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Major Article

Particle control reduces fine and ultrafine particles greater than HEPA filtration in live operating rooms and kills biologic warfare surrogate

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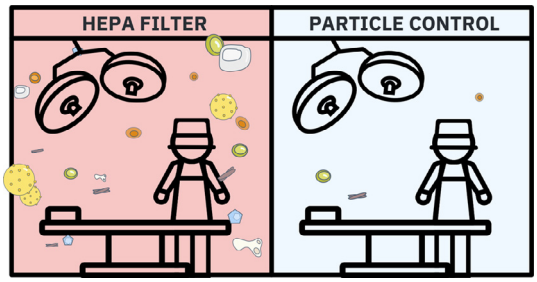

Key Words:
Indoor air purification
Airborne pathogens
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Background: Controlling indoor air quality and the airborne transmission of infectious agents in hospitals is critical. The most hazardous particles and pathogens are not easily eliminated by traditionally passive air cleansing.

Methods: We studied the effect of a novel particle control technology on airborne particulate matter in 2 live real-world operating room settings and on pathogen survival in a microbiology laboratory.

Results: Particle control technology reduced operating room particle and pathogen loads by 94.4% in a community hospital operating room, and by 95% in an academic medical center operating room. The addition of particle control technology to a collector loaded with a biologic warfare surrogate resulted in a 95% kill rate of an anthrax surrogate (*Bacillus subtilis*) within 3 hours.

Discussion: Deployment of this emerging technology could significantly reduce indoor air contamination and associated infections in operating rooms, hospital isolation rooms, and intensive care settings, as well as reduce inflammatory responses to airborne particles.

Conclusions: The particle control technology studied may protect patients from hospital-acquired infections, reduce inflammatory pulmonary disease, and mitigate exposure to biologic weapons.

New building technologies and regulations, such as tightening building envelopes and increased insulation, can increase concentrations of indoor particles, pollutants, and pathogens.[1] This is especially relevant in hospitals and health care settings, considering that hospital-acquired infections are among the leading causes of death in North America, killing more people than diabetes or influenza combined.[2] Airborne transmission is likely responsible for nearly half of all hospital-acquired infections and most surgical site infections.[3-5] Most anti-infection efforts focus on direct physical contamination between patients, providers, surfaces, and devices.[6] Increased handwashing, hand and surface purification treatment, and other quality processes have indeed reduced direct transmission of pathogens.[7,8] Yet there have been few advances in methods to reduce airborne transmission of bacteria, viruses, and fungi, or to kill airborne pathogens.

Contemporary air cleansing relies on high-efficiency particulate air (HEPA) filtration, positive and negative pressurization, high air exchanges, photocatalytic oxidation, plasma cleaning, and ultraviolet

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light to limit contamination or kill pathogens on surfaces.[4] Each of these methods has significant limitations and may reduce the presence of larger airborne particles (>2.5 μ), but they have limited impact on fine particles (<2.5 μ) and ultrafine particles (<0.25 μ). These very small particles characteristically have low settling velocities, keeping them resident within spaces even in the presence of contemporary air cleansing technologies.[9]

The majority of airborne pathogens fall into the fine particle or ultrafine particle ranges. It is a common misconception that these small particles are effectively cleared from a space (such as an operating room) via HEPA filtration. Unfortunately, most very small particles and pathogens are of insufficient mass to be controlled by bulk airflow and can remain suspended for days or even weeks.[9] Significant fractions of these suspended particles and pathogens cannot be effectively transported to or removed by conventional air filters (personal communication, Don Hess, April 2, 2019).

Coarse particles (>2.5 μ) are subject to physical forces and are reliably carried by airflow and deposited on the filter media. Conversely, submicron particles (≤0.4 μ) are influenced by electromagnetic forces within the environments in which they are suspended. Those with physical diameter between 2 and 5 μ are influenced variably by inertial and electrostatic forces. Ultralow penetration air filters and HEPA filters are only effective on those particles and pathogens that can reach the filter, not those that remain suspended in space.

The inability to eliminate airborne fine and ultrafine particles is most hazardous to those who have preexisting pulmonary disease, are immunocompromised, or are in a hospital or other health care facility. Although particulate matter 2.5 (particulate matter 2.5 μ in diameter, $PM_{2.5}$) is frequently measured, it is particulates < 2.5 μ that are the most harmful.[10,11,12]

These very small particles are inhaled and transmitted through respiratory passages, and have the ability to settle deep within the distal pulmonary alveoli.[13] They can remain there permanently, causing localized inflammation and/or infection, and even travel through cell walls into the bloodstream to be disseminated throughout the body.[13] The uptake of inhaled microparticles can contribute to generalized and localized inflammation, and is directly linked to pulmonary disease, cardiovascular disease, myocardial infarction, cerebrovascular events, dementia, and Alzheimer disease.[3,14,15-18]

PARTICLE CONTROL TECHNOLOGY

Particle control technology principally works by local electrostatic field manipulation (not ionization). These forces condition the microparticles and continuously initiate millions of particle-molecular collisions. These collisions lead to rapid and permanent ionically driven aggregations of fine and ultrafine particles into larger particles. Once the larger aggregates attain a critical mass, they fall under greater influence of physical forces and are carried by air currents to the particle collector. Finally, the aggregated fine and ultrafine particles trapped in the collector are subjected to a strong electric field that kills the previously airborne pathogens by oxidative stress.

We sought to determine (1) the effect of particle control on fine and ultrafine particle loads in live real-world operating rooms, and (2) the effect of particle control on the survival of a biologic warfare surrogate, *Bacillus subtilis*.

METHODS

Live operating room studies

Two clinical settings and 1 laboratory setting were studied. One was a single operating room within a medium-sized 40-bed Minnesota hospital with 5 operating rooms. Baseline airborne particle counts were measured for 5 consecutive weekdays during a variety of routine general, urologic, orthopedic, and gynecologic surgical procedures. The existing operating room ventilation system included a prefilter, minimum efficiency reporting value (MERV) 14, HEPA filtration, and 16 air exchanges per hour during the baseline period.[19] These specifications are compliant with ASHRAE (American Society of Heating, Refrigerating and Air-Conditioning Engineers) 170 and local state code requirements.[20] During the subsequent 5 weekday intervention period, a portable particle control device was added (Active Particle Control Technology, SecureAire Inc, Dunedin, FL). The unit was placed within the 4,200 ft^3 operating room along with a particle monitor that remained within the same location throughout both 5-day phases. The ventilation system settings also remained consistent between the baseline and intervention period in this experiment.

The second clinical setting was a 300-bed tertiary-care teaching hospital with 12 operating rooms located in Pennsylvania. This clinical study examined immediately adjacent operating rooms that were supplied by the same air-handling system. The control operating room was supplied via a prefilter, MERV 14, HEPA filtration, and 16 air changes per hour. The adjacent treated room was served by a prefilter and an installed particle control device MERV 15 system with 16 air changes per hour.

An identical laser-based particle monitor was used at both clinical sites. The device measures particles that are >0.4 μ and those that are >2.5 μ.[21] The mean particle counts were calculated throughout the baseline and particle control treatment phases. Airborne fine and ultrafine particle counts correlate with airborne contamination, and have been used and validated as surrogates for airborne pathogens.[22,23] At both clinical sites, none of the procedures during the baseline or study period involved open abdomens, bowel incisions, or emergency procedures that would further contaminate the operating room environment and potentially compromise results.

Pathogen inactivation study

Airborne pathogen inactivation studies were conducted at the University of Colorado Environmental Microbiology Laboratory (Boulder, CO). Anthrax (*Bacillus anthracis*) is a well-characterized pathogen, known for its persistence under a broad range of environmental conditions, including the atmospheric environment.[24] A closely related but less virulent bacterium, *B subtilis*, was used for controlled disinfection challenges of the particle control system because these microbes have similar environmental behavior to *B anthracis*, and have been widely used as a model for the environmental behavior of bacterial bioaerosols. In independent and replicated trials, the filter surfaces of the particle control system were loaded viable *B subtilis* cells at a density of approximately 10^7 cells/cm^2. Direct microscopic counts were concurrently performed with the standard culturing of eluents from filter coupons embedded in the particle control system, as previously described.[25,26]

Widely accepted statistical analysis was applied to compared mean particle counts before and after the engagement of the particle control system. Differences were considered statistically significant at t test alpha level of 0.05.

RESULTS

In a Minnesota community hospital operating room, the mean baseline particle counts throughout the first week (control-HEPA) were 167,408/ft^3 (peak of 629,100/ft^3). For the treatment period (HEPA plus particle control) the mean particle counts were reduced to 9,313/ft^3 (peak count of 22,600/ft^3) (Fig 1). The particle control system resulted in a 94.4% reduction in fine and ultrafine particles ($P < .0001$).

In a Pennsylvania academic medical center hospital, the control (ie, HEPA) operating room mean particle counts were 93,351/ft^3, and the operating room with the particle control ventilation system had mean

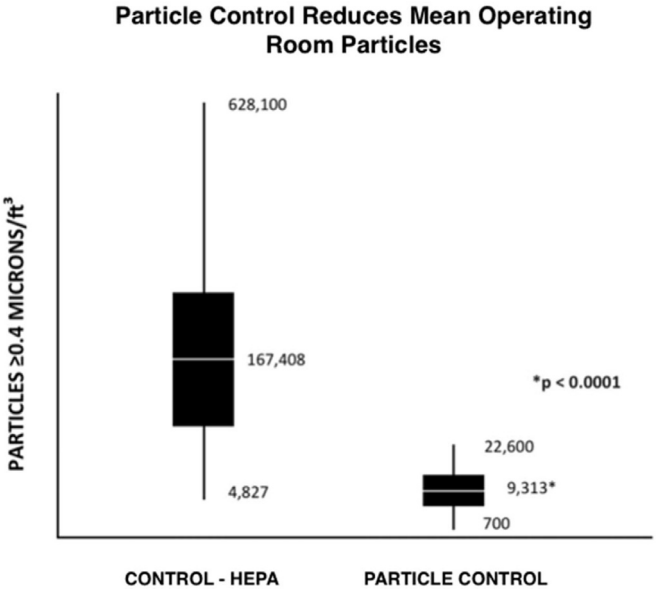

Fig 1. Particle control technology resulted in a 94.4% reduction in fine and ultrafine particle counts when added to a standard ventilation system in a live 4,200 ft^3 community hospital operating room. Standard ventilation for the 5-day control and 5-day study period included a prefilter, MERV 14, HEPA filtration, and 16 air exchanges per hour (ASHRAE 170 compliant). Mean particle counts during the control period were 167,408/ft^3 (peak of 629,100/ft^3) and were reduced to 9,313/ft^3 (peak count of 22,600/ft^3) with the addition of the portable particle control device ($P < .0001$). Data are presented as mean, 25th and 75th percentiles, and ranges. *ASHRAE*, American Society of Heating, Refrigerating and Air-Conditioning Engineers; *HEPA*, high-efficiency particulate air; *MERV*, minimum efficiency reporting value.

particle counts of 3,820/ft^3; this corresponds to a 96% reduction of fine and ultrafine airborne particles during the period of observation (Fig 2).

In the pathogen killing study, at least 95% of viable *B subtilis* (biologic warfare anthrax surrogate) cells were killed as judged by their recovery on standard culturing media after 3 hours of exposure to the electrical field in the particle control technology unit (Fig 3).

DISCUSSION

The use of particle control technology in live operating rooms resulted in approximately 95% reduction in airborne fine and ultrafine particles in 2 real-world applications. Further, the application of the particle control electrical field resulted in a 95% inactivation of otherwise viable *B subtilis* vegetative cells within 3 hours of treatment in a laboratory setting.

A strength of this study is that it was conducted in live operating rooms with real patients undergoing actual operations conducted by surgeons, anesthesiologists, and nurses. To ensure clinically relevant results, these works were conducted in 2 distinctly different facilities: a small Midwestern hospital and a large East Coast tertiary-care hospital.

One critique of this work is that the minor differences in operating room volume may have altered particle loads between the baseline and treatment phases of these studies. This is mitigated by the 5 weekday length of each control and intervention period, which served to reduce the impact of surgery case variability between baseline and treatment phases. In these live operating room studies, the number, length, and type of surgical procedures was similar (but not identical) between control and intervention (particle control) periods. It would be impossible to structure such a study with identical patient and procedure characteristics between control and intervention groups.

In some evaluations of ventilation and air purification technologies, highly controlled simulated environments are used to approximate operating room activity.[27] Although these represent sound scientific methodologies, today's clinicians demand real-world practical evaluations of new technology. Simulating clinicians working around the operating table does not give an exact representation of the disruption of airflow and potential for contamination by clinician participants. Nor does it include aerosolized contamination from preparing the patient's incision site or from the incised cavity once opened.

Airborne fine and ultrafine particle counts correlate with airborne contamination and have been used and validated as surrogates for airborne pathogens.[22,23] Successful mitigation of the short- and long-term risks of exposure to indoor airborne pathogens requires new

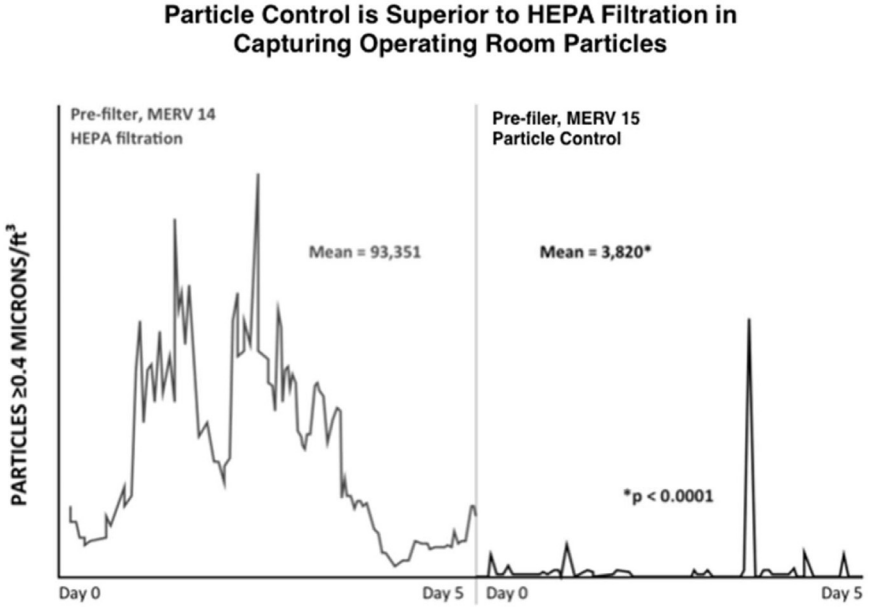

Fig 2. Particle control reduced airborne particles better than standard methods in an academic medical center operating room. The control operating room that was supplied with a prefilter, MERV 14, HEPA filtration, and 16 air changes per hour had mean particle counts of 93,351/ft^3. The operating room with the particle control intervention had a reduction in mean particle counts by 95% to 3,820/ft^3 ($P < .0001$). Data are presented as mean, 25th and 75th percentiles, and ranges. *HEPA*, high-efficiency particulate air; *MERV*, minimum efficiency reporting value.

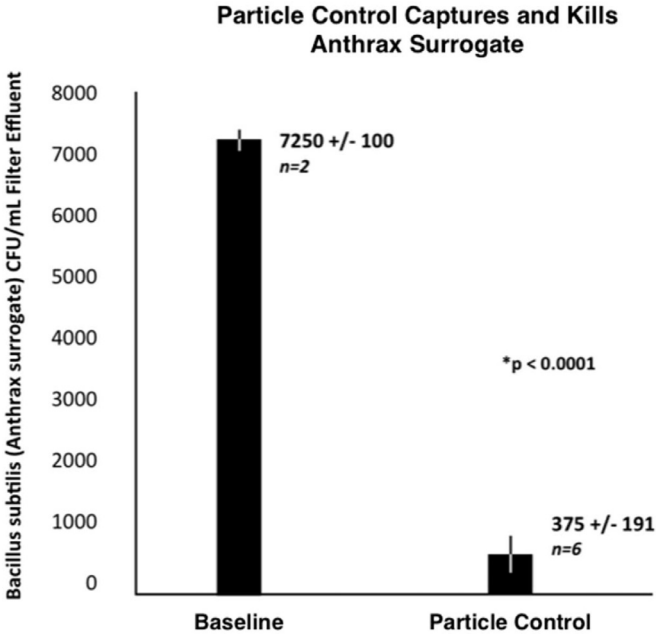

Fig 3. Particle control kills anthrax surrogate. The collector surface was loaded with >100 million viable *Bacillus subtilis* cells at a surface loading density $>10^7$ cells/cm^2. Within 3 hours of exposure, particle control technology killed 95% of the anthrax surrogate *B subtilis* ($P < .0001$). *CFU*, colony-forming units.

sustainable approaches to condition fine and ultrafine particles, such that they can be effectively cleared from the space. Other purification methods that cause a chemical reaction or oxidation are only effective on a small portion of fine and ultrafine particles that are adjacent to their reaction chambers, or can generate dangerous levels of gaseous agents, such as ozone, which compromise safety.

The use of rigorous particle and pathogen monitoring methods to evaluate novel technologies in real-world settings should become standard. Further, it is confounding that rigorous air quality standards applied to industrial cleanrooms have not been applied to health care facilities in general, and to operating rooms and intensive care units specifically.[12]

CONCLUSIONS

The use of particle control technology reduced fine and ultrafine particle counts by 95% in 2 live operating room studies. Furthermore, the particle control technology killed a pathogenic bacterial bioaerosol surrogate in a controlled laboratory study using widely accepted methods. These results demonstrate that the benefits of particle control technology in operating rooms, intensive care units, or other health care settings may be significant. Additional work applying this novel technology to other clinical settings is warranted.

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