EQI Method to Compare Air Delivery Methods in Two Functional ORs During Dynamic Simulated Surgical Procedures

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Operating room (OR) HVAC design and operation are aimed to help keep patients safe. One aspect of safety is protection from airborne contaminants that have the potential to cause surgical site infections. These airborne contaminants can land on surgical instruments, the patient or the staff resulting in the increased potential for them to enter the open surgical site and become an infection (1,2). Proper ventilation of the operating room is a multifaceted challenge of OR design and engineering. The role of the HVAC system is to maintain proper air velocity, air flow patterns, humidity, temperature and pressure relationships, as well as assisting with asepsis and creation of a sterile zone in which the patient resides. To this end, cleanrooms for pharmaceutical compounding and microchip manufacturing have historically defined protocols for testing and data interpretation, USP 797 and ISO 14644, to ensure appropriate levels of air cleanliness, measured in either particles or microbes, that range from zero to hundreds of thousands depending on the intended application of the room.

The interdisciplinary OnSite EQi Team developed, tested and implemented protocols to measure quantifiable Environmental Quality Indicators (EQIs) in a dynamic operating room environment (3). The process employs proven techniques and benchmarks used in pharmaceutical and semiconductor industries to assess the airborne environment. This simulated surgical procedure has been successfully implemented to better understand the OR environment during different air change rates (4), with different surgical attire (5,6), and with different methods of surgical instrument table covers (7).

In this study, the OnSite team employed the EQI method to compare two OR air delivery concepts with respect to airborne particles, microbial loads, air velocity, temperature and CO_2 levels, within the sterile field and outside the sterile zone at the instrument table. The two ORs were identical with respect to construction materials, HVAC units, dimensions (55 M^2), air change rates (26ACH), pressurization (min. 10 pa), HEPA filtration, return grille placement (4 low wall), surgical table and equipment placement. Both ORs had been actively used for surgery for approximately three months prior to testing. The two ORs differed only in the air delivery method. OR A was constructed as a 9 diffuser, contiguous ceiling air distribution system, a concept based on semiconductor clean room technology, in which blockages to air flow from boom mounts and gaps between filters, had been minimized (figure 1). OR B was constructed as a conventional array of multiple diffusers in the ceiling separated by non-air delivery hard ceiling surfaces with booms mounted between the diffusers (figure 2). OR B had 6 diffusers and the longitudinal axis of the array was perpendicular to the longitudinal axis of the surgical table. The EQI study took place in January 2018 in Sydney, Australia.

This study revealed a statistically significant reduction in microbial CFUs within the sterile field in OR A as compared to OR B. In both OR A and OR B, there were significantly fewer CFUs in the sterile field than at the instrument table. However, there was no difference in CFUs between OR A and B outside the sterile field at the instrument table. The velocity of delivered air was significantly greater within the sterile field in OR A as compared to OR B. In both OR A and OR B, the velocity in the sterile field was significantly higher than at the respective instrument table outside the sterile field. Significance was met at $P<0.05$. The higher contamination level and lower velocity outside the sterile zone on the instrument table suggest the need for additional design and engineering innovation to improve the air quality in the location of sterile instruments as they are a potential source of contamination of the surgical site.

Based on this study, the employment of the contiguous ceiling air distribution concept resulted in a significantly cleaner airborne environment within the sterile field, on the surgical table, as compared to the array of diffusers in the ceiling. This may suggest that not only does a contiguously constructed diffuser display superior performance at increasing velocity and removing microbes, it also eliminates the inherent variability in layout of individual diffusers within the ceiling array. This inherent variability associated with implementation of a multi diffuser array may negatively affect the performance of the system resulting in wide variations in environmental quality, and difficulty managing air flow patterns and reducing turbulence. Therefore, this study and previously published literature (3,4,7) suggest that a performance based, as opposed to a design based, standard for ORs may be appropriate.

Figure 1 – OR A Contiguous Diffuser

Figure 2 – OR B Multiple Diffusers

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