usage and optimal suctioning with HVE, where the addition of a saliva ejector resulted in a difference of less than 16% between the two means in mass concentration. Another reason particle concentration did not provide statistically meaningful results could be due to the clinical nature of this study. Variations across different dates, such as pre-procedural differences in air, could obfuscate the

differences in the results, such as variations in the air changes per hour, the general exhaust system, the way the operator performs the debonding, and daily variables as humidity and temperature.

Indeed, when we tested the pre-procedural air across the different dates, we found that they were not equivalent (supplementary material section 1). This is one of the limitations of this study that should be addressed by using clean rooms with a controlled background environment. Nonetheless, this study shows that real-world examination of aerosols is possible and that despite all the environmental confounders, one can still reduce various contaminations in particles by using good infection control and prevention strategies such as water coolant and optimal suctioning with HVE and saliva ejectors, and that future studies should aim to focus on particle concentrations as the main variable to be targeted. Using clean rooms also avoids the pitfall of multi-operator settings where particles can be resuspended multiple times, such as when a patient or dental personnel walks by. This further explains why particle size can vary and does not relate to mass concentration.

In conclusion, our data suggest that using HVE and saliva ejectors should be considered the gold standard in aerosol-generating procedures that use hand-pieces. This is due to its superior capability of capturing particles compared to HVE alone. While BriteHive is effective at targeting small particle sizes, it does not capture larger particles and, as such, might not be as effective as other methods in reducing possible cross-contamination. More studies are needed to find the true gold standard that reduces aerosol levels to the point that they are indistinguishable from pre-procedural air, which then should be supplemented with alternative analysis methods such as microbial tracking.

Bibliography

1. Singh, J., et al., *Invasive Mycobacterium abscessus Outbreak at a Pediatric Dental Clinic*. Open Forum Infectious Diseases, 2021. **8**(6).
2. Tang, J.W., et al., *Factors involved in the aerosol transmission of infection and control of ventilation in healthcare premises*. Journal of Hospital Infection, 2006. **64**(2): p. 100-114.
3. ; Available from: <https://www.who.int/news-room/speeches/item/who-director-general-s-opening-remarks-at-the-media-briefing---5-may-2023>.
4. *Colloid Dispersion*. Available from: <https://www.pharmaguideline.com/2022/04/colloidal-dispersions-classification.html>.
5. *Particulate Matter (PM) Basics*. Available from: <https://www.epa.gov/pm-pollution/particulate-matter-pm-basics#:~:text=EPA%20regulates%20inhalable%20particles.%20Particles%20of%20sand%20and,governments%20meet%20the%20Agency%E2%80%99s%20national%20air%20quality%20standards>.
6. Kasumba, J., et al., *Agricultural PM10 emissions from cotton field disking in Las Cruces, NM*. Atmospheric Environment, 2011. **45**(9): p. 1668-1674.
7. Arias-Pérez, R.D., et al., *Inflammatory effects of particulate matter air pollution*. Environmental Science and Pollution Research, 2020. **27**(34): p. 42390-42404.
8. Bourdrel, T., et al., *Cardiovascular effects of air pollution*. Archives of Cardiovascular Diseases, 2017. **110**(11): p. 634-642.
9. Kojima, S., et al., *Fine particulate matter and out-of-hospital cardiac arrest of respiratory origin*. European Respiratory Journal, 2021: p. 2004299.
10. Daellenbach, K.R., et al., *Sources of particulate-matter air pollution and its oxidative potential in Europe*. Nature, 2020. **587**(7834): p. 414-419.
11. Comisi, J.C., et al., *Aerosol and spatter mitigation in dentistry: Analysis of the effectiveness of 13 setups*. J Esthet Restor Dent, 2021. **33**(3): p. 466-479.
12. Cousins, M., et al., *A qualitative analysis of dental professionals' beliefs and concerns about providing aerosol generating procedures early in the COVID-19 pandemic*. BDJ Open, 2022. **8**(1): p. 2.
13. Dabiri, D., et al., *A Multi-Disciplinary Review on the Aerobiology of COVID-19 in Dental Settings*. Front Dent Med, 2021. **2**.
14. Din, A.R., et al., *Quantitative analysis of particulate matter release during orthodontic procedures: a pilot study*. Br Dent J, 2020: p. 1-7.
15. Epstein, J.B., K. Chow, and R. Mathias, *Dental procedure aerosols and COVID-19*. The Lancet Infectious Diseases, 2021. **21**(4): p. e73.
16. Fennelly, M., et al., *Real-time Monitoring of Aerosol Generating Dental Procedures*. J Dent, 2022. **120**: p. 104092.
17. Kumar, P.S. and K. Subramanian, *Demystifying the mist: Sources of microbial bioload in dental aerosols*. Journal of Periodontology, 2020. **91**(9): p. 1113-1122.
18. Ou, Q., et al., *Characterization and mitigation of aerosols and spatters from ultrasonic scalers*. J Am Dent Assoc, 2021. **152**(12): p. 981-990.
19. Rafiee, A., et al., *Particle Size, Mass Concentration, and Microbiota in Dental Aerosols*. Journal of Dental Research, 2022. **101**(7): p. 785-792.
20. Robertson, C., et al., *A Review of Aerosol Generation Mitigation in International Dental Guidance*. Int Dent J, 2022. **72**(2): p. 203-210.

21. Zemouri, C., et al., *Dental aerosols: microbial composition and spatial distribution*. Journal of Oral Microbiology, 2020. **12**(1): p. 1762040.
22. Deogade, S.C. and D. Naitam, *COVID-19 and dental aerosols: The infection connection*. Avicenna Journal of Medicine, 2021. **11**(02): p. 107-109.
23. Discacciati, J.A.C., et al., *Verificação da dispersão de respingos durante o trabalho do cirurgião-dentista*. Revista Panamericana de Salud Pública, 1998. **3**(2): p. 84-87.
24. Bloch, A.B., et al., *Measles outbreak in a pediatric practice: airborne transmission in an office setting*. Pediatrics, 1985. **75**(4): p. 676-83.
25. Benabed, A. and A. Boulbair, *PM10, PM2.5, PM1, and PM0.1 resuspension due to human walking*. Air Quality, Atmosphere & Health, 2022. **15**(9): p. 1547-1556.
26. Vernon, J.J., et al., *Dental Mitigation Strategies to Reduce Aerosolization of SARS-CoV-2*. J Dent Res, 2021. **100**(13): p. 1461-1467.
27. Piela, K., et al., *Aerosol reduction efficacy of different intra-oral suction devices during ultrasonic scaling and high-speed handpiece use*. BMC Oral Health, 2022. **22**(1): p. 388.
28. Suprono, M.S., et al., *A clinical investigation of dental evacuation systems in reducing aerosols*. The Journal of the American Dental Association, 2021. **152**(6): p. 455-462.
29. Choudhary, S., et al., *Comparison of aerosol mitigation strategies and aerosol persistence in dental environments*. Infect Control Hosp Epidemiol, 2022. **43**(12): p. 1779-1784.
30. Allison, J.R., et al., *Local Exhaust Ventilation to Control Dental Aerosols and Droplets*. Journal of Dental Research, 2022. **101**(4): p. 384-391.
31. Estates, N. *Dental compressed air and vacuum systems - AN UPDATE OF HTM 2022 – SUPPLEMENT 1*. Available from: https://www.england.nhs.uk/wp-content/uploads/2021/05/HTM_2022_S1.pdf.
32. *Optical Particle Sizer 3330 Specs Sheet*. Available from: [https://tsi.com/products/particle-sizers/supramicron-capable-particle-sizer-spectrometers/optical-particle-sizer-\(ops\)-3330/#resources](https://tsi.com/products/particle-sizers/supramicron-capable-particle-sizer-spectrometers/optical-particle-sizer-(ops)-3330/#resources).
33. Sullivan, G.M. and R. Feinn, *Using Effect Size-or Why the P Value Is Not Enough*. J Grad Med Educ, 2012. **4**(3): p. 279-82.
34. Stadnytskyi, V., et al., *The airborne lifetime of small speech droplets and their potential importance in SARS-CoV-2 transmission*. Proceedings of the National Academy of Sciences, 2020. **117**(22): p. 11875-11877.
35. Cokic, S.M., et al., *The effect of water spray on the release of composite nano-dust*. Clinical Oral Investigations, 2020. **24**(7): p. 2403-2414.

Appendix

Section 1: Equivalence testing of the pre-procedural air quality.

OPS – TOST – Pre-Background

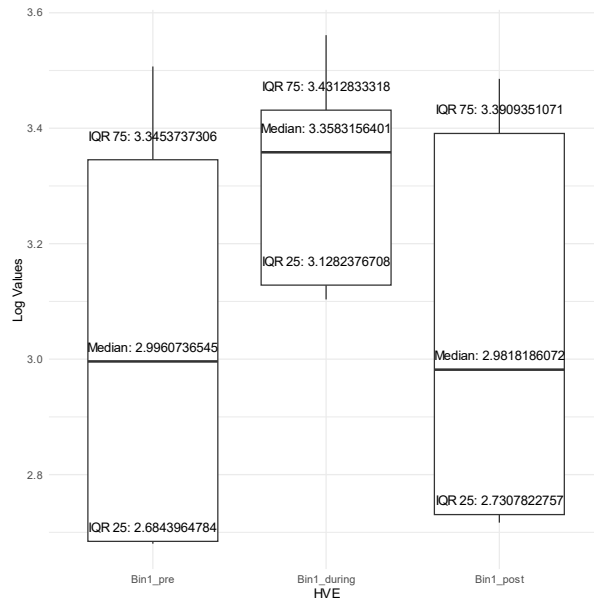
HVE x HVE and Saliva Ejector						
Bin Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation	Secondary Interpretation
Cut Point	Lower test p-value	Upper test p-value	Equivalency test p-value			
0.3µm	1	<0.001	1	<0.001	Not Equivalent	Non-Inferior
0.4µm	1	<0.001	1	<0.001	Not Equivalent	Non-Inferior
0.55µm	1	<0.001	1	<0.001	Not Equivalent	Non-Inferior
0.7µm	1	<0.001	1	<0.001	Not Equivalent	Non-Inferior
1µm	1	0.001	1	<0.001	Not Equivalent	Non-Inferior
1.3µm	1	0.001	1	<0.001	Not Equivalent	Non-Inferior
1.6µm	1	<0.001	1	<0.001	Not Equivalent	Non-Inferior
2.2µm	1	<0.001	1	<0.001	Not Equivalent	Non-Inferior
3µm	1	<0.001	1	<0.001	Not Equivalent	Non-Inferior
4µm	0.989	0.001	0.989	0.005	Not Equivalent	Non-Inferior
5.5µm	0.485	0.014	0.485	0.296	Not Equivalent	Non-Inferior
7µm	0.989	<0.001	0.989	0.001	Not Equivalent	Non-Inferior
10µm	0.995	<0.001	0.995	0.002	Not Equivalent	Non-Inferior
TOTAL	<0.01	1.000	1.000	<0.01	Not Equivalent	Non-Superior
HVE x BriteHive						
Bin Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation	Secondary Interpretation
Cut Point	Lower test p-value	Upper test p-value	Equivalency test p-value			
0.3µm	0.959	0.041	0.959	0.082	Not Equivalent	Non-Inferior
0.4µm	0.999	0.001	0.999	0.002	Not Equivalent	Non-Inferior
0.55µm	0.529	0.408	0.529	0.879	Inconclusive	Inconclusive
0.7µm	<0.001	1	1	<0.001	Not Equivalent	Non-Superior
1µm	<0.001	0.999	0.999	0.001	Not Equivalent	Non-Superior
1.3µm	0.005	0.975	0.975	0.023	Not Equivalent	Non-Superior
1.6µm	0.375	0.46	0.46	0.913	Inconclusive	Inconclusive
2.2µm	0.741	0.101	0.741	0.329	Inconclusive	Inconclusive
3µm	0.656	0.097	0.656	39.2	Inconclusive	Inconclusive
4µm	0.581	0.078	0.581	0.431	Inconclusive	Inconclusive
5.5µm	0.162	0.073	0.162	0.85	Inconclusive	Inconclusive
7µm	0.657	0.002	0.657	0.109	Inconclusive	Non-Inferior
10µm	0.040	0.621	0.621	0.306	Inconclusive	Non-Superior
TOTAL	0.031	0.968	0.968	0.063	Inconclusive	Non-Superior

DustTrak – TOST - Pre-Procedural

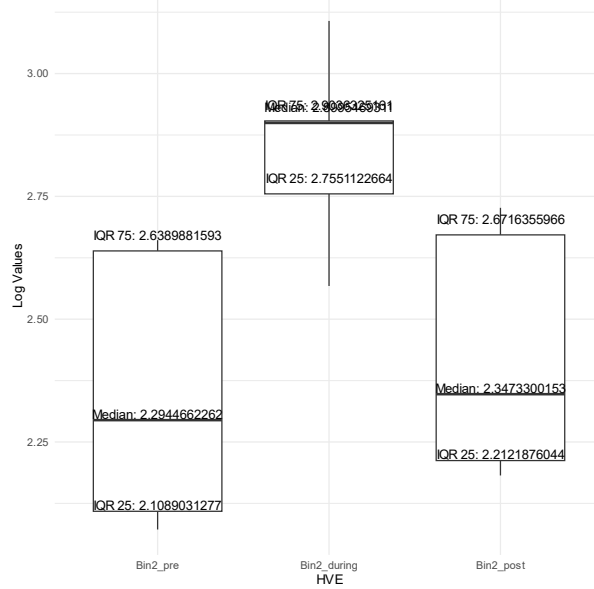
HVE x HVE and Saliva Ejector					
PM Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation
	Lower test p-value	Upper test p-value	Equivalency test p-value		
PM 1	<0.001	<0.001	<0.001	<0.001	Equivalent
PM 2.5	<0.001	<0.001	<0.001	<0.001	Equivalent
RESPIRABLE	<0.001	<0.001	<0.001	<0.001	Equivalent
PM 10	<0.001	<0.001	<0.001	<0.001	Equivalent
TOTAL	<0.001	<0.001	<0.001	0.649	Equivalent
HVE x BriteHive					
PM Size	Two One-Sided Test (TOST)			Null-hypothesis testing	Interpretation
	Lower test p-value	Upper test p-value	Equivalency test p-value		
PM 1	<0.001	<0.001	<0.001	0.175	Equivalent
PM 2.5	<0.001	<0.001	<0.001	0.186	Equivalent
RESPIRABLE	<0.001	<0.001	<0.001	0.198	Equivalent
PM 10	<0.001	<0.001	<0.001	0.425	Equivalent
TOTAL	<0.001	<0.001	<0.001	0.371	Equivalent

Section 2. Friedman test. OPS
Overlapping numbers in the boxplot are equal.

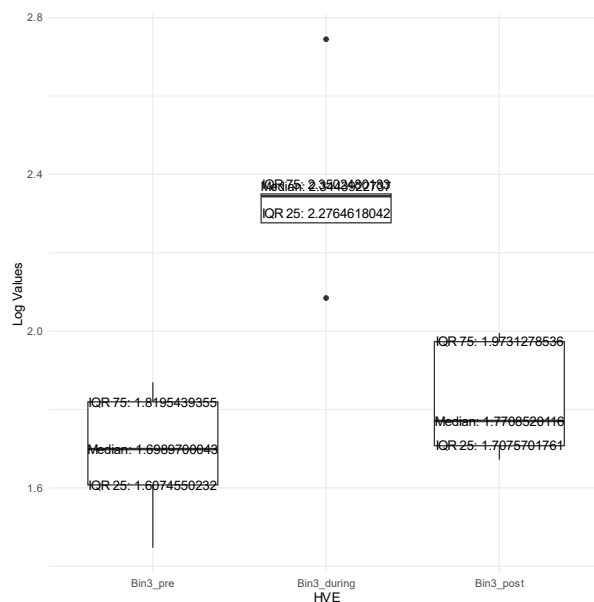
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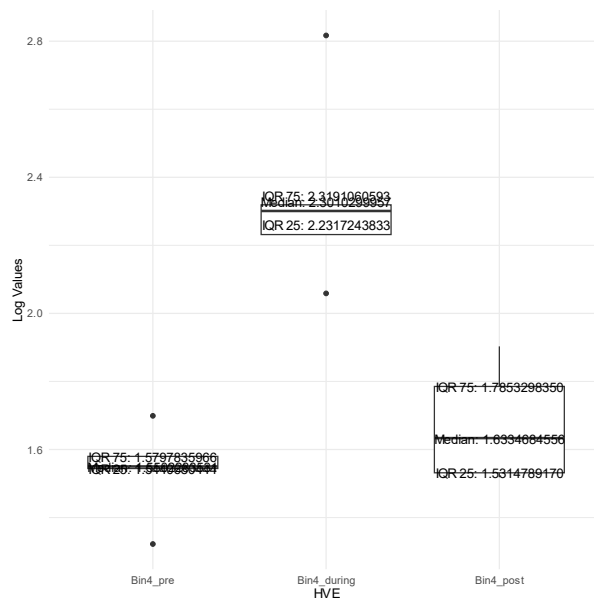
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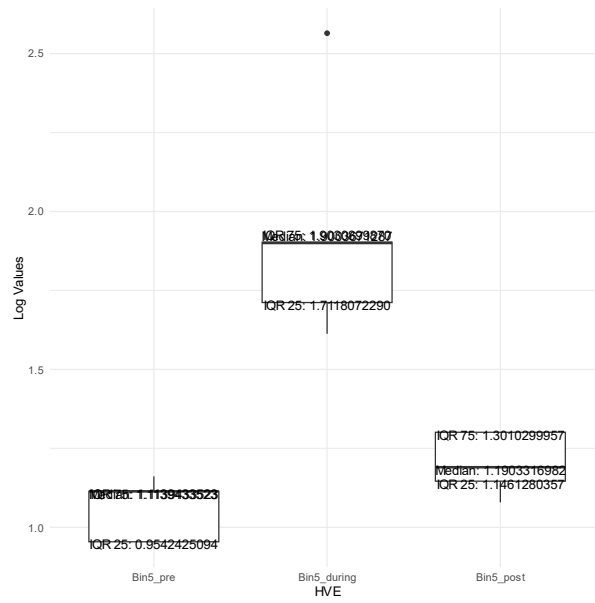
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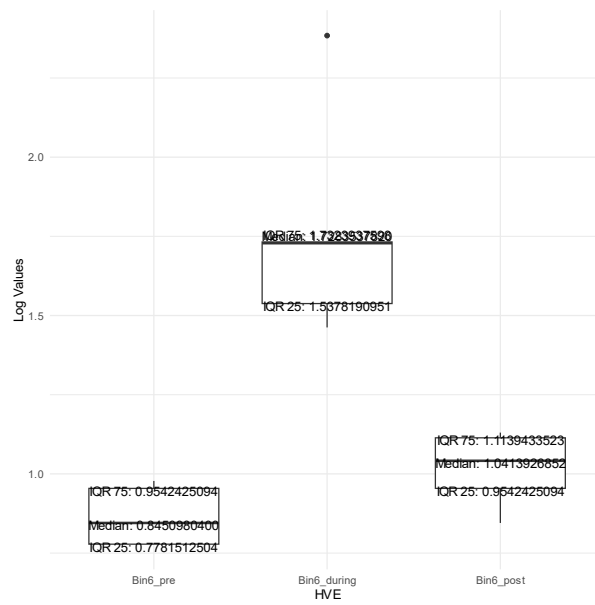
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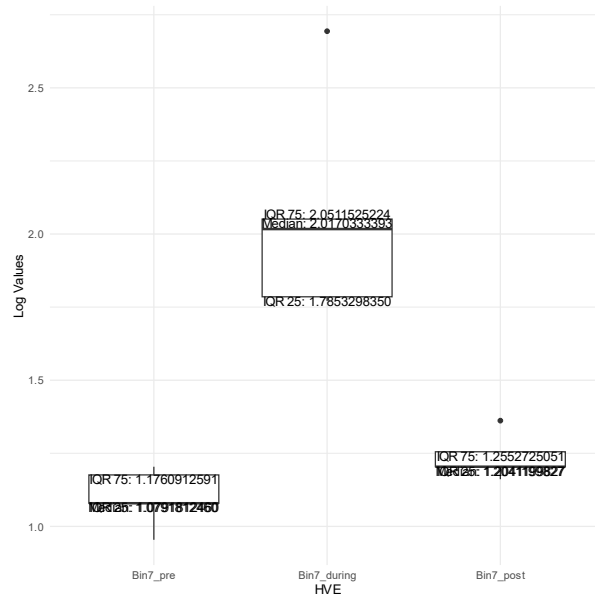
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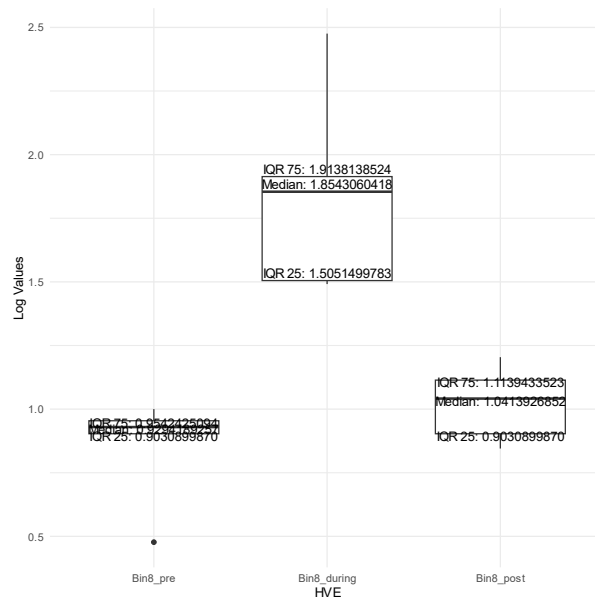
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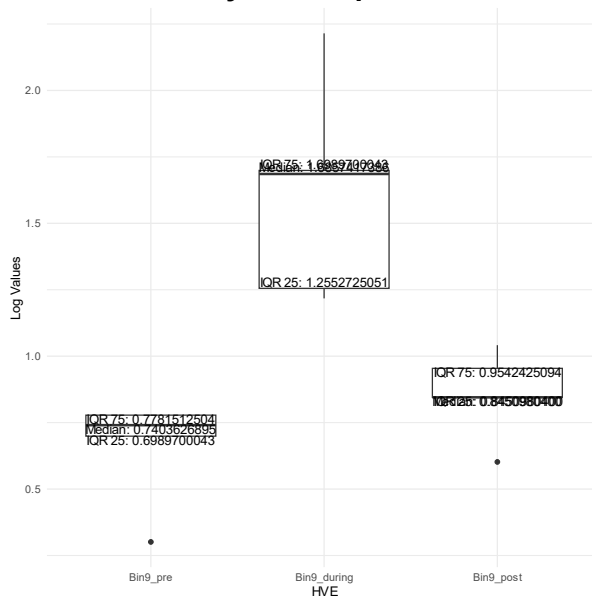
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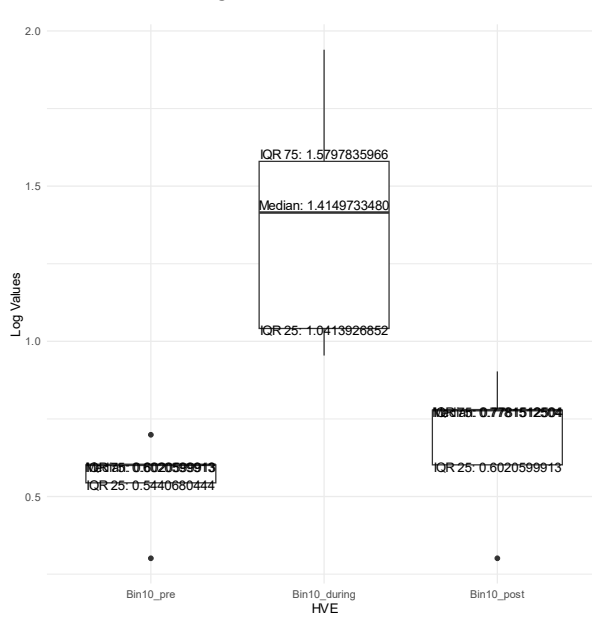
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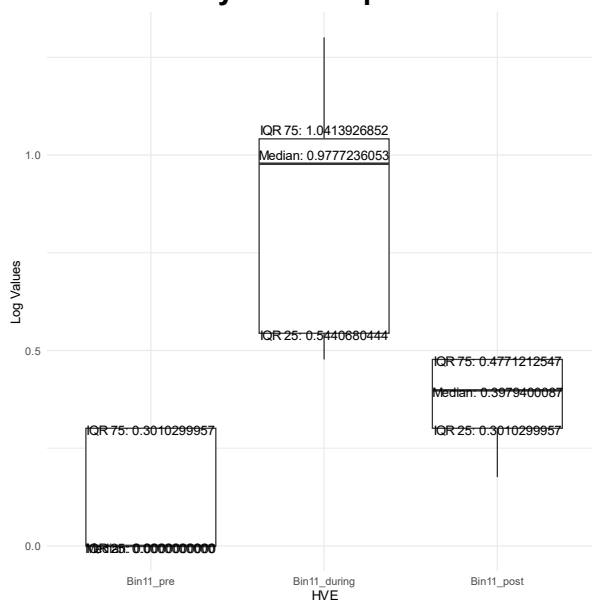
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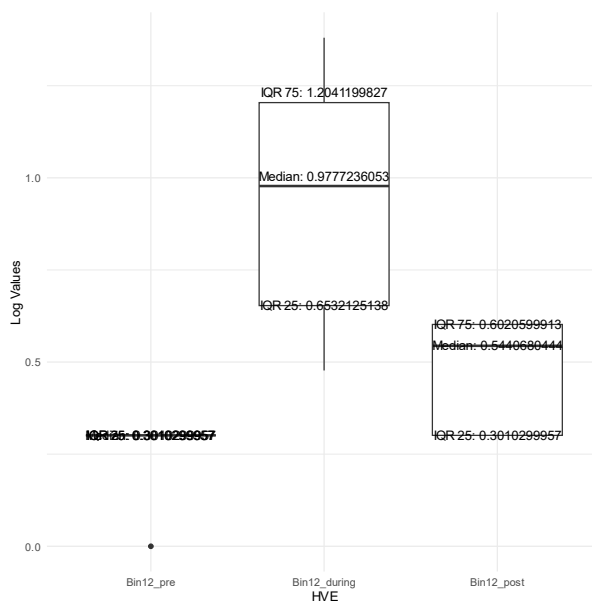
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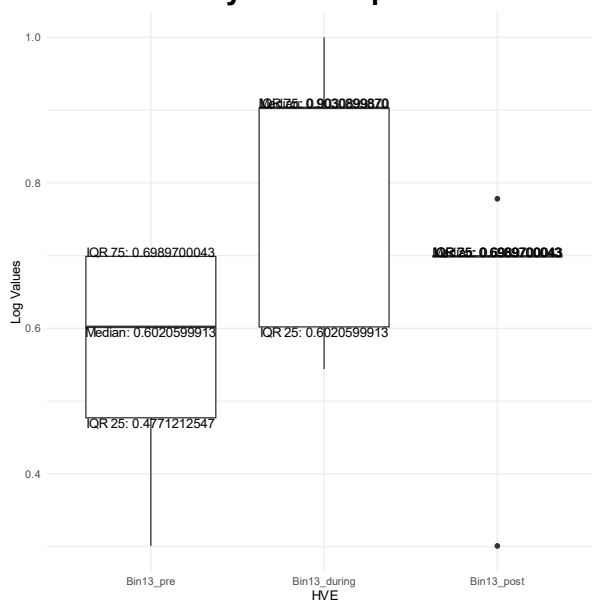
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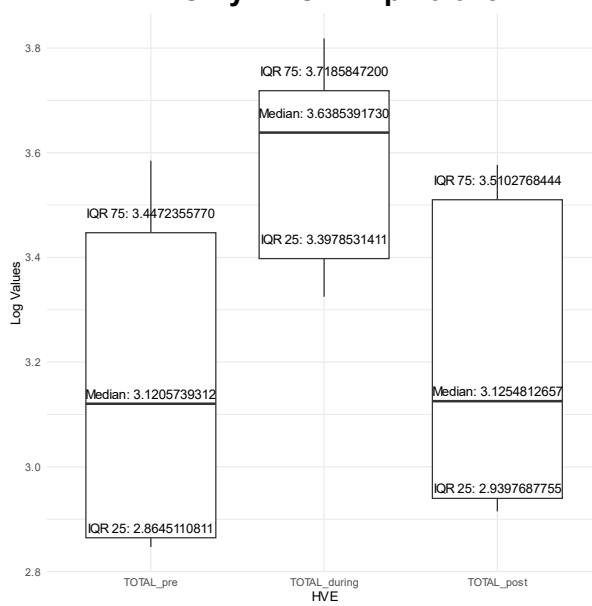
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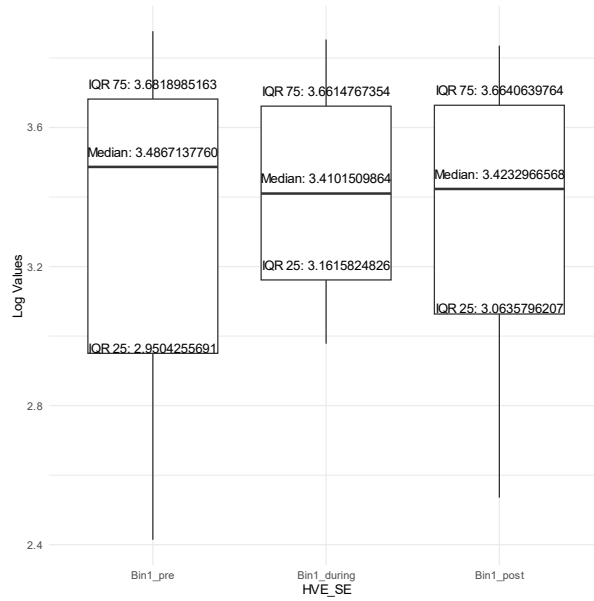
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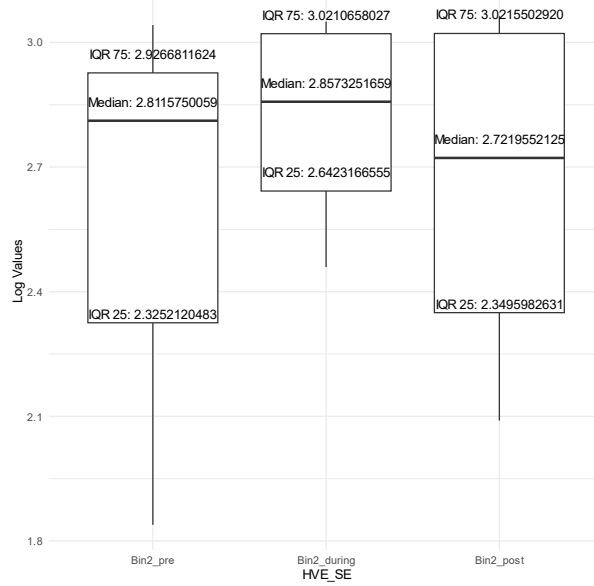
HVE Only – TOTAL p= 0.015



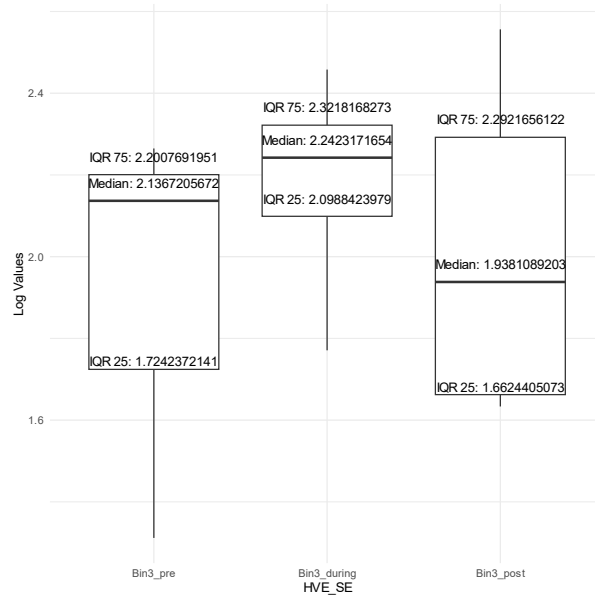
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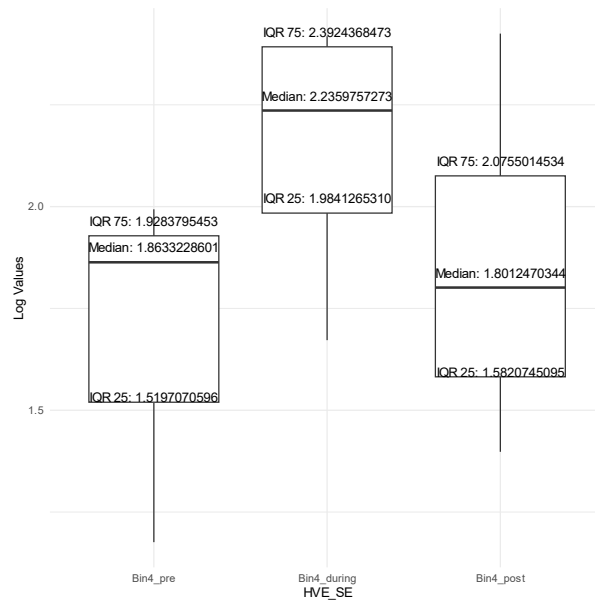
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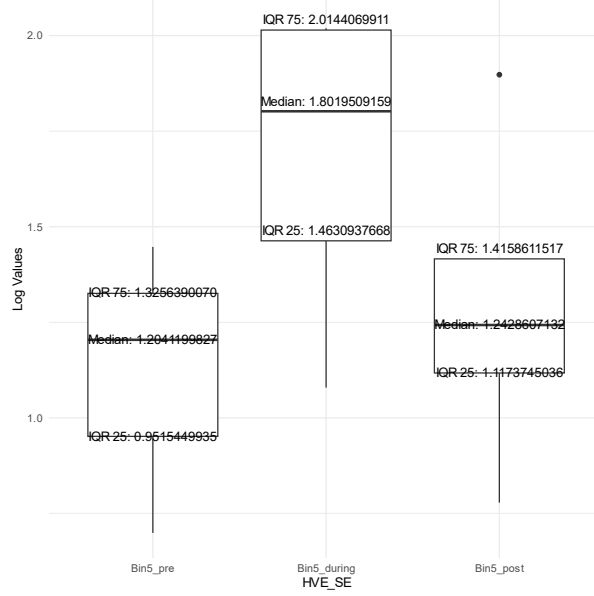
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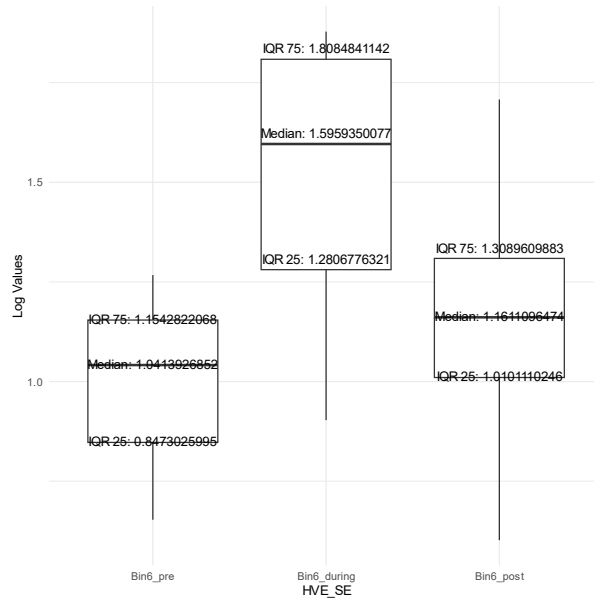
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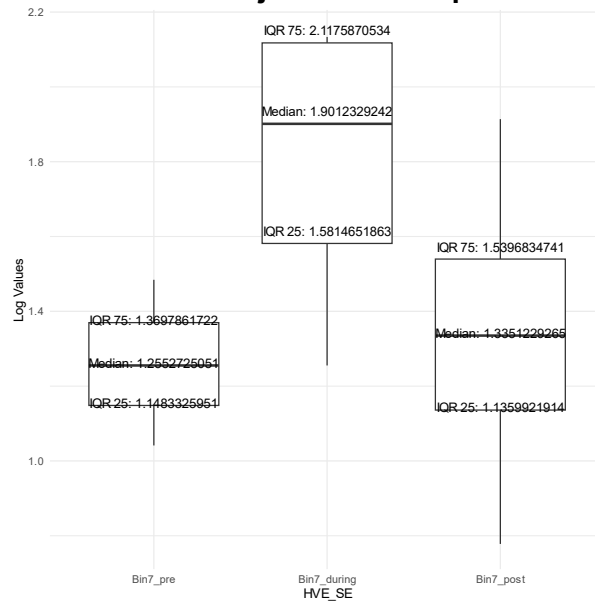
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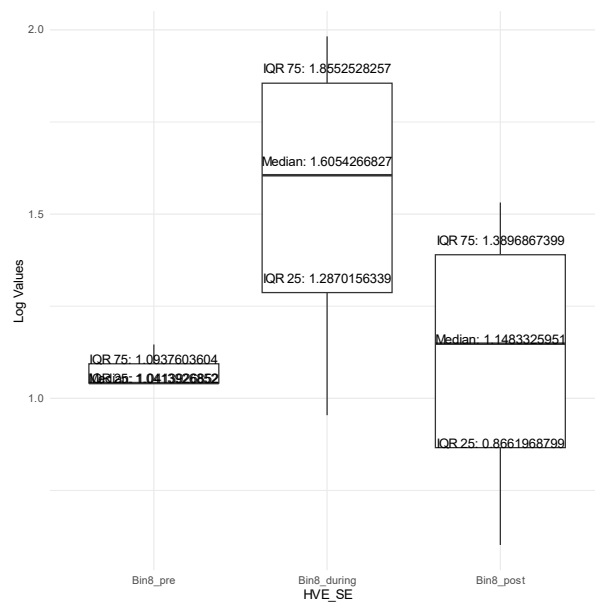
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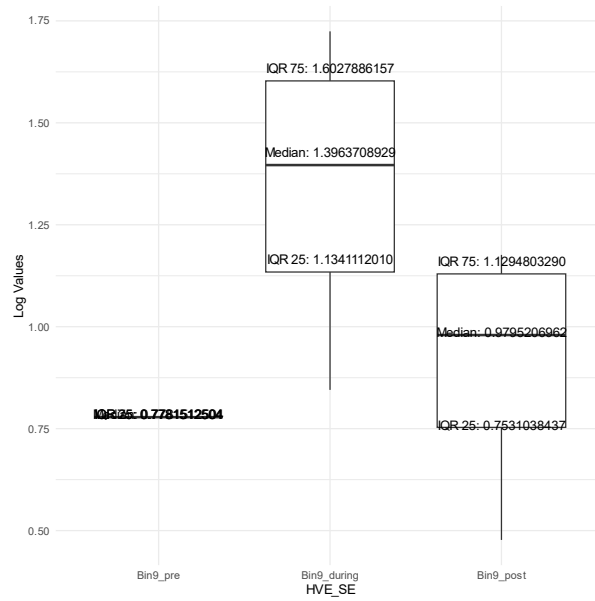
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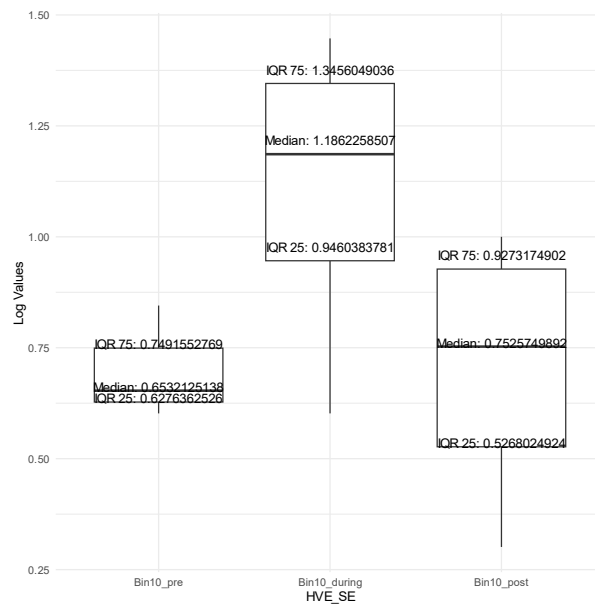
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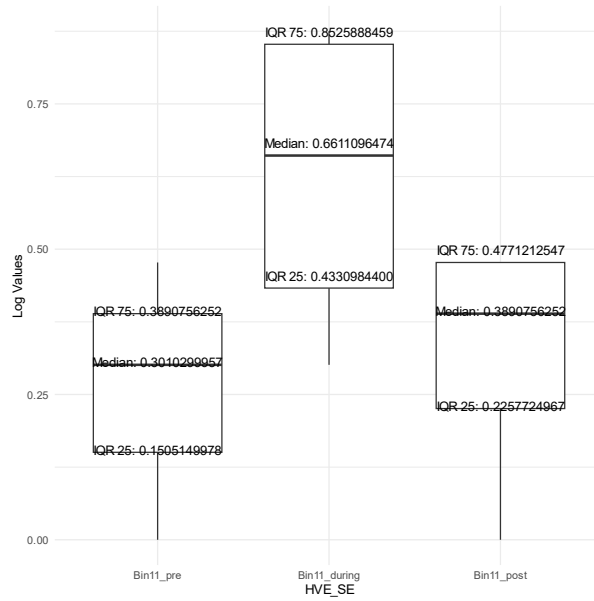
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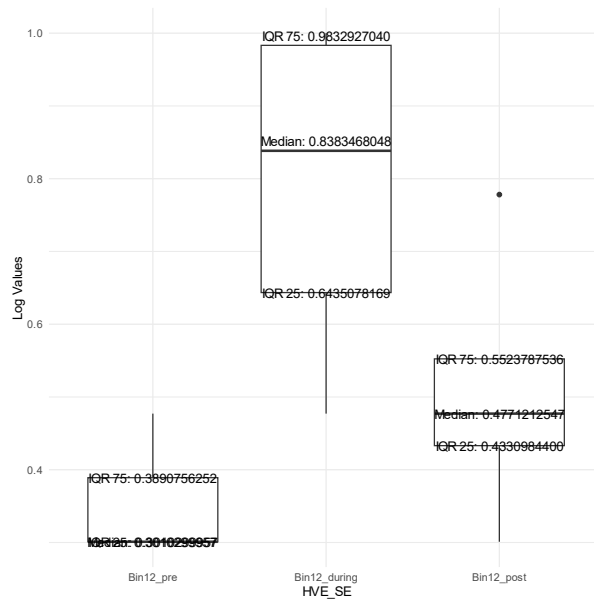
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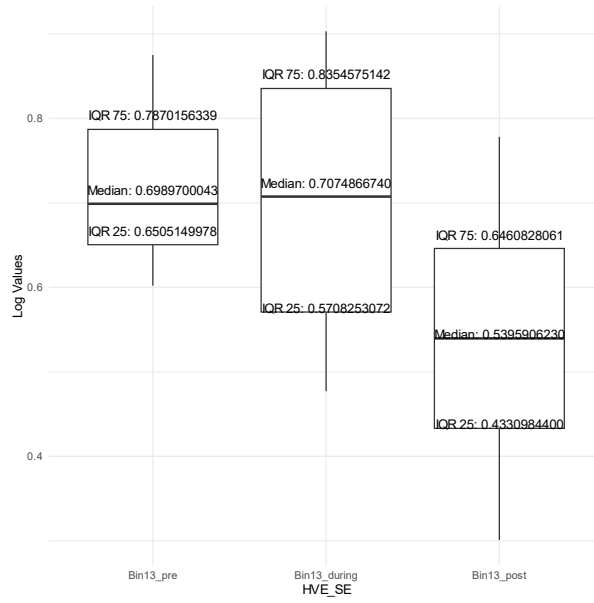
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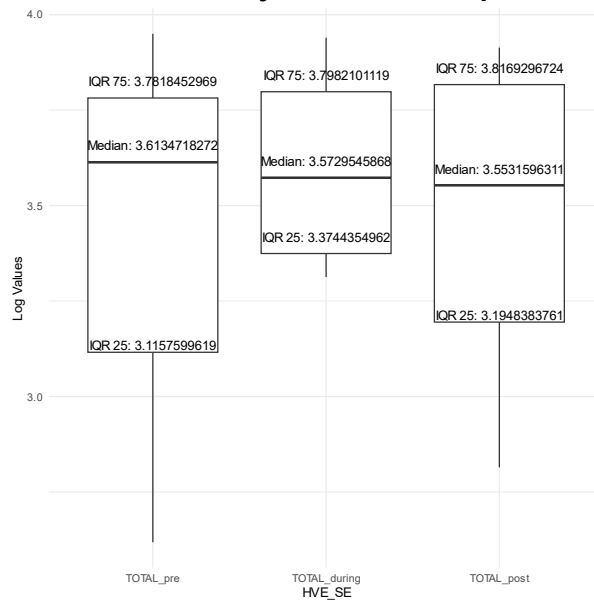
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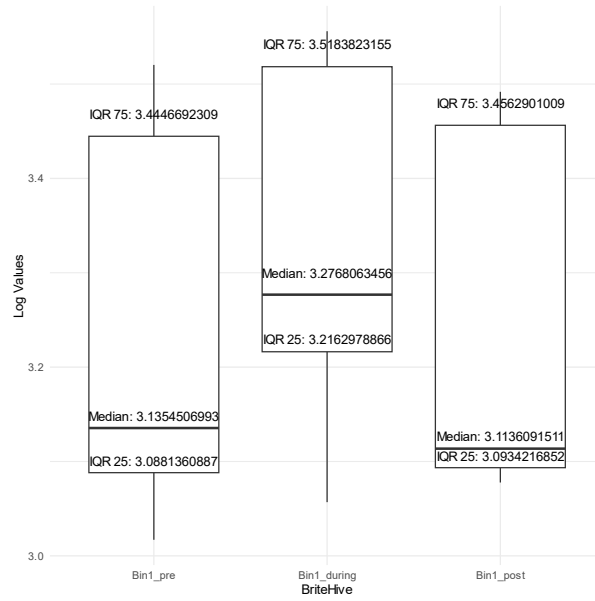
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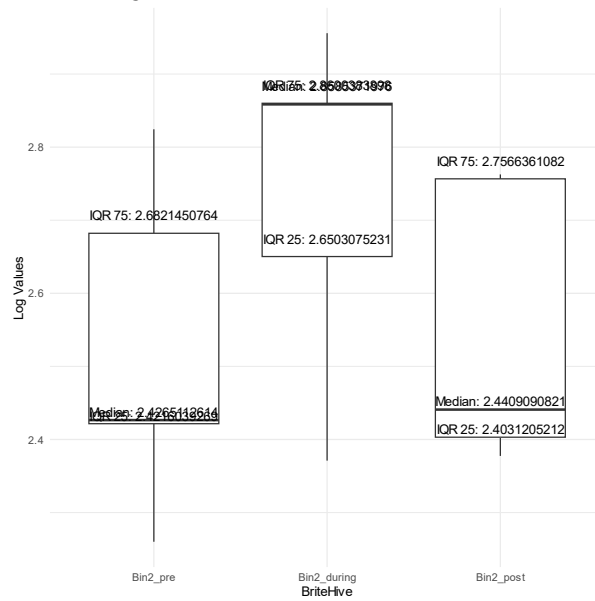
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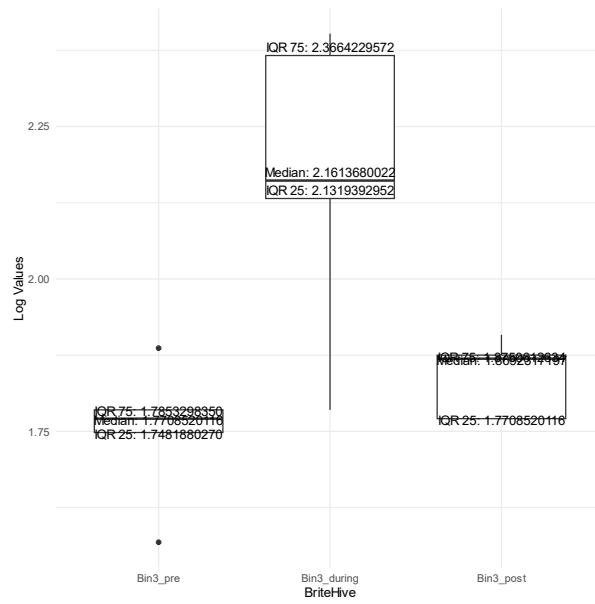
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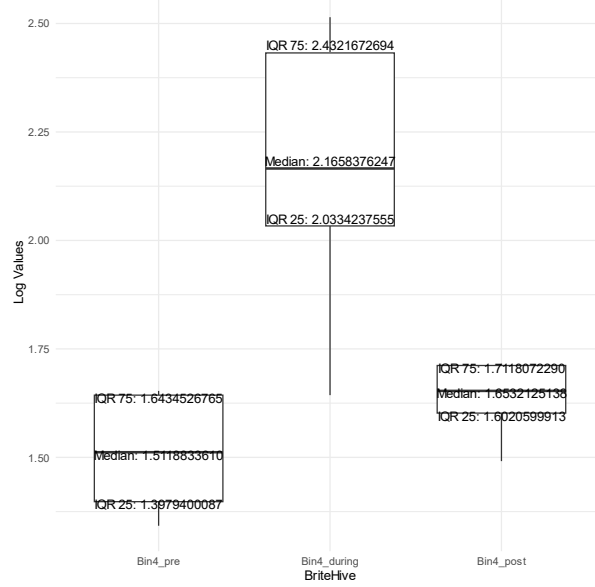
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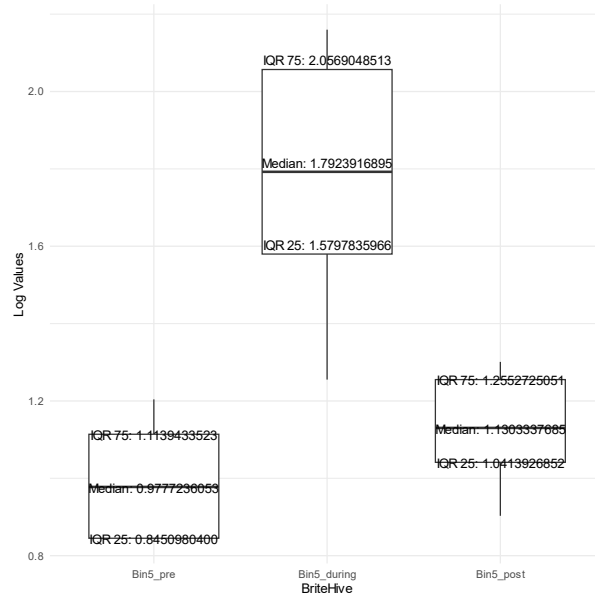
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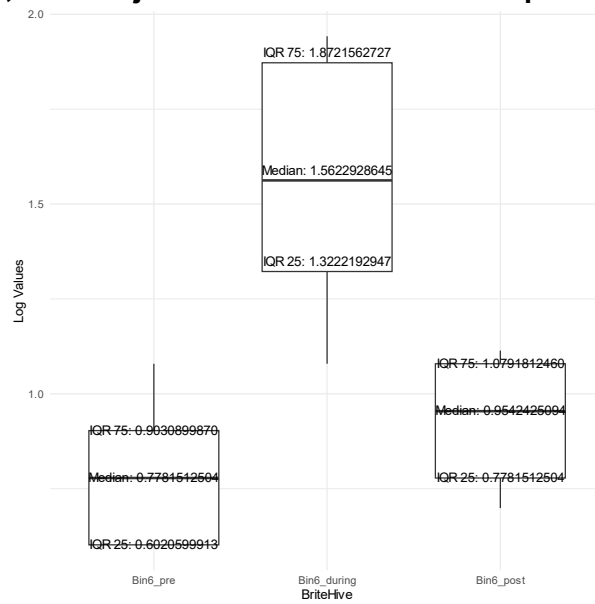
HVE, Saliva Ejector and BriteHive – Bin 4 $p= 0.02145$



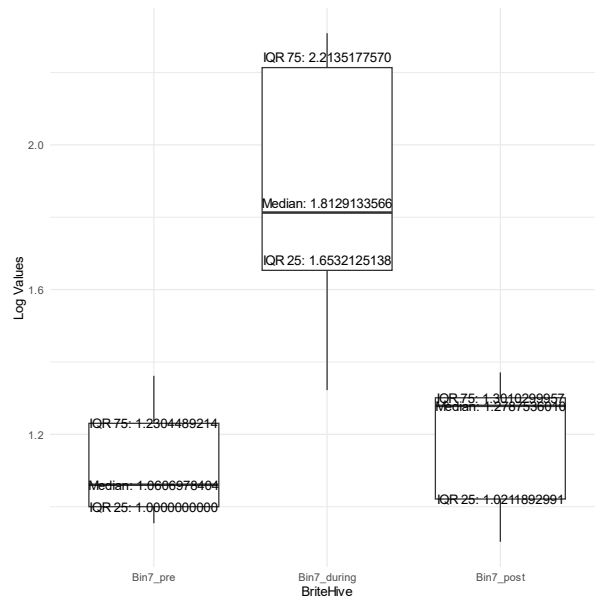
HVE, Saliva Ejector and BriteHive – Bin 5 $p= 0.04076$



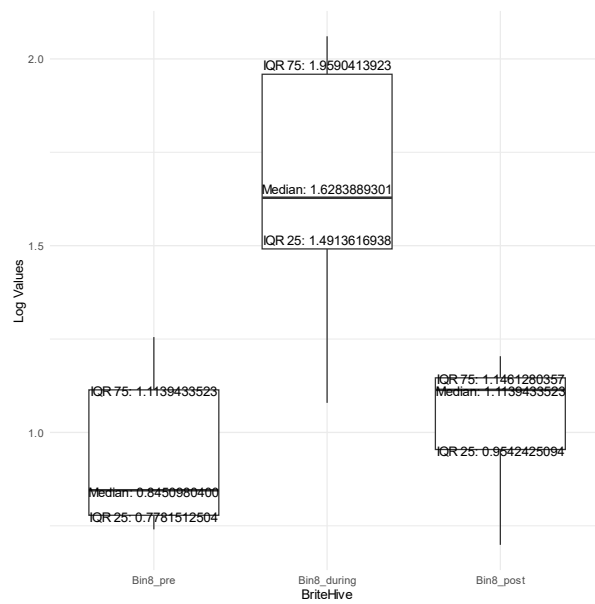
HVE, Saliva Ejector and BriteHive – Bin 6 $p= 0.04076$



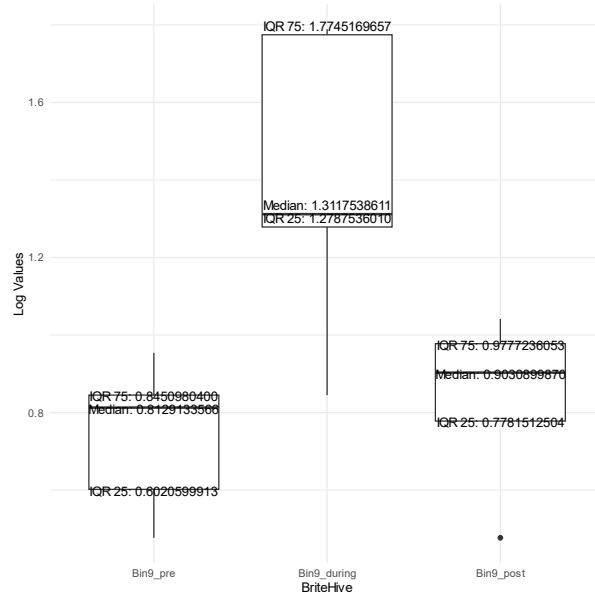
HVE, Saliva Ejector and BriteHive – Bin 7 $p= 0.09072$



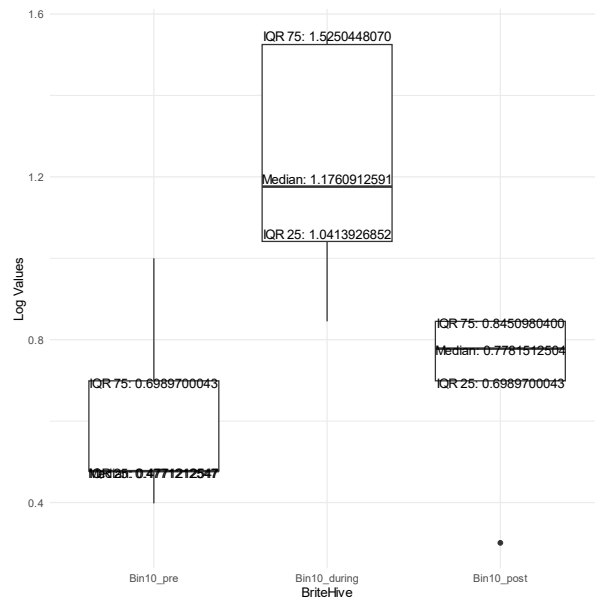
HVE, Saliva Ejector and BriteHive – Bin 8 $p= 0.07585$



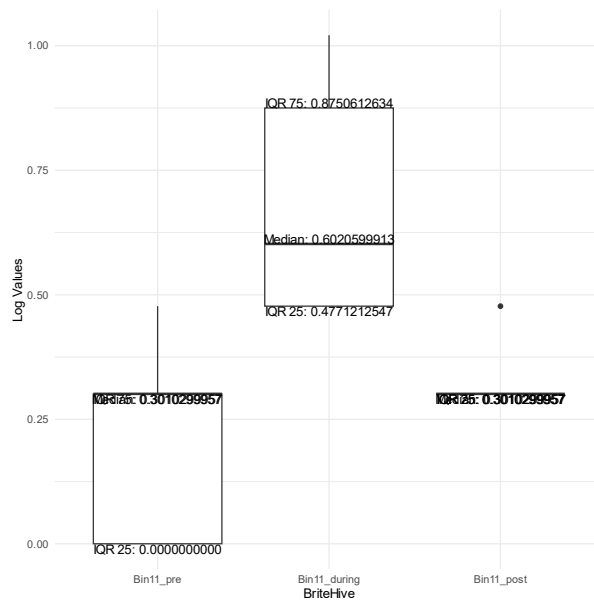
HVE, Saliva Ejector and BriteHive – Bin 9 p= 0.09072



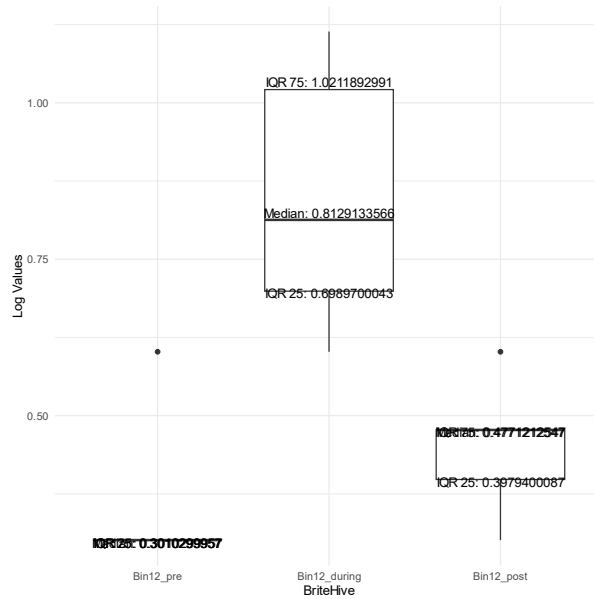
HVE, Saliva Ejector and BriteHive – Bin 10 p= 0.02237



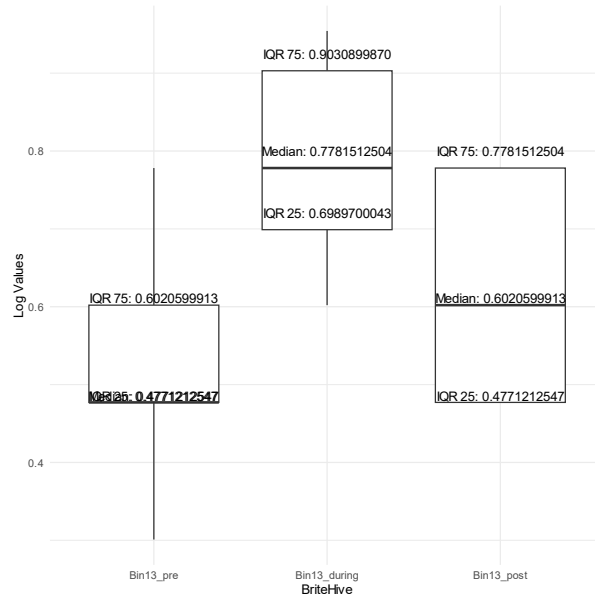
HVE, Saliva Ejector and BriteHive – Bin 11 p= 0.01564



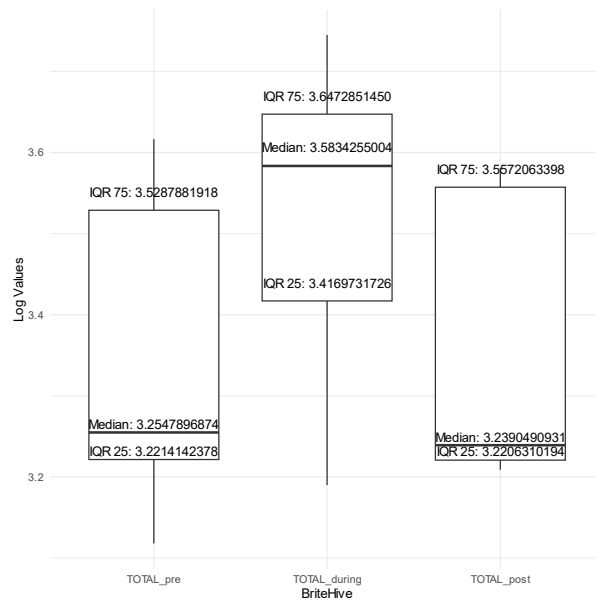
HVE, Saliva Ejector and BriteHive – Bin 12 p= 0.01564



HVE, Saliva Ejector and BriteHive – Bin 13 p= 0.0366



HVE, Saliva Ejector and BriteHive – TOTAL p= 0.090

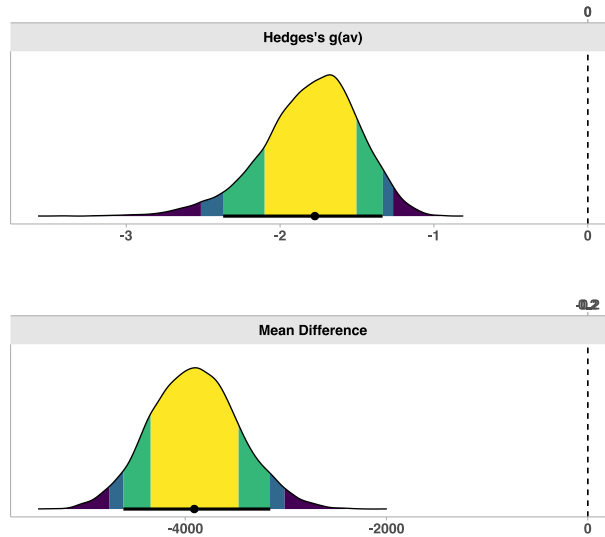


Section 3. TOST Equivalency, OPS

HVE Only X HVE and Saliva Ejector

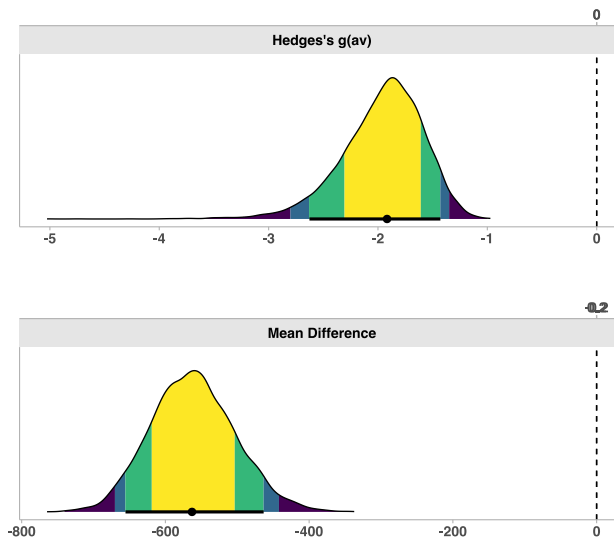
Pre-Procedural – Bin 1. Upper p value = < 0.01. Lower p value = 1.
Equivalency p value = 1.00E+00. Null p value = < 0.01

Confidence Interval 0,68 0,9 0,95 0,999



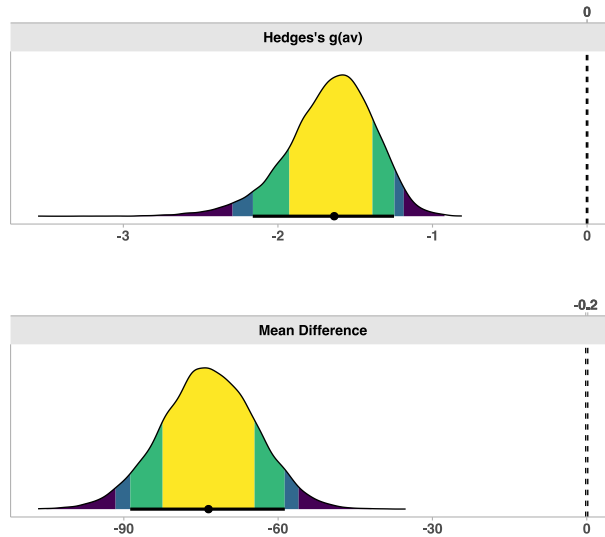
Pre-Procedural – Bin 2. Upper p value = < 0.01. Lower p value = 1.
Equivalency p value = 1.00E+00. Null p value = < 0.01

Confidence Interval 0,68 0,9 0,95 0,999



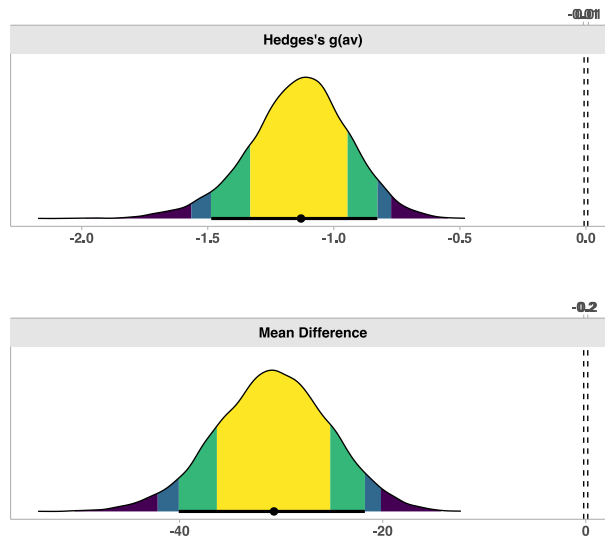
Pre-Procedural – Bin 3 Upper p value = < 0.01 Lower p value = 1
 Equivalency p value = 1.00E+00 Null p value = < 0.01

Confidence Interval 0.68 0.9 0.95 0.999



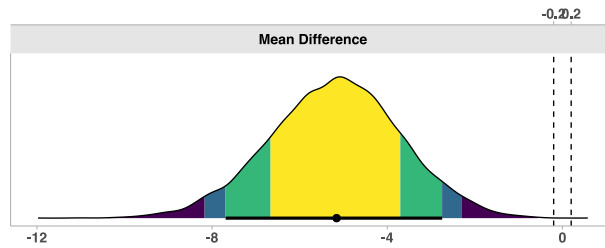
Pre-Procedural – Bin 4 Upper p value = < 0.01 Lower p value = 1.00E+00
 Equivalency p value = 1.00E+00 Null p value = < 0.01

Confidence Interval 0.68 0.9 0.95 0.999



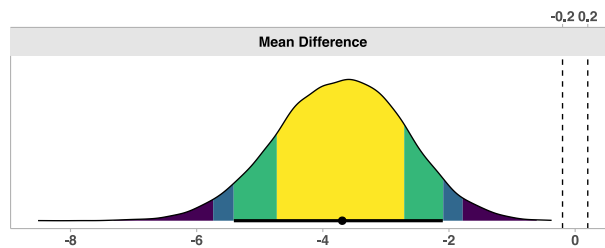
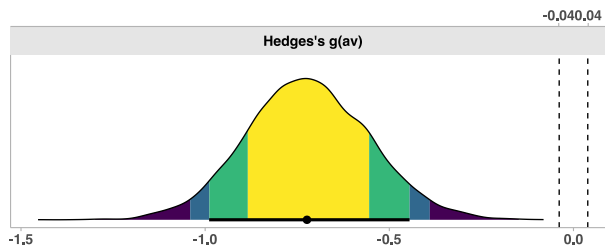
Pre-Procedural – Bin 5 Upper p value = 1.00E-03 Lower p value = 1.00E+00
Equivalency p value = 1.00E+00 Null p value = 2.00E-04

Confidence Interval 0,68 0,9 0,95 0,999



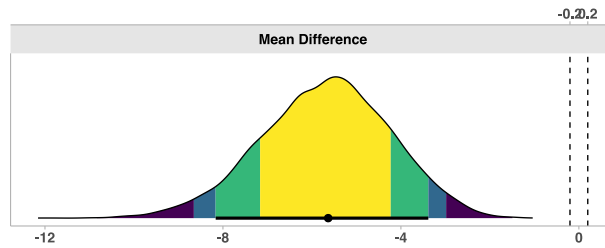
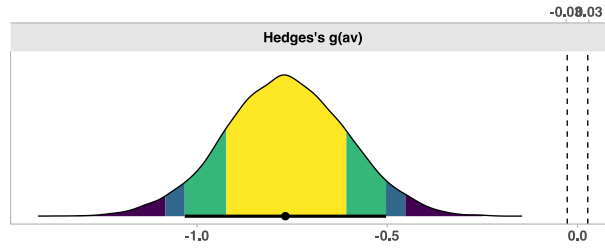
Pre-Procedural – Bin 6 Upper p value = 1.00E-03 Lower p value = 1.00E+00
Equivalency p value = 1.00E+00 Null p value = 2.00E-04

Confidence Interval 0,68 0,9 0,95 0,999



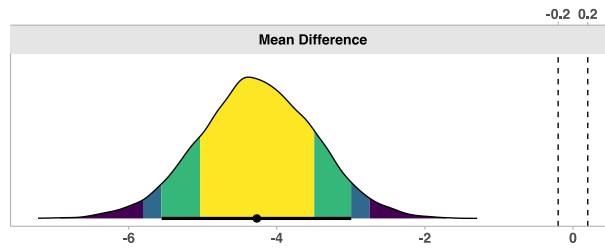
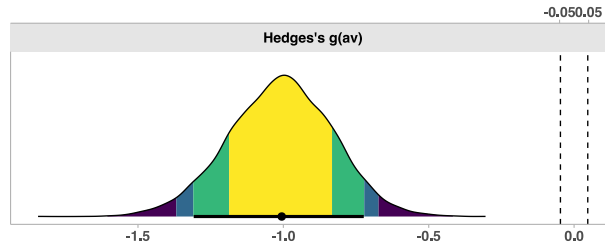
Pre-Procedural – Bin 7 Upper p value = < 0.01 Lower p value = 1.00E+00
Equivalency p value = 1.00E+00 Null p value = < 0.01

Confidence Interval 0.68 0.9 0.95 0.999



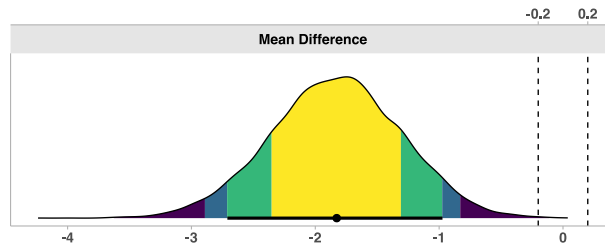
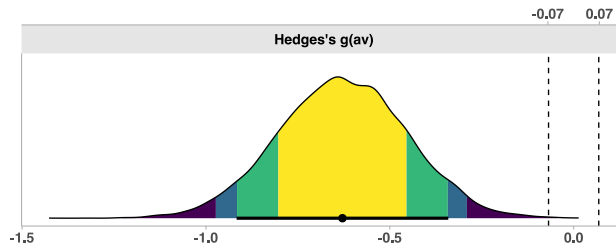
Pre-Procedural – Bin 8 Upper p value = < 0.01 Lower p value = 1.00E+00
Equivalency p value = 1.00E+00 Null p value = < 0.01

Confidence Interval 0.68 0.9 0.95 0.999



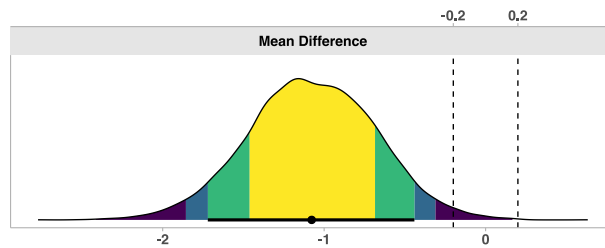
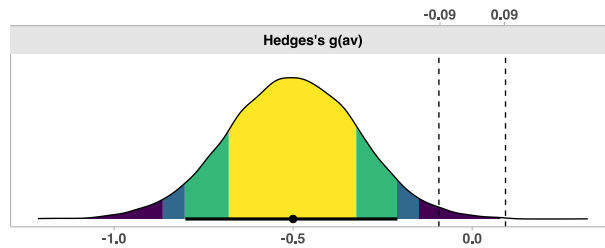
Pre-Procedural – Bin 9 Upper p value = 1.00E-04 Lower p value = 1.00E+00
Equivalency p value = 1.00E+00 Null p value = 2.00E-04

Confidence Interval 0,68 0,9 0,95 0,999



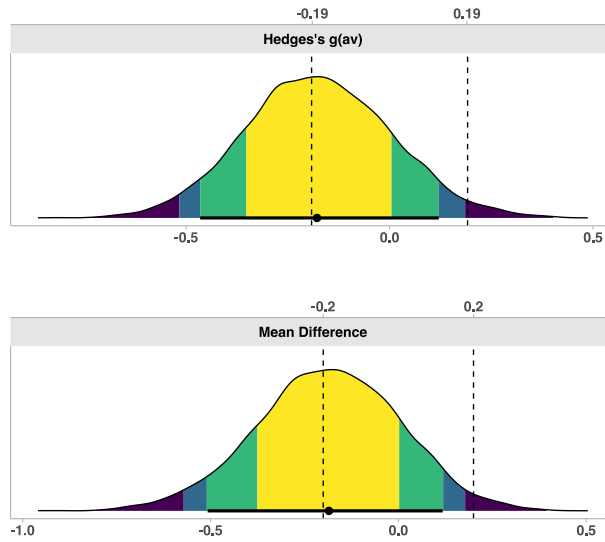
Pre-Procedural – Bin 10 Upper p value = 5.00E-04 Lower p value = 9.89E-01
Equivalency p value = 9.89E-01 Null p value = 5.20E-03

Confidence Interval 0,68 0,9 0,95 0,999



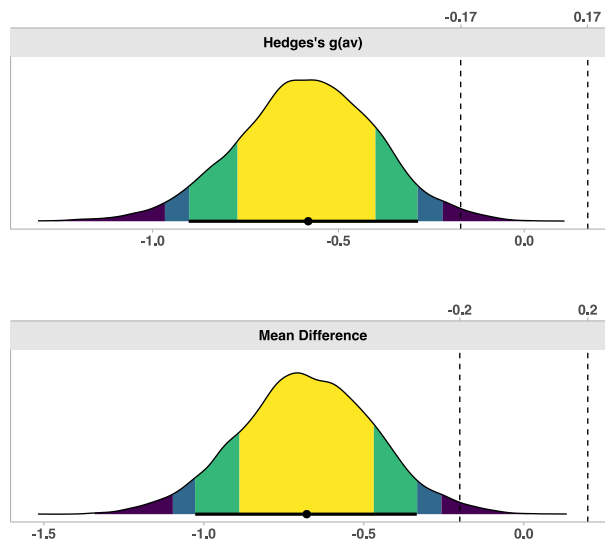
Pre-Procedural – Bin 11 Upper p value = 1.40E-02 Lower p value = 4.85E-01
Equivalency p value = 4.85E-01 Null p value = 2.96E-01

Confidence Interval 0,68 0,9 0,95 0,999



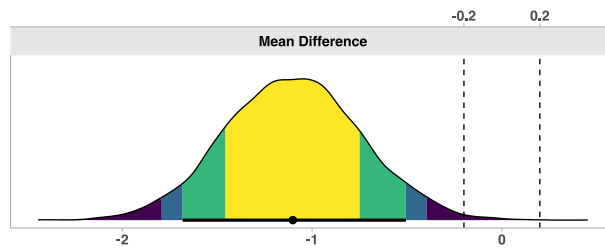
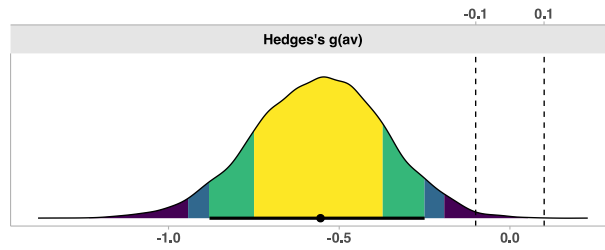
Pre-Procedural – Bin 12 Upper p value = <0.01 Lower p value = 9.89E-01
Equivalency p value = 9.89E-01 Null p value = 1.00E-03

Confidence Interval 0,68 0,9 0,95 0,999



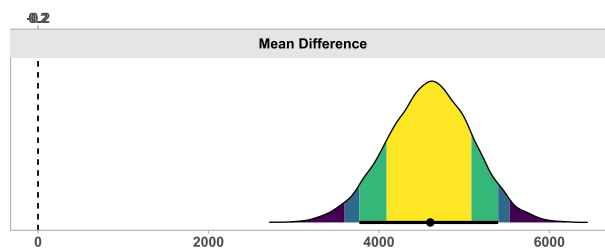
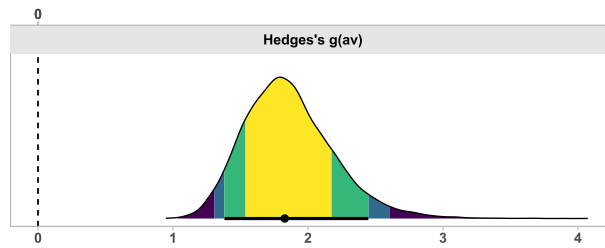
Pre-Procedural – Bin 13 Upper p value = 1.00E-04 Lower p value = 9.95E-01
 Equivalency p value = 9.95E-01 Null p value = 1.80E-03

Confidence Interval 0.68 0.9 0.95 0.999



Pre-Procedural – TOTAL Upper p value = 1.00E+00 Lower p value = <0.01
 Equivalency p value = 1.00E+00 Null p value = <0.01

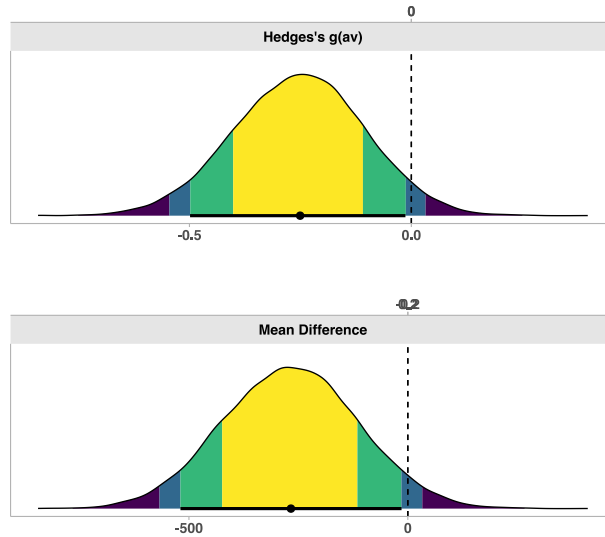
Confidence Interval 0.68 0.9 0.95 0.999



HVE Only X HVE, SE and BriteHive

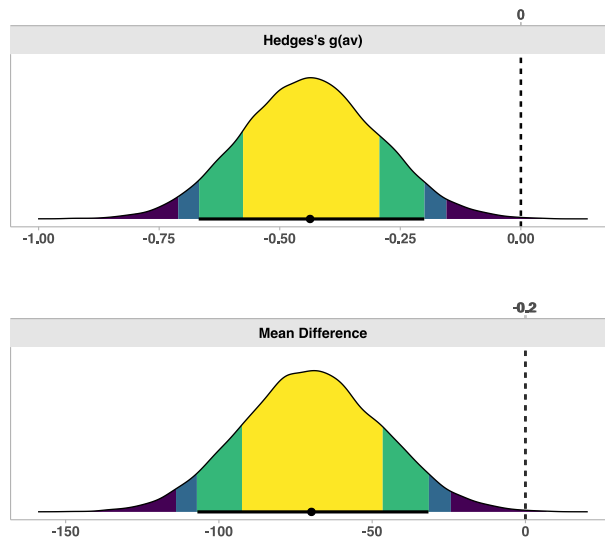
Pre-Procedural – Bin 1 Upper p value = 0.0410041 Lower p value = 0.95879588
Equivalency p value = 9.59E-01 Null p value = 8.22E-02

Confidence Interval 0.68 0.9 0.95 0.999

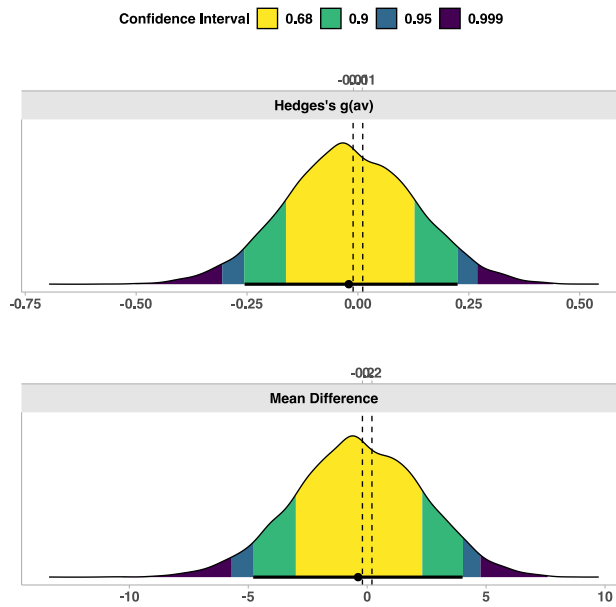


Pre-Procedural – Bin 2 Upper p value = 0.00090009 Lower p value = 0.9989999
Equivalency p value = 9.99E-01 Null p value = 2.00E-03

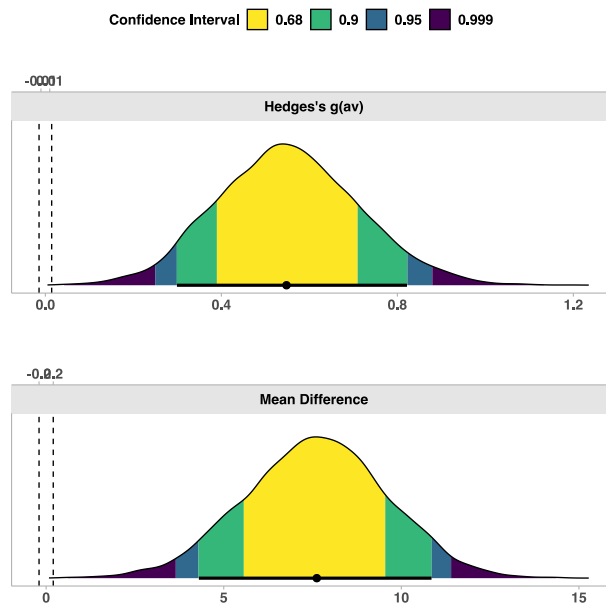
Confidence Interval 0.68 0.9 0.95 0.999



Pre-Procedural – Bin 3 Upper p value = 4.08E-01 Lower p value = 5.29E-01
 Equivalency p value = 5.29E-01 Null p value = 8.79E-01

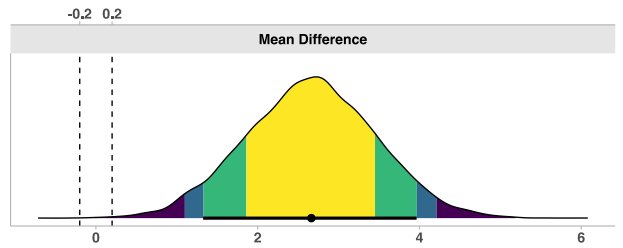
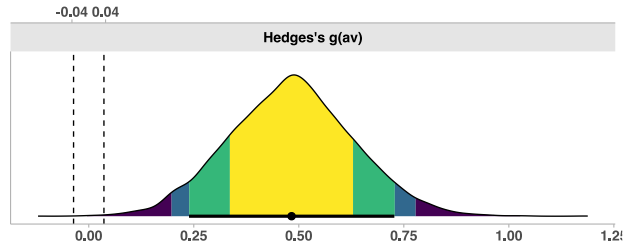


Pre-Procedural – Bin 4 Upper p value = 1.00E+00 Lower p value = 1.00E-04
 Equivalency p value = 1.00E+00 Null p value = 4.00E-04



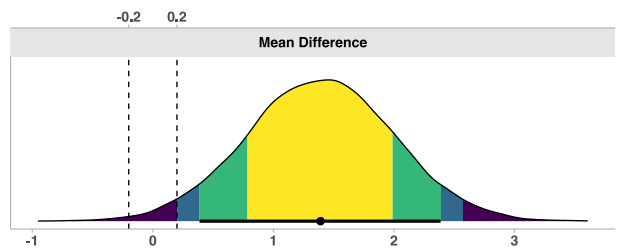
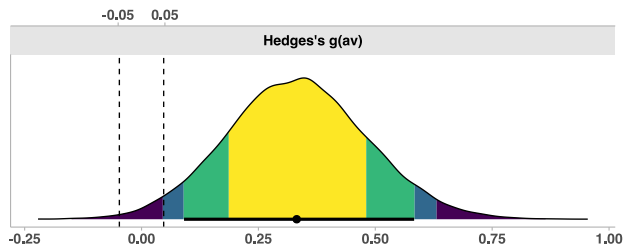
Pre-Procedural – Bin 5 Upper p value = 9.99E-01 Lower p value = 3.00E-04
 Equivalency p value = 9.99E-01 Null p value = 1.00E-03

Confidence Interval 0.68 0.9 0.95 0.999



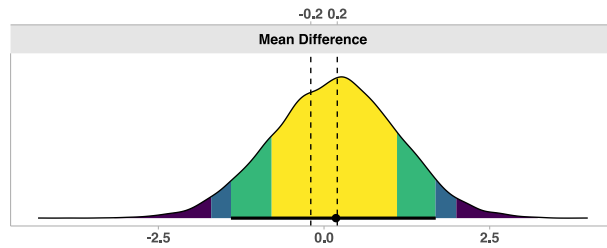
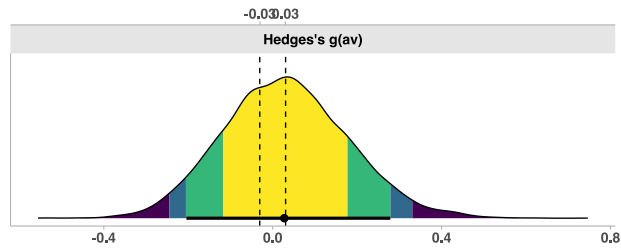
Pre-Procedural – Bin 6 Upper p value = 9.75E-01 Lower p value = 4.70E-03
 Equivalency p value = 9.75E-01 Null p value = 2.30E-02

Confidence Interval 0.68 0.9 0.95 0.999



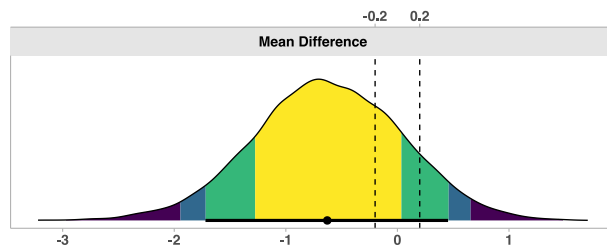
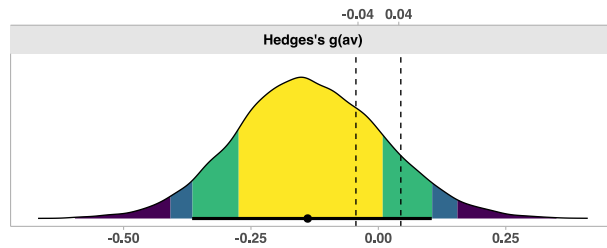
Pre-Procedural – Bin 7 Upper p value = 4.60E-01 Lower p value = 3.75E-01
 Equivalency p value = 4.60E-01 Null p value = 9.13E-01

Confidence Interval 0.68 0.9 0.95 0.999



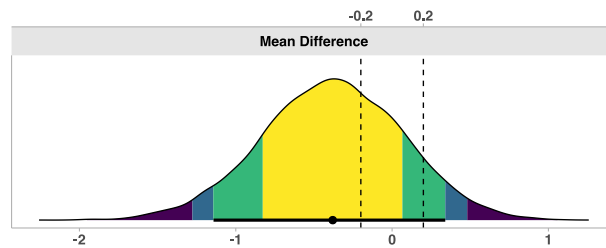
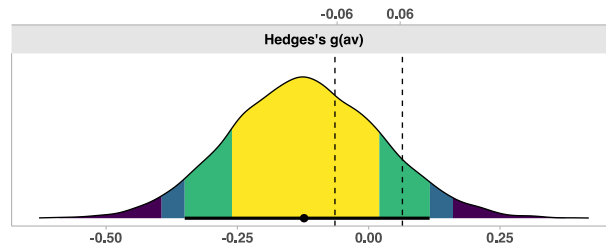
Pre-Procedural – Bin 8 Upper p value = 1.01E-01 Lower p value = 7.41E-01
 Equivalency p value = 7.41E-01 Null p value = 3.29E-01

Confidence Interval 0.68 0.9 0.95 0.999



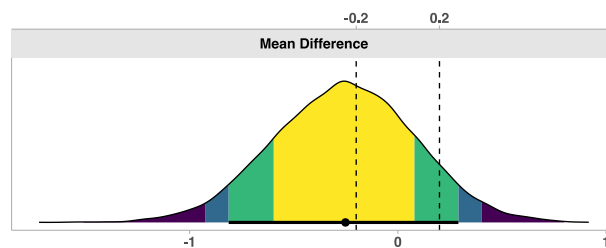
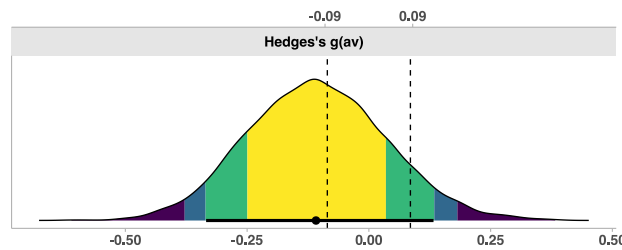
Pre-Procedural – Bin 9 Upper p value = 9.66E-02 Lower p value = 6.56E-01
Equivalency p value = 6.56E-01 Null p value = 3.92E+01

Confidence Interval 0.68 0.9 0.95 0.999



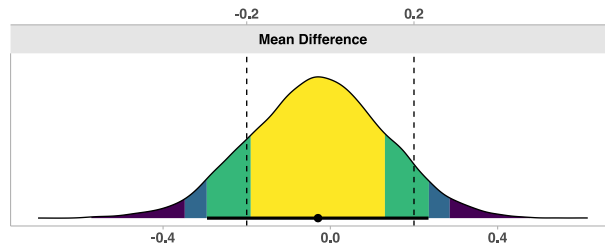
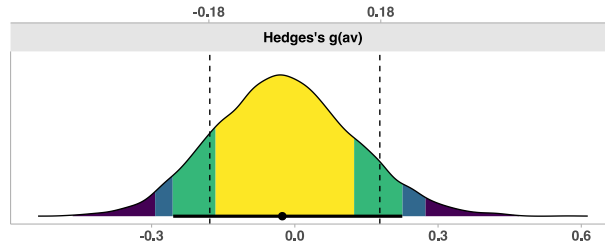
Pre-Procedural – Bin 10 Upper p value = 7.76E-02 Lower p value = 5.81E-01
Equivalency p value = 5.81E-01 Null p value = 4.31E-01

Confidence Interval 0.68 0.9 0.95 0.999



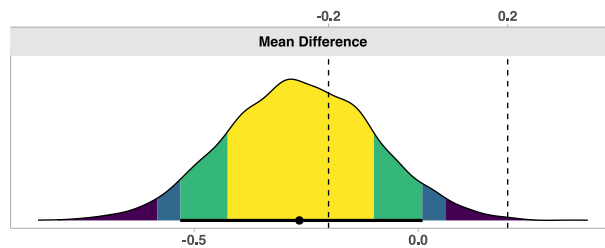
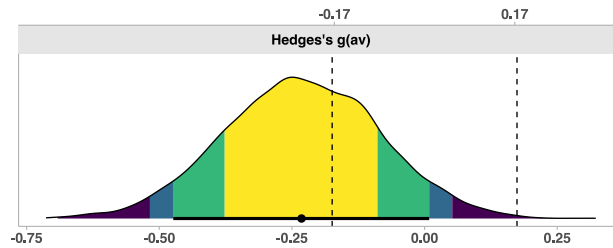
Pre-Procedural – Bin 11 Upper p value = 7.27E-02 Lower p value = 1.62E-01
Equivalency p value = 1.62E-01 Null p value = 8.50E-01

Confidence Interval 0.68 0.9 0.95 0.999

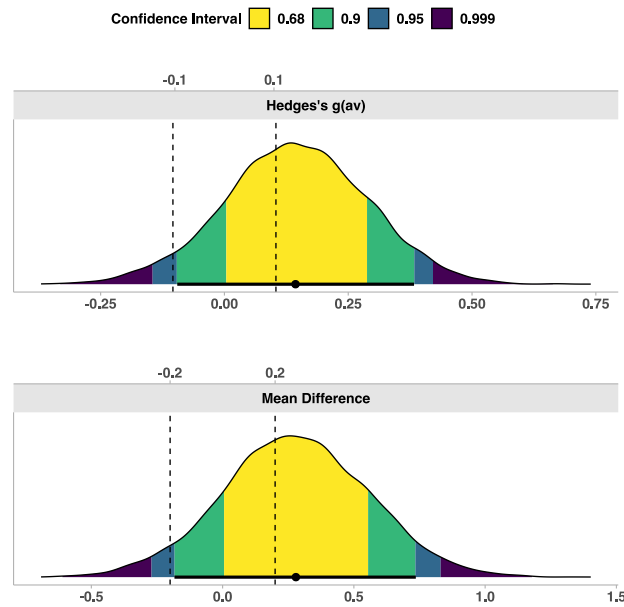


Pre-Procedural – Bin 12 Upper p value = 2.30E-03 Lower p value = 6.57E-01
Equivalency p value = 6.57E-01 Null p value = 1.09E-01

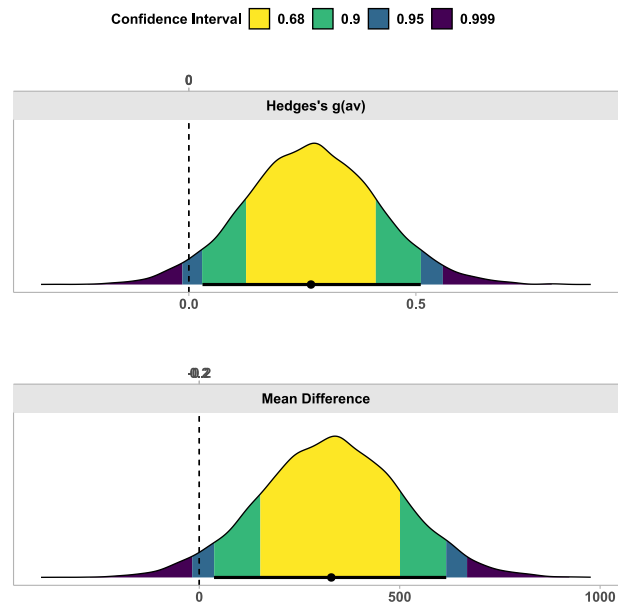
Confidence Interval 0.68 0.9 0.95 0.999



Pre-Procedural – Bin 13 Upper p value = 6.21E-01 Lower p value = 4.03E-02
Equivalency p value = 6.21E-01 Null p value = 3.06E-01



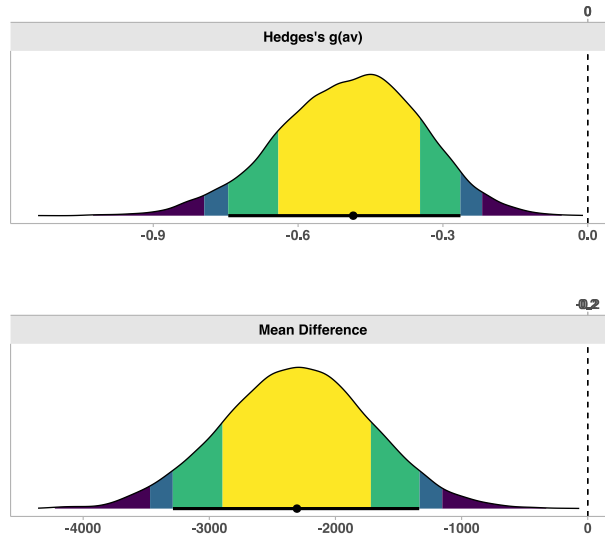
Pre-Procedural – TOTAL Upper p value = 9.68E-01 Lower p value = 3.13E-02
Equivalency p value = 9.68E-01 Null p value = 6.28E-02



HVE Only X HVE and Saliva Ejector

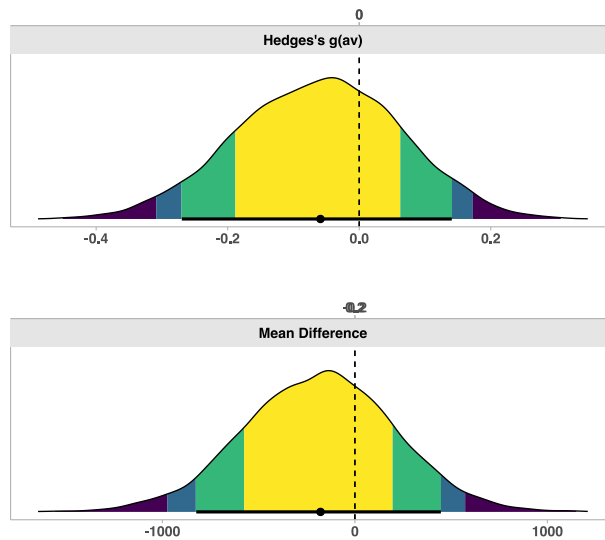
Procedural – Bin 1 Upper p value = <0.01 Lower p value = 1
Equivalency p value = 1 Null p value = <0.01

Confidence Interval 0.68 0.9 0.95 0.999



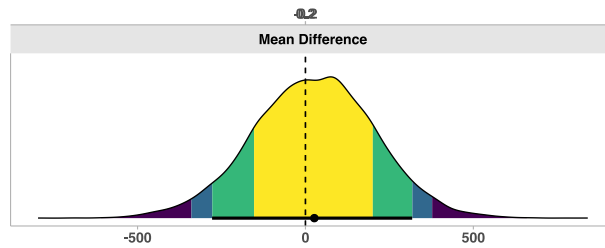
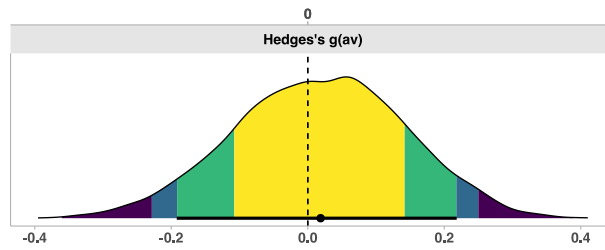
Procedural – Bin 2 Upper p value = 0.3165317 Lower p value = 0.6828683
Equivalency p value = 6.83E-01 Null p value = 6.34E-01

Confidence Interval 0.68 0.9 0.95 0.999



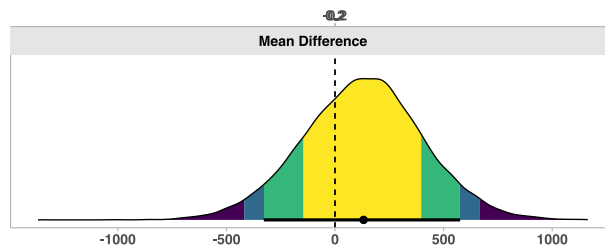
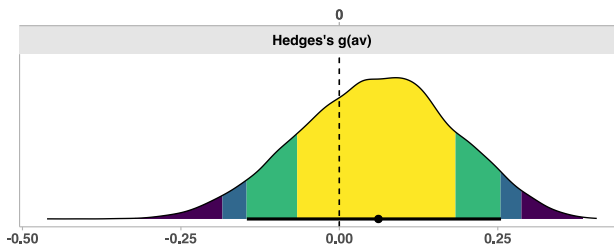
Procedural – Bin 3 Upper p value = 5.29E-01 Lower p value = 4.70E-01
Equivalency p value = 5.29E-01 Null p value = 9.41E-01

Confidence Interval 0.68 0.9 0.95 0.999



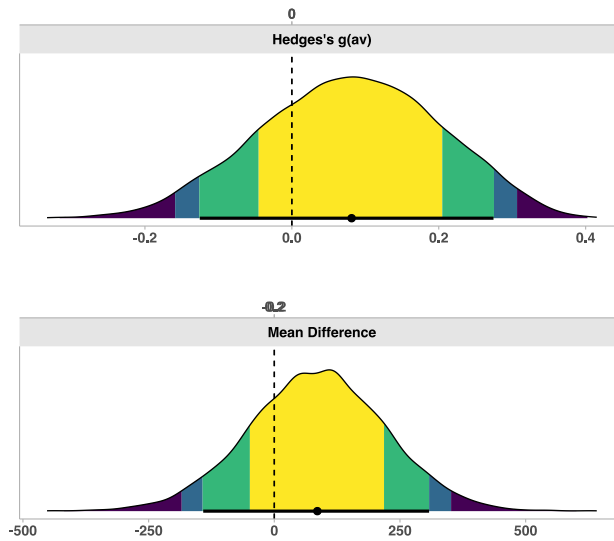
Procedural – Bin 4 Upper p value = 6.66E-01 Lower p value = 3.33E-01
Equivalency p value = 6.66E-01 Null p value = 6.67E-01

Confidence Interval 0.68 0.9 0.95 0.999



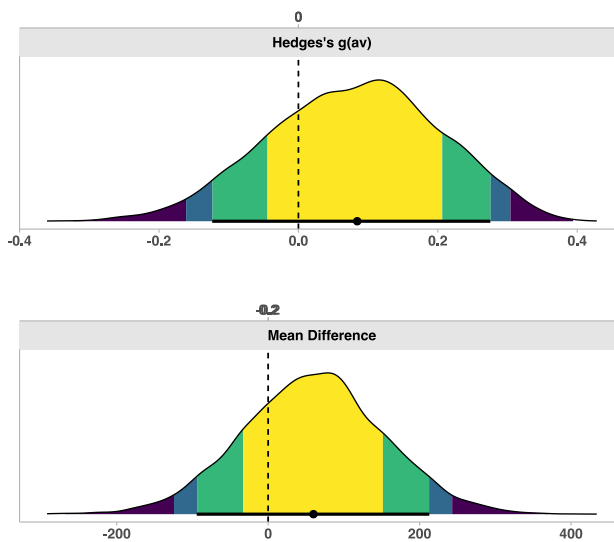
Procedural – Bin 5 Upper p value = 7.16E-01 Lower p value = 2.83E-01
Equivalency p value = 7.16E-01 Null p value = 5.68E-01

Confidence Interval 0.68 0.9 0.95 0.999



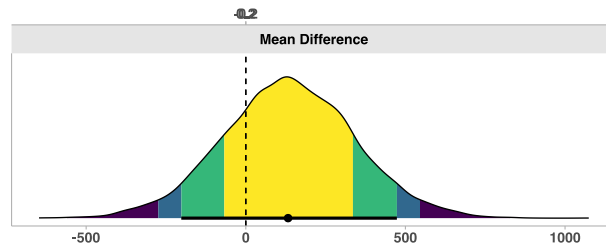
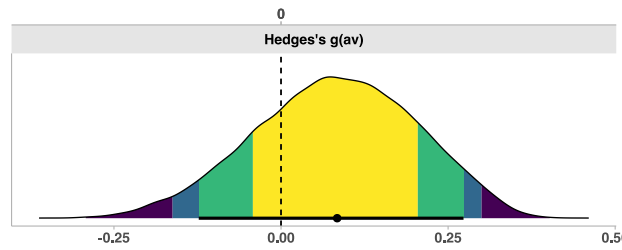
Procedural – Bin 6 Upper p value = 7.32E-01 Lower p value = 2.67E-01
Equivalency p value = 7.32E-01 Null p value = 5.34E-01

Confidence Interval 0.68 0.9 0.95 0.999



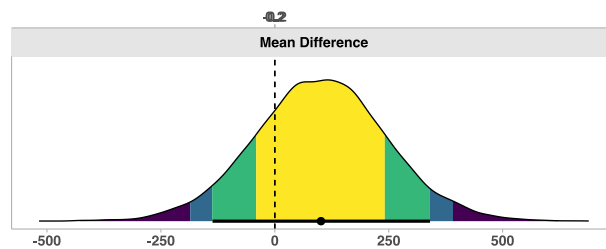
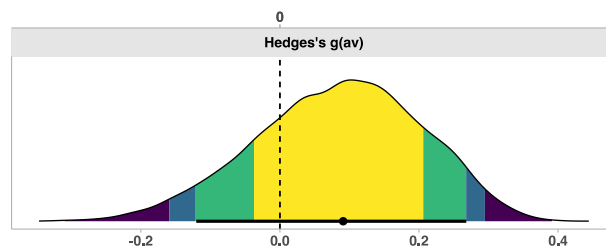
Procedural – Bin 7 Upper p value = 7.29E-01 Lower p value = 2.71E-01
 Equivalency p value = 7.29E-01 Null p value = 5.42E-01

Confidence Interval 0.68 0.9 0.95 0.999



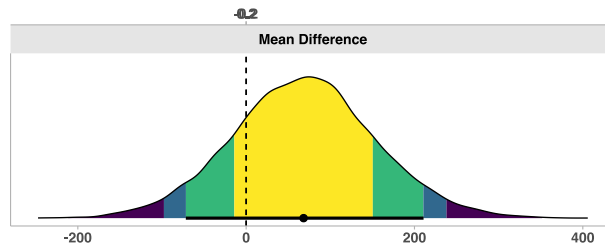
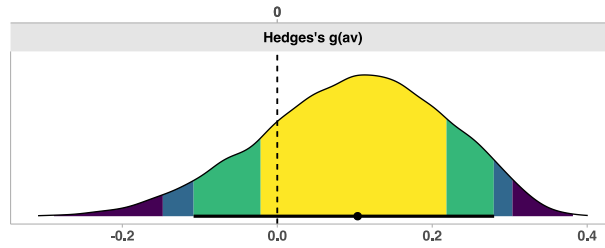
Procedural – Bin 8 Upper p value = 7.46E-01 Lower p value = 2.53E-01
 Equivalency p value = 7.46E-01 Null p value = 5.07E-01

Confidence Interval 0.68 0.9 0.95 0.999



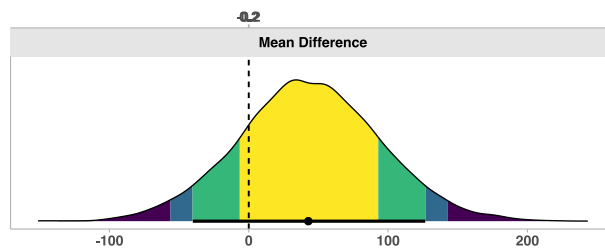
Procedural – Bin 9 Upper p value = 7.87E-01 Lower p value = 2.13E-01
Equivalency p value = 7.87E-01 Null p value = 4.26E-01

Confidence Interval 0.68 0.9 0.95 0.999

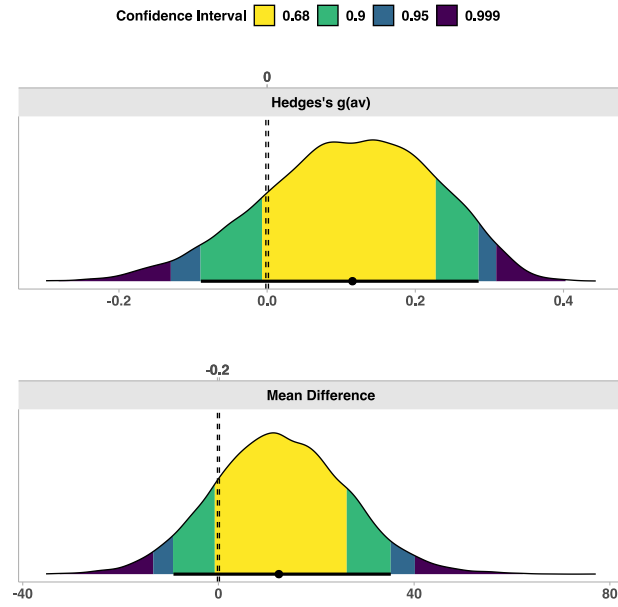


Procedural – Bin 10 Upper p value = 8.04E-01 Lower p value = 1.93E-01
Equivalency p value = 8.04E-01 Null p value = 3.89E-01

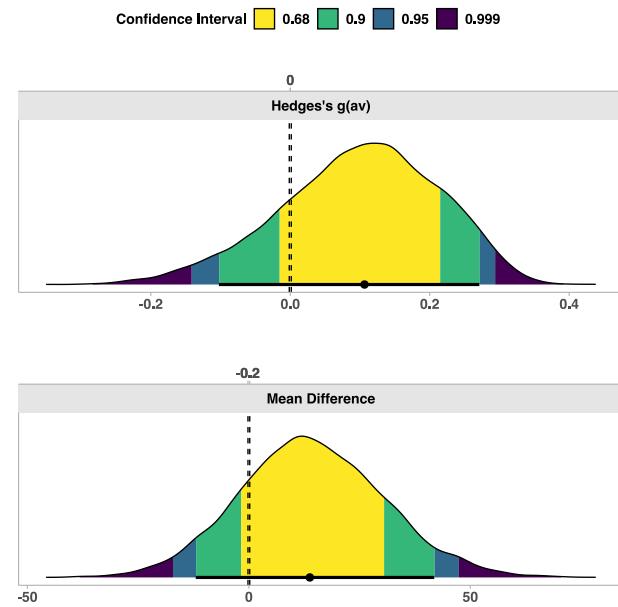
Confidence Interval 0.68 0.9 0.95 0.999



Procedural – Bin 11 Upper p value = 8.22E-01 Lower p value = 1.70E-01
Equivalency p value = 8.22E-01 Null p value = 3.48E-01

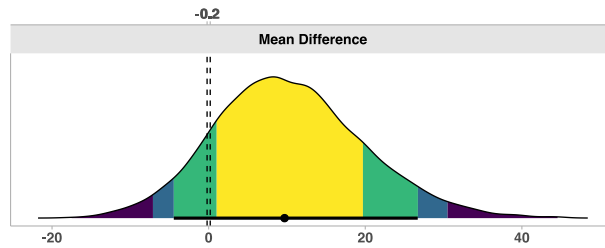
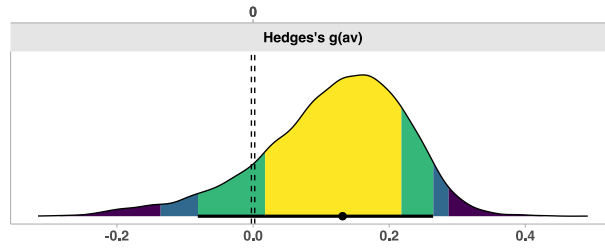


Procedural – Bin 12 Upper p value = 8.09E-01 Lower p value = 1.85E-01
Equivalency p value = 8.09E-01 Null p value = 3.76E-01



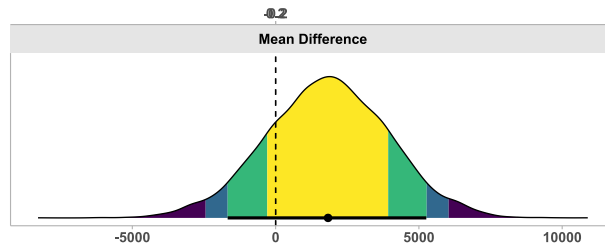
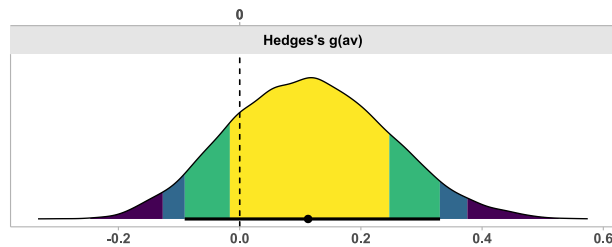
Procedural – Bin 13 Upper p value = 8.95E-01 Lower p value = 9.64E-02
 Equivalency p value = 8.95E-01 Null p value = 2.00E-01

Confidence Interval 0.68 0.9 0.95 0.999



Procedural – TOTAL Upper p value = 7.96E-01 Lower p value = 2.04E-01
 Equivalency p value = 7.95E-01 Null p value = 4.11E-01

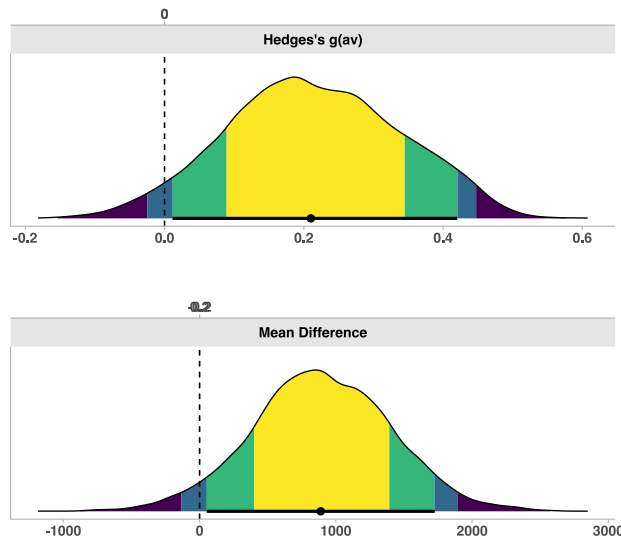
Confidence Interval 0.68 0.9 0.95 0.999



HVE Only X HVE, SE and BriteHive

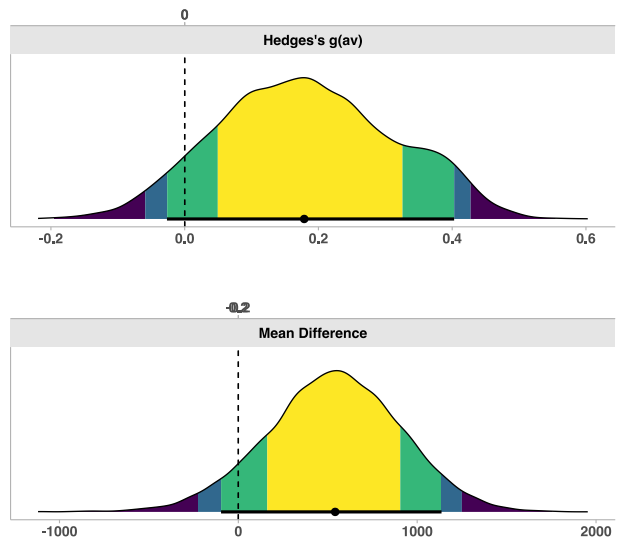
Procedural – Bin 1 Upper p value = 0.95429543 Lower p value = 0.04560456
Equivalency p value = 9.54E-01 Null p value = 9.12E-02

Confidence Interval 0.68 0.9 0.95 0.999

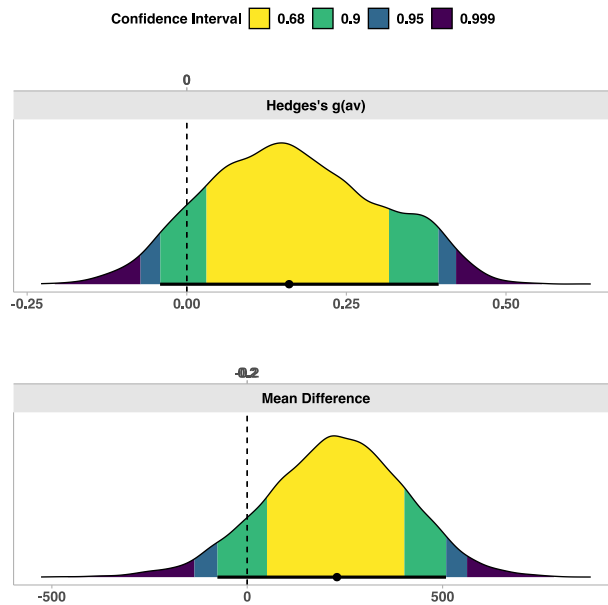


Procedural – Bin 2 Upper p value = 0.90839084 Lower p value = 0.09140914
Equivalency p value = 9.08E-01 Null p value = 1.83E-01

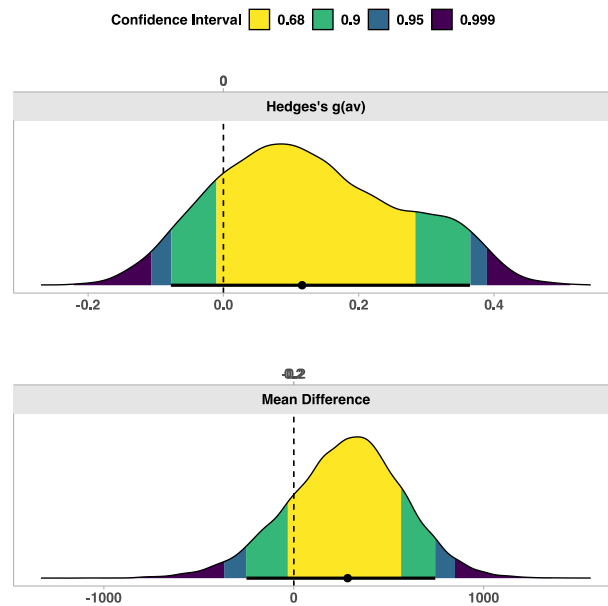
Confidence Interval 0.68 0.9 0.95 0.999



Procedural – Bin 3 Upper p value = 8.60E-01 Lower p value = 1.40E-01
Equivalency p value = 8.60E-01 Null p value = 2.79E-01

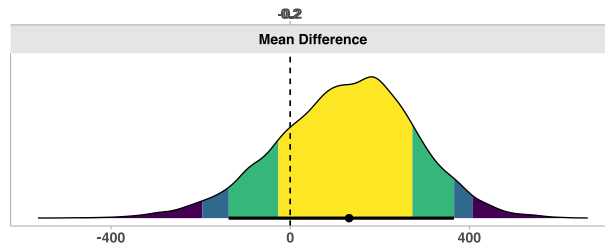
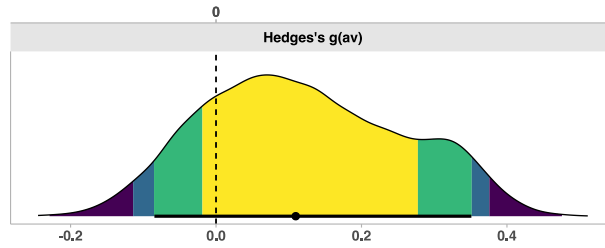


Procedural – Bin 4 Upper p value = 7.64E-01 Lower p value = 2.36E-01
Equivalency p value = 7.64E-01 Null p value = 4.72E-01



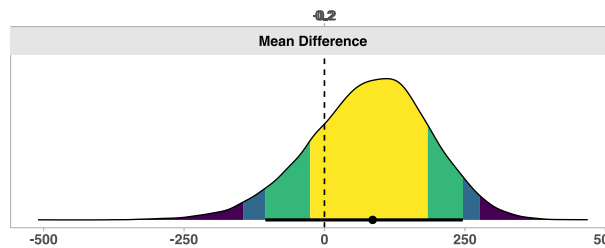
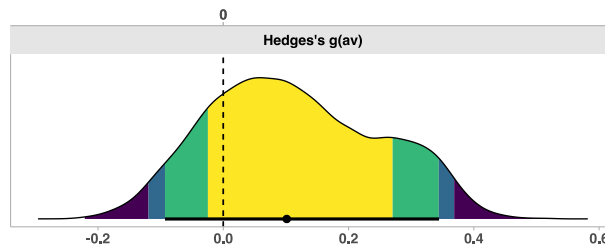
Procedural – Bin 5 Upper p value = 7.38E-01 Lower p value = 2.61E-01
Equivalency p value = 7.38E-01 Null p value = 5.23E-01

Confidence Interval 0,68 0,9 0,95 0,999



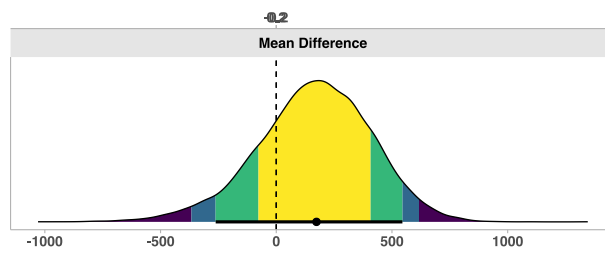
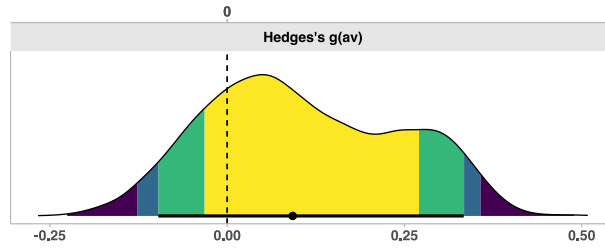
Procedural – Bin 6 Upper p value = 7.22E-01 Lower p value = 2.77E-01
Equivalency p value = 7.22E-01 Null p value = 5.54E-01

Confidence Interval 0,68 0,9 0,95 0,999



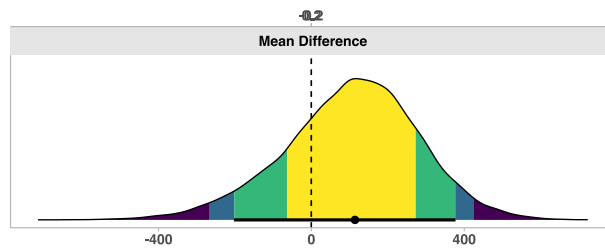
Procedural – Bin 7 Upper p value = 6.84E-01 Lower p value = 3.16E-01
Equivalency p value = 6.84E-01 Null p value = 6.33E-01

Confidence Interval 0,68 0,9 0,95 0,999



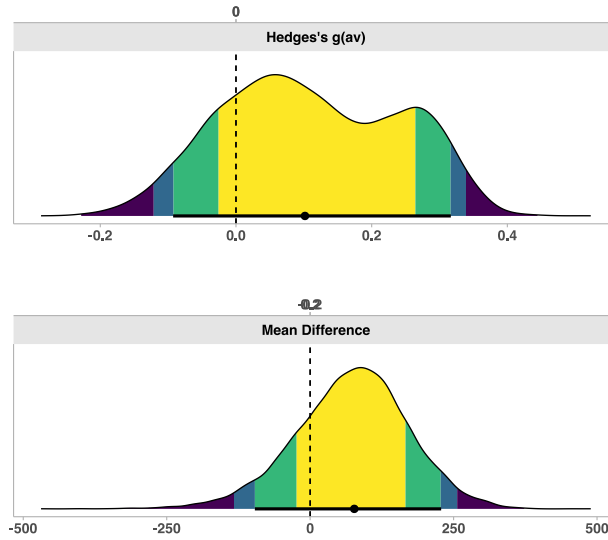
Procedural – Bin 8 Upper p value = 6.73E-01 Lower p value = 3.26E-01
Equivalency p value = 6.73E-01 Null p value = 6.53E-01

Confidence Interval 0,68 0,9 0,95 0,999



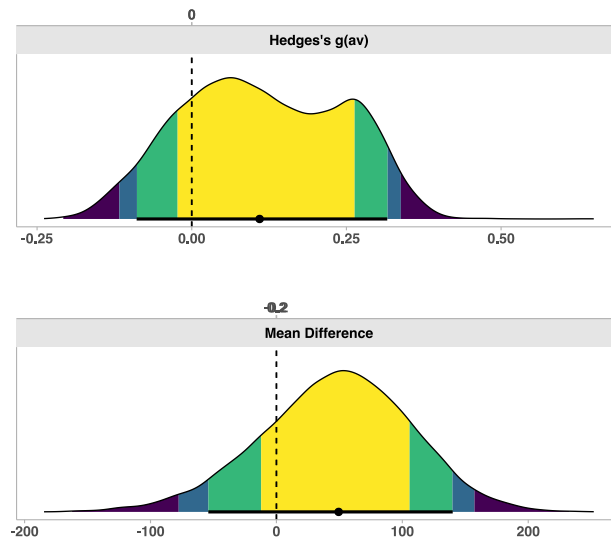
Procedural – Bin 9 Upper p value = 7.08E-01 Lower p value = 2.91E-01
Equivalency p value = 7.08E-01 Null p value = 5.83E-01

Confidence Interval 0,68 0,9 0,95 0,999



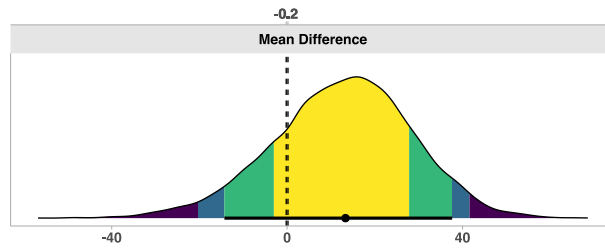
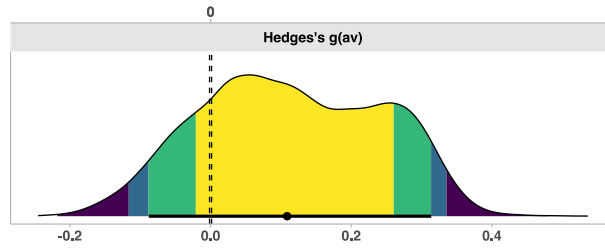
Procedural – Bin 10 Upper p value = 7.24E-01 Lower p value = 2.76E-01
Equivalency p value = 7.24E-01 Null p value = 5.52E-01

Confidence Interval 0,68 0,9 0,95 0,999



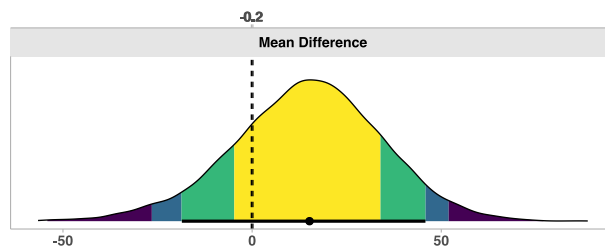
Procedural – Bin 11 Upper p value = 7.35E-01 Lower p value = 2.59E-01
Equivalency p value = 7.35E-01 Null p value = 5.24E-01

Confidence Interval 0.68 0.9 0.95 0.999



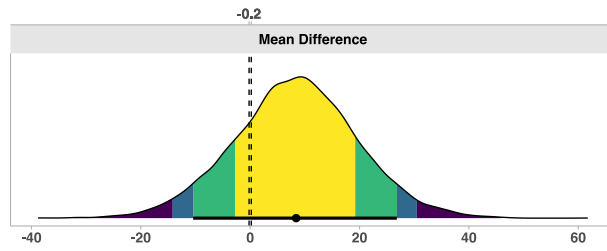
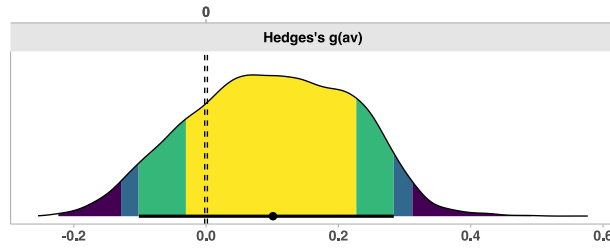
Procedural – Bin 12 Upper p value = 7.25E-01 Lower p value = 2.68E-01
Equivalency p value = 7.25E-01 Null p value = 5.43E-01

Confidence Interval 0.68 0.9 0.95 0.999



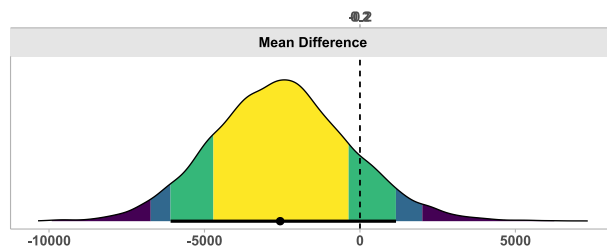
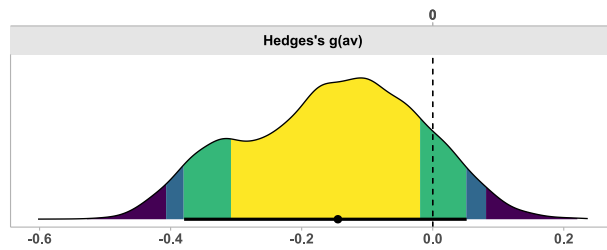
Procedural – Bin 13 Upper p value = 7.47E-01 Lower p value = 2.41E-01
 Equivalency p value = 7.47E-01 Null p value = 4.94E-01

Confidence Interval 0.68 0.9 0.95 0.999



Procedural – TOTAL Upper p value = 1.63E-01 Lower p value = 8.37E-01
 Equivalency p value = 8.37E-01 Null p value = 3.26E-01

Confidence Interval 0.68 0.9 0.95 0.999



Section 4, Geometric Means, OPS

The highest four values across all Bins are highlighted, for each patient individually.

Pre-Background – HVE only

Method	HVE				
Patient	1	2	3	4	5
Bin 1	2208.735	492.6363	3204.089	988.4386	477.2703
Bin 2	427.8783	132.6486	460.8869	194.8661	115.405
Bin 3	62.50703	40.22281	71.82651	48.86625	26.17675
Bin 4	35.69173	35.58181	47.74031	34.21908	18.51169
Bin 5	7.61877	12.3739	10.59804	10.72593	5.632135
Bin 6	5.224781	8.403206	5.274086	7.007877	4.949317
Bin 7	10.66632	13.89447	7.5868	14.65747	7.607824
Bin 8	7.38129	7.912162	1.595128	9.277437	4.746343
Bin 9	4.905181	3.717956	0.763239	4.38606	4.130442
Bin 10	1.368511	2.234445	0.552639	2.418645	3.156471
Bin 11	0.269217	0.520292	0.185257	1.145576	0.251321
Bin 12	0.929232	0.545641	0.221375	1.005144	0.473658
Bin 13	2.911306	1.25925	0.892102	2.662023	3.501892
TOTAL	2782.668	761.2818	3819.216	1328.564	682.639

Pre-Background – HVE+SE

Method	HVE+SE			
Patient	1	2	3	4
Bin 1	7540.109	2876.73	NA	257.8348
Bin 2	1082.012	563.5288	NA	69.26091
Bin 3	137.0835	136.1199	NA	19.64367
Bin 4	71.02218	78.93894	NA	13.71966
Bin 5	15.68108	22.0084	NA	4.096381
Bin 6	9.53595	13.72815	NA	4.430169
Bin 7	15.44561	22.78981	NA	9.181408
Bin 8	10.0621	10.12757	NA	9.25213
Bin 9	4.836431	5.223423	NA	4.762203
Bin 10	1.98367	3.361687	NA	5.726924
Bin 11	0.508285	0.280357	NA	1.817121
Bin 12	0.96053	0.738115	NA	2.139826
Bin 13	2.7639	2.653105	NA	4.807649
TOTAL	8899.673	3779.518	NA	410.6188

Pre-Background – HVE+SE+BriteHive

Method	BriteHive				
Patient	1	2	3	4	5
Bin 1	1221.658	3342.085	1056.46	2775.209	1358.302
Bin 2	265.6349	679.7075	188.3949	477.783	264.0382
Bin 3	60.48782	76.90357	39.39855	54.17935	59.15577
Bin 4	42.32064	32.28941	24.58572	23.3443	42.10832
Bin 5	12.31668	8.338061	6.165713	4.292381	14.94273
Bin 6	6.186495	2.464474	4.091653	1.917992	11.5038
Bin 7	16.4608	10.21356	8.77181	7.500662	21.12495
Bin 8	10.72327	4.542988	3.869234	4.92748	17.36775
Bin 9	6.015511	4.236058	1.233442	2.806302	7.975998
Bin 10	3.202086	1.173648	1.135555	1.122111	7.856552
Bin 11	0.451773	0.527556	0.309766	0.227465	1.435723
Bin 12	1.286665	1.29684	0.505032	0.4257	2.346901
Bin 13	3.330838	1.819272	0.648293	1.499846	3.759423
TOTAL	1656.644	4171.518	1353.485	3364.334	1819.777

Procedural – HVE only

Method	HVE				
Patient	1	2	3	4	5
Bin 1	3787.664	1426.794	4121.554	1384.834	2205.841
Bin 2	1193.203	583.5288	920.9565	407.1335	1017.781
Bin 3	327.0089	202.9685	229.7094	128.2727	372.3896
Bin 4	290.4316	178.9299	213.4516	118.1776	428.6731
Bin 5	113.2111	57.73942	83.26191	42.85088	191.6671
Bin 6	71.09355	34.99156	51.72509	28.2366	117.5011
Bin 7	159.6093	60.38686	99.50356	56.62621	249.3816
Bin 8	101.6033	32.51256	65.11569	34.20451	161.2235
Bin 9	56.9898	16.55618	41.15642	18.9588	92.0852
Bin 10	39.06139	7.142602	24.25877	11.37339	64.31251
Bin 11	8.397902	1.631116	6.013119	2.245372	15.18016
Bin 12	9.610969	1.677656	10.99052	3.142978	13.26021
Bin 13	10.39648	2.269241	9.206906	3.238628	7.33631
TOTAL	6764.092	2669.999	6138.224	2326.571	5248.32

Procedural – HVE+SE

Method	HVE+SE			
	1	2	3	4
Patient				
Bin 1	7216.362	5601.211	1926.481	906.1574
Bin 2	1174.632	1810.071	411.2658	387.3602
Bin 3	188.902	581.2464	104.6036	138.8205
Bin 4	134.7116	539.1589	69.086	154.2852
Bin 5	38.56074	186.7368	18.91754	47.19977
Bin 6	24.82575	113.9931	11.1912	44.51858
Bin 7	47.19745	228.9176	25.97618	93.60296
Bin 8	27.46861	126.7037	11.37428	59.07375
Bin 9	16.54561	63.5246	5.681602	34.81096
Bin 10	10.7516	40.76668	4.596094	15.53717
Bin 11	2.100085	8.742177	0.704677	4.106787
Bin 12	3.904851	11.62544	1.457186	4.806413
Bin 13	2.92265	10.25634	1.687781	5.291384
TOTAL	8952.148	10366.15	2726.062	1990.523

Procedural – HVE+SE+BriteHive

Method	BriteHive				
	1	2	3	4	5
Patient					
Bin 1	2207.122	4667.643	1210.395	3255.014	1692.179
Bin 2	820.7051	1385.587	272.2342	719.0864	463.1596
Bin 3	280.1027	350.7074	69.15115	134.1821	145.9345
Bin 4	314.1688	369.5719	49.87047	103.668	148.8521
Bin 5	124.384	150.2565	18.55481	31.0364	61.46659
Bin 6	90.88127	101.6013	10.9814	20.21018	36.92563
Bin 7	174.1612	209.3008	21.70253	42.43814	70.53301
Bin 8	99.83026	141.9882	11.99493	29.6546	38.95038
Bin 9	62.8034	72.72325	7.805256	17.48681	22.03652
Bin 10	35.24914	41.01663	5.019555	10.36017	12.39249
Bin 11	9.620164	8.549639	1.301144	1.6265	3.093577
Bin 12	11.63562	13.16138	1.933437	3.340247	3.981635
Bin 13	9.56114	10.23168	2.264356	3.156049	4.758272
TOTAL	4435.124	8356.601	1721.099	4405.272	2749.979

Post - Procedural – HVE only

Method	HVE				
Patient	1	2	3	4	5
Bin 1	2433.416	538.3876	3083.166	972.5901	520.3435
Bin 2	531.8839	163.2473	476.7696	221.1121	147.9261
Bin 3	99.42991	55.85492	97.0534	50.20383	44.17626
Bin 4	58.91682	42.24805	79.62528	32.92151	31.60679
Bin 5	17.52871	13.23658	20.59028	10.35546	10.63728
Bin 6	10.40987	8.331971	12.35609	5.641956	6.34659
Bin 7	22.37255	16.72545	15.43863	11.30239	14.28978
Bin 8	17.04258	10.53238	5.722973	6.485978	9.073966
Bin 9	9.345542	7.626462	2.408792	4.299711	5.577371
Bin 10	7.227577	4.128018	0.733947	3.039861	4.33688
Bin 11	1.073065	0.990302	0.399989	0.86198	1.286042
Bin 12	2.43364	1.660278	0.590683	1.189123	2.449945
Bin 13	4.898749	3.91373	0.847202	3.118389	2.735051
TOTAL	3225.511	876.8317	3812.057	1337.466	819.6812

Post - Procedural – HVE+SE

Method	HVE+SE			
Patient	1	2	3	4
Bin 1	6854.202	4056.617	1771.507	363.4111
Bin 2	1014.688	1149.292	287.5179	125.8912
Bin 3	159.3457	345.8186	51.99181	39.96181
Bin 4	94.3596	271.0071	27.53649	42.69454
Bin 5	19.04822	78.45638	4.980293	15.22921
Bin 6	13.25227	48.89991	2.723168	11.83595
Bin 7	18.39125	78.13779	5.046919	24.70092
Bin 8	8.172216	31.36202	2.581361	19.81831
Bin 9	5.926557	13.15603	1.428811	12.35584
Bin 10	2.717792	6.75336	0.829384	8.427394
Bin 11	0.945907	1.742366	0.287799	2.062253
Bin 12	1.267488	2.212576	0.473109	4.125211
Bin 13	2.808614	1.962146	0.744341	5.114837
TOTAL	8217.809	6099.886	2177.093	702.4377

Post - Procedural – HVE+SE+BriteHive

Method Patient	BriteHive				
	1	2	3	4	5
Bin 1	1203.194	2839.993	1347.08	3112.946	1298.831
Bin 2	279.2396	585.3805	280.4103	571.1585	254.7068
Bin 3	77.60901	74.47854	70.55958	73.43245	55.45851
Bin 4	53.96235	39.58	61.34602	28.41229	43.12252
Bin 5	16.15228	9.723656	20.7481	7.190605	12.5623
Bin 6	10.42951	5.191342	15.52183	3.74209	7.791978
Bin 7	20.93518	10.05478	28.15535	6.43032	17.06739
Bin 8	12.60427	7.043937	16.90336	4.134809	12.30025
Bin 9	8.305026	4.699724	9.007775	2.089185	6.138054
Bin 10	5.811181	3.303445	5.13801	0.746432	5.236477
Bin 11	1.592958	0.520048	1.066922	0.353494	0.950952
Bin 12	2.474295	1.129872	2.243432	0.412829	1.608823
Bin 13	3.533481	1.693807	2.59645	0.949711	4.735614
TOTAL	1711.249	3593.119	1916.733	3820.304	1730.508

Section 5, Standard Deviations, OPS

The highest four values across all Bins are highlighted, for each patient individually.

Pre-Background – HVE only

Method	HVE				
Patient	1	2	3	4	5
Bin 1	61.4804	44.12841	112.3158	45.2458	19.44222
Bin 2	26.42745	27.99065	24.01998	16.34571	16.26251
Bin 3	11.79025	11.77964	7.351584	8.676917	5.492981
Bin 4	4.494441	13.07568	7.035365	8.125679	5.006169
Bin 5	2.48998	6.25291	4.926515	3.666061	3.399346
Bin 6	2.2	4.528429	2.720791	1.878534	2.832789
Bin 7	4.20119	5.241395	2.753108	4.977282	4.807402
Bin 8	3.065942	3.063041	1.997366	3.323987	3.29099
Bin 9	1.9	2.463396	1.357517	2.792052	3.247031
Bin 10	1.455885	1.978877	1.018395	1.964417	2.108185
Bin 11	0.626418	1.009268	0.478943	1.17428	0.787087
Bin 12	1.179661	0.706321	0.913137	1.325577	1.01227
Bin 13	1.32665	1.471447	1.567304	1.694094	3.231787
TOTAL	82.77977	103.366	123.3586	51.06319	49.19149

Pre-Background – HVE+SE

Method	HVE+SE			
Patient	1	2	3	4
Bin 1	213.9745	442.0247	NA	13.06926
Bin 2	56.08591	222.5741	NA	5.965177
Bin 3	11.83075	86.27305	NA	2.793842
Bin 4	10.1008	55.01318	NA	2.828427
Bin 5	4.336335	12.65109	NA	1.490712
Bin 6	4.320402	8.178631	NA	2.645751
Bin 7	5.040384	12.45953	NA	2.867442
Bin 8	4.207179	5.075431	NA	3.435921
Bin 9	3.154371	2.91376	NA	2.114763
Bin 10	1.809731	2.785678	NA	1.067187
Bin 11	0.999346	0.877724	NA	0.816497
Bin 12	1.164976	1.248239	NA	0.942809
Bin 13	1.824682	1.577973	NA	2.054805
TOTAL	275.3877	832.393	NA	17.59735

Pre-Background – HVE+SE+BriteHive

Method	BriteHive				
Patient	1	2	3	4	5
Bin 1	38.65486	130.7774	88.25531	69.87017	102.3593
Bin 2	13.84328	42.97674	36.40747	27.00964	40.32491
Bin 3	7.920055	7.327175	23.97742	7.676302	13.54006
Bin 4	5.785419	3.807887	21.67241	6.268993	4.346135
Bin 5	4.885465	3.24037	6.315111	2.964036	2.819684
Bin 6	3.638636	2.648319	5.556746	2.60842	2
Bin 7	3.511492	2.345208	9.293303	3.18254	4.961581
Bin 8	2.335497	1.391941	3.38393	2.645578	4.121608
Bin 9	2.837179	1.653595	2.433845	1.950141	5.050364
Bin 10	1.94554	0.972031	1.847645	1.500174	2.624669
Bin 11	1.16881	0.962987	0.812381	0.657527	2.026187
Bin 12	1.390939	0.484123	0.898177	0.883841	1.396645
Bin 13	2.004128	2.009625	1.136384	1.500523	1.247219
TOTAL	48.87883	171.9099	189.1167	91.11499	148.4758

Procedural – HVE only

Method	HVE				
Patient	1	2	3	4	5
Bin 1	8640.14	1761.489	1306.756	785.8861	7826.48
Bin 2	6747.206	1283.009	654.6071	478.8938	4797.553
Bin 3	3302.063	569.309	249.2929	215.6901	1978.123
Bin 4	5462.628	720.7906	297.6837	280.6952	3003.541
Bin 5	2733.444	318.5061	136.6378	127.5206	1479.163
Bin 6	1919.21	202.6872	91.33133	92.0489	988.5608
Bin 7	4388.266	356.3819	200.065	184.2329	2147.078
Bin 8	3177.289	179.6724	132.4988	119.1548	1501.265
Bin 9	1847.786	74.9947	72.13266	68.82813	970.264
Bin 10	1121.034	30.75826	41.53713	40.87565	650.268
Bin 11	306.545	5.921641	11.50888	13.01821	165.8104
Bin 12	392.0161	7.208594	14.19406	13.18744	181.7689
Bin 13	266.8715	4.106006	12.92803	6.91723	59.11554
TOTAL	40234.97	5483.639	3011.774	2400.874	25638.48

Procedural – HVE+SE

Method Patient	HVE+SE			
	1	2	3	4
Bin 1	317.881	8547.405	3611.373	693.1261
Bin 2	170.6253	5909.982	2219.425	366.7573
Bin 3	84.13202	2683.454	1096.097	148.1788
Bin 4	78.94466	4324.645	865.893	171.472
Bin 5	29.27712	2124.665	277.7664	73.34132
Bin 6	19.26849	1436.785	185.0165	52.84947
Bin 7	40.33357	3196.133	354.0566	91.86692
Bin 8	23.07589	2206.585	229.6108	68.22461
Bin 9	13.11922	1229.391	125.9786	34.62488
Bin 10	7.937103	733.9937	63.32331	19.48837
Bin 11	2.040429	196.9997	14.58523	4.609955
Bin 12	2.75276	231.016	15.74375	5.289979
Bin 13	2.753427	105.9143	9.781063	4.030496
TOTAL	729.2422	31585.29	8616.711	1696.276

Procedural – HVE+SE+BriteHive

Method Patient	BriteHive				
	1	2	3	4	5
Bin 1	5803.49	11042.09	185.124	190.9295	294.1084
Bin 2	4476.969	8966.679	100.3524	97.13038	181.5907
Bin 3	2071.259	4591.954	42.06422	44.92189	78.37914
Bin 4	3271.568	8692.202	42.33145	45.50133	98.78589
Bin 5	1542.311	4353.882	19.72846	18.08929	44.97562
Bin 6	1068.859	3062.073	13.90117	12.13852	27.63745
Bin 7	2130.75	7343.014	24.56567	21.87343	57.5094
Bin 8	1362.662	5346.347	16.83414	19.05783	36.97304
Bin 9	673.8847	2935.599	10.09921	13.87904	21.2855
Bin 10	377.1228	1744.649	7.832363	10.80681	13.09123
Bin 11	104.4664	458.8945	2.341718	2.774223	3.190651
Bin 12	109.0396	559.4116	3.292638	4.208858	4.272772
Bin 13	75.75922	293.3452	3.779209	3.318549	2.845374
TOTAL	23057.06	59382.73	422.9486	435.5832	847.18

Post-Procedural – HVE only

Method	HVE				
Patient	1	2	3	4	5
Bin 1	84.13708	33.57646	95.21466	58.62726	53.52371
Bin 2	34.62947	20.50648	48.51466	19.05769	41.8292
Bin 3	14.26262	10.60299	23.8126	8.912476	21.66041
Bin 4	11.99704	10.92581	24.81899	7.899719	16.40214
Bin 5	4.373659	5.050963	9.818859	3.701201	7.156649
Bin 6	4.177187	4.461689	6.481169	3.896009	4.986347
Bin 7	5.304086	6.266755	10.44584	5.47205	9.608976
Bin 8	5.463414	2.89079	4.194706	4.273432	6.794234
Bin 9	4.467164	3.77477	2.366516	3.55649	4.692307
Bin 10	2.699794	2.872918	1.61314	4.124977	5.47623
Bin 11	2.305202	1.335336	1.171063	1.468544	2.61275
Bin 12	1.756689	1.706341	1.350592	2.808165	3.078379
Bin 13	1.939072	2.232089	1.377421	3.734031	3.556226
TOTAL	104.0309	68.96411	187.8211	59.16794	158.4573

Post-Procedural – HVE+SE

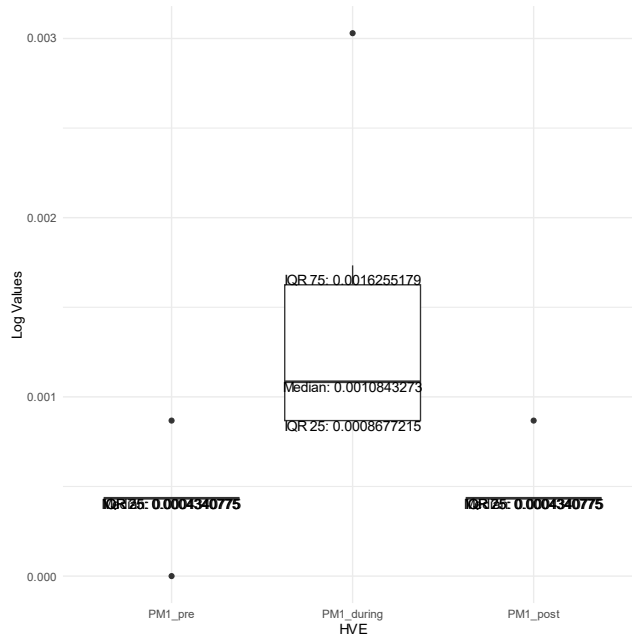
Method	HVE+SE			
Patient	1	2	3	4
Bin 1	121.9122	431.5762	200.002	192.9394
Bin 2	59.76906	207.7195	108.7131	110.0195
Bin 3	36.40313	79.78833	46.72118	45.00794
Bin 4	33.85543	59.4204	31.35787	53.9175
Bin 5	13.56633	18.48033	7.43809	29.45074
Bin 6	9.391703	13.35226	6.692385	21.36326
Bin 7	10.71397	18.731	7.877113	40.2726
Bin 8	5.010646	7.108499	2.430238	29.79774
Bin 9	2.751211	4.864745	2.216859	18.86394
Bin 10	2.706338	2.752743	2.209362	11.30408
Bin 11	1.945283	1.366872	1.113954	4.201603
Bin 12	2.125048	1.796844	1.319776	5.527952
Bin 13	4.910076	2.00763	2.413245	6.092722
TOTAL	232.9995	802.0647	397.3742	553.7114

Post-Procedural – HVE+SE+BriteHive

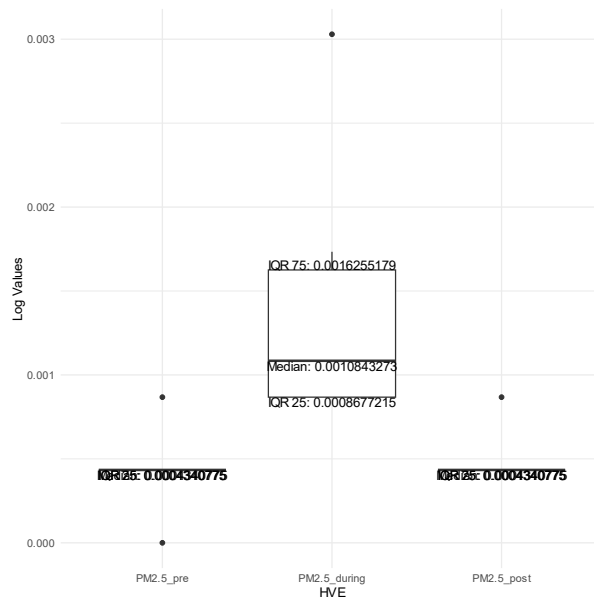
Method	BriteHive				
Patient	1	2	3	4	5
Bin 1	60.9601	97.58536	514.7963	88.67584	55.75033
Bin 2	39.502	27.76856	285.3825	20.26143	26.82223
Bin 3	14.17471	13.7419	112.9308	9.925046	11.6857
Bin 4	17.88909	8.972125	135.5604	7.906409	11.57896
Bin 5	6.543419	5.450684	59.46952	3.166411	5.34374
Bin 6	6.658798	2.400968	41.85913	3.321655	4.071036
Bin 7	8.931759	6.061453	79.5334	3.231092	7.116569
Bin 8	5.525747	5.41906	57.26743	2.496133	4.668571
Bin 9	4.964856	3.178142	34.57192	1.907785	2.830919
Bin 10	4.177172	1.771905	21.44525	0.979262	2.315167
Bin 11	1.552047	1.078043	5.27147	0.620402	1.258765
Bin 12	2.409617	2.35405	6.512583	0.846255	2.048851
Bin 13	4.250526	2.353422	3.6141	1.235782	2.440401
TOTAL	137.9911	147.6135	1348.706	100.5185	106.2233

Section 6, Friedman Test, Dust-Trak
Overlapping numbers in the boxplot are equal.

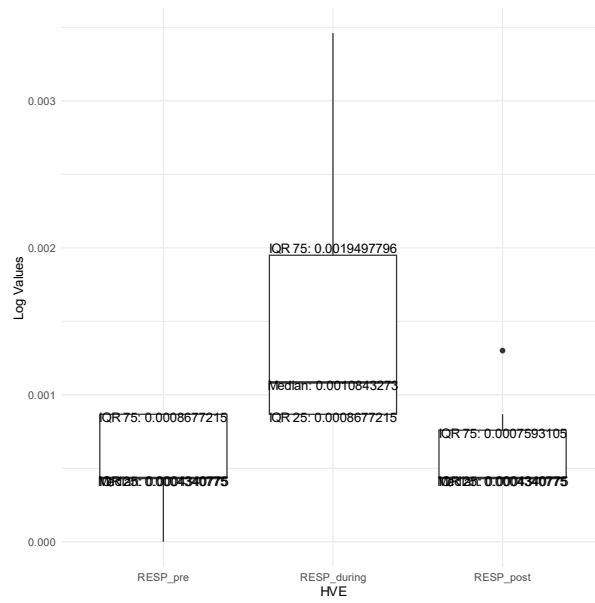
HVE only – PM1 p= 0.008652



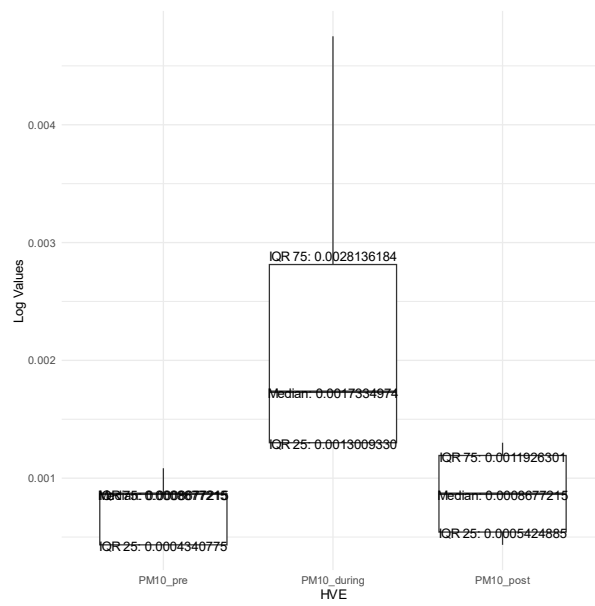
HVE only – PM2.5 p= 0.008652



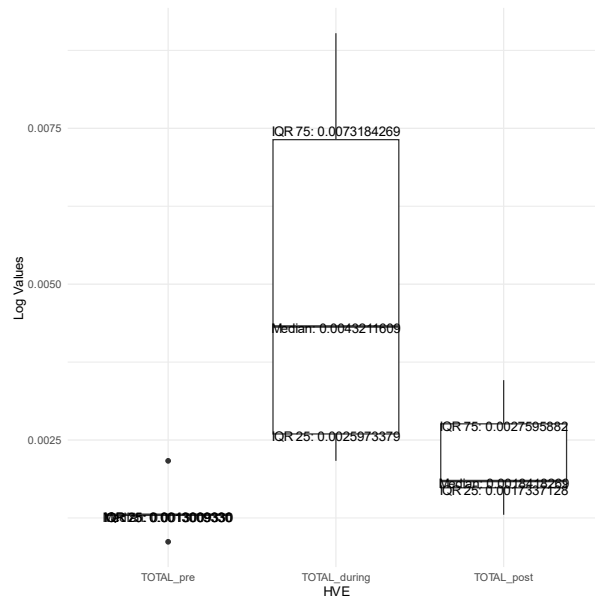
HVE only – RESP p= 0.02765



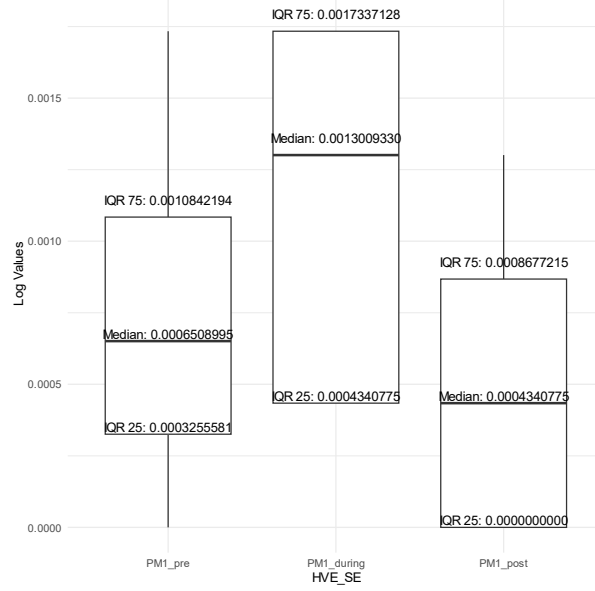
HVE only – PM10 p= 0.01467



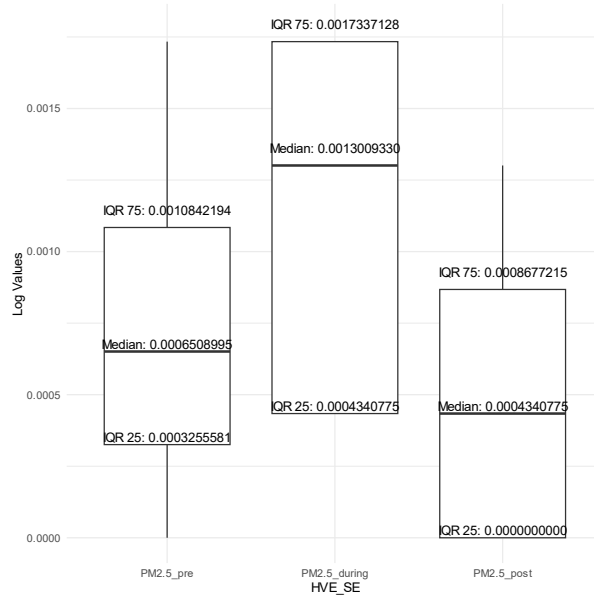
HVE only – TOTAL p= 0.0302



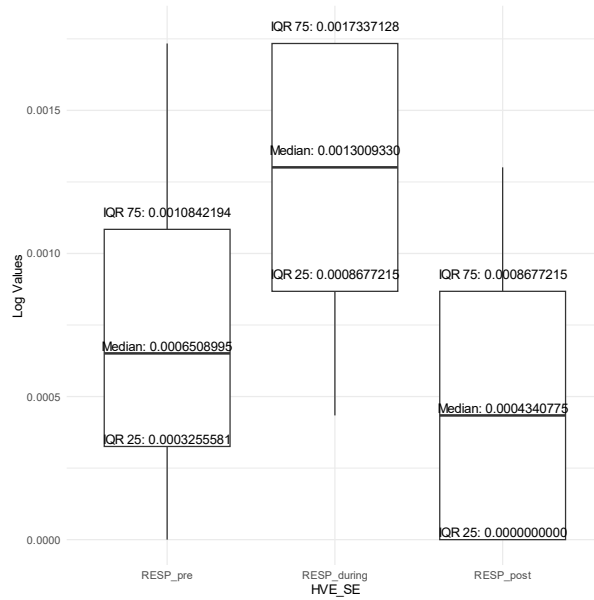
HVE and Saliva Ejector – PM1 p= 0.116



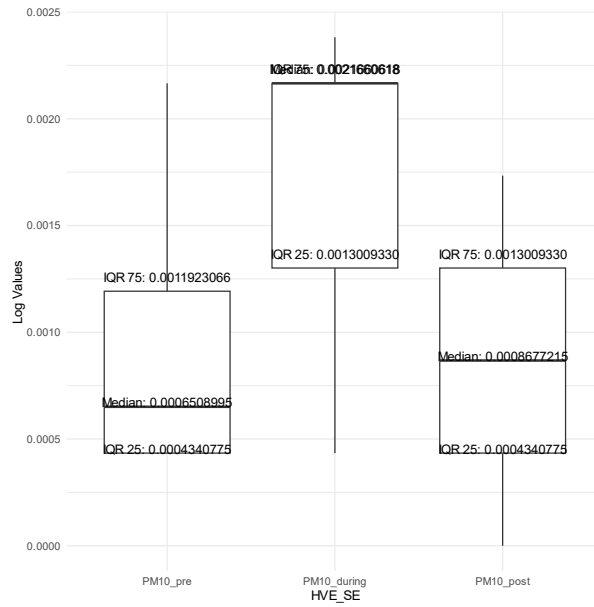
HVE and Saliva Ejector – PM2.5 p= 0.116



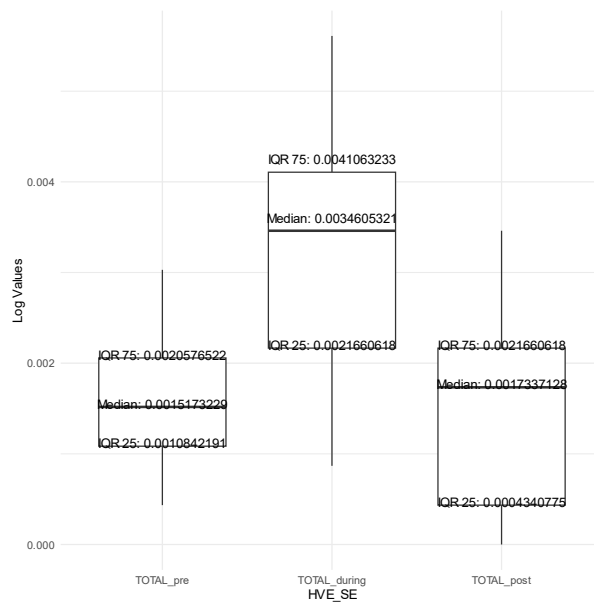
HVE and Saliva Ejector – RESP p= 0.06169



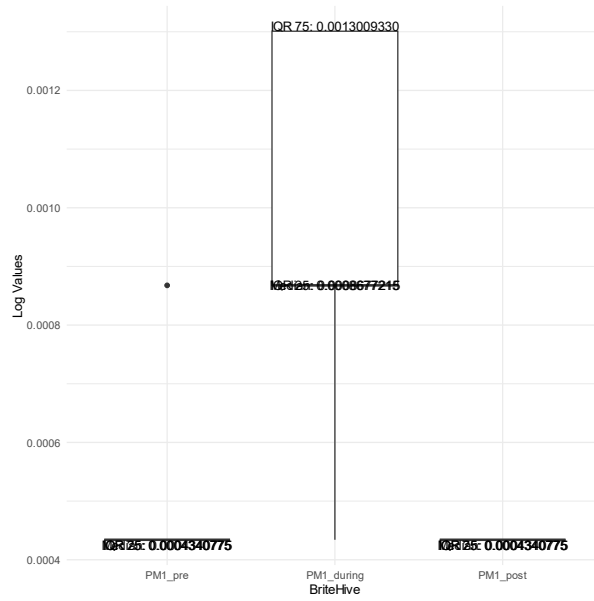
HVE and Saliva Ejector – PM10 p= 0.07116



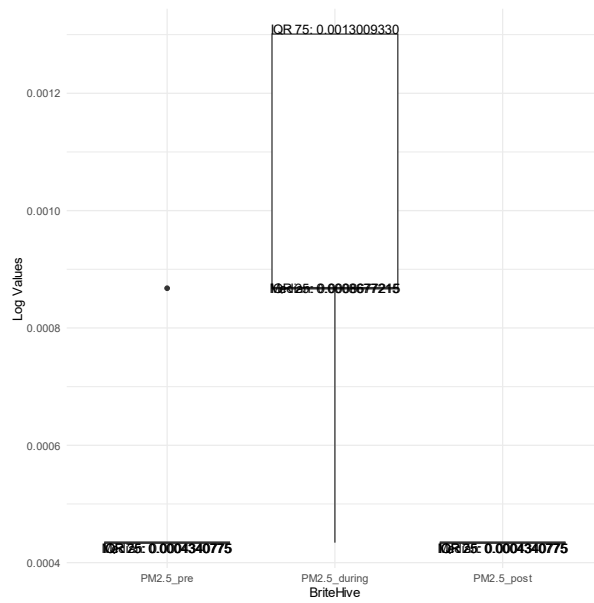
HVE and Saliva Ejector – TOTAL p= 0.0366



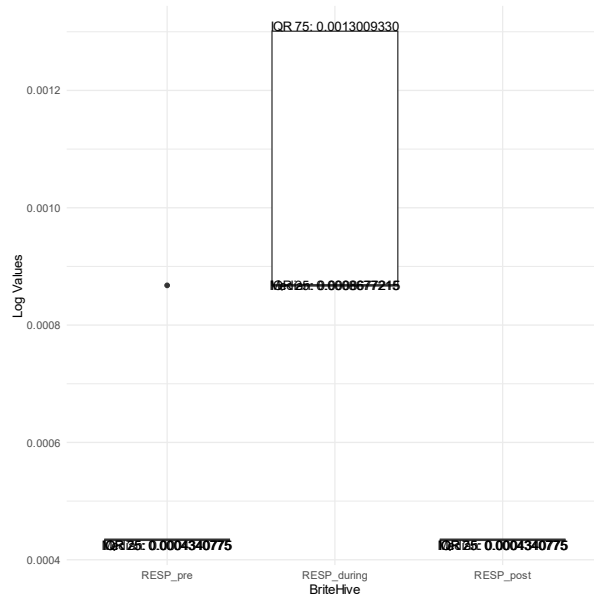
HVE, SE and BriteHive – PM1 p= 0.02307



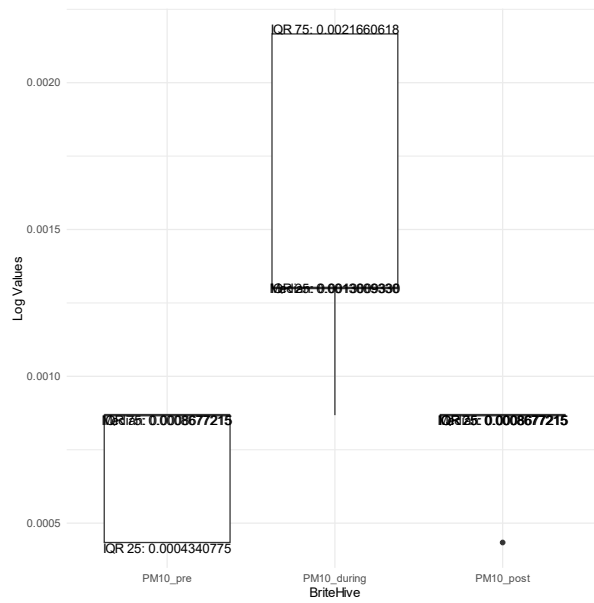
HVE, SE and BriteHive – PM2.5 p= 0.02307



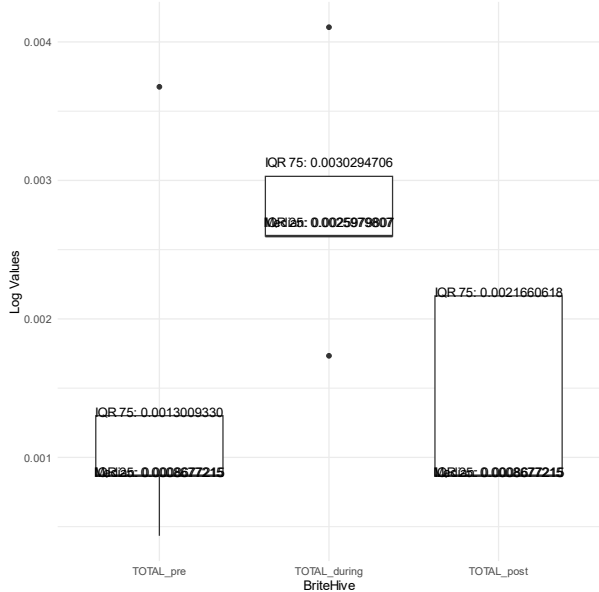
HVE, SE and BriteHive – RESP p= 0.008652



HVE, SE and BriteHive – PM10 p= 0.02458



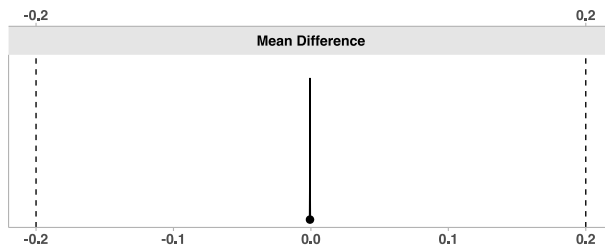
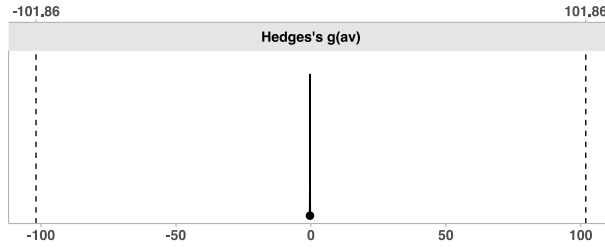
HVE, SE and BriteHive – TOTAL p= 0.07585



**Section 7, TOST Equivalency, Dust-Trak
HVE Only X HVE and Saliva Ejector**

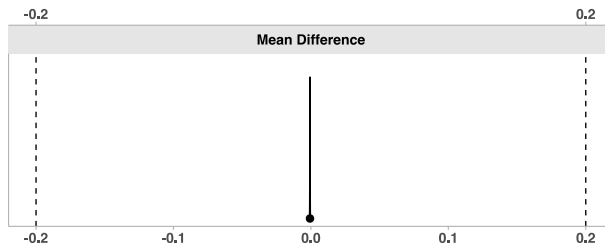
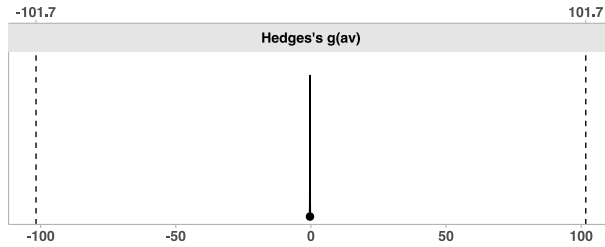
Pre-Procedural – PM1 Upper p value = <0.01 Lower p value = <0.01
Equivalency p value = <0.01 Null p value = <0.01

Confidence Interval 0.68 0.9 0.95 0.999

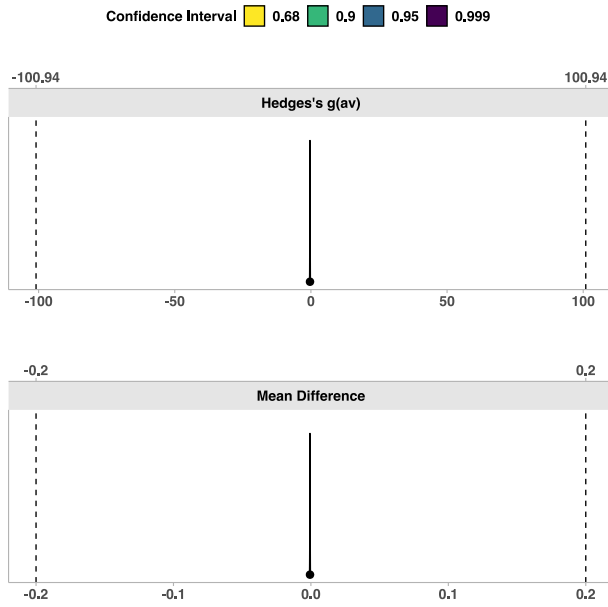


Pre-Procedural – PM2.5 Upper p value = <0.01 Lower p value = <0.01
Equivalency p value = <0.01 Null p value = <0.01

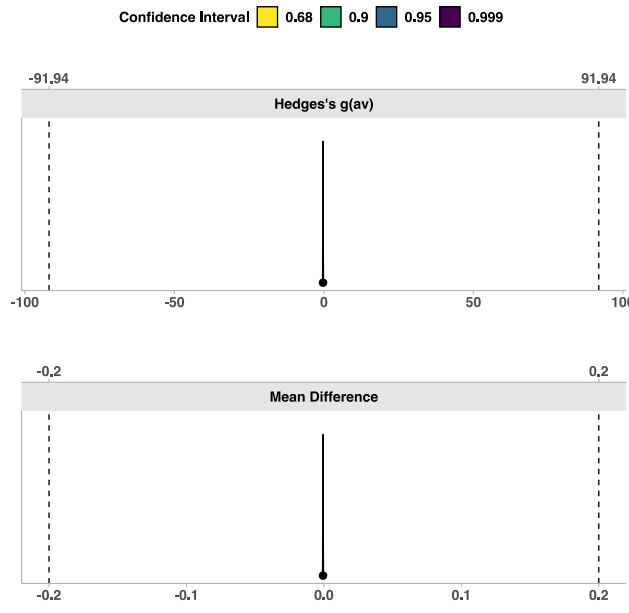
Confidence Interval 0.68 0.9 0.95 0.999



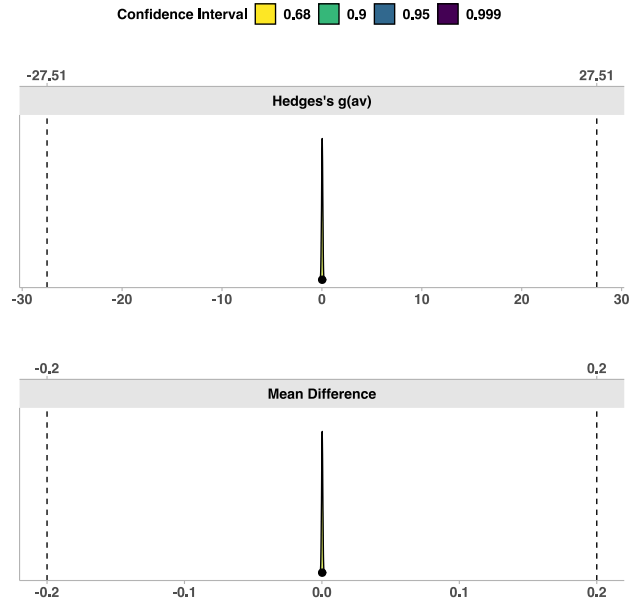
Pre-Procedural – RESP Upper p value = <0.01 Lower p value = <0.01
Equivalency p value = <0.01 Null p value = <0.01



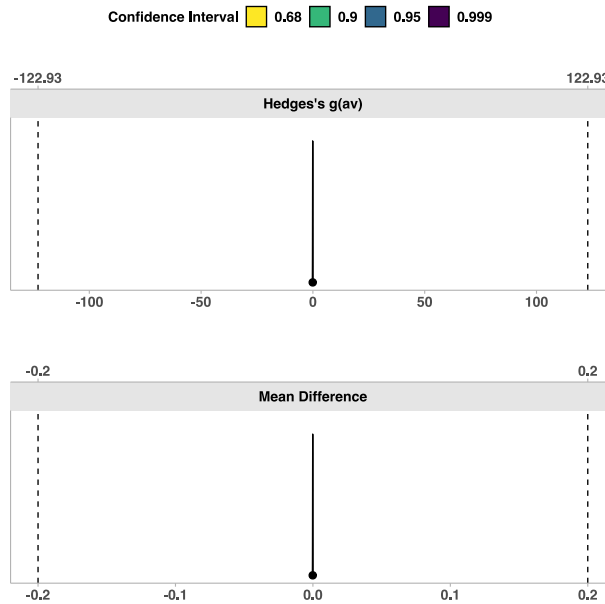
Pre-Procedural – PM10 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = <0.01



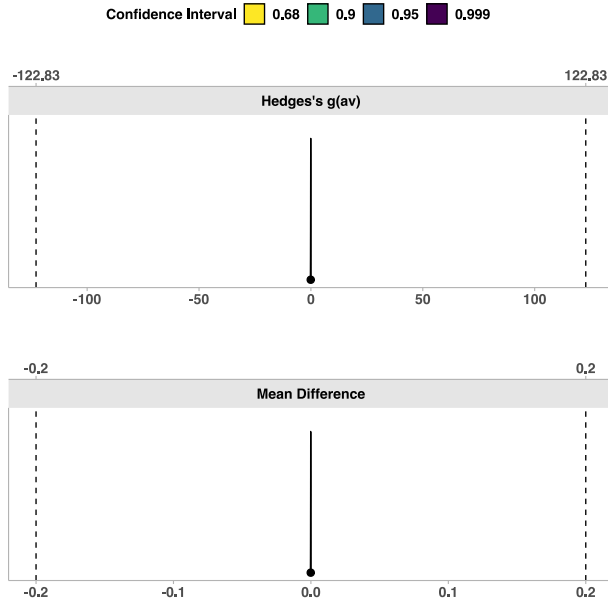
Pre-Procedural – TOTAL Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 6.49E-01



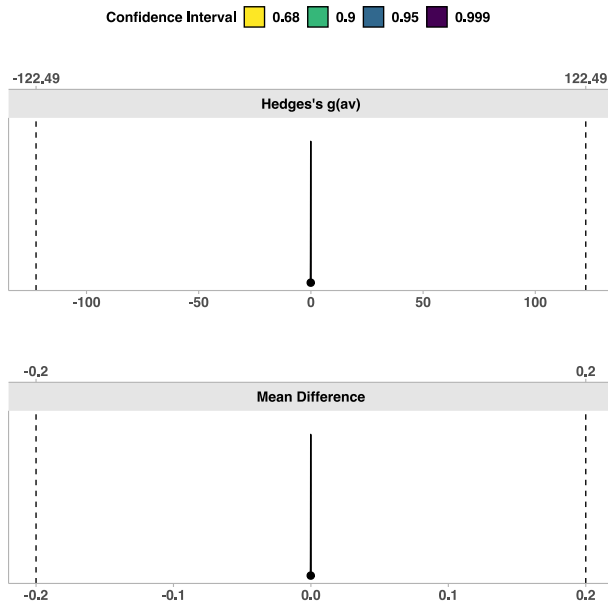
HVE Only X HVE, SE and BriteHive
 Pre-Procedural – PM1 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 1.75E-01



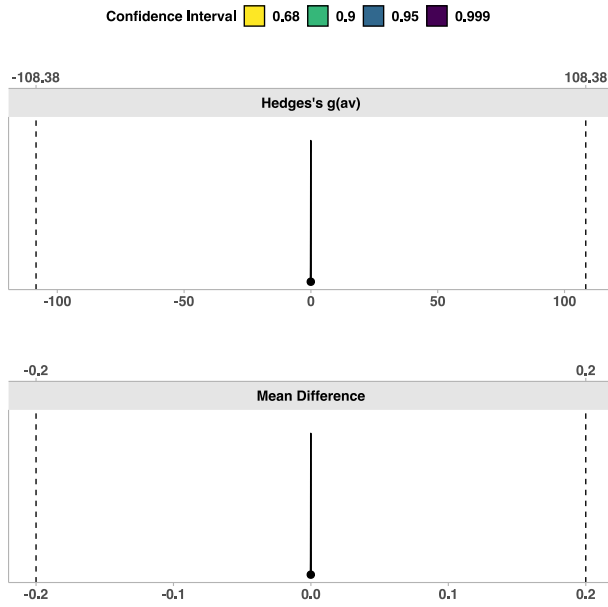
Pre-Procedural – PM2.5 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 1.86E-01



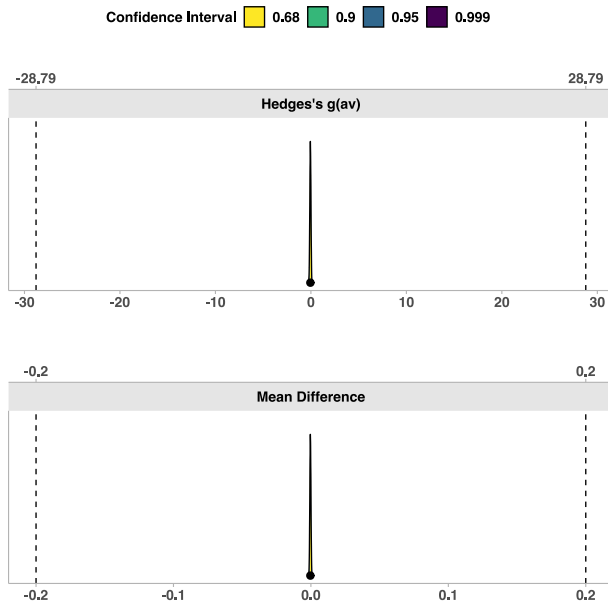
Pre-Procedural – RESP Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 1.98E-01



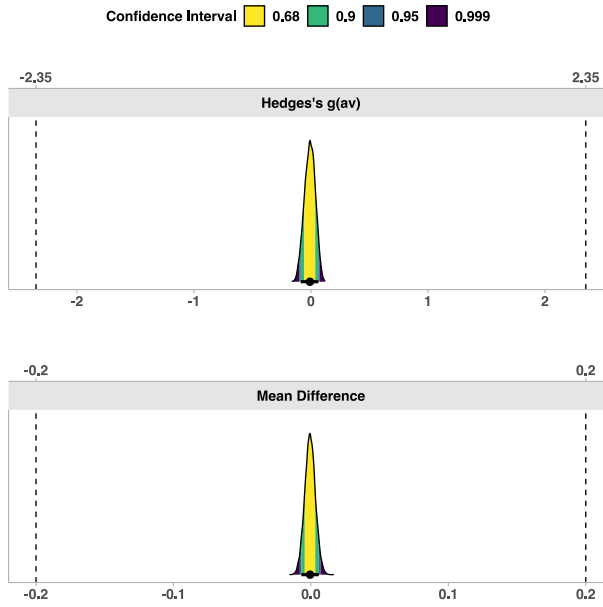
Pre-Procedural – PM10 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 4.25E-01



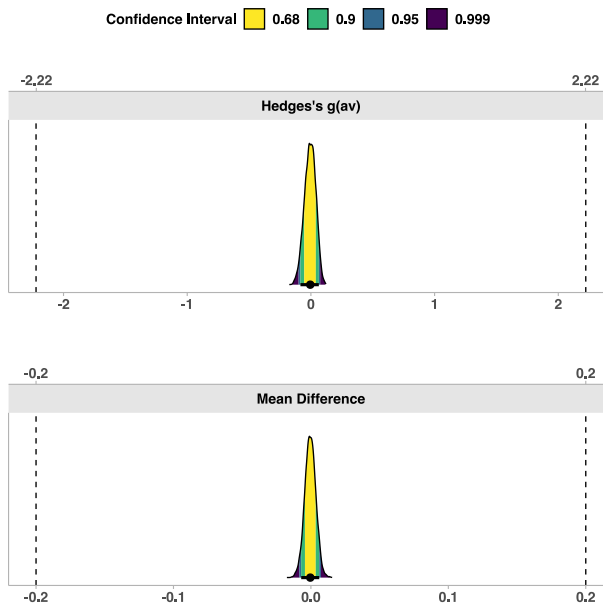
Pre-Procedural – TOTAL Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 3.71E-01



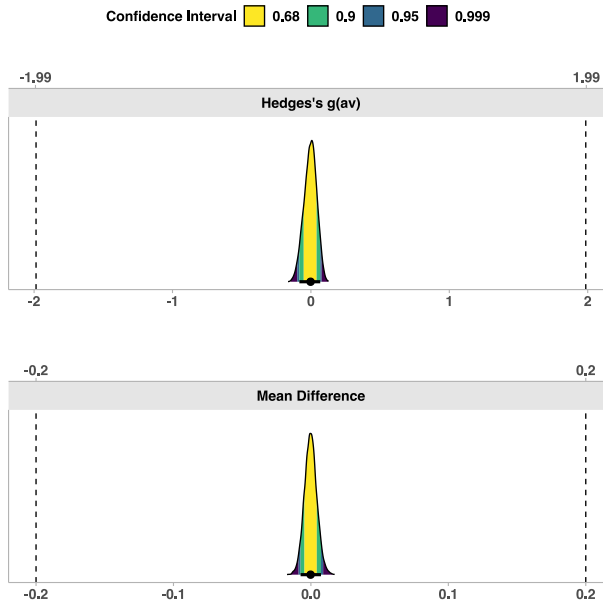
HVE Only X HVE and Saliva Ejector
 Procedural – PM1 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 9.01E-01



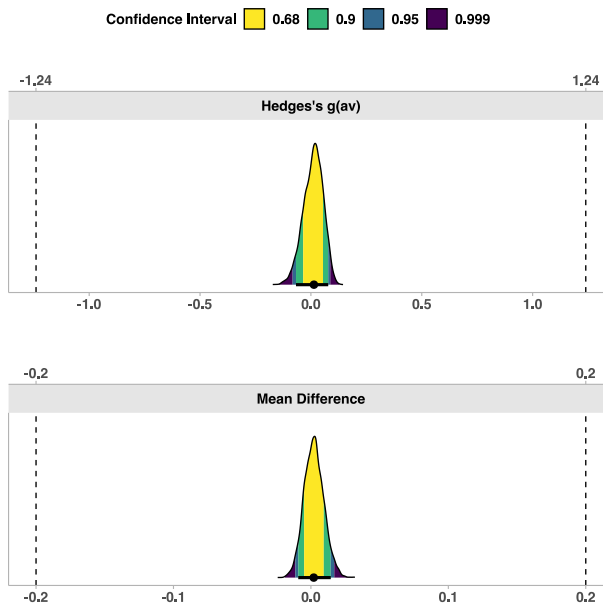
Procedural – PM2.5 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 9.14E-01



Procedural – RESP Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 9.97E-01

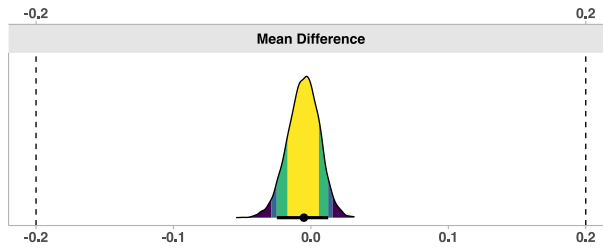
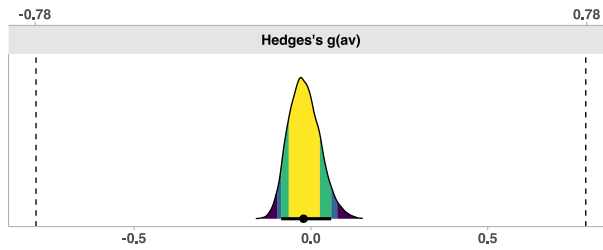


Procedural – PM10 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 7.59E-01



Procedural – TOTAL Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = 6.11E-01

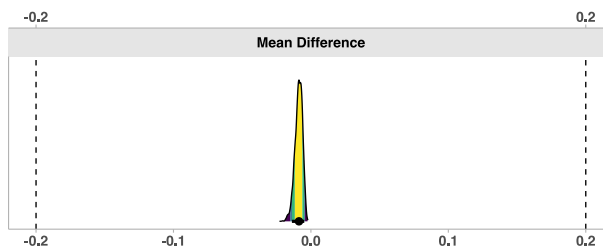
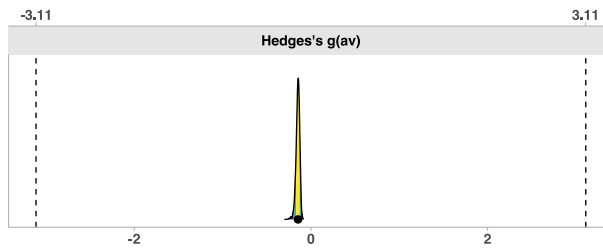
Confidence Interval 0,68 0,9 0,95 0,999



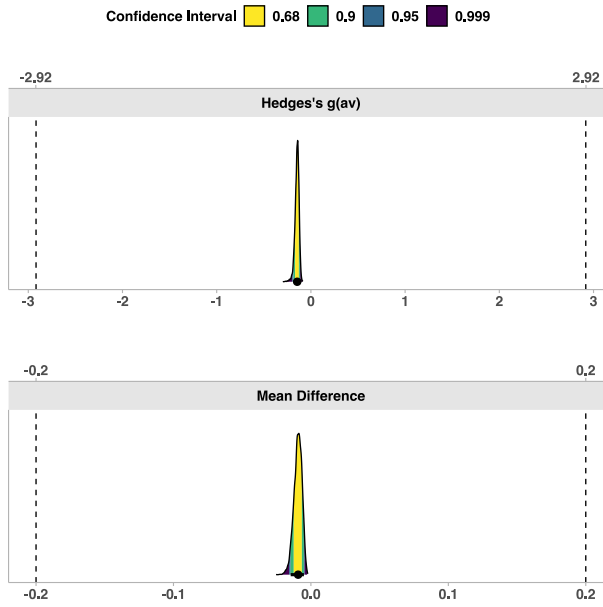
HVE Only X HVE, SE and BriteHive

Procedural – PM1 Upper p value = <0.01 Lower p value = <0.01
Equivalency p value = <0.01 Null p value = <0.01

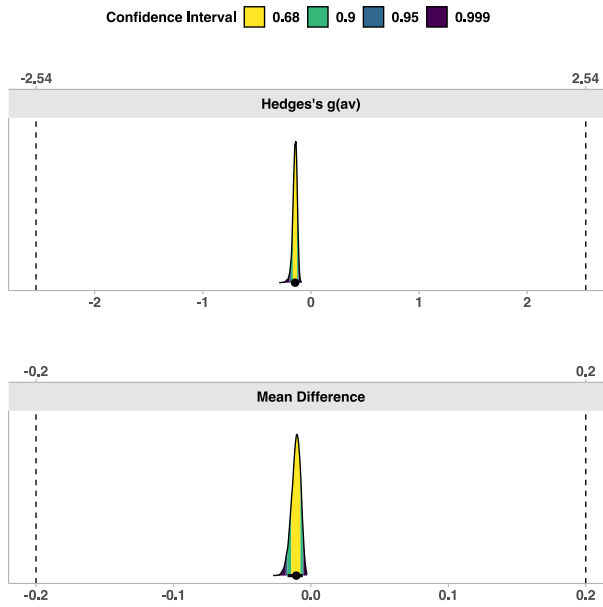
Confidence Interval 0,68 0,9 0,95 0,999



Procedural – PM2.5 Upper p value = <0.01 Lower p value = <0.01
Equivalency p value = <0.01 Null p value = <0.01

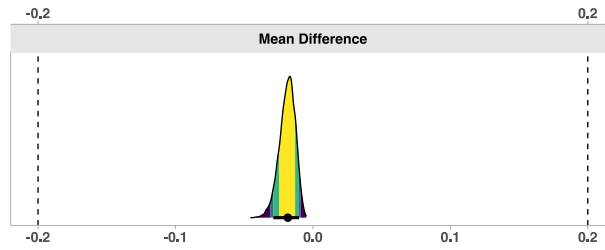
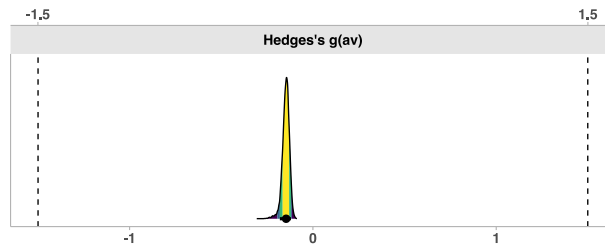


Procedural – RESP Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = <0.01



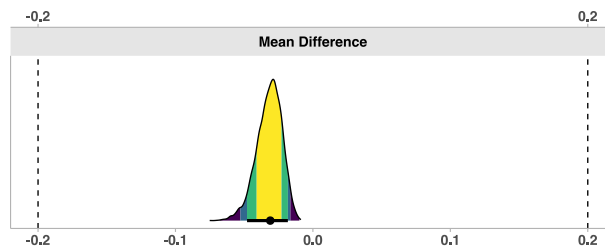
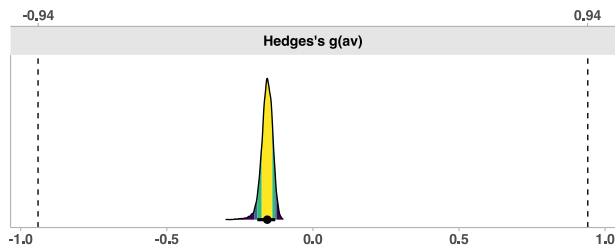
Procedural – PM10 Upper p value = <0.01 Lower p value = <0.01
 Equivalency p value = <0.01 Null p value = <0.01

Confidence Interval 0,68 0,9 0,95 0,999



Procedural – TOTAL Upper p value = <0.01 Lower p value = <0.01
Equivalency p value = <0.01 Null p value = <0.01

Confidence Interval 0,68 0,9 0,95 0,999



Section 7 – Geometric Means – Dust-Trak

The highest two values across the four PM sizes, excluding the TOTAL, are highlighted, individually per patient

Pre-Background

Method	Patient	PM1	PM2.5	RESP	PM10	TOTAL
HVE	1	0.000219	0.000238	0.000278	0.000442	0.00112
	2	NA	NA	NA	NA	NA
	3	0.002371	0.002371	0.002402	0.002581	0.003476
	4	0.001573	0.001588	0.001595	0.002038	0.004911
	5	0.001486	0.001497	0.001551	0.001807	0.003149
	6	5.79E-05	7.45E-05	7.48E-05	0.000174	0.00093
HVE+SE	1	0.004475	0.004499	0.004557	0.005044	0.008125
	2	5.86E-05	5.86E-05	5.86E-05	0.000176	0.001229
	3	NA	NA	NA	NA	NA
	4	0.001658	0.001677	0.00174	0.002235	0.003832
	5	0.001001	0.001001	0.001001	0.001027	0.001145
BriteHive	1	0.000216	0.000246	0.000281	0.000671	0.001193
	2	0.001184	0.001188	0.001205	0.001396	0.002192
	3	0.002015	0.002066	0.002115	0.00234	0.003501
	4	0.001043	0.001056	0.001374	0.002128	0.00653
	5	0.001433	0.001437	0.001493	0.001951	0.003687

Procedural

Method	Patient	PM1	PM2.5	RESP	PM10	TOTAL
HVE	1	0.00264	0.002739	0.003149	0.005411	0.010686
	2	0.001694	0.001746	0.00199	0.003228	0.007208
	3	0.007114	0.00729	0.007787	0.010899	0.020663
	4	0.001539	0.001633	0.001768	0.002731	0.004826
	5	0.002087	0.002139	0.002244	0.002961	0.005424
	6	0.001899	0.002098	0.002611	0.005574	0.011147
HVE+SE	1	0.004333	0.004402	0.004592	0.005512	0.008657
	2	0.000756	0.00088	0.001139	0.00227	0.004225
	3	0.000234	0.000251	0.000271	0.00048	0.00096
	4	0.00654	0.006872	0.007445	0.01073	0.01816
	5	0.002031	0.002371	0.002819	0.004364	0.007766
BriteHive	1	0.002017	0.002184	0.002693	0.003769	0.005739
	2	0.001529	0.00159	0.0017	0.002273	0.004242
	3	0.003126	0.003243	0.003377	0.004674	0.009095
	4	0.001792	0.00199	0.002094	0.002907	0.006132
	5	0.003176	0.003344	0.00369	0.005135	0.007204

Post-Procedural

Method	Patient	PM1	PM2.5	RESP	PM10	TOTAL
HVE	1	0.000951	0.001007	0.001391	0.002179	0.005862
	2	0.000972	0.001065	0.001165	0.00232	0.005597
	3	0.002508	0.002526	0.002579	0.002876	0.003917
	4	0.000178	0.000187	0.000232	0.000625	0.00184
	5	0.00129	0.001274	0.001292	0.001739	0.004025
	6	0.000137	0.000145	0.000161	0.000385	0.001074
HVE+SE	1	0.003618	0.003618	0.003665	0.004276	0.007483
	2	0.000145	0.000155	0.000172	0.000854	0.002409
	3	3.35E-05	3.46E-05	3.76E-05	7.02E-05	0.000128
	4	0.002436	0.002517	0.002639	0.003284	0.005269
	5	7.37E-05	7.67E-05	8.53E-05	0.000244	0.000594
BriteHive	1	0.000799	0.000839	0.000918	0.001757	0.004111
	2	0.001284	0.001311	0.001358	0.001698	0.002768
	3	0.001342	0.001356	0.001386	0.001616	0.002526
	4	0.000183	0.000189	0.000225	0.000677	0.002537
	5	0.001434	0.001449	0.001476	0.001831	0.003078

Section 8 – Standard Deviation – Dust-Trak

Pre-Procedural

Method	Patient	PM1	PM2.5	RESP	PM10	TOTAL
HVE	1	0.002451	0.002447	0.002443	0.002697	0.007929
	2	NA	NA	NA	NA	NA
	3	0.000837	0.000837	0.000838	0.000901	0.004319
	4	0.002286	0.002305	0.002307	0.002538	0.009094
	5	0.000941	0.000939	0.000954	0.001148	0.006297
	6	0.001112	0.001103	0.001163	0.001506	0.007291
HVE+SE	1	0.002007	0.002007	0.002011	0.002149	0.007949
	2	0.002329	0.002329	0.002329	0.002543	0.012252
	3	NA	NA	NA	NA	NA
	4	0.001581	0.001576	0.001575	0.001798	0.007638
	5	0.000335	0.000335	0.000335	0.00038	0.001801
BriteHive	1	0.00156	0.00155	0.001552	0.002095	0.007294
	2	0.001915	0.001915	0.001931	0.002223	0.00705
	3	0.001484	0.00148	0.001471	0.001631	0.006565
	4	0.001555	0.001551	0.001528	0.001819	0.008495
	5	0.001039	0.001122	0.001112	0.001265	0.005672

Procedural

Method	Patient	PM1	PM2.5	RESP	PM10	TOTAL
HVE	1	0.047292	0.050377	0.057741	0.098455	0.186987
	2	0.012248	0.013011	0.014506	0.021672	0.037015
	3	0.006123	0.00634	0.00687	0.010357	0.022856
	4	0.09894	0.106641	0.123319	0.204169	0.30287
	5	0.002605	0.002678	0.002786	0.003389	0.009027
	6	0.206722	0.219617	0.251428	0.430815	0.697662
HVE+SE	1	0.005922	0.005929	0.005943	0.006072	0.008668
	2	0.007895	0.008603	0.010089	0.015347	0.023661
	3	0.12556	0.129516	0.131143	0.135343	0.138018
	4	0.145234	0.153292	0.172619	0.285451	0.486691
	5	0.014034	0.0148	0.016708	0.028239	0.054884
BriteHive	1	0.014522	0.014804	0.015432	0.019135	0.028786
	2	0.002017	0.002039	0.002089	0.002816	0.007922
	3	0.004411	0.004432	0.004505	0.005485	0.012853
	4	0.003731	0.00394	0.004534	0.006676	0.012051
	5	0.010159	0.010565	0.011564	0.015865	0.031239

Post-Procedural

Method	Patient	PM1	PM2.5	RESP	PM10	TOTAL
HVE	1	0.001638	0.001657	0.00163	0.002341	0.010948
	2	0.003327	0.003328	0.003328	0.003685	0.010626
	3	0.000861	0.000888	0.000885	0.001043	0.004737
	4	0.002116	0.002112	0.002101	0.002691	0.00923
	5	0.002409	0.002413	0.002418	0.002567	0.007023
	6	0.002068	0.002108	0.002151	0.002885	0.011208
HVE+SE	1	0.001572	0.001572	0.001642	0.002335	0.010542
	2	0.001947	0.001989	0.002063	0.002933	0.008372
	3	0.001205	0.001215	0.001244	0.001655	0.005578
	4	0.001694	0.001677	0.001725	0.002094	0.006367
	5	0.000838	0.000837	0.00085	0.001066	0.005445
BriteHive	1	0.001827	0.001832	0.001911	0.002488	0.01163
	2	0.001853	0.002011	0.002241	0.002998	0.007064
	3	0.001063	0.001098	0.001146	0.001329	0.004667
	4	0.00204	0.00205	0.002063	0.002336	0.006977
	5	0.001459	0.001456	0.001458	0.001852	0.007052

Chi-Square – Dust-Trak

Nominal frequency of aerosols, per PM size and Method

