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Major Article

Comparison of operating room air distribution systems using the environmental quality indicator method of dynamic simulated surgical procedures

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Back instrument table

Background: Ensuring aseptic airborne environments for sterile fields and back instrument tables in operating rooms (ORs) is crucial to reducing microbial and particle contamination during surgery. Configurations of in-ceiling air delivery mechanisms impact the effectiveness of the system at eliminating contamination in critical zones.

Methods: The environmental quality indicator method was used to assess airborne environments in ORs equipped with a single large diffuser (SLD), a multidiffuser array (MDA), or a 4-way throw diffuser during dynamic, simulated surgical procedures. Environmental quality indicators measured included particles, microbes, carbon dioxide, velocity, humidity, and temperature at 26 air changes per hour.

Results: SLD ORs performed better than MDA ORs and 4-way throw diffuser ORs at removing microbes and carbon dioxide from the sterile field ($P < .05$). SLD ORs had higher velocity and lower temperature over the sterile field than the other 2 ORs ($P < .05$). MDA ORs had lower total particle counts than the other ORs ($P < .05$). The sterile fields in all ORs were cleaner than the respective back instrument tables ($P < .05$).

Conclusions: Air delivery systems that eliminate blockages to uniform airflow directly over sterile zones, such as boom mounts and access panels, and deliver unidirectional, downward flow of clean filtered air provided a cleaner airborne environment within the sterile field. Expansion of air delivery systems to include areas outside the sterile field, where other surgical aides reside, may further reduce contamination within critical zones.

Operating room (OR) heating, ventilation, and air conditioning (HVAC) design and operation aim to provide comfortable and safe working environments for staff and patients. One aspect of safety is protection from airborne contaminants with the potential to cause surgical site infections (SSIs). These contaminants can come from the environment or the people in the space and can land on surgical instruments, the patient, or staff, resulting in increased potential to enter open surgical sites and lead to infection.[1,2] Properly controlled temperature, pressure, relative humidity, and airflow distribution are multifaceted challenges of OR design, engineering, and operation. When the HVAC maintains proper conditions, it assists with asepsis and can create multiple sterile zones in which the patient and instrumentation reside.[3] To this end, cleanrooms for the pharmaceutical and semiconductor industry have standards coupled with rigorous testing and strictly enforced compliance requirements per United States Pharmacopeia Standard 797[4] and the International Organization for Standardization Standard 14644-1,[5] to ensure appropriate levels of air cleanliness, which have virtually eliminated particle contamination and vastly improved product yields[6] ORs, however, do not have a commensurate level standard for air cleanliness. The current guidelines for airflow distribution in ORs, defined by American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 170-2017,[7] specify air exchange rates, velocity, pressurization, relative humidity, temperature, and filter specifications. In addition, these guidelines suggest minimum ceiling diffuser coverage directly above

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the sterile field, with maximum 30% for non–air delivery devices (ie, boom mounts, access panels, or space between diffusers).

Some aspects of cleanroom design may enhance performance of an OR. These include eliminating blockages to airflow by moving booms to the perimeter of the supply array, placing diffusers close together to minimize non–air delivery space, and ultimately creating an uninterrupted, unidirectional, seamless flow of air over the sterile field from a ceiling-mounted, contiguous air distribution system. Eliminating blockages to the airflow in combination with providing directed air exit paths through several low-wall air-return grilles also guide the airflow and eliminate turbulence in the space. Effectively controlling the downward flow of air over the critical zones within the room reduces the potential for entrainment of contaminants from nonsterile areas into the critical spaces encompassing the patient and surgical instrumentation.[8]

Cleanroom design concepts also provide an environment for the instrumentation that is equally aseptic as the product itself. Extrapolating this concept to ORs includes providing the instrument tables, Mayo stands, or locations where implants are staged, outside the sterile surgical field, with an equally clean environment, and may require further expansion of the diffuser or array of diffusers or adding diffusers dedicated to critical spaces outside the realm of the patient.

To further explore the applicability of cleanroom design, we compared the performance of 3 different, fully functional, currently used operating theaters with respect to their environmental quality indicators (EQIs) during dynamic, simulated surgical procedures.[9] The OR configured to incorporate cleanroom air delivery concepts, commonly referred to as a single large diffuser (SLD), was compared with an OR configured with a more conventional multidiffuser array (MDA). Both newer ORs were compared with an older OR configured with 4-way throw diffusers (4TDs). The EQIs included temperature, humidity, air velocity, room pressurization, air change rates, endogenous particle and microbial counts, and carbon dioxide (CO_2).

We hypothesized that the OR with the SLD would (1) perform better than the MDA OR and the 4TD OR at removing both microbes and particles from the OR; (2) provide a more consistent air velocity over the sterile field; (3) more effectively clear the controlled contaminant from the sterile field; and (4) provide a cleaner environment at the instrument table.

METHODS

OR setup and air delivery methods

The 4TD room was constructed in 1992. The SLD and MDA rooms were newly constructed and opened for surgery in October 2017.

The 4TD OR was 44.3 m^2 in dimension, 6.9 Pa positive to the anesthetic bay, and high-efficiency particulate air filtered with 4 4TDs in the ceiling and 2 low-wall returns. Diffusers were 0.109 m^2 each. The 4TD room did not have air distribution over the surgical table/sterile field as per ASHRAE 170, although it did have placement of the supply diffusers outside the sterile field directly over the back instrument table (Fig 1A). SLD and MDA rooms were identical with respect to construction materials, HVAC units, 55 m^2, 26 air changes per hour (ACH), pressurization (minimum 10 Pa), high-efficiency particulate air filtration, return grille placement (4 low-wall), and equipment placement. The 2 ORs differed only in the air delivery method. MDA was an array of 6 diffusers, each 1,170 mm x 575 mm, in the ceiling separated by non–air delivery hard ceiling surfaces with booms mounted between the diffusers (Fig 1B). SLD was 9 diffusers placed immediately adjacent to each other with a 2,350 mm x 2,950 mm total dimension, in which blockages to airflow from boom mounts and gaps between diffusers had been eliminated (Fig 1C). All 3 ORs were designed to operate at 26 ACH. Twenty ACH is the current OR minimum per ASHRAE Standard 170. The EQI study took place in Australia in January 2018.

Study design

The EQI method was used to compare the 3 OR air delivery configurations with respect to air velocity, temperature, pressurization, airborne microbial load, CO_2 levels, and airborne particles within the sterile field and outside the sterile zone at the back instrument table. The 1-hour-long scripted surgical procedure, which included realistic movement of the surgical team within the OR, door opening and closing, and staff entering and exiting, was repeated 3 times in each of the 3 ORs, for a total of 9 tests (N = 3 each, for a total of N = 9), as further described in Gormley et al.[9] The order of rooms tested was randomized prior to beginning the study.

Personnel and simulated surgical procedure

The team consisted of a surgeon, a microbiologist, 2 engineers (1 specializing in hospital HVAC, the other a specialist in indoor environments), and an industrial hygienist. These 5 people, in addition to 4 surgical nurses and a script timekeeper, performed 1-hour-long simulated surgical procedures as previously described.[9] Study personnel wore standard hospital-issued scrub attire, head covers, surgical masks, and shoe covers and scrubbed for the procedure as per standard procedures.

To provide consistent execution of the simulated procedure and to ensure an unbiased and repeatable experiment, a detailed, timed process was developed and displayed on computer monitors within the ORs. This "script" defined the physical actions (including passing instruments, entering/leaving the room, and the use of surgical diathermy on an uncooked steak to generate particulate tissue matter[9]) for each team member to perform in 4-minute increments to simulate actual OR conditions.

Environmental quality indicators

Assessment of EQIs was performed as described previously.[9] Air velocity, temperature, and relative humidity measurements at key locations in the rooms were measured using calibrated meters (Model 9565; TSI Velocicalc) every 2 minutes during 1-hour mock procedures at the surgical table (sterile field, N = 90 data points per air delivery method), and at the instrument table (back table, N = 90 data points per procedure), and recorded in meters per second. Relative humidity was not a variable tested in these experiments but was maintained between 52% and 56%.

Microbial contamination was actively measured with Bioscience viable surface air samplers (SAS180) placed in the sterile field and at the instrument table. Air samplers acquired 1,000 L of ambient air over 5.5 minutes onto Petri plates with Trypic Soy Agar + 5% sheep blood. The plates were changed in regular cycles to collect bacteria during the scripted procedure (N = 48 agar plates assessed at the sterile field and instrument table for each procedure). The samples were sent under chain of custody to Eurofins, New South Wales, Australia.

CO_2 was released as a controlled contaminant at a known rate of 10 L per minute just outside the head of the surgical table (point of release) and measured just inside the sterile field at the foot of the surgical table (point of detection). The levels of the point of release and the point of detection were measured using calibrated meters (Model 7565; TSI Q Track, TSI Incorporated, Shoreview, MN). The amount of CO_2 that was released and reached the sensor at the opposite side of the surgical table was measured in parts per million (ppm). Release of CO_2 was continuous throughout the procedure at the point of release, and point of detection levels were recorded every 2 minutes (30 times per procedure).

Particle contamination was measured using calibrated counters (Model 9500; TSI Aerotrack, TSI Incorporated) at a rate of 100 L per minute. International Organization for Standardization Standard

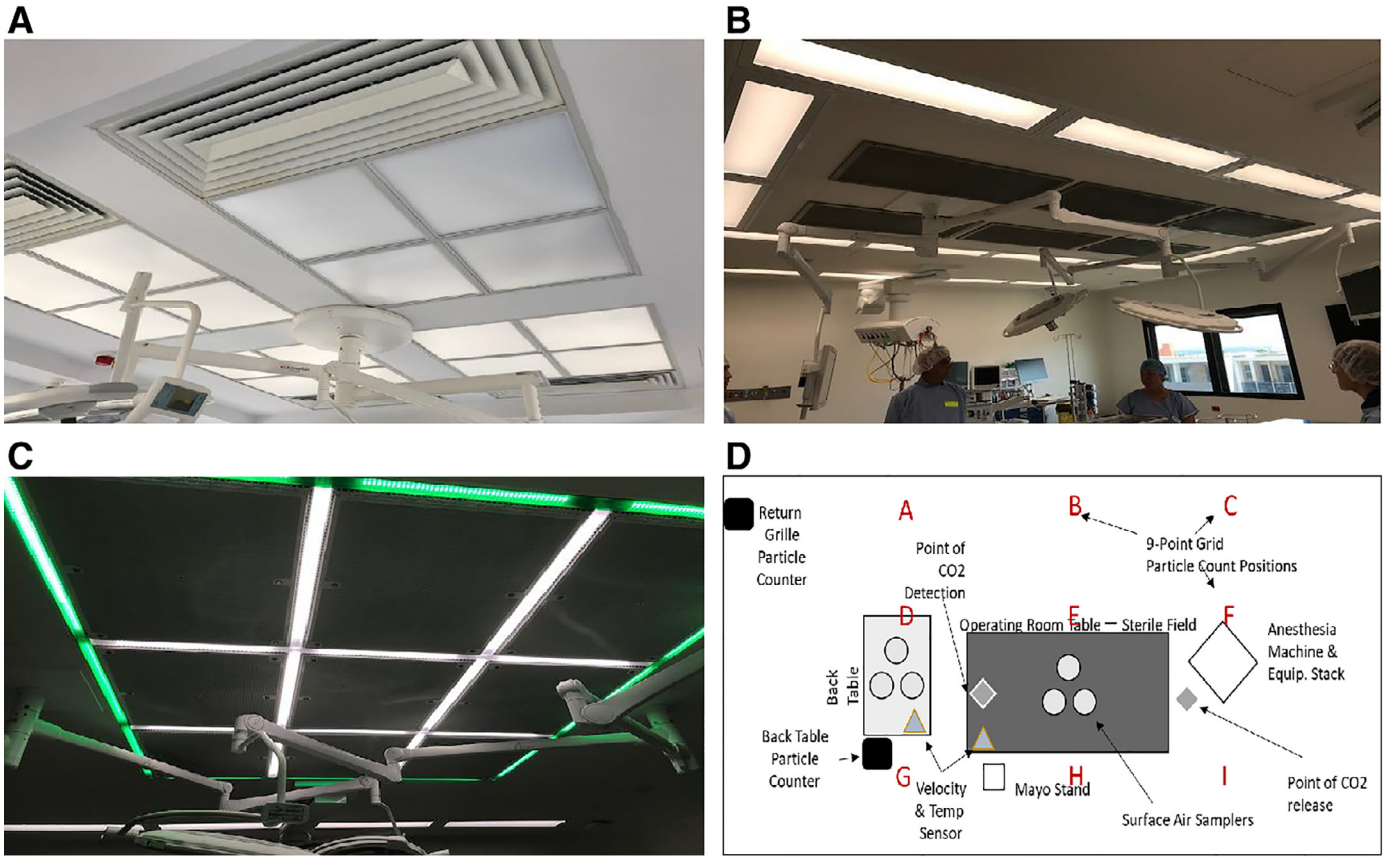

Fig 1. Images of the 3 air delivery designs and OR testing layout. A 4-way throw diffuser (A), multidiffuser array (B), single large diffuser (C) layout during testing. Locations of OR equipment, including surgical table, back instrument table, Mayo stand, anesthesia, and sterile field perimeter. Locations of sampling equipment, microbial and particle samplers, velocity and temperature sensors, and CO_2 release and detection meters. CO_2, carbon dioxide; OR, operating room.

14644-1 was used to measure room particulate levels in a 9-point grid throughout the room. This resulted in 3 complete passes through the grid during the 1-hour procedure. Particle sizes recorded were 0.5, 1.0, 5.0, and 10.0 microns in particles per cubic meter (particles/m^3, N = 27 data points for each particle size per procedure). There were also 2 stationary particle counters, 1 dedicated to the return air grille and 1 dedicated to the back table (N = 30 data points for each particle size per procedure at the return and back table).

Statistics

Statistical analysis was performed with GraphPad Prism 7 (GraphPad Software, La Jolla, CA). Data were assessed for normalcy with Shapiro-Wilk and Kolmogorov-Smirnov tests. Data were determined to be nonparametric and therefore were reported as the median with interquartile range (IQR). Data were compared with the Mann-Whitney U test, and $P < .05$ was considered significant. Three-wise group comparison was performed with the Mann-Whitney U test with Bonferroni correction, and $P < .0167$ was considered significant.

RESULTS

Airborne microbial assessment

The sterile field (4TD = 39 colony-forming units [CFU]/m^3 [IQR] = 9.75), SLD = 3 CFU/m^3 [IQR = 3.00], and MDA = 15.5 CFU/m^3 [IQR = 10.50]) had fewer microbes than the respective back table (4TD = 43 CFU/m^3 [IQR = 22.25], SLD = 48 CFU/m^3 [IQR = 21.00], and MDA = 50 CFU/m^3 [IQR = 24.00]) in all 3 rooms ($P < .05$). Both ORs with SLD and MDA had fewer microbes in the sterile field than the 4TD OR ($P < .0167$), and SLD had fewer microbes in the sterile field than MDA ($P < .05$), but no difference was noted in groups at the back table (Fig 2).

Air velocity

The air velocity in ORs with SLD and MDA was higher at the sterile field (SLD = 0.18 m/s [IQR = 0.10] and MDA = 0.14 m/s [IQR = 0.09]) than at the respective back tables (SLD = 0.08 m/s [IQR = 0.04] and MDA = 0.07 m/s [IQR = 0.04]) ($P < .05$). Conversely, in the 4TD OR, the velocity was lower in the sterile field (0.04 m/s [IQR = 0.02] than at the back table (0.07 m/s [IQR = 0.03]) ($P < .05$). Within the sterile field, both SLD and MDA had higher velocities than 4TD ($P < .0167$), whereas SLD maintained a higher velocity than MDA ($P < .05$). At the back table, SLD had higher velocity than 4TD ($P < .0167$), but no statistical difference was observed in velocities between ORs with SLD and MDA (Fig 3).

Airborne CO_2 controlled contaminant

The OR with the SLD (90 ppm [IQR = 69.00]) performed better at preventing the controlled contaminant, CO_2, from reaching the detection point than either MDA (157 ppm [IQR = 207.5]) or 4TD (247 ppm [IQR = 345.50]) ($P < .0167$), whereas MDA performed better than 4TD ($P < .0167$) (Fig 4).

Temperature

For ORs with SLD and MDA, the temperature was significantly lower in the sterile field (SLD = 16°C [IQR = 0.45] and MDA = 17°C

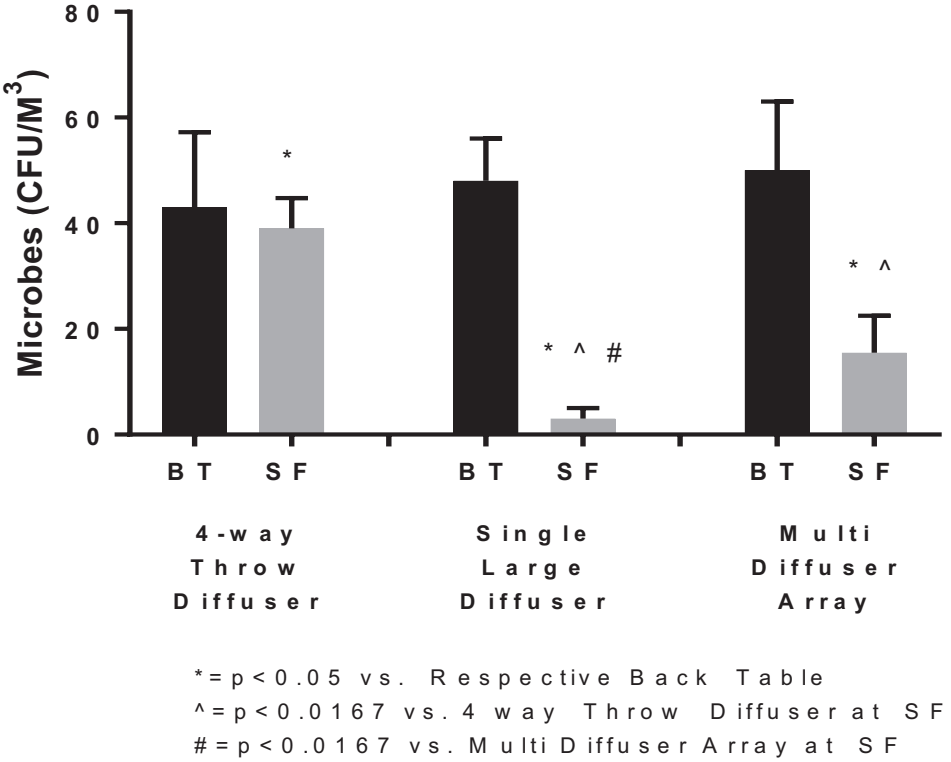

Fig 2. Microbial CFUs per cubic meter comparison between a single large diffuser, multidiffuser array, and 4-way throw diffuser, and between BTs and SFs in all 3 rooms. *BT*, back table; *CFU*, colony-forming unit; *SF*, sterile field.

[IQR = 0.25]) than at the respective back instrument tables (SLD = 17.7°C [IQR = 0.30] and MDA = 18°C [IQR = 0.40]) ($P < .05$). For the 4TD OR, no difference in temperature was observed between the sterile field (20.3°C [IQR = 0.35] and back table (20.4°C [IQR = 0.3]). The temperature in SLD was significantly lower than in MDA and 4TD, both in the sterile field ($P < .0167$) and at the back table ($P < .0167$). The temperature in MDA was lower than in 4TD both in the sterile field ($P < .0167$) and at the back table ($P < .0167$).

Airborne particles

Particle counts for the 9-point grid (0.5, 1.0, 5.0, and 10.0 microns) were lower in the MDA room than in either SLD or 4TD ($P < .0167$), whereas SLD had lower particle counts than 4TD ($P < .0167$) (Table 1). Particle counts at the return grille in SLD were higher than either MDA or 4TD for 5.0 and 10.0 micron-size particles but not for 0.5 and 1.0 micron-size particles ($P < .0167$). SLD had higher 5.0 and 10.0 micron-size particle counts than MDA ($P < .05$). Particle counts at the back table in 4TD were higher than both MDA and SLD for all particle sizes, and SLD was higher than MDA for 0.5, 5.0, and 10.0 micron-size particles but not for 1.0 micron-size particles ($P < .0167$).

DISCUSSION

The emission of squames and other particles into the OR air can come from inside or outside the sterile field, including the surgical staff and support staff, patient, improperly sterilized equipment, nonsterile locations beneath and around the surgical table, and many others. The air currents in the room can move the squames and associated bacteria from one location to another; therefore, proper ventilation in the OR is essential. The OR ventilation can be used to direct these potential contaminants away from the sterile field and out of the room. However, many factors impact the effectiveness of the OR ventilation in contamination control, including temperature, humidity, air velocity, air change rates, blockages to airflow, and locations of supply and exhaust vents.[3] Based on the literature, the ASHRAE 170-2013 guidelines for design and function of the OR recommend unidirectional, downward airflow from the ceiling that is vented out several low-wall exhaust vents. These guidelines also specify the use of minimum efficiency reporting value 7 in filter bank 1 and minimum efficiency reporting value 14 in filter bank 2 to deliver clean air at a specified face velocity (25-35 feet per minute [fpm]), number of ACH (20-25 ACH with 3-4 outside), humidity (30%-60%), and temperature ranges (68°F to 75°F), as well as room dimensions ($20 \times 20 \times 10$), ceiling grid coverage (12%-16%), and pressure maintenance (+0.01).[7] ASHRAE guidelines also recommend laminar airflow if indicated by surgical staff, which is somewhat controversial in the literature,[3,10-17] pointing to the need to consider all design and operational aspects of the OR. Achieving laminarity in an OR is difficult due to the presence of obstructions to the air currents, and unidirectional downward airflow may be a more accurate description of the operational airflow typically achieved.[18,19] Furthermore, increased ACH rates tend to clear contaminants from the room quickly but may not prevent them from settling on surfaces, and increased velocity above 35 fpm may increase turbulence. In summary, the literature primarily agrees that unidirectional downward airflow at approximately 30 fpm from filtered vents with 90%-95% efficiency at 0.3 microns in the ceiling with low-wall returns and an air exchange rate of 20 ACH is industry standard as long as positive pressure, relative humidity, and temperature are maintained in recommended ranges.

It has been suggested that the cleanroom air delivery configuration of an SLD, which eliminates the blockages to airflow by placing diffusers immediately adjacent to each other and boom mounts on the periphery of the supply, will decrease the turbulence of air currents, provide better unidirectional downward flow of clean air, and ultimately result in fewer particles and microbes in field(s) of

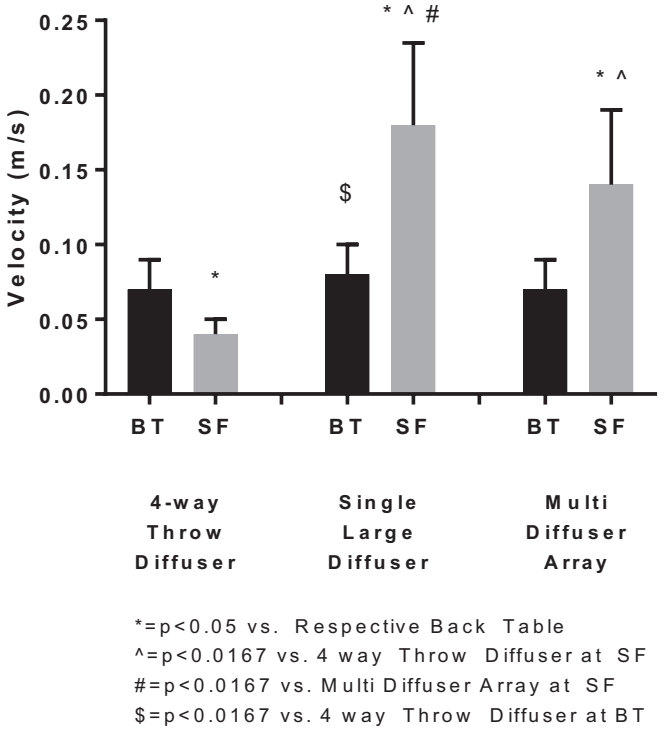

Fig 3. Velocity in meters per second comparisons between a single large diffuser, multidiffuser array, and 4-way throw diffuser and between the back table and the sterile field in all 3 rooms. *BT*, back table; *SF*, sterile field.

interest.[20] The successful employment of this concept in combination with other measures, including air filtration over areas of instrumentation, has enabled the semiconductor and pharmaceutical industries to achieve ultraclean environments.[21] As discussed earlier, reduction of OR contamination to cleanroom levels is likely unnecessary and impractical. However, improvement of OR airborne environments

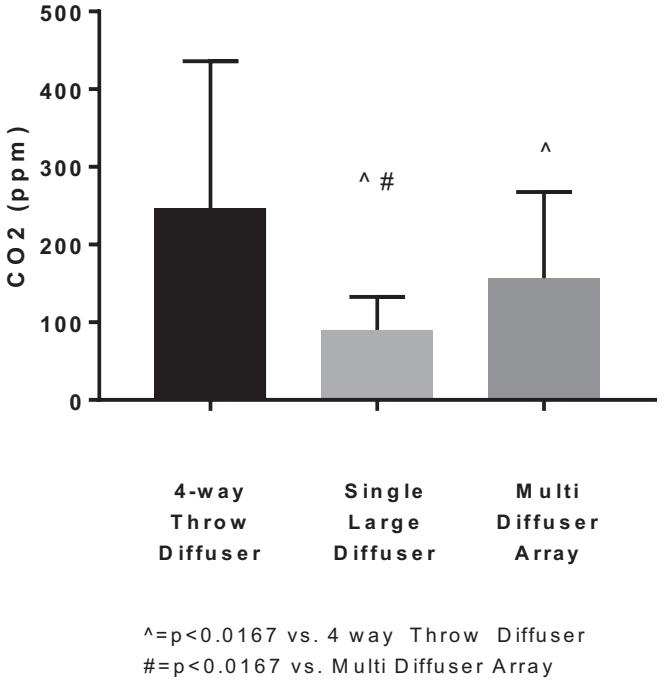

Fig 4. CO_2 in parts per million comparison between a single large diffuser, multidiffuser array, and 4-way throw diffuser. CO_2, carbon dioxide.

Table 1
Nine-point grid particle counts for an SLD, an MDA, and a 4TD at 26 air changes per hour

Particle size (μm)	4TD	SLD	MDA	*P* 4TD vs SLD	*P* 4TD vs MDA	*P* SLD vs MDA
0.5 μm, median	321,590	337,380	155,980	.805	.004	.023
IQR	709,567	802,962	247,085			
1.0 μm, median	89,380	81,015	64,160	.360	.001	.064
IQR	145,213	151,540	51,693			
5.0 μm, median	7,975	8,875	6,975	.444	.004	.017
IQR	2,835	4,353	3,463			
10.0 μm, median	3,470	3,735	2,940	.618	.040	.088
IQR	1,320	2,085	1,883			

4TD, 4-way throw diffuser; *IQR*, interquartile range; *MDA*, multidiffuser array; *SLD*, single large diffuser.

with respect to microbes and particles that transport microbes may reduce incidence of wound contamination. It is currently difficult, owing to many confounding factors, to directly connect the airborne environment to SSIs.[1] However, it is generally accepted that airborne contaminates contribute to increased rates of SSI.[22-26] These data suggest that the air as a transmission mode for microbes cannot be ruled out, and due diligence to better understand, build, and operate ORs is essential.

In this study, we compared the performance of ORs equipped with an SLD, an MDA, and 4TDs in functional ORs during dynamic, simulated surgical procedures in their ability to effectively provide clean airborne environments with respect to microbial and particle contamination. We also compared their abilities to maintain proper air velocities and to clear a controlled contaminant from the surgical field. Based on the data presented above, with respect to removing microbes and CO_2 from the sterile field, the SLD performed better than both the MDA and 4TD, and the MDA OR performed better than the 4TD OR. The air velocity was higher and the temperature lower in the sterile field in ORs with SLD and MDA than in those with 4TD. These results reflect the configuration of the air delivery mechanisms, with maximized concentration of unidirectional, downward airflow providing higher velocity over the sterile field and a cleaner airborne environment within the sterile field.

Outside the sterile field at the back instrument table, both SLD and MDA had significantly higher microbial counts than their respective sterile fields; however, no difference was observed in the bacterial loads when MDA was compared with SLD. SLD and MDA rooms had lower microbial loads than the 4TD room. Both SLD and MDA were configured to have concentrated air delivery over the sterile field; however, neither system had airflow dedicated to the back table. Therefore, the velocities were lower and microbial counts higher for both systems outside the sterile field, with no significant difference observed between the systems. This phenomenon further defines the necessity for air delivery over the areas of instrument setup and suggests that expanding the footprint of both systems would aid in protecting instrument setup points from potential contamination. Considering that the 2 ORs performed equally outside the sterile field, these results also suggest that the concept of the SLD, with minimization of non–air delivery hard-lid surface and perimeter placement of boom mounts, is superior to that of an MDA within the sterile field.

Furthermore, the inherent variability in designs of the multidiffuser array may result in unpredictable performance; therefore, an SLD-type configuration provides the added benefit of consistency in design and performance.

With respect to the 9-point grid particle counts outside the sterile field, MDA provided a cleaner environment than SLD or 4TD. SLD

provided cleaner air than 4TD. These data suggest that the configuration of SLD is more effective at moving particles from the sterile field into the remainder of the room. These particles would then be detected in higher numbers outside the perimeter of the sterile field in SLD than in MDA or 4TD. Additionally, SLD had higher particle counts at the return grille than either MDA or 4TD. These results suggest that the SLD OR was more effective at directing the particles and moving them to the return grille and ultimately out of the OR. Lastly, these results suggest that the current guidelines provide better performance than older guidelines, and that the reduction of variability within OR design inherent to the SLD could further improve room contaminant reduction in critical zones.

LIMITATIONS

Hospital ORs used in this study were chosen by the hospital, not the EQI team, and were based on case load and availability. Specific limitations included the inability to equally balance return air grilles, relocate room medical equipment and surgical table locations for more optimal air delivery, and minimize OR door open/close times, since they were automatically controlled and set to a 30-second hold open time. All studies were conducted at a single hospital site (repeating the testing at additional hospital sites would be ideal), and the team members were not blinded nor were they were unaware of the study being conducted.

Although SLD demonstrated superior performance within the sterile field in this study, it must be noted that the MDA was configured with 6 diffusers in 2 lines of 3 each, separated by a longitudinal hard surface with light booms mounted directly above the surgical table. Therefore, an air delivery configuration that places diffusers adjacent to each other, removes non–air delivery hard surfaces, and places the boom mounts outside of the array is likely to perform better than the array tested in this study.

CONCLUSION

Air delivery systems that minimize or eliminate non–air delivery hard surfaces in the ceiling, place boom mounts at the periphery, and deliver unidirectional, downward flow of clean filtered air directed away from the sterile field toward low-wall return grilles provide a cleaner airborne environment within the sterile field. OR air delivery systems that cannot be designed in numerous configurations based on independent interpretation of the current guidelines may improve consistency in design and functionality and provide a more effective manner to control and remove airborne contaminants from patients and staff at the sterile field. Additionally, expansion of air delivery systems to include areas outside the sterile field, where surgical instruments, implants, and other sterile items reside, may further reduce contamination and subsequent SSI risk within critical zones required to support surgical procedures in the operating theater.

Acknowledgments

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