



Effect of using ceiling-mounted systems for imaging in hybrid operating rooms on the level of colony-forming units during surgery

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ARTICLE INFO

Article history:

Received 5 September 2018

Accepted 16 October 2018

Available online 23 October 2018

Keywords:

Ceiling-mounted system

Hybrid operating theatre

cfu/m³

Air quality

Hybrid operating room

UDF system



SUMMARY

Background: Large imaging systems in hybrid operating rooms are used increasingly. However, the effect of these ceiling-mounted imaging systems on air quality during surgical procedures has not been studied to date.

Aim: To evaluate the level of colony-forming units (cfu)/m³ near the surgical wound and near the instrument table during surgery.

Methods: Measurements were performed in four hybrid operating rooms at four different hospitals. During surgical procedures, at least three samples were taken with active slit air samplers. At the end of the day's surgical schedule, simulations involving movement of the ceiling-mounted system were also performed. The threshold value for the average cfu level during a surgical procedure was set at ≤ 10 cfu/m³, and for individual samples was set at ≤ 30 cfu/m³.

Results: The median value near the surgical wound was 1 cfu/m³ and at the instrument table was 2 cfu/m³. However, in one hybrid operating room (two procedures out of 16) where the instrument table was not positioned directly under the unidirectional flow (UDF) system, the threshold value for the average cfu level at the instrument table was exceeded. For one of these procedures, the maximum value for an individual sample was also exceeded.

Conclusions: A ceiling-mounted imaging system in combination with a UDF system can result in cfu levels near the surgical wound and at the instrument table that are well below the threshold value of 10 cfu/m³ during surgery. If the instrument table is not positioned directly under the UDF system, the cfu level is higher.

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<https://doi.org/10.1016/j.jhin.2018.10.016>

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Introduction

Hybrid operating rooms (HORs) are used increasingly in surgical interventions for which imaging techniques are indispensable. HOR procedures performed most frequently are endovascular interventions. However, HORs are also used for trauma and orthopaedic interventions, neurosurgery and minimally invasive cardiac valve surgery.

Endovascular procedures require the introduction of guidewires, catheters and stents into the vasculature. The introduction of pathological micro-organisms during such procedures can result in severe infections. A large-scale study by Faizer *et al.* using US patient data from Medicare records found an overall infection rate (including all types of infections) after endovascular aneurysm repair (EVAR) of 3.2% during hospitalization, and a level of surgical site infection after EVAR of 1.27% [1].

The incidence of surgical site infection (SSI) is influenced by multiple factors which include both endogenous (patient-determined) factors and exogenous factors. A substantial number of these factors relate to air quality and might affect the incidence of SSI through airborne contamination. They include staff behaviour and discipline, cleanliness of the operating room environment, presence of equipment with moving parts or other objects in the operating room, and the type and dimensions of the ventilation system [unidirectional flow (UDF) system or other] [2–18].

HORs usually have large dimensions (70–80 m² is common in the Netherlands) to ensure effective use. In addition to the usual operating room equipment such as operating lamps, pendants and monitors, an HOR is equipped with large format imaging equipment (C-arm and large displays). The imaging equipment can be mounted on the ceiling, fixed to the floor or mounted on a mobile base. To ensure high air quality, HORs are also equipped with large UDF systems. In the Netherlands, supply air canopies for UDF systems used in HORs commonly measure at least 12 m² (3 × 4 m). All objects within the canopy area will disrupt the UDF air flow and potentially have a negative effect on the performance of the UDF system. When ceiling-mounted imaging systems are present within the UDF area, it is obvious that such a system, through its carrier arrangement, will disrupt air flow.

Test methods to determine the efficiency of UDF systems are often based on counts of airborne particles, because they act in the same way as airborne micro-organisms [19–21]. Through controlled emission of particles, the behaviour (movement through the air) of micro-organisms released into the operating room environment (amongst others released by the surgical team) can be simulated in order to determine the performance of the ventilation system [22,23]. However, for UDF systems, it has been shown that there is no clear correlation between the number of particles and the number of micro-organisms in the air during surgical procedures [24,25]. A recent study by Birgand *et al.*, for instance, showed that whilst there is a correlation between the number of particles and the number of colony-forming units (cfu) in the air in the case of dilution mixing ventilating systems, no such correlation exists in the case of UDF systems [26]. This implies that measurement of particles in UDF systems cannot be used to predict the concentration of micro-organisms, and can only be used as a way to simulate the spread of released micro-organisms through the air.

Several studies, carried out in the 1980s but considered valid and accepted internationally, have suggested that a concentration of 10 cfu/m³ or less during surgery should be used as an upper threshold for joint replacement surgeries if the infection rate is to be kept below 1.5%. Research carried out by Lidwell shows correlation between the type of air handling system and the number of cfu/m³, and between the number of cfu/m³ and the number of SSIs [27]. Darouiche states that reduction of airborne cfu, particularly at the

incision site during surgery, may be an effective strategy to reduce SSIs [28].

The most critical locations within the surgical area for air quality during procedures are the surgical site itself and the instrument table. To establish the risk in terms of SSI incidence of the ceiling-mounted imaging system, the optimal method is to measure the cfu levels at these critical positions with the system in a working position during a surgical procedure [29].

The aim of this study was to evaluate the microbiological pollution of the air by measuring the cfu levels near the surgical wound and on the instrument table during surgery in different HORs using a ceiling-mounted imaging system. To the authors' knowledge, no data are currently available on air pollution in HORs.

Methods

Principles

Measurements for the study were taken from March to June 2018. In this period, cfu levels were measured in four HORs, each in a different Dutch hospital. The hospitals were selected based on the presence of a UDF system in the HOR and the approval of the hospital to conduct the measurements. Measurements were taken according to a measuring protocol based on Swedish technical specification SIS-TS 39:2015 [30]. Samples were taken during surgery, and no adjustments were made to the surgical procedures to accommodate for the air sampling tests. Each sample was taken over a period of 10 min with a quantity of 100 dm³/min, resulting in a sample volume of 1 m³ of air. At least three samples were taken for each procedure. The Klotz impaktor FH6, a slit air sampler, was used for the measurements. Tryptose soy agar cultivation plates were used. Exposed plates (reference plates) were incubated aerobically for at least two days at 35 ± 2 °C [30].

Experiments

Two types of measurements were taken to quantify the effect of the ceiling-mounted system on air quality at the surgical wound and the instrument table. The first type of measurement was conducted during actual surgical procedures. The second type of measurement was performed during simulated movements of the ceiling-mounted system without a patient or surgical team present in the HOR. The former was designed to analyse the impact of procedures, and the presence of staff and patient on air quality, whereas the latter was designed to isolate the impact of the ceiling-mounted imaging system.

Measurement of cfu level during surgery

During each surgical procedure, a sterile sample tube was used to sample near the surgical wound. The sterile sample tube was positioned, by the operating team, not more than 0.5 m away from the surgical incision. At the second measurement location, the air sampler was placed close to the sterile instrument table. The instrument table furthest from the surgical site was used as the sampling location. The aim was to consider the position of the instrument table in the worst case in terms of air contamination. Measurements were also performed in

the periphery of the HORs. Sampling started from the first incision and continued until the wound was closed. During the measuring period, the number of door openings and staff present in the HOR were recorded.

Simulated movements of the ceiling-mounted system

Measurements were taken after the planned (day) operating schedule to determine if particles carrying micro-organisms collected by the ceiling-mounted system during the day entered the surgical area during simulated movements. During these simulations, no staff or patients were present. Measurements were taken at the head end of the operating table, just below the edge of the carrier, in the middle of the operating table and near the patient's feet. Two types of simulation were conducted. During simulation S_a , the system was moved from the operational position towards the stand-by position and back to the operational position every 2 min for a period of 10 min. During simulation S_b , a sample was taken when the system was moved from the operational position towards the stand-by position and back to the operational position every 1 min for 10 min.

Systems

The characteristics of the systems measured are shown in Table I. Different technologies can be used to optimize the protective effect of UDF systems against entrainment, and to optimize the diluting effect for the concentration of potential micro-organism-carrying particles. One of the options is to divide the UDF canopy into two different temperature zones. The inner zone will supply air with a lower temperature, typically by 1–2°C. Due to the temperature difference, the air in the inner zone has an increased air speed. All HORs use this technology. Additional to this technology, HORs A and B were equipped with a UDF system with a higher supply air speed around the canopy. This increased speed around the outer surface of the canopy further reduce entrainment.

Results

Measurements were taken during 16 procedures: three pacemaker implants, two heart valve replacements, nine EVAR procedures, one constricted blood vessel procedure and one

angioplasty. The average number of people present was 8 (3.75–11.1) per procedure and the number of door openings towards the corridor was 7.3 (0–22), with a third quartile of 10 door openings towards the corridor per procedure.

Table II shows that the cfu levels at the surgical wound and at the instrument table in HORs A–C were below the threshold average value of ≤ 10 cfu/m³ and the maximum admissible value for an individual sample of ≤ 30 cfu/m³ [30]. For Procedures 1 and 2 in HOR D, the maximum average value was minimally exceeded. That was also the case for the maximum value of one individual sample in HOR D during Procedure 1. This measurement took place during a very lengthy procedure (time from incision to closure of more than 6 h and 40 min), which also saw a high level of activity in the HOR because of complications occurring during the procedure. In this hospital, the instrument table was not positioned directly under the UDF system (Figure 1).

Figure 2 shows that the median value of all measurements was 1 cfu/m³ at the surgical wound and 2 cfu/m³ at the instrument table. The average values at these measurement positions were 2 cfu/m³ and 4.5 cfu/m³, respectively. The value of the third quartile (75th percentile) was 3 cfu/m³ at the surgical wound and 7 cfu/m³ at the instrument table. However, during the surgical procedures in HOR D, the instrument table was not positioned directly under the UDF system (Figure 1). This resulted in a significant ($P < 0.05$) increase in the cfu level near the instrument table compared with HORs A–C. Figure 2 shows the results at the surgical wound and near the instrument table for all HORs (A–D), as well as for HORs A–C. The increase in cfu level at the instrument table is clearly visible. Due to the position of the instrument table, the mean value increased from 1.5 to 4.5 cfu/m³. The third quartile increased from 3 cfu/m³ for HORs A–C to 7 cfu/m³ for HORs A–D.

A significant difference was found between the cfu level near the wound and the cfu level near the instrument table ($P < 0.05$) when all HORs (A–D) were considered. When considering HORs A–C alone, there was no significant difference between the cfu level near the wound and the cfu level near the instrument table. The difference in cfu levels between the wound and instrument table on the one end, and the operating room periphery on the other was also significant ($P < 0.05$).

The results of the experiments with simulated movement of the C-arm of the ceiling-mounted imaging system are shown in

Table I
Characteristics of the four hybrid operating rooms (HORs)

Characteristics	HOR A	HOR B	HOR C	HOR D
Dimensions of HOR, length x width (m)	7 × 11.4	8 × 12	8.7 × 11.5	6.6 × 7.2
Dimensions of air supply canopy, length x width (m)	3 × 6	3 × 4	3 × 4	2.8 × 2.8
Final HEPA filter class	H14	H14	H14	H13
Supply air amount (m ³ /h)	15,550	17,250	16,000	9030
Average supply air speed (m/s)	0.27	0.31	0.31	0.32
Type of system	UDF with two temperature zones and two air velocities (higher velocity at the outer edge)	UDF with two temperature zones and two air velocities (higher velocity at the outer edge)	UDF with two temperature zones	UDF with two temperature zones

UDF, unidirectional flow; HEPA, high-efficiency particulate air.

Table II
Results for each system and procedure, and total of all procedures in all hospitals

Hybrid operating room	Procedure	Maximum value (cfu/m ³)			Average value (cfu/m ³)		
		Wound area ^a	Instrument table ^a	Periphery	Wound area ^b	Instrument table ^b	Periphery
A	1–5 (N=25)	3	6	22	0.5	2.4	11.1
	1 (N=4)	1	3	9	0.5	2.0	6.0
	2 (N=5)	3	6	10	0.8	4.6	6.4
	3 (N=5)	1	6	16	0.4	2.6	9.4
	4 (N=5)	3	4	16	0.8	2.0	13.6
	5 (N=6)	1	3	22	0.2	0.8	17.8
B	1–3 (N=28)	3	3	74	1.4	0.3	35.9
	1 (N=15)	3	3	74	1.5	0.3	35.3
	2 (N=3)	3	1	58	1.7	0.3	53.3
	3 (N=10)	3	2	57	1.1	0.2	31.6
C	1–5 (N=47)	6	12	67	1.7	1.7	18.0
	1 (N=14)	3	3	10	1.1	0.4	4.4
	2 (N=11)	5	11	35	1.9	3.8	15.1
	3 (N=7)	2	12	32	0.9	3.3	19.7
	4 (N=7)	3	1	38	1.7	0.6	24.6
	5 (N=8)	6	3	67	3.1	0.9	38.6
D	1–3 (N=58)	15	34	240	3.3	9.8	62.4
	1 (N=38)	11	34 ^c	53	2.0	10.1	19.4
	2 (N=13)	15	28	240	6.6	10.2	157.2
	3 (N=7)	7	12	184	3.9	7.1	119.6
A–D (N=158)		15	34	240	2.0	4.5	36.4

Bold values are above the threshold value, maximum value of a sample during the surgical procedure was 30 cfu/m³ and average value during the surgical procedure was 10 cfu/m³.

cfu, colony-forming units.

^a Threshold value for a single sample was ≤30 cfu/m³.

^b Threshold value for the average value of a surgical procedure was ≤10 cfu/m³.

^c Only one sample was above the threshold value.

Table III. This table shows the results for test conditions without any activity in the operating room, and for test conditions with some activity in the operating room. However, this was in contrast to the design of this experiment. The fact that some activity took place during two of the simulated exercises

was helpful to show the disturbance of the UDF air flow at Position 1 ('head').

In all cases, the cfu level at the 'head' position was equal to or higher than that at the other measurement positions. This was most probably caused by disruption of the UDF by the

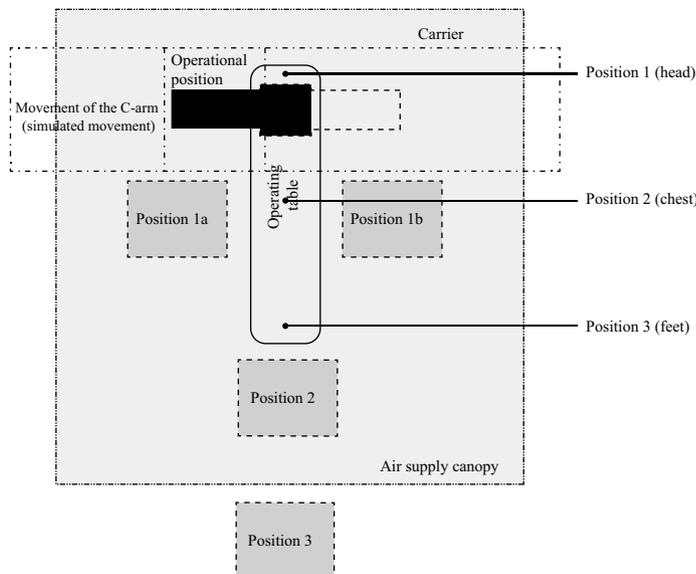


Figure 1. Schematic positioning of the instrument tables in the different hybrid operating rooms and a photo of the system in the parked position.

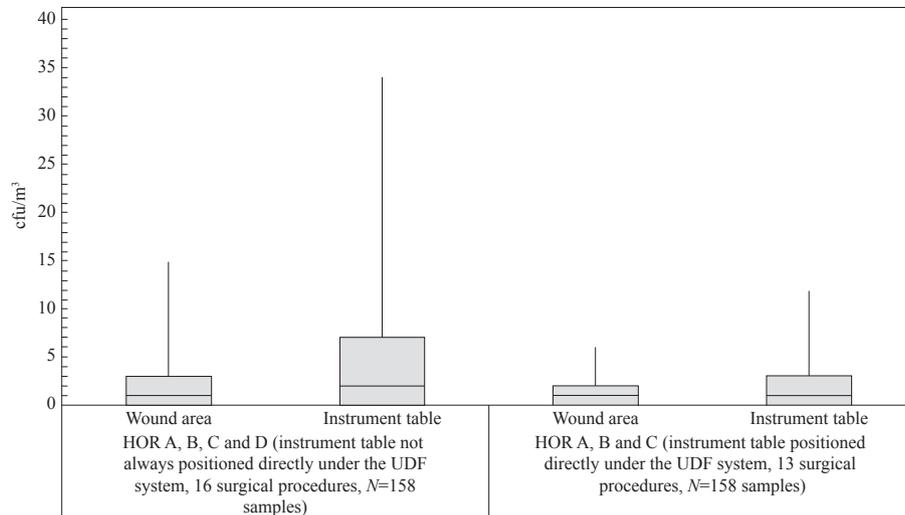


Figure 2. Results of the measurements. HOR, hybrid operating room; UDF, unidirectional flow; cfu, colony-forming units.

carrier when positioned directly above the head, and by the movement of the C-arm (due to the resulting turbulence). It is less likely that the values measured were caused by micro-organism-carrying particles falling from the system itself. Table II also shows that a higher concentration in the periphery caused by a high level of activity was associated with an increase in the cfu level on the operating table.

Discussion

This study showed that if the instrument table is positioned directly under the UDF system, the cfu levels near the surgical wound and at the instrument table will be <10 cfu/m³. Even if the instrument table is not positioned directly under the UDF system, the average cfu level remains close to the threshold value at this position. Based on these results, it seems that a ceiling-mounted imaging system in combination with a large UDF system can fulfil the requirements for infection-sensitive surgery. The cfu levels measured at the instrument table

were significantly higher than those measured near the surgical wound. Positioning of the instrument table is critical to achieve cfu levels well below the threshold value.

A major risk factor for the occurrence of SSI is microbiological contamination of long guidewires, catheters and (covered) stents through micro-organism-carrying particles in the air of the HOR. These instruments can become contaminated if they are left exposed for a considerable period of time in an environment with a high cfu level (e.g. not directly under the UDF system). Air quality in the areas where these instruments are located is most likely to be more important in preventing infections than air quality near the small incision site. However, no studies regarding the aerogenic contamination of guidewires and catheters in HORs were found in the literature.

The higher cfu level at the 'head' position during the simulated movements of the C-arm is most probably caused by disturbance of the UDF by the carrier when positioned directly above the measuring position. Another likely cause is the

Table III

Results of the simulations performed at the end of the day programme in colony-forming units/m³

Simulation	HOR	Simulations without any activity in the HOR					
		Simulation S _a ^a			Simulation S _b ^b		
		Position 1 (head)	Position 2 (chest)	Position 3 (feet)	Position 1 (head)	Position 2 (chest)	Position 3 (feet)
1	A	1	1	0	2	1	0
2	B	2	0	0	3	0	0
3	C	2	0	0	4	0	0
4	D ^c	1.7 (0–3)	0.3 (0–1)	0	2.3 (2–3)	0.7 (0–1)	0
Simulations with activity in the HOR							
5	B ^d	16	5	1	10	4	0
6	D ^e	39	24	11	65	38	7

HOR, hybrid operating room.

^a From the operational position towards the stand-by position and back to the operational position every 2 min for a period of 10 min.

^b From the operational position towards the stand-by position and back to the operational position every 1 min for a period of 10 min.

^c Average value of three measurements.

^d During this measurement, some additional activities (preparation for next day) by staff members took place.

^e During this simulation, there was one staff member present with a high level of activity and numerous door openings.

movement of the C-arm itself (due to the resulting turbulence). A less probable cause is contamination by micro-organism-carrying particles falling from the system itself. This is based on the fact that, during simulated experiments, additional activity in the HOR, outside the UDF canopy, also increased the cfu levels at Positions 2 ('chest') and 3 ('feet'). This suggests that the higher cfu levels were most likely caused by disruption of the UDF air flow, and were not the result of micro-organism-carrying particles falling from the system itself.

Limitations

This study had a number of limitations. The results are only applicable for the specific type of ceiling-mounted imaging system used in the tests in combination with large UDF systems. The effects of a combination of the ceiling-mounted imaging system with other ventilation systems, such as diluting mixing systems and temperature-controlled systems or small UDF systems, have not been investigated [31]. The direct effect on the air flow of the UDF system has likewise not been investigated. However, the effectiveness of an airflow system is the resulting cfu level during surgery. A comparison between imaging systems mounted on the ceiling and on the floor has not been performed. Although a relatively large number of measurements ($N=158$) were taken, these were located in just four different HORs.

Simulations were performed at the end of the day with no staff or patients present, using iterations of two different movement patterns for the ceiling-mounted system. The relevance and representativeness of the simulated movements used have not been assessed systematically.

In conclusion, the use of a ceiling-mounted imaging system in combination with a large 3×4 m UDF system can result in low cfu/m³ values (<10 cfu/m³) at the surgical wound and at the instrument table. However, the position of the instrument table is critical. If the instrument table is not positioned directly under the UDF system, the cfu level will increase. This finding is particularly relevant for endovascular procedures, as these procedures often require the insertion of long guidewires and devices to deploy stent grafts, but may also apply for other procedures in HORs where implants are used, such as in trauma and orthopaedic surgery.

The number of interventions performed in HORs is increasing steadily. The results of this study may therefore help to further reduce SSIs and other infections. They also show that critical procedures can be performed safely in an HOR, even with multiple movements of the table and C-arm.

Acknowledgements

The authors wish to thank all participating hospitals – Catharina Hospital, Eindhoven, Deventer Hospital, Deventer, VUmc, Amsterdam, Tergooi Hospital, Hilversum – for facilitating the project by allowing measurements during surgery in HORs.

Conflict of interest statement

None declared.

Funding source

Philips Medical Systems Nederland B.V.

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