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Review

Operating room ventilation systems: recovery degree, cleanliness recovery rate and air change effectiveness in an ultra-clean area

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SUMMARY

Background: Entrainment test methods are described in most European standards and guidelines to determine the protected area for ultra-clean ventilation (UCV) systems. New UCV systems, such as temperature-controlled airflow (TcAF) and controlled dilution ventilation (cDV) systems, claim the whole operating room (OR) to be ultra-clean. However, current test standards were not developed to assess ventilation effectiveness outside the standard protected area.

Aim: To assess and compare the ventilation effectiveness of four types of OR ventilation systems in the ultra-clean area using a uniform test grid.

Methods: Ventilation effectiveness of four ventilation systems was evaluated for three different ultra-clean (protected) areas: the standard protected area (A); the area outside the standard protected area (B); and a large protected area (AB). Ventilation effectiveness was assessed using recovery degree (RD), cleanliness recovery rate (CRR) and air change effectiveness (ACE).

Findings: RD, CRR and ACE were significantly higher for the unidirectional air flow (UDAF) system compared with the other systems in area A. In area B, the UDAF and cDV systems were comparable for RD and CRR, and the UDAF and conventional ventilation (CV) systems were comparable for ACE. In area AB, the UDAF and cDV systems were comparable for CRR and ACE, but significant differences were found in RD.

Conclusion: In area A, the ventilation effectiveness of the UDAF system outperformed other ventilation systems. In area B, the cDV system was best, followed by the UDAF, TcAF and CV systems. In area AB, the UDAF system was best, followed by the cDV, TcAF and CV systems.

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Introduction

Contaminated air in operating rooms (ORs) is considered to be a risk factor for surgical site infection (SSI) due to the possibility that airborne bacteria from the OR, the surgical staff, medical devices or patients themselves can infect the wound [1,2]. SSI is a public health problem with a major impact on the healthcare system and heavy cost burden [3–6]. Furthermore, SSI has a major impact on patient well-being due to increased hospital stay, possible morbidity and even mortality [6]. Ventilation systems are widely used in ORs to prevent SSI, as well as other measures such as regular cleaning, disinfection of the operated body parts, hand disinfection by washing, and topical application of disinfectants.

The aim of OR ventilation systems is to create a comfortable and safe environment for the patient and surgical staff, to lower the concentration of anaesthetic gases and odours, and to reduce the burden of airborne bacteria in the ultra-clean area [7–9]. The wound area, the area surrounding the surgical staff, and instrument tables are defined as ultra-clean areas.

An OR ventilation system maintains constant air quality by introducing high-efficiency particulate filtered air (HEPA) [10] into the OR. Traditionally, ORs with conventional mixing ventilation (CV) systems are used for generic procedures. Ultra-clean ventilation (UCV) systems are used for infection-prone surgeries [11–15]. CV systems mix the supply air evenly in the entire OR, diluting the concentration of harmful substances. UCV systems supply the air via uni-directional air flow (UDAF) into the protected area, displacing the air present. The protected area or 'clean zone' [14] is intended for positioning the patient wound, sterile staff and instrument tables.

New ventilation systems such as temperature-controlled air flow (TcAF) and controlled dilution ventilation (cDV) systems have been introduced to the market for ultra-clean ORs to provide a system suitable for all types of surgery (class 1a, 1b) [11–15], and to allow more space to position the patient, surgical staff and instrument tables because the whole OR is claimed to be ultra-clean during surgery [16,17].

The World Health Organization (WHO) has not recommended any specific type of ventilation system; rather, WHO has advised that there should be a proper ventilation rate in the OR [18]. The studies included in this WHO guideline have been criticized in various articles, with the result that the advice is also under discussion [2,19,20]. European standards and guidelines [11–14] have been defined to assess the performance of UDAF or CV ventilation systems in 'at rest' situations [21]. For the UDAF system, these standards differ in the method of assessing the ventilation system, but all focus on performance by means of defining an ultra-clean protected area. Mixing systems (CV systems) are assessed based on recovery times or particle concentrations, and are, according to the standards and guidelines, not intended to be used for infection-prone clean surgeries.

However, the test methods for current standards and guidelines [11–14] were not primarily developed for assessing newly developed ventilation systems which focus on larger ultra-clean areas, or which claim that the whole OR is ultra-clean [16,17]. Therefore, the aim of this study was to assess and compare the ventilation effectiveness of four types of OR ventilation systems using a uniform test grid that covers a larger ultra-clean area. This means that the four systems in the ultra-clean areas were tested and evaluated in the same way. The ventilation effectiveness of the systems was assessed and compared in three ultra-clean areas based on recovery degree (RD), cleanliness recovery rate (CRR) and air change effectiveness (ACE).

Methods

This study was performed in four fully functioning ORs in four hospitals in the Netherlands.

ORs which were newly built, handed over in 2020 and fully functional were selected for inclusion in this study. All selected ORs had comparable room sizes and heights. One exception was the CV system, which was >20 years old. The CV system was included in this study in order to compare the ventilation effectiveness of an old generic OR equipped with a CV system with the ventilation effectiveness of the newly built UCV systems.

Before measurements were taken, a technical inspection of ventilation performance was carried out to ensure that the system functioned as intended. Table I shows the characteristics of the ORs and ventilation systems.

Operating room ventilation systems

The four different ventilation systems were categorized as UDAF or non-UDAF ORs according to ISO 14644-3 [22]. Technical dissimilarities and working principles of ventilation effectiveness and air distribution of the OR ventilation systems are explained below.

Conventional ventilation

A CV system (Figure 1b) is a mixed airflow system. The CV system introduces HEPA-filtered air into the OR through a perforated plate system installed above the ultra-clean area (Figure 1a).

Temperature-controlled airflow systems

A TcAF system (Figure 2b) combines a mixed airflow system in the periphery with controlled UDAF directly above the OR table. A TcAF system is defined as a temperature-controlled ventilation system where cooler HEPA-filtered air is supplied above the OR table, and warmer air with air diffusors is released in the periphery. The air introduced above the OR table flows downwards out of a circular UDAF ($\varnothing$ 2.0 m) with eight air diffusors. Mixed air flow is created in the periphery (Figure 2b).

Controlled dilution ventilation

A cDV system (Figure 3b) is a diluting mixed airflow system. Air is filtered inside the air inlet modules by HEPA filters and supplied to the OR through air nozzles located in the ventilation system. The supply air flow from the ventilation system is directed partly towards the ultra-clean area and partly towards the room periphery, creating optimal mixing of the supply air with the air present (Figure 3a).

Unidirectional airflow systems

A UDAF system (Figure 4b) controls UDAF directly above the protected area, displacing the air present. It creates a HEPA-

Table I
Characteristics of the examined operating rooms (ORs) and OR ventilation systems

Ventilation system	Number of different ORs	Filter class EN 1822-1	Air volume (m³/h)	Air changes (per h)	Ceiling height (m)	Average room dimensions (m²)	Volume of OR (m³)	Position extraction	System description
Conventional	5	H13	3.220–3.344	24–26	2.90	43–45	125–135	Low and high	3.0 x 2.4 m perforated plate inlets
Controlled dilution ventilation	6	H14	9.800	69	3.05	47	143	Low and high four corners	3.6 x 3.6 m—20 air inlets with adjustable nozzles
Temperature-controlled airflow	5	H14	6.848–7.180	45–53	3.00	50	135–150	Only low four corners	∅ 2 m plenum box with 8 x half-spherically-shaped air diffusors in the centre and 12 x in the periphery
Unidirectional airflow	6	H14	10.032–10.379	66–73	2.90	49–52	141–151	Low and high four corners	Plenum 3.1 x 3.1 m

filtered protected area with a steady velocity [23,24] and parallel UDAF airstreams (Figure 4a) above the wound area, surgical staff and (partly) instrument tables.

Measurements

Three measuring areas of 1x1 m were defined within a 4x4 m² measuring grid:

- area A with nine measuring points (Figure 5a);
- area B with 16 measuring points (Figure 5b); and
- area AB with 25 measuring points (Figure 5c).

The methodology used was based on the recovery test described in ISO 14644-3; B.12 [22].

Each measuring grid, with measuring points 1.2 m above floor level, was situated with its centre (point C3) in the middle of the OR. Measuring points were 1 m from each other. Measurements were performed per row.

For each row, five Lighthouse 3016 handheld particle counters with a flow rate of 2.83 L/min (0.1 ft³/min) were placed at the measuring point locations. The measurement cycle of each row was 10 min and the total duration of the measurements of the OR lasted approximately 1.5 h. At each point, the particle counter measured, with a measuring cycle of 1 min for 10 min, the quantity of particles with particle size $\geq$0.5 µm. During the measurements, medical equipment, respirators and operating lights (switched on) were positioned in operational position. The operating lights were positioned according to VCCN RL7 and DIN 1946-4 [12,13].

Before the measurements started, particles were emitted in the whole operating room with a calibrated Topas aerosol generator (model ATM 226, aerosol Emery 3004). Emission stopped when all particle counters in the measuring row displayed a background concentration between $\geq 10^7$ and 10^9 particles per m³ ($\geq$0.5 µm). The exact route of the emitted particles cannot be indicated with these measurements. RD, CRR and ACE were calculated from the number of particles measured at each point.

Recovery degree

RD shows the ability of the ventilation system to eliminate or reduce the quantity of airborne particles, at the measuring locations, from the maximum concentration after emission. RD is defined as the logarithm of the quotient (ratio) of the number of particles $\geq$0.5 µm per m³. In this study, RD was measured every minute for 10 min, so RD_{10} is used in this study. RD_{10} is the recovery degree over a 10-min period.

RD was derived from the recovery test described in ISO 14644-3: B12 [22]. An RD of 2 means that the number of particles at the measuring location is 100 times [$\log_{10}(100) = 2$] lower than at the start of the measurement during the 10-min period. To avoid disproportional outcomes in relation to outcomes of other ventilation systems in this study of RD, the result was trimmed to a maximum of 6 [$\log_{10}(10^6)$].

RD was calculated as follows:

$$RD_{tx} = -\log \frac{C_{tx}}{C_{t0}} \qquad \text{(Eq.1)}$$

where RD_{tx} is RD after time tx, C_{tx} is the concentration of particles at the location at time tx, and C_{t0} is the initial concentration at t_0, directly after emission.
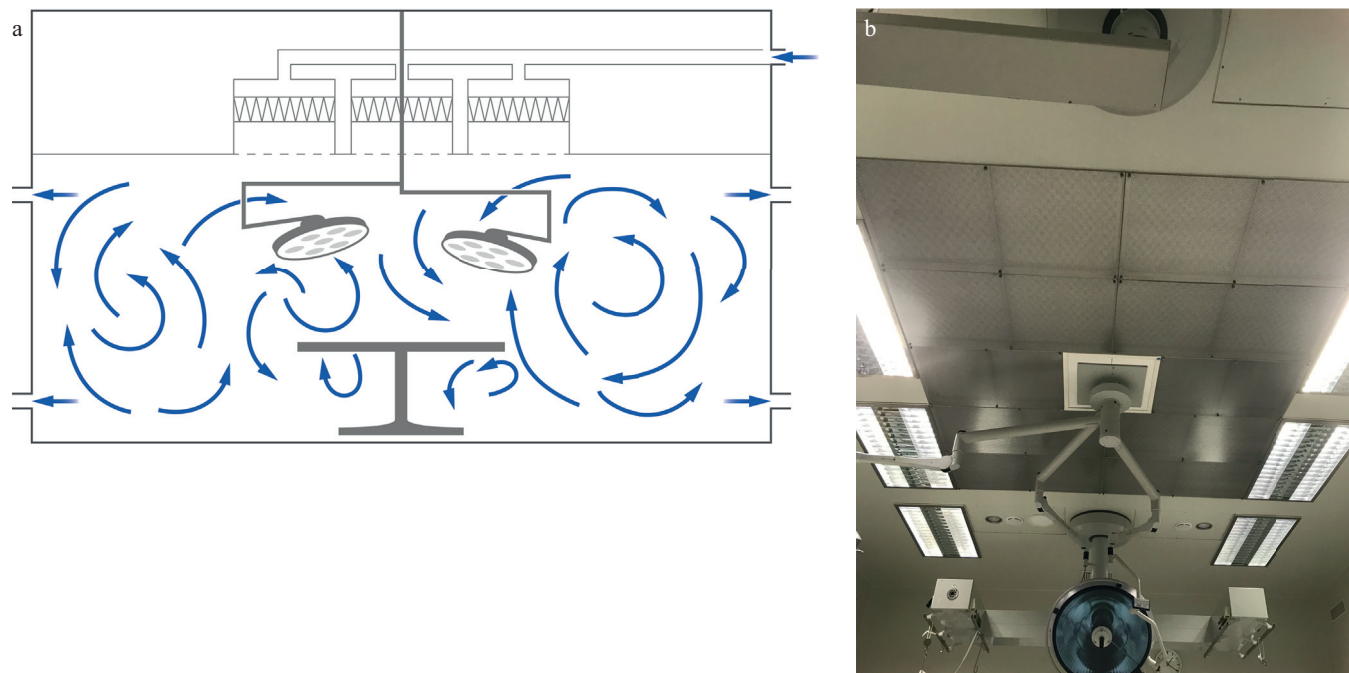
Figure 1. (a) Working principle and (b) photo of conventional ventilation system.

Cleanliness recovery rate

CRR, or decay rate, is closely related to RD. CRR is used as a method [25] to determine the local air change rate at the measuring location. Local air change rate per minute is equal to CRR. Calculation of CRR, as given in ISO 14644-3, was performed over the period of exponential decay. This period is ascertained by plotting the particle concentration over time [25], and defines the inclination angle of particle decay. In this study, CRR was used to compare air distribution in the OR of the different ventilation systems.

To avoid disproportional outcomes in this study, CRR was trimmed to a maximum of 6, meaning a local air change rate ≥ 360/h.

CRR (local air change rate) was calculated as follows:

$$\text{CRR} = -\frac{1}{t}\ln\left(\frac{C_1}{C_0}\right) = -2.3\frac{1}{t}\log\frac{C_1}{C_0} \qquad \text{(Eq.2)}$$

where t is the time in minutes between the first and last measurements in the measurement interval, C_0 is the concentration at the start of exponential decay, and C_1 is the concentration at the end of exponential decay.

Air change effectiveness

Ventilation effectiveness was determined using ACE [25−27]. This study compared average CRR for each system in areas A, B and AB with the overall average air change rate. The overall average air change rate is the total air volume (m^3/h) introduced into the OR divided by the volume of the OR (m^3). If supplied HEPA-filtered air and room air are mixed perfectly, ACE will have a value of 1 at all measuring points. If less introduced air reaches the measuring location than the OR volume average, ACE will be <1. If more introduced air reaches the measuring points, ACE will be >1. The aim of a UCV system is to have a higher ACE (>1) in the ultra-clean area [25].
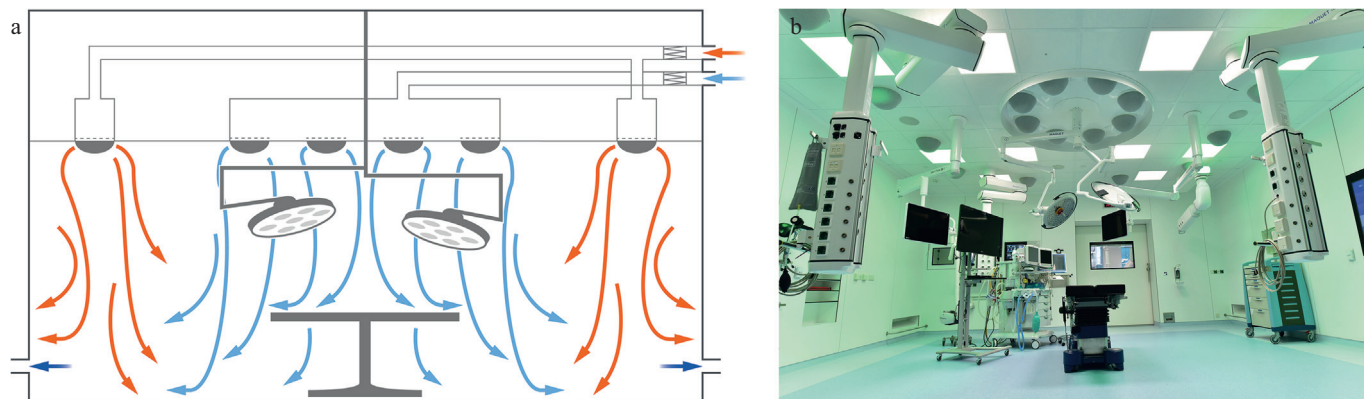

Figure 2. (a) Working principle and (b) photo of temperature-controlled airflow system.
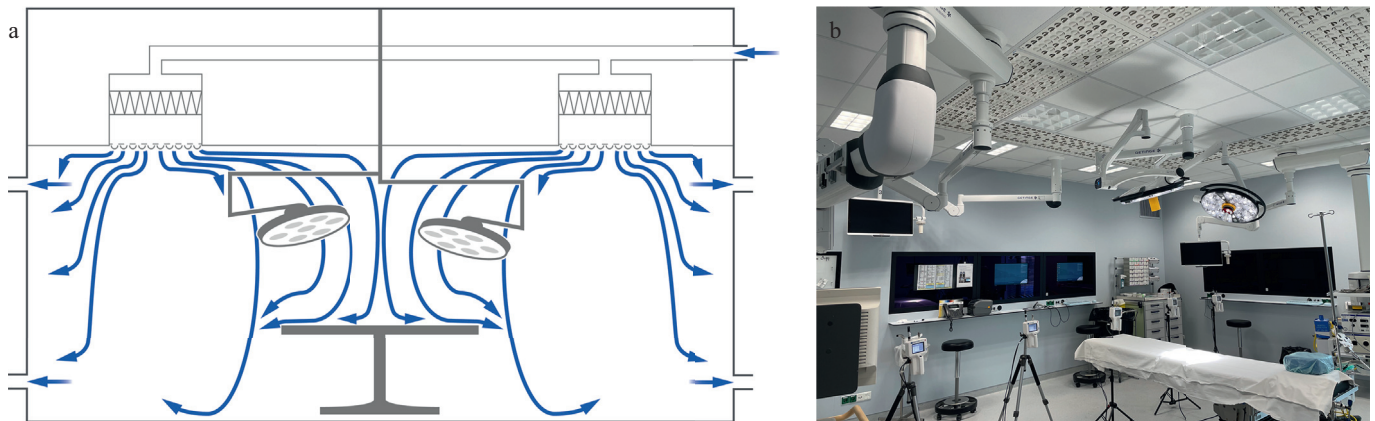
Figure 3. (a) Working principle and (b) photo of controlled dilution ventilation system.

ACE was calculated as follows:

$$ACE = \frac{\text{local air change rate per minute (CRR) at measuring location} \times 60}{\text{overall average air change rate} (m_3/h) \text{ operating room}}$$

(Eq.3)

where local air change rate per minute is the average CRR per measuring location per system, and overall average air change rate operating room is the total air volume introduced (m^3/h)/OR volume (m^3).

Statistical analysis

Kruskal−Wallis test was performed to determine differences between the ventilation systems in terms of CRR, ACE and RD_{10}, as a normal distribution could not be assumed. Mann−Whitney *U*-test was performed with Bonferroni's correction for post-hoc analysis. SPSS Version 25 (IBM Corp., Armonk, NY, USA) was used for statistical analyses. $P \leq 0.05$ was considered to indicate statistical significance.

Results

Airborne particle concentrations and RD per minute in the middle row (C1−C5, Figure 5c) are shown in Figure 6 for the four ventilation systems.

The CV and cDV systems showed stable decay of airborne particles at each measuring point (Figure 6a,b) over time. The decay of airborne particles over time at each measuring point

of the cDV system was faster compared with the CV system. In contrast, the decay of airborne particles at point C3 (TcAF, Figure 6c) and points C2−C3−C4 (UDAF, Figure 6d) was faster than decay at other points in the measuring row.

High RD and faster decay of airborne particles was seen when higher air volumes were introduced into the OR (Figure 6b,d). Introducing clean air into ultra-clean areas via a plenum (Figure 6c,d) also led to higher RD in the centre of the OR. The RD for the UDAF system at measuring points C2−C3−C4 (Figure 6d) and point C3 (Figure 6b) for the TcAF system was 6. All other measuring points in the measuring row did not reach this level.

Ventilation effectiveness

Ventilation effectiveness of the ventilation systems in areas A, B and AB is presented in Table II. Comparisons of the four ventilation systems in areas A, B and AB are shown in Figures 7, 8 and 9, respectively.

RD_{10}, CRR and ACE were significantly higher for the UDAF system compared with the other systems in area A. In area A, no differences in RD_{10} and CRR were found between the CV and TcAF systems, and no differences in ACE were found between the cDV and TcAF systems, and the cDV and CV systems.

In area B, the UDAF and cDV systems were comparable in terms of RD_{10} and CRR, and the UDAF and CV systems were comparable in terms of ACE. Significant differences in
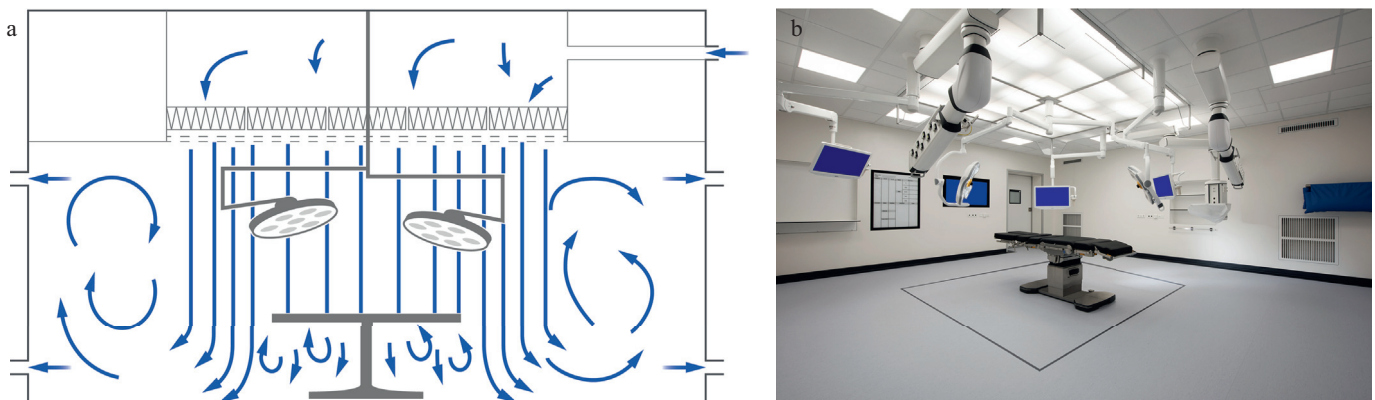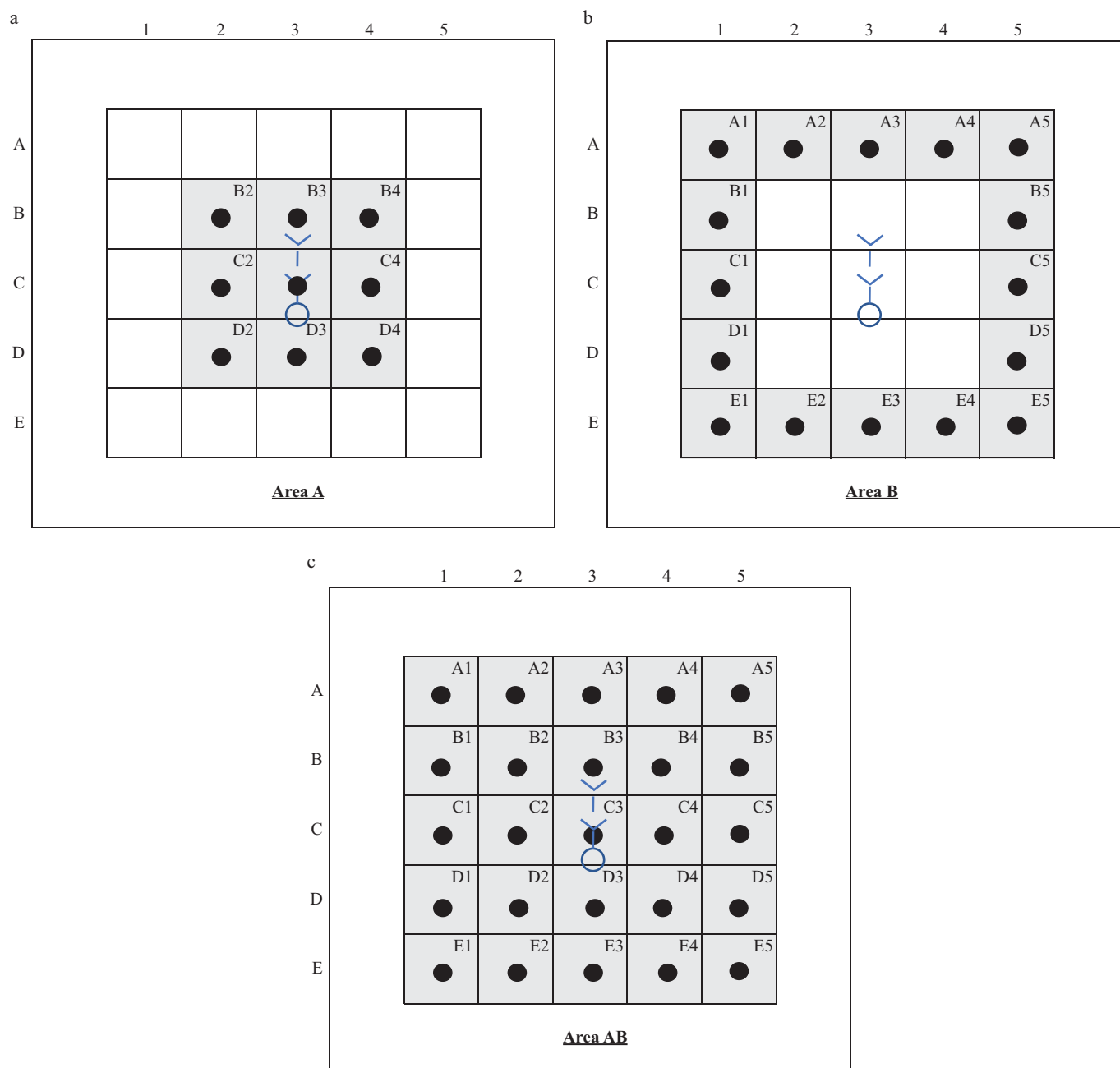

Figure 4. (a) Working principle and (b) photo of unidirectional airflow system.

Figure 5. Measuring point, dots are the position of particle counters. (a) Area A, nine measuring points (B2—B3, C2—C3, D2—D4). (b) Area B, 16 measuring points (A1—A5, B1 and B5, C1 and C5, D1 and D5, E1—E5). (c) Area AB, 25 measuring points (A1—A5, B1—B5, C1—C5, D1—D5, E1—E5).

ventilation effectiveness were found in area B between all other examined ventilation systems.

In area AB, the cDV and CV systems were comparable in terms of ACE. The UDAF and cDV systems were comparable in terms of CRR and ACE. All RD_{10} values for the ventilation systems in area AB were significantly different.

Discussion

This study compared the ventilation effectiveness of OR ventilation systems in different ultra-clean areas. The aim of this study was to assess and compare four types of OR ventilation systems using a uniform test grid and methodology. In this way, the performance of the systems in ultra-clean areas could be evaluated using comparable measurements. The ventilation effectiveness of the systems was assessed using RD_{10}, CRR and ACE.

The ventilation effectiveness of the UDAF systems was found to outperform all other examined systems in area A. This can be explained by the technical design of the UDAF system [24]. No significant differences in area A were found in RD_{10} and CRR between the CV and TcAF systems, and no significant difference in ACE was found between the cDV, CV and TcAF systems. The
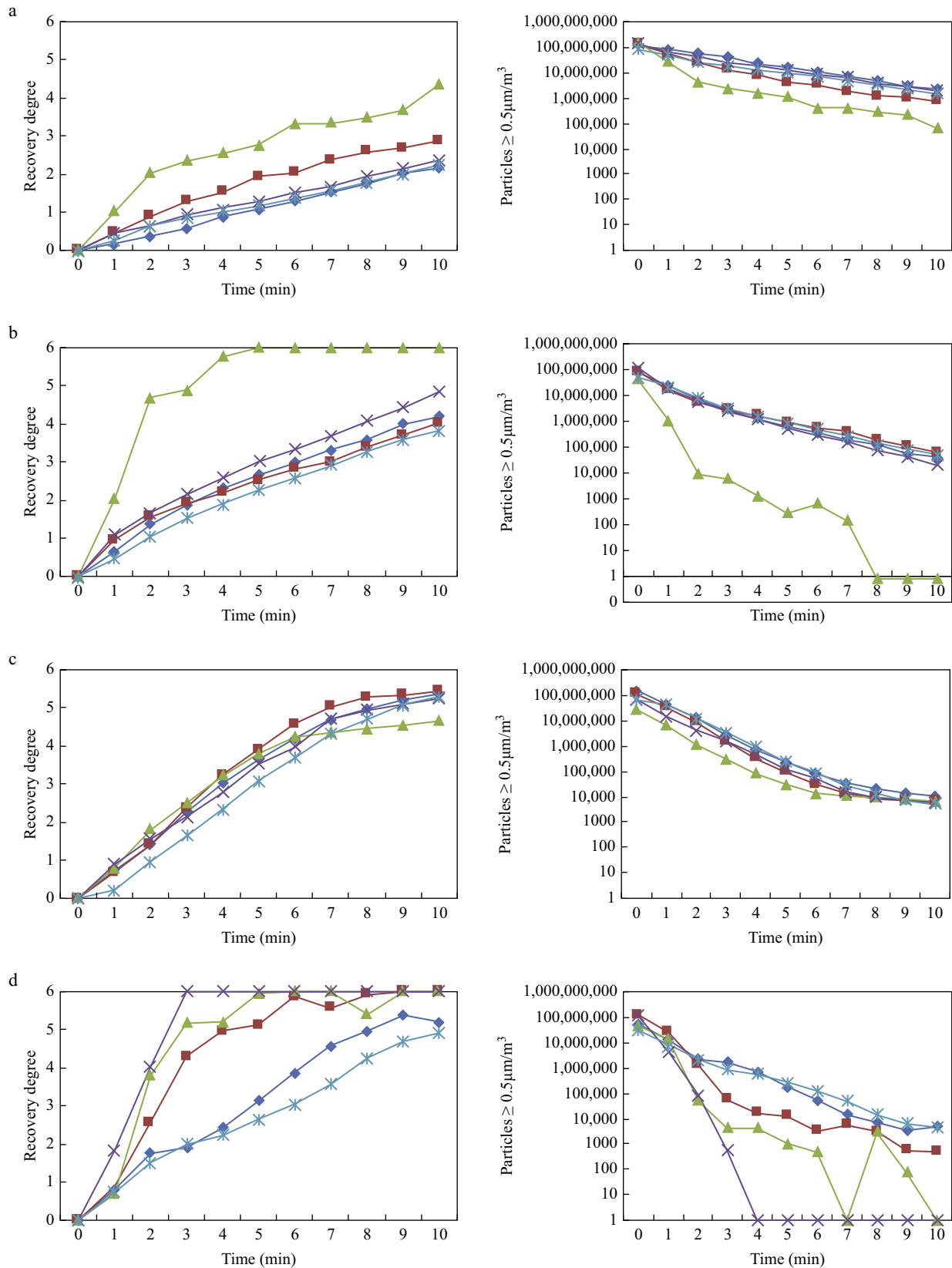
Figure 6. (a) Recovery degree (RD) (left) and decay of airborne particle concentration (right) per minute at row C1−C5 of the conventional ventilation system. (b) RD (left) and decay of airborne particle concentration (right) per minute at row C1−C5 of the temperature controlled air flow. (c) RD (left) and decay of airborne particle concentration (right) per minute at row C1−C5 of the controlled dilution ventilation system. (d) RD (left) and decay of airborne particle concentration (right) per minute at row C1−C5 of the unidirectional airflow system.

Table II
Descriptives examined OR ventilation systems, Area A, B and AB. Results are presented as median (IQR)

Ultra-clean Area	CV	cDV	TcAF	UDAF
Area A				
n	45	54	45	54
RD_{10}	2.22 (1.72 3.42)	4.18 (3.67 4.49)	2.96 (2.75 3.61)	6.00 (5.00 5.00)
CRR	0.50 (0.38 0.66)	1.21 (1.11 1.34)	0.73 (0.58 0.86)	5.41 (3.20 5.96)
ACE	1.20 (0.91 1.58)	1.07 (0.98 1.18)	0.97 (0.74 1.11)	4.62 (2.96 5.05)
Area B				
n	80	96	80	96
RD_{10}	1.82 (1.59 2.33)	4.60 (4.02 5.58)	2.91 (2.34 3.98)	4.45 (3.86 5.00)
CRR	0.38 (0.33 0.42)	1.21 (1.09 1.30)	0.67 (0.55 0.73)	1.10 (0.96 1.29)
ACE	0.93 (0.81 1.05)	1.06 (0.96 1.14)	0.81 (0.73 0.96)	0.96 (0.84 1.15)
Area AB				
n	125	150	125	150
RD_{10}	1.94 (2.52 5.00)	4.40 (3.95 4.95)	2.92 (2.41 3.86)	5.20 (4.16 5.00)
CRR	0.41 (0.54 1.27)	1.21 (1.10 1.31)	0.70 (0.55 0.77)	1.34 (1.02 3.45)
ACE	0.98 (0.87 1.21)	1.07 (0.97 1.15)	0.87 (0.73 1.00)	1.17 (0.95 3.21)

CV, conventional ventilation; cDV, controlled dilution ventilation; TcAF, temperature-controlled airflow; UDAF, unidirectional airflow; RD_{10}, recovery degree over a 10-min period; CRR, cleanliness recovery rate; ACE, air change effectiveness.

reason for lower CRR for the CV and TcAF systems, as well as lower ACE for the CV, TcAF and cDV systems compared with the UDAF system is due to the design of the CV, TcAF and cDV systems, resulting in the introduction of less air into area A.

In areas B and AB, significant differences were found in the ventilation effectiveness of the ventilation systems. CRR of the UDAF and cDV systems was comparable for areas B and AB. A possible explanation could be the higher air volumes introduced [2,28] by the UDAF and cDV systems.

An important role of the ventilation system for the protection of ultra-clean area is the level of displacement of the air and the dilution of airborne particles (RD) in the ultra-clean area [25]. As RD is expressed on a logarithmic scale, the difference in RD_{10} between the ventilation systems in area AB was approximately a factor of 10 (logarithm) per system (Table II).

In this study, the wound area, the area surrounding the surgical staff, and the instrument tables were defined as ultra-clean areas. Current standards [11—14] were not developed to measure the performance of ventilation systems within the whole OR [16,17] or larger ultra-clean areas. Standards and guidelines for infection-prone surgeries are focused on a protected area alone and for generic ORs on a recovery test. However, new systems have been developed which claim that the entire OR is ultra-clean during surgery, as the standard protected area is sometimes not large enough to position and protect all instrument tables and to allow enough additional space between sterile staff and instrument tables [29—31].

In this study, ventilation effectiveness was based on CRR and ACE of the examined ventilation systems, calculated in accordance with other studies [25,32]. It is proposed that RD_{10} should also be used for the assessment of ventilation effectiveness. RD_{10} enables the comparison of different ventilation systems over a 10-min measurement period after emission.

Ventilation effectiveness is measured by the recovery test, which is adapted from ISO 14644-3 [22]. This test is primarily designed for cleanrooms, not ORs, and does not prefer a UDAF installation to be tested [22]. However, the recovery test was used in this study for the UDAF systems. The reasons for using the recovery test were that operating lights were positioned underneath the UDAF, and areas B and AB were larger than the UDAF. With the recovery test, it was possible to compare all systems in all areas in the same way as part of ventilation effectiveness.

By introducing a new measurement method based on this test grid method, cost-savings could be achieved when larger ultra-clean areas are needed. Measurements performed according to the latest standards and guidelines [11—14] are time consuming. In some cases, measurements can take a whole day, during which the OR cannot be used for surgeries. In contrast, the method used in this study only takes 1.5 h per OR.
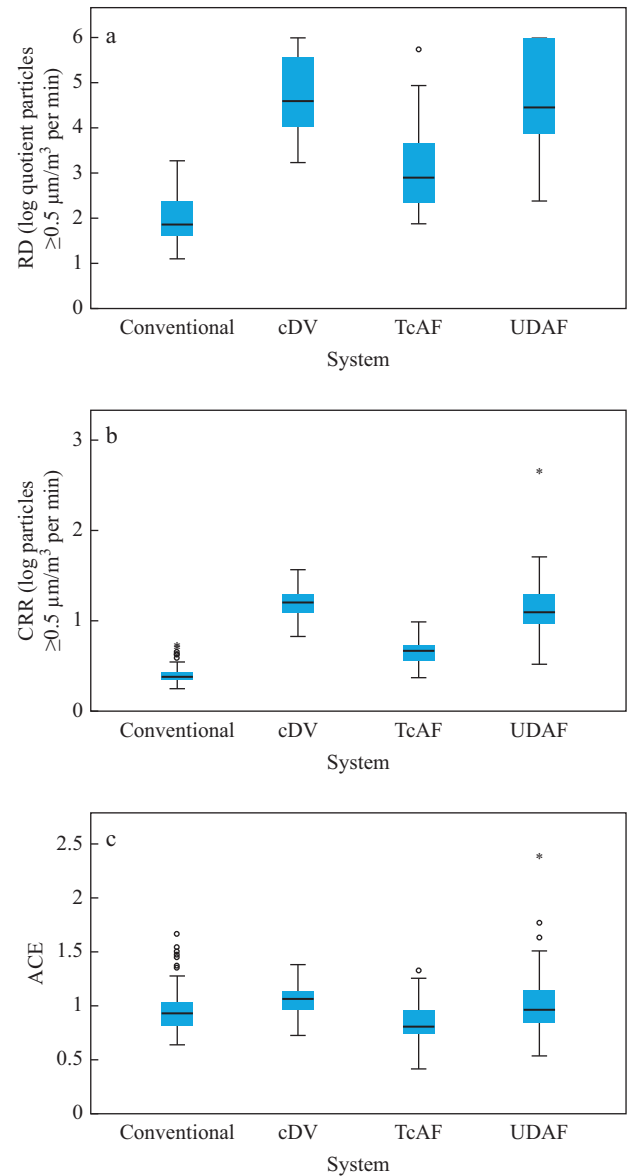
This study has several limitations. First, the study was executed in an 'at-rest' situation. Dispersal and contamination dynamics in the OR caused by the behaviour of surgical staff, number of surgical staff, quality of clothing [33,34] used, number of door openings during surgery [35—37], etc. were not considered. The aim of the study methodology was not to test the performance of the ventilation systems during real surgery individually, but to test all ventilation systems technically in the same way. The methodology can be seen as a technical evaluation of the installed ventilation system. It would be interesting to see how the four different systems behave in the examined areas while real surgery is performed, taking into account the dispersion dynamics and other parameters influencing contamination in the ultra-clean area. Furthermore, no measurements outside the AB area were performed; however, the authors believe that the examined areas are of greatest importance to determine the ventilation effectiveness of the OR in an 'at rest' situation.

Second, the total amount of air introduced was not the same for each system. The four systems were tested as if functioning during surgery. However, the amount of air introduced may have influenced ventilation effectiveness. Furthermore, it would be interesting to determine the minimum RD_{10} and minimum amount of air to maintain ultra-clean air in an ultra-clean area.
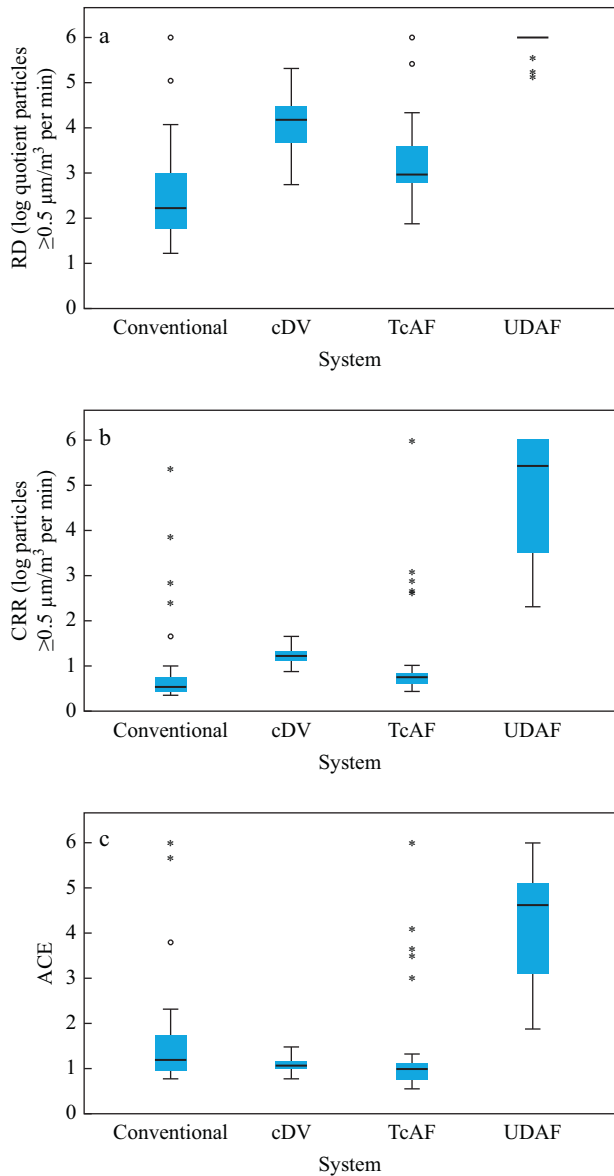
Figure 7. (a) Recovery degree over a 10-min period (RD_{10}), (b) cleanliness recovery rate (CRR) (c) and air change effectiveness (ACE) for conventional ventilation (CV), controlled dilation ventilation (cDV), temperature-controlled airflow (TcAF) and unidirectional airflow (UDAF) systems in area A. The CV and TcAF systems were comparable in terms of RD_{10} ($P=0.09$) and CRR ($P=0.60$). The TcAF and cDV systems ($P=0.62$) and CV and cDV systems ($P=0.51$) were comparable in terms of ACE. All other comparisons between systems showed significantly different RD_{10}, CRR and ACE ($P<0.01$).

Figure 8. (a) Recovery degree over a 10-min period (RD_{10}), (b) cleanliness recovery rate (CRR) (c) and air change effectiveness (ACE) for conventional ventilation (CV), controlled dilation ventilation (cDV), temperature-controlled airflow (TcAF) and unidirectional airflow (UDAF) systems in area B. The cDV and UDAF systems were comparable in terms of RD_{10} ($P=0.73$) and CRR ($P=0.05$). The UDAF and CV systems were comparable in terms of ACE ($P=1.00$). All other comparisons between systems showed a significantly different RD_{10}, CRR and ACE ($P<0.01$).

Third, each system was calculated without considering other parameters known to affect ventilation effectiveness. There may be locations where clean air from the OR ventilation system does not reach the ultra-clean area because of the position of air inlets, characteristics of air inlet diffusers, temperature differences between supply and room air, placement of exhausts, obstructions to air flow, air rising from heat sources, surgical lights [38] and room geometry [39,40]. These variables can influence the airflow patterns within the ultra-

clean area, and reduce the amount of ultra-clean air that reaches the ultra-clean area.

A further study is recommended to explore how the different systems behave in ultra-clean areas during real surgery, and the total cost of ownership of each ventilation system. As environmental awareness and economic aspects are becoming more important in decision-making processes, it is important to know the minimum RD (RD_{10}) in order to achieve the level of ultra-clean air in the ultra-clean area. Future studies will have
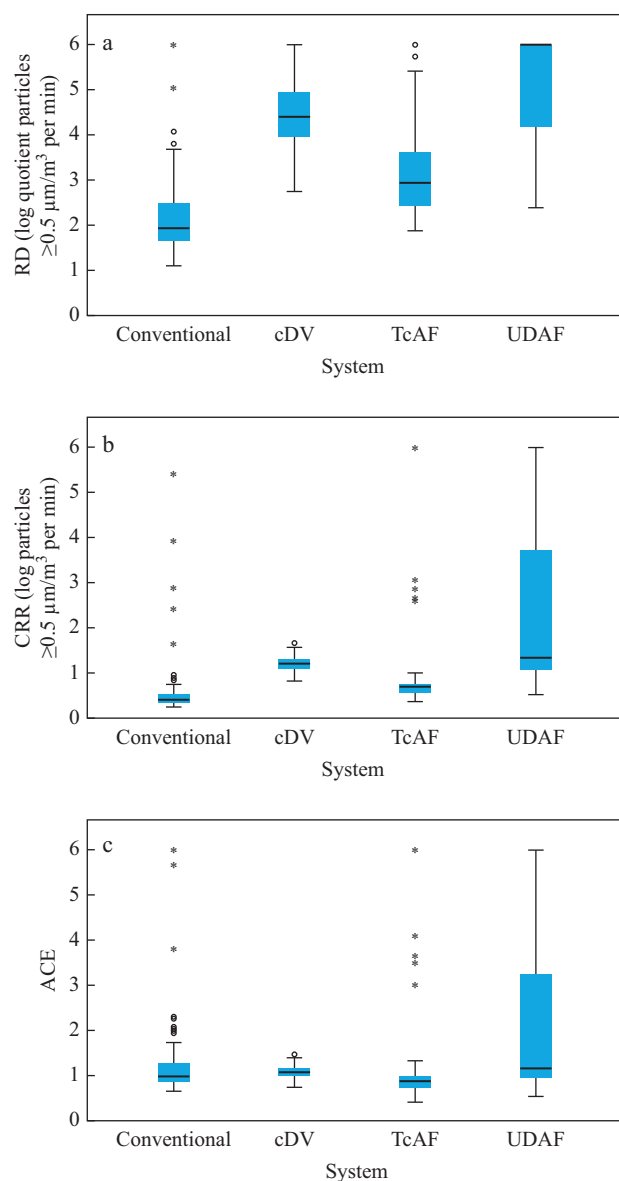
Figure 9. (a) Recovery degree over a 10-min period (RD$_{10}$), (b) cleanliness recovery rate (CRR) (c) and air change effectiveness (ACE) for conventional ventilation (CV), controlled dilation ventilation (cDV), temperature-controlled airflow (TcAF) and unidirectional airflow (UDAF) systems in area AB. The cDV and UDAF systems were comparable in terms of CRR ($P=0.93$) and ACE ($P=0.40$). The CV and cDV systems were comparable in terms of ACE ($P=0.17$). All other comparisons between systems showed significantly different CRR and ACE ($P<0.01$). In area AB, all systems had significant different RD$_{10}$.

to address this in further detail, and will also have to consider RD, microbiological (colony-forming units), environmental and economic aspects.

In conclusion, this study found high ventilation effectiveness of the UDAF system in area A, and the mixed character of the other examined systems. In area A the ventilation effectiveness of the UDAF ventilation system is outperforming all other ventilation systems (see Table II, area A). In areas B and AB, significant differences were found regarding ventilation effectiveness of the examined systems.

This study offers insights into the technical functioning of different OR ventilation systems currently available on the market. The test procedures presented in this study help to compare, enhance and facilitate decision-making for the selection of OR ventilation systems when building new ORs or renovating old ones. The type of surgical procedure, and not the standard, should determine the size of the ultra-clean area. Possible effects of taking measurements in an empty operation room compared with obtaining data in a real-world situation during a complex surgical procedure requires further investigation.

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