Validation of a Temperature Controlled Airflow Ventilation System

BY JENNIFER WAGNER, PH.D.; KATHY WARYE; DAMON GREELEY, P.E., MEMBER ASHRAE

Temperature controlled airflow (TcAF) has become widely accepted as best practice for reduction of contamination both inside and outside the sterile field and at the periphery of the operating room. TcAF aims to control airborne microbiological contamination by using temperature gradients to provide cool air over the sterile field and warmer air outside the sterile field. The objective of the study described in this article was to use a U.S. published methodology of studying the airborne contamination in an operating room (OR) during dynamic simulated conditions and during live surgeries[1] to validate the aseptic efficacy of a temperature controlled airflow (TcAF) system.

Background

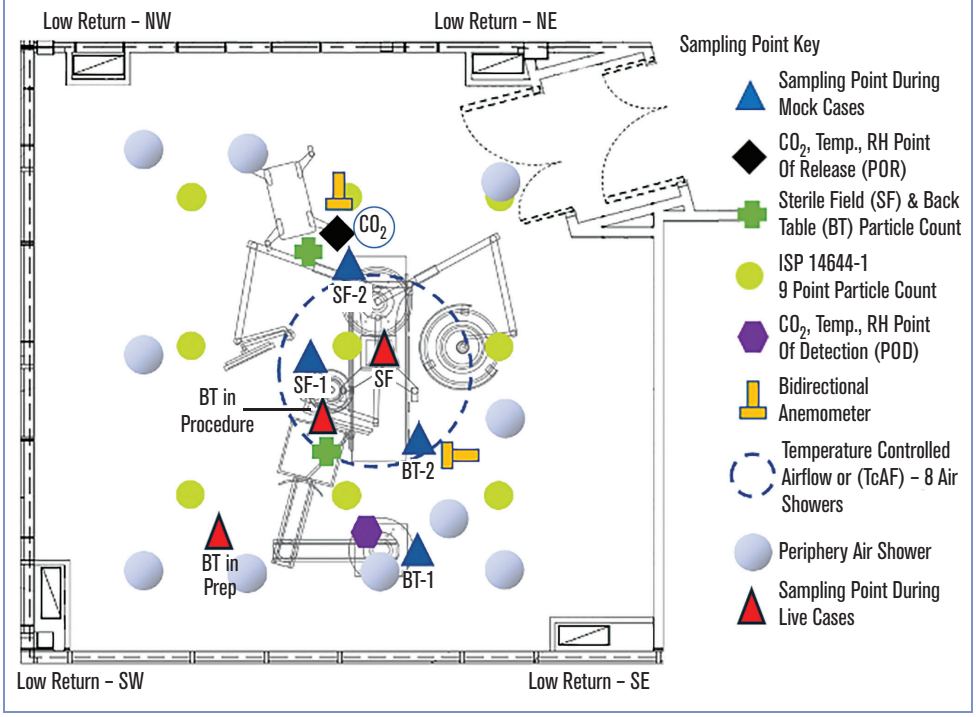
Temperature Controlled Airflow (TcAF)

In the U.S., the general modern concept of OR air delivery requires supply air from the ceiling to flow down over the surgical field, essentially bathing the patient in clean, filtered air and washing the contaminants away from the surgical team and patient to the perimeter of the room, and out low wall returns. These systems rely on supplying the air at a certain velocity and maintaining a forced air speed until it reaches the sterile field. Most of these systems do not address the perimeter of the room, and we have found consistently that the air in the periphery is dirtier than the air within the sterile field.[2–5] In Europe, TcAF has become widely accepted as best practice for reduction of contamination both inside the sterile field and at the periphery of the room. TcAF aims to control airborne microbiological contamination by using temperature gradients to provide cool air over the sterile field and warmer air outside the sterile field. The temperature

Jennifer Wagner, Ph.D., is microbiologist and managing partner and Damon Greeley is managing partner at Onsite LLC. Kathy Warye is infection preventionist and owner of Infection Prevention Partners.

differential is typically 1.5°C – 3°C (2.7°F – 5.4°F) cooler. The cooler supplied air falls from the delivery device in the ceiling faster toward the surgical table, assisted by gravity, and reaches its maximum velocity at the breathing zone of the OR staff, effectively washing contamination away from the sterile field and into the periphery of the OR. Then the downward flow of warmer air outside the sterile field assists with the suppression of re-entrained contamination and the exit of the air out the low wall returns.[6] This technology was installed in several locations on the eastern coast of the United States in 2023.

FIGURE 1 Locations of instruments to measure EQI in the scripted mock procedures.



Microbiological Standards for ORs in U.S.

In the U.S., there are no microbiological standards for operating rooms, and most ORs are tested during static conditions when no people are present. Guidelines for ORs are prescriptive design guidance as opposed to performance based. For example, ASHRAE Standard 170-2017 prescribes that an OR should have a minimum air change rate of 20 air changes per hour (ach), no more than 30% non-air delivery over the sterile field and the sterile field should extend a minimum of 12 in. (305 mm) beyond the footprint of the surgical table, among other prescribed parameters.[7]

In Europe there are performance-based standards, meaning how the room performs when being used: the German standard specifies particle counts (3,500 particles/m^3),[8] and the British standard specifies microbial counts (10 colony forming units per cubic meter [CFU/m^3] in unidirectional airflow or 180 CFU/m^3 in turbulent airflow)[9] that measure the performance of the OR during live surgical cases. Europe also defines ultraclean ORs as those with fewer than 10 CFU/m^3 both inside the sterile field and outside the sterile field in the perimeter of the OR.[10–12]

Study Purpose

In this study, investigators sought to validate the efficacy of maintaining an aseptic environment using a TcAF system under routine conditions during mock procedures and live surgical cases. The environmental quality indicator (EQI) method was used to assess the in-room airborne environment during dynamic, simulated, scripted surgical procedures and in two live cases, one total hip arthroplasty and one total knee arthroplasty. EQIs measured included particle and microbial counts, controlled contaminant (carbon dioxide) quantification, velocity, humidity and temperature at 41.3 air changes per hour (ach). Maximum and median concentration of microorganisms (CFU/m^3) were reported at the sterile field, back instrument table(s) and in the room's periphery.

Materials and Methods

OR Setup and Air Delivery Methods

The airflow inside the TcAF footprint was 2829 m^3/h (1,665 cfm), and the airflow external to the TcAF footprint was 2876 m^3/h (1,693 cfm) for a total airflow of 5705 m^3/h (3,358 cfm). The operating room had a net floor area of 46 m^2 (495 ft^2) and a floor to ceiling height

of 3 m (10 ft) for total net volume of 138 m^3 (4,873 ft^3). The resulting air change rate was 41.3 air changes per hour (ach). The room was positive to an airlock space and to the common restricted access hallways. The air diffusers were half spherical and constructed of an antimicrobial polymer material. There were eight diffusers that formed the TcAF footprint with a diameter of 1940 mm (6.4 ft) and 10 diffusers outside the footprint in the room periphery (*Figure 1*).

The airflow resulting in coverage over the operative field would be ASHRAE Standard 170 compliant; however, the configuration is not currently defined in U.S. guidelines. This system is approved by local governing authorities in Europe for installation and use.

Study Configuration

The published EQI method was used to study a TcAF system in one regularly used OR with respect to air velocity, temperature, pressurization, airborne microbial load, CO_2 levels and airborne particles and microbes within the sterile field and outside the sterile zone at the back instrument table and in the periphery of the room.[1] The one-hour long scripted surgical procedure was repeated three times in the operating room for a total of three tests (N = 3). The EQI method was used to compare airborne microbial load only in two surgical cases for a total of two tests (N = 2).

Scripted Mock Procedures

The team consisted of seven individuals: four surgical nurses, an anesthesiologist, a microbiologist and a health-care ventilation engineer. Study personnel wore standard hospital-issued scrub attire, head covers, gowns (for the operative field or scrub team), surgical masks and shoe covers, and they were scrubbed for the procedure 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 operating rooms. 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) for each team member to perform in four-minute increments to simulate actual operating room conditions.[1]

Live Surgical Cases

The team consisted of six individuals: four surgical nurses, a microbiologist and an anesthesiologist. Study personnel dressed and scrubbed as described above.

Environmental Quality Indicators—Mock Procedures

Assessment of EQIs was performed as previously described (*Figure 1*).[1] Microbial contamination was actively measured with slit air samplers connected to sterile tubing placed near the wound site, back instrument table and the periphery of the room (*Figure 1*). Air samplers acquired 1000 L (35 ft^3) of ambient air over 10 minutes onto Petri plates with tryptic soy agar 5% sheep blood. The plates were changed in regular cycles to collect bacteria during the three scripted mock procedures (N = 72 agar plates). The samples were sent under chain of custody to a microbiology laboratory and incubated at 35°C (95°F) constant temperature.

Environmental Quality Indicators—Live Cases

Assessment of EQIs was performed as previously described (*Figure 1*). Microbial contamination was actively measured with slit air samplers placed near the near head and center of the operative field, the instrument table and the periphery of the room. (*Figure 1*). Air samplers acquired 1000 L (35 ft^3) of ambient air over 10 minutes onto Petri plates with tryptic soy agar 5% sheep blood. The plates were changed in regular cycles to collect bacteria during the three scripted mock procedures (N = 33 agar plates). The samples were sent under chain of custody to an independent microbiology laboratory.

Three-Dimensional Room Mapping and EQI—Calibrated Ultrasonic Anemometers

Air velocity, temperature and relative humidity (RH) measurements at key locations in the rooms were measured using calibrated ultrasonic anemometers every two minutes during one-hour mock procedures at the surgical table (sterile field [SF], N = 90 data points per air delivery method) and at the instrument table (back table [BT], N = 90 data points per procedure) and recorded in meters per second, degrees Celsius and RH, which were maintained between 20°C–21°C (68°F–70°F) and 45%–48%, respectively.

Controlled Contaminant—Carbon Dioxide

Carbon dioxide (CO_2) was released as a controlled contaminant at an approximate rate of 10 L/m (0.35 cfm) just outside the head of the surgical table (point of release [POR]) and measured just inside the sterile field at the foot of the surgical table [point of detection or POD]). The levels of the POR and the POD were measured using calibrated meters (CO_2 detector; temperature and relative humidity CO_2 meter; CO_2 monitor; NDIR channel sensor, 0 ppm–5,000 ppm range). 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 mock procedure and POR and POD levels were recorded every two minutes (30 times per procedure).

Particle Counting—ISO 14644-1 Classification

ISO 14644-1 was used to measure room particulate levels in a nine-point grid throughout the room. This resulted in three complete passes through the grid during the one-hour procedure. Particle sizes recorded were 0.5, 1.0, 5.0 and 10.0 microns in particles/m^3, N = 108 data points for each particle size per procedure. There were also two stationary particle counters, one dedicated to the sterile field and one to the back table (N = 108 data points for each particle size per procedure at the return and back table).

Particle contamination was measured using calibrated counters at a rate of 100 L/m (3.5 cfm) near the sterile field (inside of the TcAF footprint) and at the nine points at a rate of 100 L/m (3.5 cfm) near the back instrument table (outside of the TcAF footprint).

Statistics

Data from statistical analysis were assessed for normalcy by Shapiro-Wilk and Kolmogorov-Smirnov tests and 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 $p < 0.05$ was significant.

Three-wise group comparison was performed with the Mann-Whitney U test with Bonferroni correction, and p <0.0167 was considered significant.

Results

Mock Procedures—Airborne Microbial Assessment

In the Sterile Field 1, at the Patient Right (SF 1 Pat. Rt.) (median = 1.5 CFU/m^3, IQR = 2.25 CFU/m^3) and in the Sterile Field 2, at the Patient Head (SF 2 Pat. Hd.) (median = 1 CFU/m^3, IQR = 1 CFU/m^3, the CFU/m^3 levels were significantly less than the Back Table 1 in the Setup (BT 1 Setup) location (median = 3 CFU/m^3, IQR = 1.25 CFU/m^3. At the Back Table 2, In-Procedure (BT 2 In-Proc.) location (median = 3 CFU/m^3, IQR = 3 CFU/m^3), there was no statistically significant difference between Sterile Field 1 or Sterile Field 2 and the Back Table 2 (*Figure 2*).

FIGURE 2 Microbial contamination statistical analysis—mock procedures.

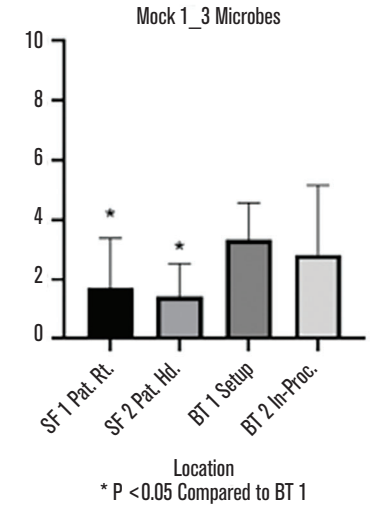
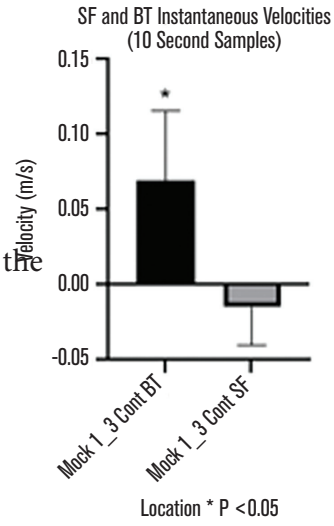


FIGURE 3 Air velocities statistical analysis (SF is inside and BT is outside the TcAF footprint).



Mock Procedures—Air Velocities

The air velocity was higher at the location near the back instrument table (median = 0.066 m/s), IQR = 0.061 m/s, than at the location near the sterile field (median = –0.015 m/s, IQR = 0.031 m/s (*Figure 3*).

FIGURE 4 Mock procedure Temp_RH_CO_2 levels statistical analysis.

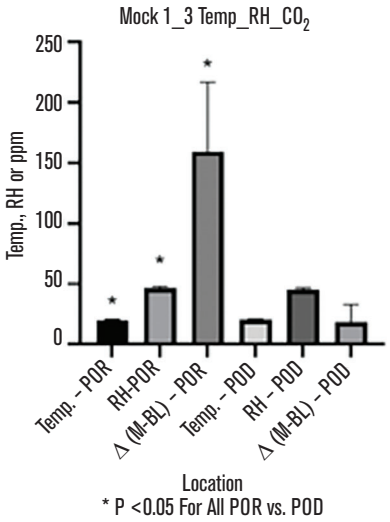
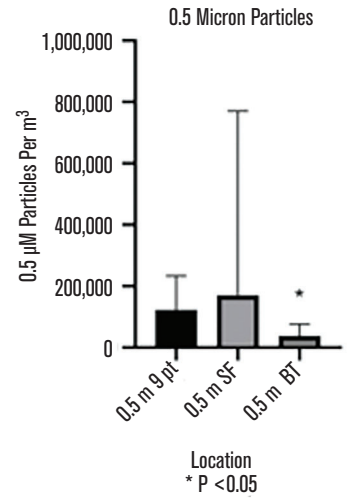


FIGURE 5 Particle contamination statistical analysis.



Mock Procedures—Temperature

The air temperature was higher at the location near the back instrument table (median = 21°C [70°F], IQR = 1°F [0.6°F]), than at the location near the sterile field (median = 20°C [68°F], IQR = 0°C [32°F]) (*Figure 4*).

Mock Procedures—Relative Humidity

The relative humidity was higher at the location near the back instrument table (median = 45% RH, IQR = 3%), than at the location near the sterile field (median = 46%, IQR = 1%) (*Figure 4*).

CO_2 Controlled Contaminant

The CO_2 ppm levels were measured above the baseline and were lower at the location near the back instrument table (median = 12 ppm, IQR = 26.5 ppm), than at the location near the sterile field (median = 174 ppm, IQR = 98 ppm) (*Figure 4*).

Mock Procedure—Airborne Particles

Per current ISO 14644-1 guidelines, only 0.5 micron particle counts are allowed to establish the operational ISO Class. Particle counts were lowest near the back instrument table (median = 25 993/m^3, IQR = 29 162/m^3), than at the location near the sterile field (median = 18 346/m^3, IQR = 41 053/m^3) or the 9 pt. grid (median = 97 396/m^3, IQR = 71 148/m^3 (*Figure 5*).

Live Cases—Airborne Microbial Assessment

The Sterile Field and fewer microbial counts (median = 0 CFU/m^3, IQR = 0 CFU/m^3), then the Back Table In-Procedure (median = 0 CFU/m^3, IQR = 1 CFM/m^3, or the Back Table Prep (median = 1 CFU/m^3, IQR = 1) (*Figure 1* and *Table 1*). *Figure 1* also shows the locations of the samples collected during live cases.

Discussion

This study was conducted in Europe on an air delivery technology, TcAF, which is installed in more than 400 institutions globally including leading orthopedic surgical centers in Europe and the U.S. such as Saint Martens in the Netherlands and the University of Rochester Medical Center in the U.S. The study was conducted using a published method developed in the U.S. that has been used in more than 110 operating room studies in the U.S. Each study was conducted with a strict and repeatable script to ensure high quality and statistically significant data. It measured the environmental qualities within each OR during each procedure.

The main objective of these studies is to understand how the environment contributes to microbial contamination within the OR as the microbe is the only one of these parameters capable of causing a surgical site infection. However, each of the non-microbiological environmental qualities, such as velocity, temperature and humidity, door openings, number of people and particle counts, influence the microbial bioburden in the room. Background information regarding surgical site infections and technologies to reduce airborne microbiological contamination can be found online at https://tinyurl.com/journalextras.

Studying new technologies developed to control these environmental parameters involves measuring them during realistic activity within the operating room—the performance of the OR.

The TcAF system studied here was successful in both creating ultraclean space inside and outside the sterile field, as well as controlling each one of the measured parameters in a manner that moved contamination away from the sterile field, or surgical site, to the perimeter of the room and out the air returns. In this study, the TcAF maintained significantly fewer particles, cooler temperature, higher humidity and velocity; hence, fewer microbes were within the sterile zone compared to the zones outside the footprint of the TcAF. Furthermore, the use of CO_2 as a controlled contaminant measured the ability of the system to clear contamination from the sterile field. The TcAF system effectively cleared the CO_2 from the sterile field, and significantly less CO_2 was detected at the detection point compared to the release point. With respect to the nine-point grid used in the U.S. to classify cleanrooms, the TcAF performed at ISO 6 during activity, which is comparable to the best performing U.S. OR air delivery designs tested using the EQI method.[2,8]

In nearly all surgical cases in the U.S., the instrument tables are staged in the periphery of the room, and may not be covered, potentially exposing the instruments and implants to contamination. Furthermore, contaminants pushed to the perimeter of the room can also be detrimental to the surgical team. Therefore, like the sterile field, the periphery of the room needs to be protected from contaminants as well. Although there was an increase in the microbial contamination at the perimeter of the OR, the TcAF did maintain an aseptic ultraclean environment both in the sterile field and in the periphery of the room.

Conclusion

In this study, the TcAF system was effective at providing an aseptic and ultraclean environmental quality with fewer than 10 CFU/m^3 both inside the sterile field, within the footprint of the TcAF and in the periphery of the OR where surgical instruments and implants are staged.

Limitations

The operating room used in this study was chosen by the clinic, not the EQI team, and was based on caseload and availability. All studies were conducted at a single outpatient clinic site, and the team was not blinded, nor were they unaware of the study being conducted. Additionally, in orthopedic operating rooms in Europe, the procedures and protocols are highly controlled. All surgical staff entering the OR have their head, ears and neck completely covered, there are no door openings once the case has started, the number of people in the room is limited, and entry and exit are through an air lock, double door chamber.

Acknowledgments

This study was funded by Avidicare, Medicon Village, Lund, Sweden, and performed at an outpatient clinic in Goteborg, Sweden. Special thanks to Avidicare and the hospital staff for their support and tireless contribution.

References

1. Gormley, T., T. Markel, H. Jones, J. Wagner., et al. 2017. "Methodology for analyzing environmental quality indicators in a dynamic operating room environment." *Am J Infect Control* 45(4):354–9.

2. Wagner, J., D. Greeley, T. Gormley, T. Markel. 2019. "Comparison of operating room air distribution systems using the environmental quality indicator method of dynamic simulated surgical procedures." *Am J Infect Control* https://doi.org/10.1016/j.ajic.2018.07.020

3. Wagner, J, F. Dexter, D. Greeley, K. Schreiber. 2021. "Op-in particles released at surgical table having greater concentration along walls of the room than at the instrument tray." *Am J Infect Control* 49(5):593–596. https://doi.org/10.1016/j.ajic.2020.10.003

4. Markel, T., T. Gormley, D. Greeley, J. Ostojic, J. Wagner. 2018. "Covering the instrument table decreases bacterial bioburden: An evaluation of environmental quality indicators. *Am J Infect Control* 46(10):1127–1133. https://doi.org/10.1016/j.ajic.2018.02.032

5. Alsved, M, A. Civilis, P. Ekolind, A. Tammelin, et *al. 2018. "Temperature-controlled airflow ventilation in operating rooms* compared with laminar airflow and turbulent mixed airflow." *Journal of Hospital Infection* 98(2):181–190.

6. ANSI/ASHRAE/ASHE Standard 170-2017, *Ventilation of Health Care Facilities*.

7. European Standards 2012. DIN EN 15224:2012, "Health Care Services—Quality Management Systems–Requirements Based on EN ISO 9001:2008. German Version EN 15224:2012." European Standards.

8. NHS. 2021. "Health Technical Memorandum 03-01 Specialised ventilation for healthcare premises Part A: The concept, design, specification, installation and acceptance testing of healthcare ventilation systems." https://tinyurl.com/2x43ebum

9. Air France. Undated. "Comprendre La Norme NF s 90-351 En Hygiene Hospitaliere." Air France. https://tinyurl.com/3y8m4cwb

10. Swedish Institute for Standards. 2015. "Teknisk specification SIS-TS 39:2015." Swedish Institute for Standards.

11. Whyte, W., O. Lidwell, E. Lowbury, R. Blowers. 1983. "Suggested bacteriological standards for air in ultra-clean operating theatres." *J of Hosp Inf* 4(2):133–139.

12. Lans, J., N. Mathijssen, A. Bode, J. van den Dobbelsteen, et al. 2022. "Operating room ventilation systems: recovery degree, cleanliness recovery rate and air change effectiveness in an ultra-clean area." *J Hosp Infect* 122:115–125. https://doi.org/10.1016/j.jhin.2021.12.018 ■