

A Comparison of Aerosol and Spatter with Genius.Shield and HVE or HVE used alone

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Purpose:

A pilot study to compare aerosol and spatter generated during use of a high-speed handpiece when using a new adjunctive extraoral device, designed to contain aerosol and spatter, when used with high-volume evacuation (HVE) compared to using HVE alone.

Challenge Device:

Genius.Shield is a transparent protective shield connected to a flexible arm that attaches to the headrest of the dental chair and a hose which integrates into the operatory suction. Using the provided adapter, the end of the hose attaches to a shield which is arched over the patient's face. The shield can be disinfected and replaced as necessary.

Experimental Design:

Materials:

Genius.Shield (Brite Hive Innovations), standard HVE with suction tips, SAS Super 180 Bioaerosol Sampler, TSA with Lecithin and Poly 90 Contact Plates, TSA Settling Plates, patient volunteers (A, B, and C), licensed dentist volunteer, licensed dental assistant volunteer, face shields, PPE including a Level 3 surgical face mask and a face shield.

Methods:

Each aerosol generating procedure was completed while the office was closed, and all procedures were completed in one designated operatory. Prior to the first patient, HVE lines were cleaned with an evacuation line cleaner and traps were changed. The dental unit waterlines are routinely maintained and tested. A **DentaPure™ DP365B** cartridge (HuFriedyGroup) was utilized in a closed system (water bottle). Additional SE (1) and HVE (2) lines were running in all four operatories during the study to simulate simultaneous treatment in each operatory. The dentist and dental assistant wore PPE for all procedures, including a Level 3 mask and face shield. New face shields were used for each patient and each condition (total 3 per patient). Before testing, all volunteers agreed to participate in the study and to having their photos taken. The same dental professionals performed all procedures in this study. For each procedure, all quadrants of the mouth were treated; anterior and posterior, buccal and lingual. For each of three patients, the sequence of tested conditions was **Genius.Shield** without the curtain together with HVE, **Genius.Shield** with the curtain together with HVE, then HVE alone. Additionally, the positioning of each plate was consistent for all testing for the duration of the study.

Prior to any aerosol generation, an initial control sample of the operatory air was taken for 5 minutes while patient A, the dentist, and the dental assistant were in the room. This was performed using the SAS Super 180 Bioaerosol Sampler with a TSA with Lecithin and Poly 90 Contact Plate placed 18 inches from the patient's mouth (ASP; air sampling plate). For patients B and C, the last ASP sample in the previous series served as the baseline. During the 5-minute aerosol generating procedure in patient A, which included use of the **Genius.Shield** without the curtain together with standard HVE, a new ASP was used for the Bioaerosol Sampler, a TSA Settling Plate was placed on the patient's chest 8 inches from their mouth (Chest SP). At the end of the 5-minute procedure, the ASP and Chest SP were collected, and separate samples taken of the face shields worn by the dentist (Dentist Shield CP) and dental assistant (Assistant Shield CP). These were cultured separately using two additional TSA with Lecithin and Poly 90 Contact Plates.

Device



Control



Following use of the high-speed handpiece, the patient, dentist, and dental assistant remained in the operatory for 2 minutes. During these 2 minutes, for tested conditions involving *Genius.Shield*, the device was left on in the same position as during the procedures, before then being switched off.

At the conclusion of the 2-minute waiting period, another bioaerosol sample was taken for 5 minutes, utilizing the SAS Super 180 Bioaerosol Sampler and a new ASP and again placed 18 inches from the patient’s mouth (ASP 2-7 min). At the conclusion of this 5-minute sample, additional bioaerosol samples were taken for two subsequent 5-minute periods in the same manner, each time using a new ASP (ASP 7-12 min; ASP 12-17 min). The same procedure and sampling protocol was then repeated twice in patient A, first utilizing the *Genius.Shield* with the curtain together with HVE, then utilizing HVE alone. Operatory turnaround was then performed, including appropriate cleaning and disinfection. Subsequently, the exact same procedures were followed in the same sequence for patients B and C. After each test run in each patient, the exposed plates were immediately processed and incubated at 37°C for 48 hours. Microbial growth was quantified, analyzed and recorded for all plates.

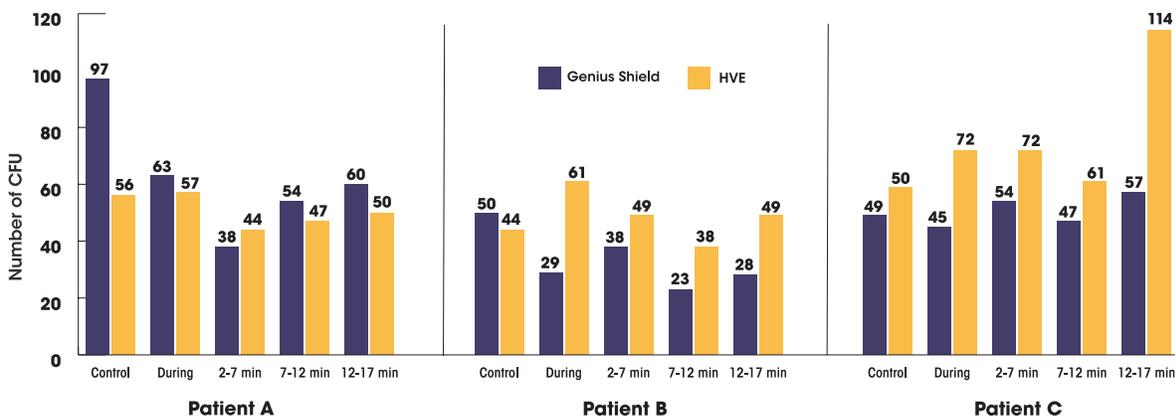
Results:

ASP samples taken during the procedure showed reduced bacterial counts compared to the control ASP bacterial counts in all three patients with the use of *Genius.Shield*. The reductions were 35%, 42% and 8%, respectively, for patients A, B and C. When utilizing HVE alone, a slight increase was observed in the ASP bacterial count sampled during the procedure in one of three patients, and a larger increase was observed in the other two patients. The observed increases were 2%, 39% and 44%, respectively, for patients A, B and C. No trends were observed for the *Genius.Shield* with the curtain.

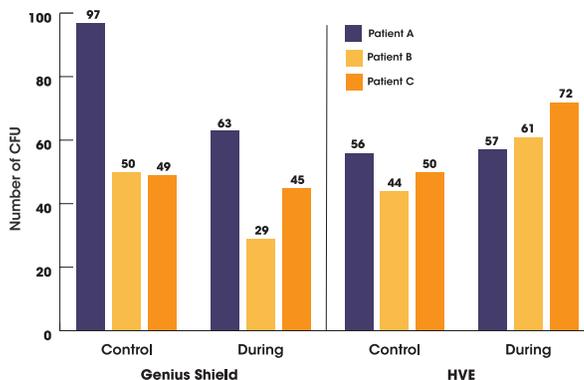
When utilizing *Genius.Shield* with HVE, the bacterial loads from the first post-procedural ASP samples taken for 5 minutes after stopping the use of the device were lower than prior to the procedure for two of the three patients and slightly higher for the third patient. The reductions were 61% and 24%, respectively, in two of the three patients, while a 10% increase was observed for the third patient. When utilizing HVE alone, the bacterial loads from the comparative ASP samples were higher than prior to the procedure for two of the three patients and slightly lower for the third patient. The differences showed a 44% and an 11% increase in two of the three patients, respectively, and a 21% decrease in the third patient. There was variability at other time points post-procedurally for both conditions, including an outlier for patient C for HVE at the last time point.

The data from the bacterial load collected on the Chest SPs was inconclusive due to high variability between patients. No trends were observed. In addition, almost no CFU were observed from the samples cultured for either the Dentist Shield CPs or the Assistant Shield CPs for any of the procedures or conditions.

Genius Shield and HVE ASP Comparison



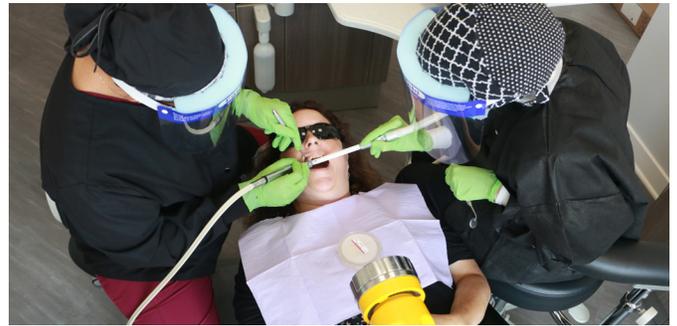
ASP Comparison During Procedure



Genius.Shield + HVE



HVE used alone



Patient A: ASP



Genius.Shield + HVE: Control (CFU = 97)



Genius.Shield + HVE: During (CFU = 63)



Genius.Shield + HVE: 2-7 min (CFU = 38)



Genius.Shield + HVE: 7-12 min (CFU = 54)



Genius.Shield + HVE: 12-17 min (CFU = 60)



HVE: Control (CFU = 56)



HVE: During (CFU = 57)



HVE: 2-7 min (CFU = 44)



HVE: 7-12 min (CFU = 47)



HVE: 12-17 min (CFU = 50)

Patient B: ASP



Genius.Shield + HVE: Control (CFU = 50)



Genius.Shield + HVE: During (CFU = 29)



Genius.Shield + HVE: 2-7 min (CFU = 38)



Genius.Shield + HVE: 7-12 min (CFU = 23)



Genius.Shield + HVE: 12-17 min (CFU = 28)



HVE: Control (CFU = 44)



HVE: During (CFU = 61)



HVE: 2-7 min (CFU = 49)



HVE: 7-12 min (CFU = 38)



HVE: 12-17 min (CFU = 49)

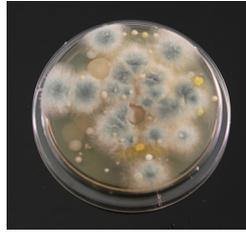
Patient C: ASP



Genius.Shield + HVE: Control
(CFU = 49)



Genius.Shield + HVE: During
(CFU = 45)



Genius.Shield + HVE: 2-7 min
(CFU = 54)



Genius.Shield + HVE: 7-12 min
(CFU = 47)



Genius.Shield + HVE: 12-17 min
(CFU = 57)



HVE: Control
(CFU = 50)



HVE: During
(CFU = 72)



HVE: 2-7 min
(CFU = 72)



HVE: 7-12 min
(CFU = 61)



HVE: 12-17 min
(CFU = 114)

Discussion:

The preliminary data from the pilot study showed that *Genius.Shield* used in conjunction with standard HVE could contribute to reduced bacterial load from aerosols collected on the ASPs during an aerosol generating procedure when compared to the use of HVE alone. In all 3 patients, decreases were observed for *Genius.Shield* and increases for standard HVE. There was variability across patients. The bacterial spatter on the Chest SP, however, varied greatly, allowing no conclusions to be drawn. Cultures from the face shields consistently showed no or negligible CFU, suggesting that spatter and aerosol was not reaching the face shields. It is possible that the lack of trends for the *Genius.Shield* with the curtain were due to the limitations of the curtain, since operators found this difficult to work with and the curtain may have shifted during use. Limitations in the pilot study included the small sample size. Results for chest plates and face shield cultures are shared in the Appendix.

Conclusion:

Based on preliminary data, the use of *Genius.Shield* contributed to a higher reduction in bacterial counts when used in conjunction with HVE than when HVE was used alone. Fewer Colony Forming Units were found during the procedure when using *Genius.Shield* compared to the control, indicating that *Genius.Shield* could make a difference. It should be noted that there was a small sample size; a larger sample size would permit determination of statistical significance.

Future Directions for Research:

- A larger sample size would enable determination of statistical significance for differences observed between devices.
- A laboratory test would also be interesting as supplemental data comparing the test device and standard HVE.
- Since no testing was performed with saliva ejector alone, a comparison between *Genius.Shield* and saliva ejector cannot be made. It would be interesting to perform an assessment of this, since the test device incorporates a suction line and might aid solo operators.
- In addition, HVAC air exchange analysis would be helpful to determine any variations in environmental quality.