Validation of a Temperature-Controlled Air Flow Ventilation System during Scripted Mock Procedures and Live Surgical Cases

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Abstract

The investigators sought to validate a Temperature controlled air flow (TcAF) system under routine conditions during simulated procedures and live surgical cases using the Environmental Quality Indicator (EQI) method. In-room testing of microbial contamination took place during three simulated procedures and two live arthroplasty cases. The EQI method was used to assess the airborne environment during dynamic, simulated, scripted surgical procedures and in two live cases. EQIs measured included particle and microbial counts, controlled contaminant (carbon dioxide) quantification, velocity, humidity, and temperature at 41.3 air changes per hour. Simulated and live case sampling revealed statistically significant reduction in microbial and particle contamination within the sterile field (footprint of the TcAF) as compared to the periphery of the room even though the sterile field, back instrument tables and periphery were all ultra-clean (<10 CFU/m^3). Additionally, CO_2 and temperature were significantly reduced within the sterile field and humidity was significantly increased. The study concluded that uniform air flow directly over the sterile zones, and better control of the overall supply air, will provide cleaner airborne environments. If the air delivery systems also include areas outside the sterile field, where surgical instruments, implants, and other surgical aids are placed, further reduction in contamination within critical aseptic zones will be achieved.

Background

Surgical site infections (SSI) continue to be a substantial cause of extended hospital stays, increased readmission after surgery and death in the US and Europe with over 150,000 SSIs per year (1-3). Roughly 20% of SSIs are caused by microbes that enter the open surgical site either by direct contact with a contaminated surface or through the air (4). SSIs are also the most expensive healthcare acquired infection (HAI) (5, 6-8). It is widely accepted that microbiological contamination in the Operating Room (OR) contributes to SSI (9-16). It is also widely accepted that the major contributor to airborne bacterial contamination is the people in the space, who shed bacteria carrying squames (17-27). Over 60 years of evidence supports the correlation between airborne contamination and surgical site infection. With infection sensitive surgeries, such as total hip and knee arthroplasty expected to grow exponentially over the next several decades as are the comorbidities of patients as life expectancy increases (28, 29). Therefore, finding new pathways to reduction of infection is imperative.

In addition to the prevention of SSIs within the sterile field, the perimeter of the room is also important. Back instrument tables are often staged in the perimeter and can be subject to contamination outside the footprint of the sterile field. Furthermore, there is concern for the OR team, such as the anesthesiologist and circulating nurses, who spend substantial time in the periphery of the room and can be exposed to contaminants washed away from the sterile field, such as surgical smoke, anesthetic waste gasses or infectious agents like Tuberculosis or SARS. In fact, during the first phases of the Covid-19 pandemic, surgeons were hesitant to perform procedures because of the inadequacy of conventional operating room ventilation in managing airborne contamination both inside and outside the sterile field (30).

Innovative technologies exist that reduce airborne microbiological contamination. In the US, 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 (30-36). In Europe, technology using Temperature Controlled Air Flow (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 differential is typically 1.5-3^{0}C 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 thereby 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 (11, 36). This technology was installed in several locations on the eastern coast of the United States in 2023, including the new University of Rochester Medicine Orthopedics and Physical Performance Center, in Henrietta, NY.

The objective of this study was to use a US published methodology of studying the airborne contamination in an operating room during dynamic simulated conditions and during live surgeries (34). In the US, there are no microbiological standards for ORs 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 170 prescribes an OR should have a minimum air change rate of 20 air changes per hour, 30% non-air delivery over the sterile field, and the sterile field should extend a minimum of 12 inches beyond the foot print of the surgical table, among other prescribed parameters (37). In Europe there are performance based standards, meaning, how the room performs when being used: the German standard specifies particle counts (3500p/m^3) (38) and the British standard specifies microbial counts (10 colony forming units per cubic meter (cfu/m^3) unidirectional or

180 cfu/m3 turbulent) (39), that measure the performance of the OR during live surgical cases. Europe also defines ultra-clean 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 (40-43).

In this study, the investigators sought to validate a TcAF system under routine conditions during mock procedures and live surgical cases. In-room testing of microbial contamination took place during three mock procedures and two live cases that included one total hip arthroplasty and one total knee arthroplasty. Maximum and median concentration of microorganisms (CFU/m^3) were reported at the sterile field, back instrument table(s) and in the periphery of the room.

Materials and Methods

OR Set-Up and Air Delivery Methods

The airflow inside the Opragon footprint was 2829m^3/h (1665 CFM) and the airflow external to the Opragon footprint was 2876m^3/h (1693 CFM) for a total airflow of 5705m^3/h (3358 CFM). The operating room had a net floor area of 46 m^2 and a floor to ceiling height of 3.00 meters for total net volume of 138 m^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 Diffusers (referred to as air showers) were half spherical shaped and constructed of an antimicrobial polymer material. There were eight air showers that formed the Opragon footprint with a diameter 1940 mm, and 10 air showers outside the footprint in the room periphery (Figure 1).

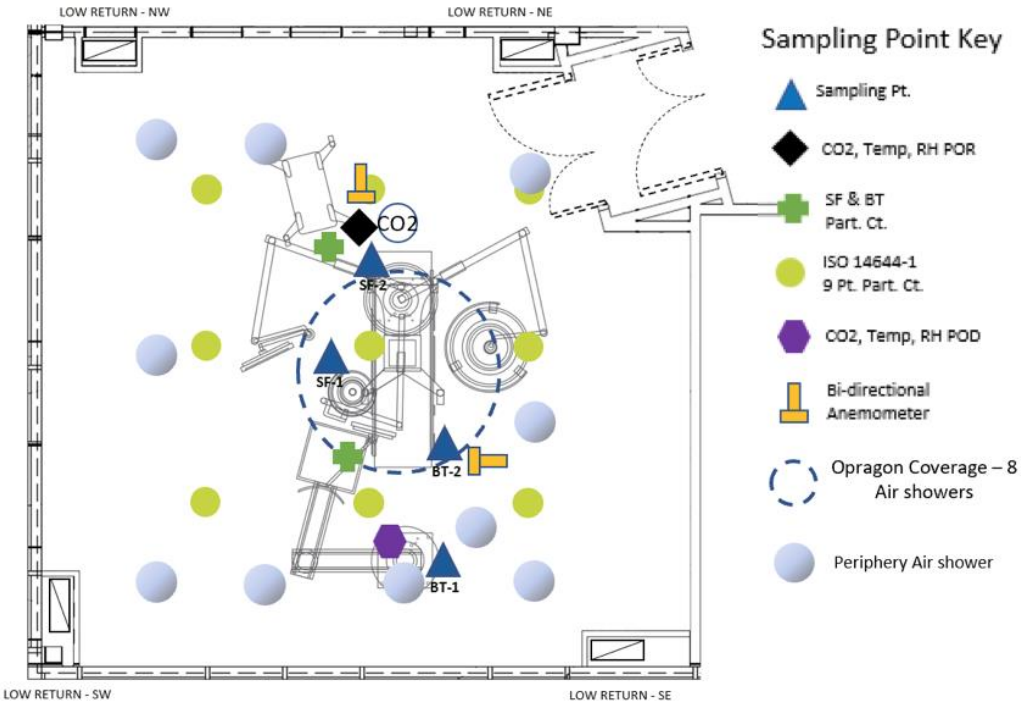

Figure 1 – Locations of Instruments to Measure EQI in the Scripted Mock Procedures

The airflow resulting coverage over the operative field would be ASHRAE Standard 170 compliant, however the configuration is not defined in US guidelines, likely due to unfamiliarity with this system. This system is approved by local governing authorities in Europe for installation and use.

Study Configuration

The published EQI method was used to compare a TcAF configuration 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 (34). 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 2 tests (N=2).

Scripted Mock Procedures

The team consisted of four surgical nurses, an anesthesiologist, a microbiologist, and a healthcare ventilation engineer, for a total of seven individuals. Study personnel wore standard hospital issued scrub attire, head covers, gowns (for operative field or scrub team), 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 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 (34).

Live Surgical Cases

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

Environmental Quality Indicators – Mock Procedures

Assessment of EQIs was performed as previously described (34) (Figure 1). Microbial contamination was actively measured with slit air samplers (Model: Impaktor FH6, Klotz) connected to sterile tubing placed near the wound site, back instrument table, and the periphery of the room (Figure 2).

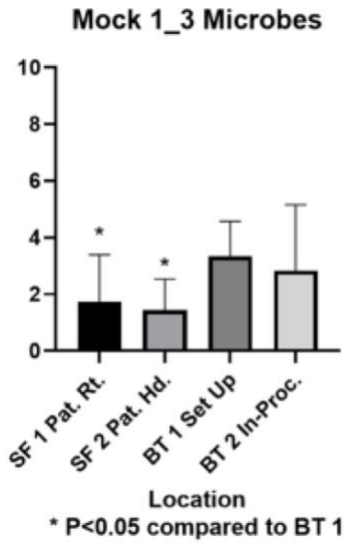

Figure 2 – Microbial Contamination Statistical Analysis – Mock Procedures

Air samplers acquired 1000L of ambient air over 10-minutes onto Petri plates with Trypic 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 Avidicare microbiology laboratory, Medicon Village, Lund, Sweden and incubated at 35^{o}C, 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 (Model: Impaktor FH6, Klotz) 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 1000L of ambient air over 10-minutes onto Petri plates with Trypic 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 and independent microbiology laboratory, Labmedicin, Klinisk Mikrobiologi, Lund, Sweden.

Three dimensional room mapping and EQI - AirStatEQI

Air velocity, temperature, and relative humidity measurements at key locations in the rooms were measured using calibrated ultrasonic anemometers (Model AirStatEQI ™,VIU Insight Inc.) 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 percent relative humidity which was maintained between 20-21 deg. C and 45-48% respectively.

Controlled Contaminant – Carbon Dioxide

Carbon Dioxide (CO_2) was released as a controlled contaminant, at an approximate rate of 10 liters per minute (LPM) 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 (Air Quality Monitor CO2 Detector, Air Quality Monitor Temperature and Relative Humidity CO2 Meter, CO2 Monitor, NDIR Channel Sensor, 0~5000ppm Range, MYWHITENG). 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 point of release and point of detection levels were recorded every two minutes (thirty times per procedure).

Particle Counting – ISO 14644-1 Classification

ISO 14644-1 was utilized to measure room particulate levels in a 9-point grid throughout the room. This resulted in three complete passes through the grid during the one-hour long procedure.

Particle sizes recorded were 0.5, 1.0, 5.0, and 10.0 microns in particles per cubic meter (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 dedicated 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 (Markus Klotz GmbH Impaktor FH6) at a rate of 100 LPM near the sterile field (inside of TcAF footprint) and at the 9-points at a rate of 100 LPM near the back instrument table (outside of TcAF footprint).

Statistics

Statistical analysis was done using GraphPad Prism 7 (GraphPad Software, La Jolla, CA). Data were assessed for normalcy by Shapiro-Wilk and Kolmogorov-Smirnov tests. Data were determined to be nonparametric, and therefore, were reported as the median with interquartile range. Data were compared with Mann-Whitney U test and $p<0.05$ was significant. Three-wise group comparison was performed with Mann-Whitney U test with Bonferroni correction, and $p<0.0167$ was considered significant.

Results

Mock Procedures Airborne Microbial Assessment

The Sterile Field-1, patient right (median = 1.5 CFU/M^3, IQR = 2.25), Sterile Field-2, patient head (median = 1 CFU/M^3, IQR=1), ($p<0.05$ compared to BT-1). Back Table-1, Setup (median = 3 CFU/M^3, IQR=1.25), and Back Table-2, In-Procedure (median = 3 CFU/M^3, IQR=3) (Figure 1 and 2).

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 = -0.015m/s, IQR = 0.031), ($p<0.05$) (Figure 3).

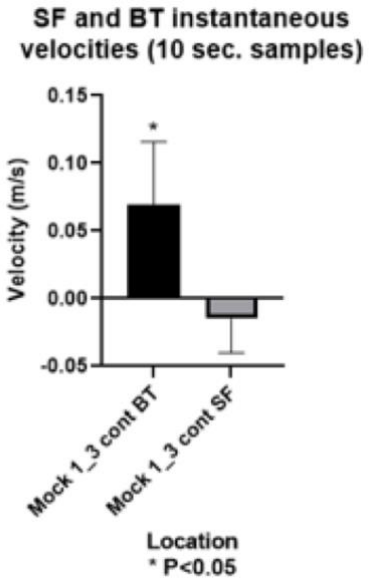

Figure 3 – Air Velocities Statistical Analysis (SF is inside and BT was outside TcAF footprint)

Mock Procedures Temperature

The air temperature was higher at the location near the back instrument table (median = 21 deg. D, IQR = 1 deg.), than at the location near the sterile field (median = 20 deg. D, IQR = 0 deg.), ($p<0.05$) (Figure 1 and 4).

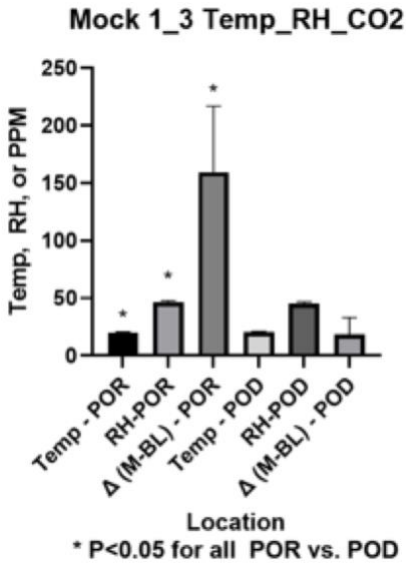

Figure 4 – Mock Procedure Temp_RH_CO2 Levels Statistical Analysis

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 %), ($p<0.05$) (Figures 1 and 4).

CO_2 Controlled Contaminant

The CO2 ppm levels were measured above the baseline and was 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), ($p<0.05$) (Figure 1 and 4).

Mock Procedure Airborne Particles

Per current ISO 14644-1 guidelines, only 0.5 micron particle counts are allowed to establish operational ISO Class. Particle counts were lowest near the back instrument table (median = 25,993/m3, IQR = 29,162/m3), then at the location near the sterile field (median = 18,346/m3, IQR = 41,053/m3) or

the 9 pt. grid ((median = 97,396/m3, IQR = 71,148/m3), ($p<0.05$ for both SF and BT compared to the 9 pt. grid) (Figures 1 and 5)

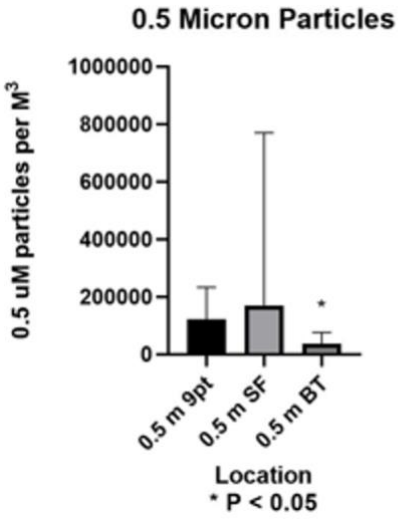

Figure 5 – Particle Contamination Statistical Analysis

Live Cases Airborne Microbial Assessment

The Sterile Field and fewer microbial counts (median = 0 CFU/M^3, IQR = 0), then the Back Table In-Procedure (median = 0 CFU/M^3, IQR=1), or the Back Table Prep (median = 1 CFU/M^3, IQR=1) (Fig. 6 and Table 1).

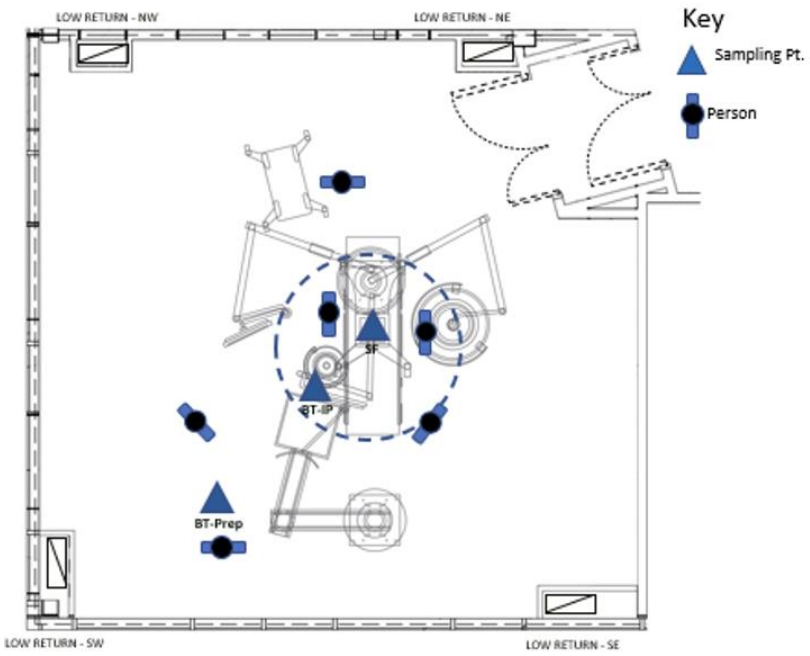

Figure 6 – Locations of Instruments to Measure EQI in the Live Cases

Sample #	Sterile Field	Back Table - Procedure	Back Table - Prep
1	2	4	2
2	0	0	0
3	0	0	0
4	0	1	0
5	0	0	0
6	1	1	0
8	0	1	2
9	0	1	1
10	0	0	0
11	0	0	0
12	0	6	0
Median CFU/m^3, IQR	**0/1**	**0/1**	**1/1**

Table 1 - Live case colony forming units per cubic meter of air (CFU/m^3) for eleven samples collected (sample #7, the air pumps failed) within the sterile field at the surgical site, at the back table position during procedure, and at the location where the back table would be prepared prior to the start of the case. The medians and interquartile ranges were not significantly different between the three locations, p>.05.

Discussion

This study was conducted in Europe on an air delivery system that is accepted as best practice in Europe but is not currently utilized in the United States. The study was conducted using a published

method developed in the US that has been employed in over one hundred-ten operating room studies in the US. Each study was conducted with a strict and repeatable script to ensure high quality, statistically significant data and 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 inanimate environmental qualities, such as velocity, temperature and humidity, door openings, number of people, and particle counts, influence the microbial bioburden in the room. Validating 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 ultra clean 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, and hence fewer microbes within the sterile zone as compared to the zones outside the footprint of the TcAF. Furthermore, the use of CO2 as a controlled contaminant measured the ability of the system to clear contamination from the sterile field. The TcAF system effectively cleared the CO2 from the sterile field and significantly less CO2 was detected at the detection point as compared to the release point. With respect to the 9-point grid used in the US to classify clean rooms, the TcAF performed at ISO 6 during activity, which is comparable to the best performing US OR air delivery designs tested using the EQI method (44).

In the US, common modern designs of air delivery include unidirectional downward flow of air supplied either through multi diffuser arrays or seamless manifold systems paired with two to four low wall air returns. Best practice also includes reducing blockages to the air flow by moving booms and equipment out of the flow of air. Seamless manifold systems further aim to eliminate blockages by eliminating areas of low pressure within the footprint of the supply air. In some cases however, these

designs result in higher levels of contamination at the periphery of the room as they are extremely effective at moving the contamination away from the sterile field to the perimeter on its way out of the room (dexter). In nearly all surgical cases, 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, as mentioned previously, contaminants pushed to the perimeter of the room can be detrimental to the surgical team as well. Therefore, like the sterile field, the periphery of the room needs to be protected from contaminants as well. Although there was a statistical increase in the microbial contamination at the perimeter of the OR, the TcAF did maintain an ultra-clean environment both in the sterile field and in the periphery of the room.

Conclusion

Air delivery systems that deliver clean air to both the sterile field and perimeter of the OR while controlling the movement of contamination out of low wall returns provide better environmental control and result in ultra clean operating rooms. TcAF systems utilize air temperature differentials to direct contaminants away from critical zones within the operating room and minimize potential re-entrainment of contaminants in the perimeter of the room. The TcAF technology is effective at providing improved environmental quality with fewer than ten colony forming units per cubic meter both inside the sterile field, within the footprint of the TcAF, and in the periphery of the OR.

Limitations

The operating room used in this study was chosen by the clinic, not the EQI team, and was based on case load 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.

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