Collaboration among Regional Organizations to Deliver a Demonstration Project for Improved Indoor Air Quality

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BACKGROUND

Infectious airborne diseases pose a persistent threat for vulnerable populations. The recent SARS-CoV-2 pandemic demonstrated how harmful airborne pathogens can be towards public health. Government and other relevant organizations throughout the world have recognized the need to develop significant preventive strategies to stop emerging infections before they reach epidemic or pandemic proportions. There are many methods currently available to improve indoor air quality, however these methods have limitations. Ventilation air exchange only dilutes the contaminates in indoor air; it does not eliminate contaminants [1]. High Efficiency Particulate Absorbing (HEPA) air filtration is only efficient in removing particles ≥ 0.30 microns. Harmful pathogens remain alive on the filter [2]. UV light can be harmful to the skin and eyes if a person is exposed. It also has limited field of view and can take too long to remove pathogens [1]. Bipolar Ionization emits harmful ozone and increases CO_2 build up. It is not effective in eliminating mold/fungal spores (<1 log reduction) [4-5].

Why SteriSpace® air sterilization is the answer?

- SteriSpace® - air sterilizer that eliminates all airborne organisms by compressive heating. The device takes in the indoor air, heats it to 240°C (464°F), then cools it down to room temperature before releasing the cleansed air back into the indoor area [3].
- Tested independently by the U.S. Department of Defense (DOD).
- Eliminated >99.9999% (>6-log reduction) of airborne biological threats in a single pass.

OBJECTIVES

1. Evaluate the efficacy of SteriSpace® at elimination biological agents under controlled conditions.
2. Real world implementation and evaluation of the SteriSpace® air sterilization technology and assess its efficacy in areas that serve vulnerable populations.
3. Demonstrate cooperative effort between the Rethink Western New York Health Collaborative and You First Services, Inc., the developers and manufacturers of SteriSpace®, in implementing an air sterilization project.

METHODS

Evaluating the efficacy of SteriSpace® under controlled conditions.
In controlled experiments, a titer of bacterial aerosols (MS2 bacteriophage, *Bacillus globigii, Bacillus stearothermophilus, Bacillus thuringiensis*) was injected at a station near the inlet of the SteriSpace® machine. Impingers filled with nutrient-rich agar were used to capture air samples at the inlet (untreated air) and outlet (treated air) of the SteriSpace® machine. Biological agents collected from the air samples are then incubated before subsequent analyses. MS2 bacteriophage was titrated *via* plaque assay using *E. coli* as a host. After incubation, plaques caused by MS2 were counted and averaged per sample. Effectiveness of SteriSpace® was calculated by subtracting the titer recovered from the treated samples from the titer recovered from baseline samples.

Real-world evaluation of SteriSpace® technology
A) Location. Two SteriSpace® units were installed at the Schoellkopf Health Center of Niagara Falls Memorial Medical Center (NFMMC) (Figure 2). The SteriSpace® units were installed to treat the Patient Recreation Room, an area where elderly patients and caretakers regularly congregate.
B) Approach. For this real-world experiment, baseline air sampling was done with an *Andersen Airborne Impaction Sampler* to assess airborne bacteria and fungal spores. After the baseline sampling, the SteriSpace® machines were activated for air sterilization. Two follow-up air samplings were later conducted to evaluate the effectiveness of SteriSpace® in eliminating contaminants. Follow-up samples were taken at the outlet and inlet of the SteriSpace® machines. Culture media selected for the project included 2% malt extract agar (MEA) to assess fungal growth and trypticase soy agar (TSA) to collect environmental bacteria growth.

RESULTS

Figure 1. In independent air sterilization and airborne biological agents testing studies under controlled conditions, SteriSpace® effectively eliminated aerosolized viruses in the first pass. The results yielded an elimination rate of 99.9999% or a six-log reduction in viral counts.

Test Objective(s)	Temperature (°C)	Challenge organism/ Field testing	Log or % Kill rate/	Unit-Protype used
University at Buffalo				
Kill efficacy against Bacteria	247	Bacillus globigii (Bg)^	> 3 log (99.9%)	Initial Prototype
U.S. Department of Defense				
Kill efficacy against Bacteria	240	Bacillus stearothermophilus (Bst)	>6-log (99.9999%)	Initial Prototype
Research Triangle Institute				
Kill efficacy against Bacteria and Virus	240	Bacillus globigii (Bg), Bacillus thuringiensis (Bt), MS2 Bacteriophage [B]	>6-log (99.9999%)	300 CFM (GD 450)
U.S. Department of Defense(2006 Program)				
Kill efficacy against Bacteria	240	Bacillus globigii (Bg)	>6-log (99.9999%)	300 CFM (GD 540) Varied flow rates and temperature
Kill Efficacy against Bacteria, E. coli & Virus	240	Bacillus globigii (Bg), E. coli, MS2 Bacteriophage	>6-log (99.9999%)	300 CFM GD (HF-408), Tri-lobe PD Blower
Kill Efficacy against Bacteria	240	Bacillus globigii (Bg)	>6-log (99.9999%)	300 CFM(GD HF 408) tri-lobe PD blower, higher Effectiveness Counterflow Heat Exchanger
U.S. Department of Defense (2009) Program)				
Kill Efficacy against Bacteria	240	Bacillus globigii (Bg)	>6-log (99.9999%)	300 CFM (GD HF-408, Alpha prototype Varied Flow rates and Temperature
Kill Efficacy against Bacteria	240	Bacillus globigii (Bg)	>6-log (99.9999%)	300 CFM (GD HF-408) optimized prototype
Kill Efficacy against Bacteria	220	Bacillus globigii (Bg)	>6-log (99.9999%)	1000 CFM (Centrifugal counter flow)
U.S. Department of Defense SBIR Program				
Maintenance of Kill efficacy	240	Bacillus globigii (Bg)	>7-log (99.9999%)	5000 CFM (Centrifugal counter flow)

[A] *Bacillus globigii has been widely* used as a biological warfare simulant. [B] MS2 bacteriophage was cultured for use as a test organism to assess the performance of SteriSpace®. MS2 bacteriophage is a model organism used within several important areas of research (i.e., viral replication infection and assembly).

Figure 1. Survival of the biological agents **after first pass** through the SteriSpace® unit. Impingers were used to acquire samples from the inlet and the outlet sections. Acquired organisms were absorbed by a culture media and incubated to determine the number of biological species as explained under the methods section. The flow is cooled before entering the impingers to avoid evaporation of the agar.

Figure 2. Performance of the installed SteriSpace® machine in a real-world scenario. Data analysis shows optimal performance of the machine regarding variables like rotations per minute, efficiency, pressure, temperature, and air flow.

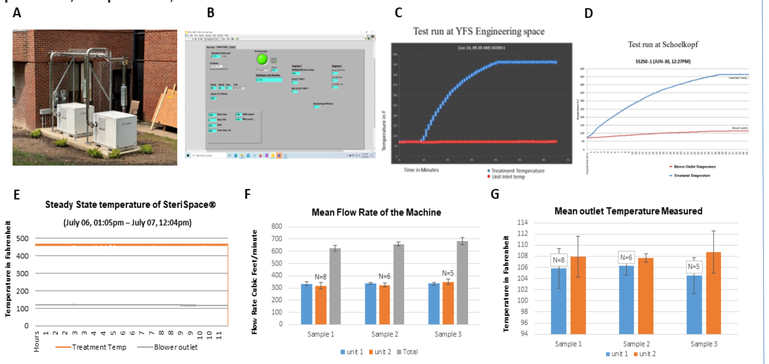

Figure 2. In cooperation with Rethink WNY and the City of Niagara Falls as part of the Clean Air Initiative, two SteriSpace® 250 CFM devices were installed at NFMMC to treat their extended care facility's recreational space. We evaluated the operational efficacy of SteriSpace. (A) Image of installed SteriSpace® at the Schoellkopf Health Center. (B) Screenshot of the LabVIEW program used to monitor vital statistics of SteriSpace®. (C) A representative image of the vital metrics monitored in terms of inlet temperature and the time taken to reach optimal treatment temperature. (D) A representative image of the relationship between the SteriSpace® treatment temperature and the outlet temperature. (E) A representative image of the steady-state relationship between the SteriSpace® treatment temperature and the outlet temperature monitored over an 11-hour period. (F) Graphic showing the mean ± SD of CFM flow-rate monitored at the outlet of both units, measured by hand-held meters. (G) Graphic of the mean ±SD of the temperatures measured from outlets of both the units inside the hall, assessed by hand-held thermometers.

Figure 3. Baseline air sample collected on 06/29/2023 followed by microbial analysis show the presence of both bacteria and fungal/mold spores.

Date of Sampling	6/29/2023		Fungal Species (n)	Bacterial Species (n)
Temperature and RH	Temperature (69.4 °F)	RH (54.1%)	-	-
Sample Locations	Bacteria	Fungi		
Sitting Area	OVG	OVG	OVG	OVG
Front Exit	35	NGP	-	*Bacillus sp (5)*
10' South of Front Exit	57	7	*Auerobasidium sp (1)*	*Bacillus sp (3), Streptococcus sp (2), Actinomycetes (1), Gram Neg Bacteria (1), Rhodococcus sp (1)*
20' South of Front Exit	21	14	*Cladosporium sp (2)*	*Bacillus sp (2), Streptococcus sp (1)*
Sink	57	28	*Cladosporium sp (4)*	*Bacillus sp (3),Staphylococcus sp (1) Streptococcus sp (1), Actinomycetes (2)*
Kitchenette	7	35	*Cladosporium sp (5)*	Bacillus sp (1)
Average Concentration	35	17		

Figure 3. Baseline Air Sample Analysis for bacterial/fungal/mold spores. Air sampling was based on the procedure & guidelines outlined in the NIOSH Method 0800 – BIOAEROSOL SAMPLING (Indoor Air). Six samples each for airborne bacterial and fungal spores were collected from different areas of the site (Figure 3 Column 1). Collected samples were transported to the laboratory and incubated for further analysis. Field and laboratory quality control samples were also incubated for each sampling event. Macroscopic, microscopic, and quantitative morphology results were documented every 24-48 hours following the initial incubation for a total of 7 days. NGP indicates No Growth Promoted and OVG indicates overgrowth-promoted sample designation. Baseline sampling analysis shows an average CFU for bacteria (35 CFU/m^3), mold, and fungi (17 CFU/m^3), clearly indicating the non-sterile nature of the room. The most prevalent species of viable fungi/mold was *Cladosporium sp.* Additional fungal species of note present include *Penicillium sp* and *Trichophyton sp*. The most dominant group of bacteria observed was the *Bacillus sp.* Additional bacterial species present include *Staphylococcus sp.*, *Streptococcus sp.* and *Actinomycetes*.

Figure 4. An impressive decline in bacterial and fungal spores' post-sterilization of air samples by SteriSpace®

Collection Date	Sample Location	Sample ID	Volume (L)	Count	Bacterial CFU/m^3	Bacterial Species Identified	Fungal Count	Fungal CFU/m^3	Fungal Species Identified
07/20/2023	Supply 2 - at outlet	1	141.5	NGP	-	-	1	7	*Aspergillus fumigatus (1)*
07/20/2023	Supply 2 - 6" from outlet	2	141.5	1	7	Bacillus sp. (1)	4	28	*Aspergillus versicolor (1) Aspergillus niger (1), Alternaria alternata (2)*
07/20/2023	Return 2 – 6" below diffuser	3	141.5	1	7	Actinomycete (1)	7	50	*Acremonium (3), Aspergillus versicolor (1), Alternaria a lternata (4)*
		Mean		<1	<7		4	28	

Figure 4. Post SteriSpace® treated air samples show NGP status for bacteria **in the first pass** at the outlet carrying sterile air from the machine into the room. However, fungal/mold spores analysis showed 7CFU/m^3 counts where sterile air enters the room and low counts at two other locations. These levels are impressively low based on two institutional guidelines (NIOSH and ACGIH) pertaining to the acceptable levels of viable bioaerosols in indoor air, which is 1000 CFU/m^3.

Figure 5. Repeat analysis of samples on 08/09/2023 shows no growth promoted(NGP) for both bacteria and fungi/mold in the first pass.

Collection Date	Sample Location	Sample ID	Volume (L)	Count	CFU/m^3	Status
8/9/23	Supply 2 – at outlet	1	141.5	0	<7	No Growth Promoted (NGP)
8/9/23	Return – at outlet	1	141.5	0	<7	No Growth Promoted (NGP)

Figure 5. Suspecting assay artifact in the sample collected on 07/20/2023 a repeat analysis for fungal/mold spores was performed at the outlet (A) to assess efficacy after **the first pass** and not to have interference from confounding variables associated with factors beyond our control. The results of the analysis showed NGP status at first pass even after 7 days of incubation. The analysis of the air samples collected for fungal/mold spores on 07/20/23 shows 7 CFU/m^3 at outlet (A), delivering air from SteriSpace® into the room.

DISCUSSION

- Results of Figure 1 is aligned with the known susceptibility of viruses above 60ºC [6-7].
- The real-world implementation of SteriSpace® installation and performance of the engineering controls was better than the performance under controlled conditions. This success was mainly due to ductwork integration and attention towards the commitment to excellence of healthcare technologies.
- In Figure 3, the most probable reason for the spores detected are through personal traffic, leaky windowpanes or doors, or old cardboard boxes stored in the room because *penicillium sp.* are known to be propagated via damaged cellulose [8].
- The results shown in Figure 4 is considerably less than those observed in a high-grade operating room even after 40 air changes/hour [9] demonstrating the high efficacy of SteriSpace® in eliminating biological agents.
- The fungal/mold spores detected in Figure 4 are potentially due to settled spores on surfaces becoming air-bound by turbulence created when sterile air from the duct enters the room. This is not reflective of the level of spores in the sterile air coming into the room as it is well-known that turbulence disrupts settled spores and makes it air-bound [10].
- Results of analysis shown in Figure 5 confirm that the sterile air coming into the room is completely void of both bacterial and fungal/mold spores.

CONCLUSIONS

- In independent air sterilization and microbial testing studies in controlled conditions, SteriSpace® effectively eliminated aerosolized viruses in the **first pass** at both high and low treatment temperatures, ranging from 64.5°C to 143°C. The results yielded a kill rate of 99.9999% or a six-log reduction in viral counts.
- In a real-world scenario at an extended care facility, the performance of SteriSpace® was successfully replicated with optimum levels observed for RPM, motor efficiency, pressures, and temperature in field conditions.
- With SteriSpace® implemented to optimize air quality, no detectable growth of bacterial spores was observed **in the first pass** under field conditions that reflect daily indoor traffic patterns, despite numerous potentially complicating variables. The data from this real-world setting are consistent with our previous environmentally controlled experiments that resulted in an observed kill rate of 99.9999% or a six-log reduction in bacterial and viral counts.
- With SteriSpace® operational in a real-world scenario, the data indicate that no growth in fungal/mold spores was detectable **in the first pass** despite the presence of multiple factors that could have contributed to microbial growth.
- Rethink WNY helped establish a working collaborative with You First Services, Inc., the Niagara Falls Memorial Medical Center, and other organizations in WNY to mobilize the first real-world air sterilization

REFERENCES