Can clothing systems and human activities in operating rooms with mixing ventilation systems help achieve 10 CFU/m^3 level during orthopedic surgeries?

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Summary

The level of airborne microbial contamination in operating rooms (ORs) is an important indicator of indoor air quality and ensures a clean surgical environment. It is necessary to research how different factors affect the colony forming unit (CFU) level during surgery in a mixing ventilation (MV) operating room (OR) to fulfil an ultra-clean air requirement. The main objective of this study is to clarify the possibility of achieving the requirement for an ultraclean operating room ($\leqslant$ 10 CFU/m^3) with mixing ventilation from two factors of clothing and human activities. The experiment results verified that the average CFU/m^3 of three of five mock-up surgeries was 8.5 which was below or equal to the ultra-clean requirement, while the other two mock-up surgeries did not meet the ultra-clean requirement. Surgical activities together with clothing level of surgical staff in ORs seem to be the most significant reason for the high CFU level during surgery. It is possible to achieve the ultraclean

air requirement ($\leqslant$ 10 CFU/m^3) during a surgical process with proper clothing and low surgical activities in ORs. This study clarifies the effect of clothing and human activities on the CFU level in the surgical microenvironment in ORs and contributes to developing new code of products for the surgical team.

Keywords: Hospital operating room; Surgical site infection; Mixing ventilation; Human activity; Clothing

1 Introduction

Almost 313 million surgical procedures are performed each year around the world [1], which is twice the number of babies born every year [2]. Surgical site infection (SSI) is a leading cause of healthcare associated infections. A previous study has shown that airborne microbial contaminants are an important source of SSIs in clean operations [3]. Today, many countries measure the colony forming unit per cubic meter of air (CFU/m^3) in ORs during surgery as a parameter to classify the expected microbial level (including bacteria, fungi, and viruses) in operating rooms (ORs). For an OR with an ultraclean requirement, a value of $\leq$ 10 CFU/m^3 within 30 cm of the surgical wound was suggested [4] and is often used. To fulfil the ultraclean requirement, most ORs built today utilize an unidirectional airflow system (UDF-system), which is also known as laminar air flow (LAF) system, as this type of system has proven to deliver a cleaner operating environment compared to the traditional mixing ventilation (MV) system [5,6]. However, there were only very few clinical studies proving a clear correlation between decreased SSI rates and the use of UDF-system. In fact, a recent study showed that postoperative SSI rates increased in ORs with UDF-system [7]. A few studies showed significantly higher SSI rates after knee prosthesis surgery and hip prosthesis surgery using UDF-system [8, 9]. Due to the ambiguity of UDF-system in the decrease of SSI rate, UDF-system is not recommended by the World Health Organization guideline for patients undergoing total arthroplasty surgery [10].

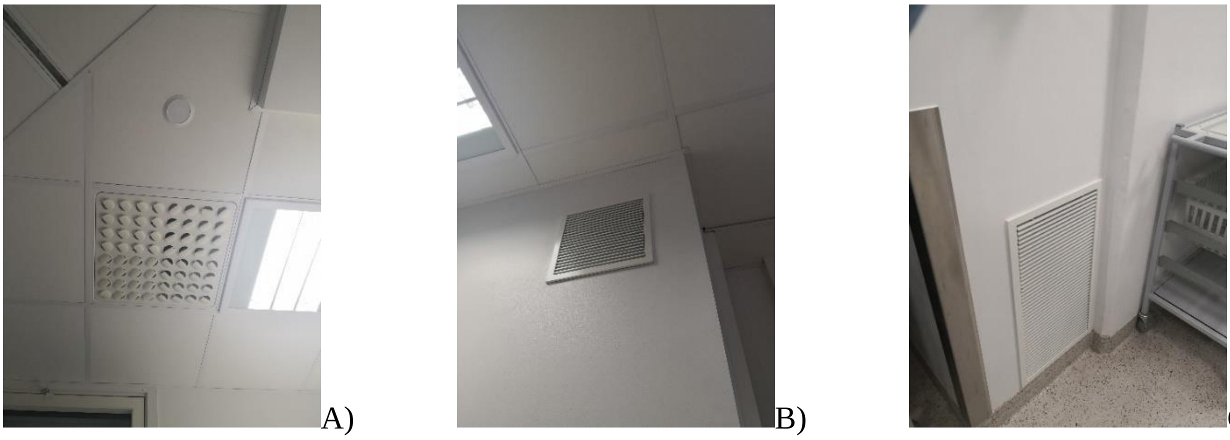
MV is based on the mixing principle and may achieve high dilution efficiency by introducing high-speed air from diffusors placed in the ceiling, forming a highly turbulent flow pattern inside a room. However, the dilution principle of MV potentially makes the contaminant source spread throughout the entire room and reach the surgical wound and sterile instrument table following the turbulent air pattern. In ORs with MV, the requirement of air cleanliness is ≤ 100 CFU/m^3 in many countries [11]. Earlier studies have shown that it is possible to achieve microbial concentrations ≤ 10 CFU/m^3 during surgery in ORs with MV [12.13].

Most of the earlier studies considered air quality of the whole space in ORs, and only a few studies focused on the zone close to the wound. A recent study defined the specific risk zone close to the surgical wound bounded by the surgeons, the patient, and the surgical lights as the operating microenvironment [11]. The air quality of the operating microenvironment could have a direct impact on the SSI. The main objective of this study is to clarify the possibility of achieving the requirement for an ultraclean OR (≤ 10 CFU/m^3) with MV from two factors of clothing and human activities. To achieve this, bacterial level of the operating microenvironment was measured in St. Olavs Hospital through five mock surgeries.

2 Materials and methods

2.1 Operation room for mock surgeries

All measurements through the mock surgeries were conducted in an actual OR with MV in the Emergency, Heart and Lung Centre at St. Olavs Hospital in Trondheim. The OR has an area of 53 m^2 and a floor height of 2.9 m. The OR was equipped with four radial air diffusors located in the ceiling in each corner of the room (Fig. 1). There were four exhaust grills in this OR. Two exhaust grills were installed on the wall of the entrance door, with one exhaust grill close to the floor and one close to the ceiling. The other two exhaust grills were installed in the same manner on the opposite wall. The total supply airflow rate was 3700 m^3/h, and the average airflow rate in the exhaust was 3300 m^3/h. The air change rate of the OR was 22.5 air changes per hour (ACH). The OR has a 5 Pa higher pressure than the adjacent rooms to avoid any leakage of contaminated air. The room temperature for all experiments was set 23 ºC.

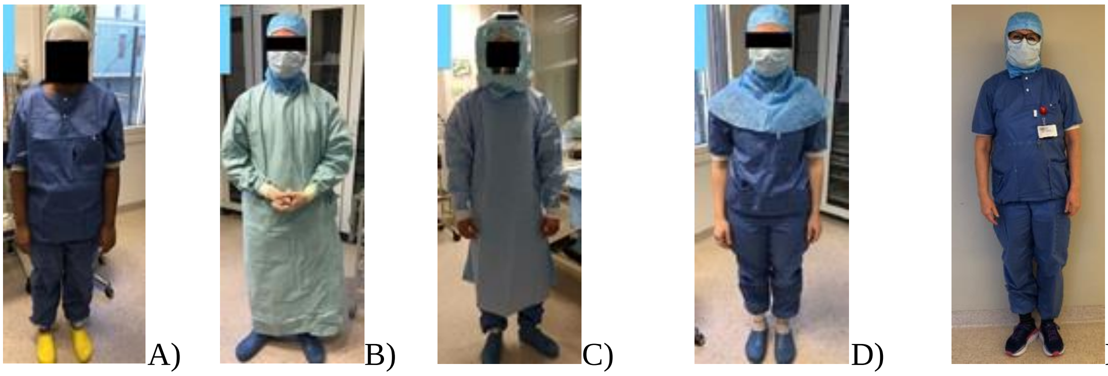


A) B) C)

Fig. 1. Air diffusors and exhaust grills: A) radial air diffusor, B) exhaust grill close to the ceiling, C) exhaust grill close to the floor

2.2 Clothing systems used in mock surgeries

Five different types of OR clothing were used in mock surgeries (Fig. 2). The clean air suit (clothing A) fulfilling the requirements of EN13795-2:2019 was used for a patient with a two-piece disposable nonwoven suit made of polypropylene [14]. Surgical members wore a clean air suit inside clothing B and clothing C. Clothing B, surgical gowns, were made of nonwoven polyester/polyethylene and were approved according to the EN13795-2:2019 standard. The surgical helmet system (SHS, clothing C, without a face mask) was made of a three-layer, liquid-proof fabric. A surgical cap was worn inside clothing C. Clothing D and clothing E were the combination of a clean air suit and a surgical hood, with incorrect hood position and correct hood position, respectively. The surgical hood also had a flexible strap securing a tight fit around the exposed parts of the face. The surgical masks used were EN 14683 type II approved and were of the double band, tie-on type, with an integrated adjustable nose clamp [15].



A) B) C) D) E)

Fig. 1. The different OR clothing of the five cases: A) clean air suit, B) surgical gown, C) surgical helmet system, D) clothing with incorrect hood position, E) clothing with correct hood position

2.3 Mock surgery

Five mock surgeries were conducted to simulate typical real operating conditions that can occur during orthopedic surgeries, as shown in Fig. 3. The mock surgeries can generally be divided into three main phases according to the activity level: incision (50 minutes); joint replacement (33 minutes); and wound suture (37 minutes). In addition, zero activity (20 minutes) was added before the start of three mock surgeries. During this phase, the patient and surgical members keep still with non-activity and non-talking. The different activity phases allowed for the investigation of how the activity level influences the CFU/m^3 level during surgery. The activities of incision and wound suture were similar. The joint replacement was differed from the two other phases by a hammering and shaking of arm action performed by the main surgeon (simulating hammering and drilling), squatting action by the assistant surgeon (simulating the maneuvering of the patient’s leg), and a shaking of the arm action by the sterile nurse (simulating mixing of cement). During the mock surgery, talking was performed by the surgical members who said the alphabet (a-z) loudly every 7th minute. All five mock surgeries were performed by 5 surgical members with a female patient. Most of participants of the mock up surgeries were the same with only change of one female and one male in case 1-2 and case 3-5, respectively. Detailed information on these five cases is presented in Table .

Fig. 3. The setup for the mock surgery (case 1)

Table 1. Conditions for the five mock surgeries

Mock surgeries	Case 1	Case 2	Case 3	Case 4	Case 5
Clothing of surgeon and sterile nurse	Clothing C	Clothing B	Clothing B	Clothing B	Clothing B
Clothing of unsterile nurse	Clothing C	Clothing D	Clothing E	Clothing E	Clothing E
Total duration	1 h 55 min	1 h 51 min	2 h 01 min	2 h 02 min	2 h 01 min
Door openings	1	No	1	1	No
Gender of staff	3 males, 2 females	3 males, 2 females	2 males, 3 females	2 males, 3 females	2 males, 3 females
Zero activity phase	No	No	Yes	Yes	Yes

2.4 Microbial contaminant measurements

To measure the CFU/m^3 in the OR, an active air sampler (AirIdeal 3P from Biomerieux) was placed on the stomach of the simulated patient, and air samples were collected at 10-minute intervals.

After the experiment, the agar plates were incubated at 35+/-2°C for two days and then for one day at room temperature before colony counting. The bacterial level of the empty OR (at rest state) was measured in cases 3-5 using the active sampler before each experiment. According to a guideline, a mixing ventilation system with 20 ACH removes 99% of the contaminants in an empty room in 14 minutes [16]. Hence, a delayed starting time of 15 minutes was used to allow any bacteria carrying particles (BCP) to be introduced when placing the sampler, to be either ventilated or to settle. The sampler had a constant suction volume of 100 L/min and used the impaction principle for particle collection. The device was calibrated 8 months prior to the start of the experiment. Agar plates had an external diameter of 90 mm and an internal diameter 85 mm with 5-7% cattle blood and maintains a pH of 7.4.

3 Results and discussion

3.1 The effect of clothing on CFU level

Clean air suits are designed to limit microbial dispersion from the wearer to the OR air, which is not the case for regular scrub suits [14]. Many studies have confirmed the protective effect of clean air suits compared to regular scrub suits by showing reduced airborne BCP concentration during surgery or in dispersal chamber tests. Surgical masks used in surgery must be EN-14683-type II approved, which ensures that the filter fabric has a minimum bacterial filtration efficiency of 98% for particles with a size of 3.0±0.3 μm [15]. Air leaks between the face of the wearer and the mask are known to reduce the occlusive effect of the mask. As much as 10%-40% of BCP can reach the OR air through leaks as a result of poor mask fit [17]. A double-tie-on mask with an adjustable nose clamp has been shown to provide a better seal than ear-loop masks [17].

The measured CFU levels in five cases are shown in Fig. 4. It can be seen that the CFU levels of cases 1-2 were higher than cases 3-5. In these five mock surgeries, the surgical team and the patient wore clean air suits with masks made of double tie-on type and folded under the chin. In Case 1, where the SHS was used, the surgical staff did not wear any surgical hood, and in Case 2, the surgical hood was not tucked under the clean air suit. In fact, the surgical hood should be tucked under the clean air suit to improve the seal, preventing the dispersion of airborne BCP. In cases 3-5, this measure was implemented. This may be one of the reasons why there was a reduction in the CFU/m^3 level compared to cases 1-2. The use of SHS does not reduce the CFU/m^3 level in a dilution ventilation OR compared to using regular OR clothing [18]. If the ultraclean requirement is to be met in a dilution ventilation OR, it seems to be a necessity that the surgical team wear clean air suits with the surgical hood tucked under the clean air suit.

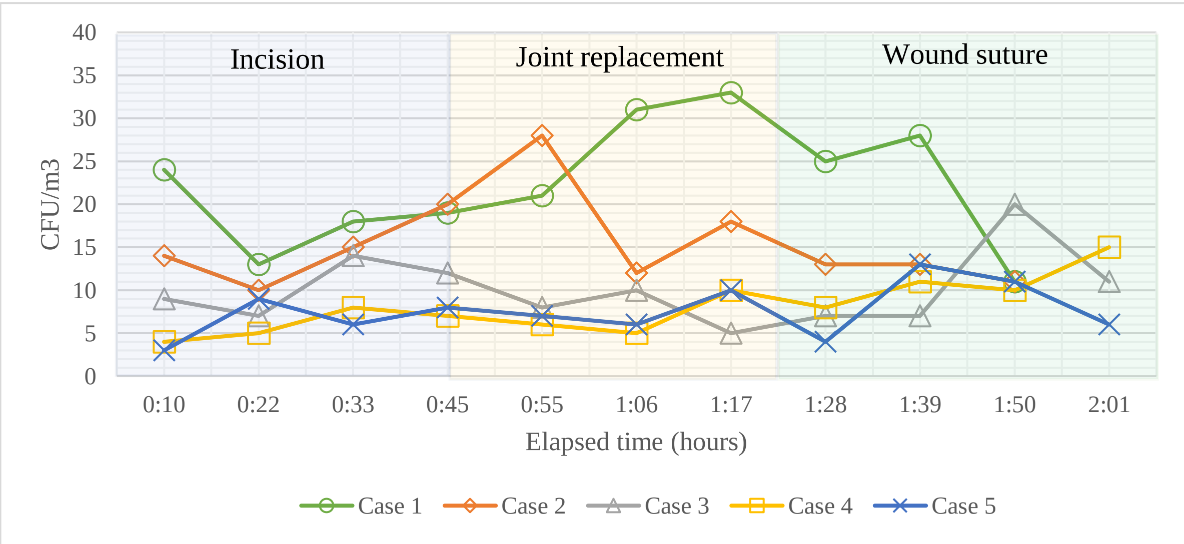


Fig. 4 CFU values of five mock up surgeries

3.2 The effect of human activities on CFU level

By calculating the average CFU/m^3 of each phase in these cases, a distribution of measured CFU levels are shown in Fig. 5. Many studies have suggested that activity level is an important mechanism that influences the CFU/m^3 level during surgery. In our study, a clear difference could be seen in the average CFU/m^3 level for the zero-activity phase in cases 3-5 compared with the activity phase in the same experiments. The average values of 2.5 CFU/m^3 for the zero-activity period and 8.5 CFU/m^3 for the activity period were observed in this study. This corresponds to an increase in CFU/m^3 by a factor of 3.4 for a surgical team that performs surgical procedures versus a surgical team standing still. In cases 3-5, the average CFU/m^3 was 8.5 CFU/m^3, which is below or equal to the ultraclean requirement. And the average CFU/m^3 for cases 1-2 was 19.4 CFU/m^3, which did not meet the ultraclean requirement. These results support the hypothesis and observations made in other studies that activity level is an important mechanism in influencing the CFU/m^3 level and that the activity level is a more important factor than the number of people present in the OR [19]. According to our results, one person moving can disperse the same amount of bacteria as 3-4 persons standing still.

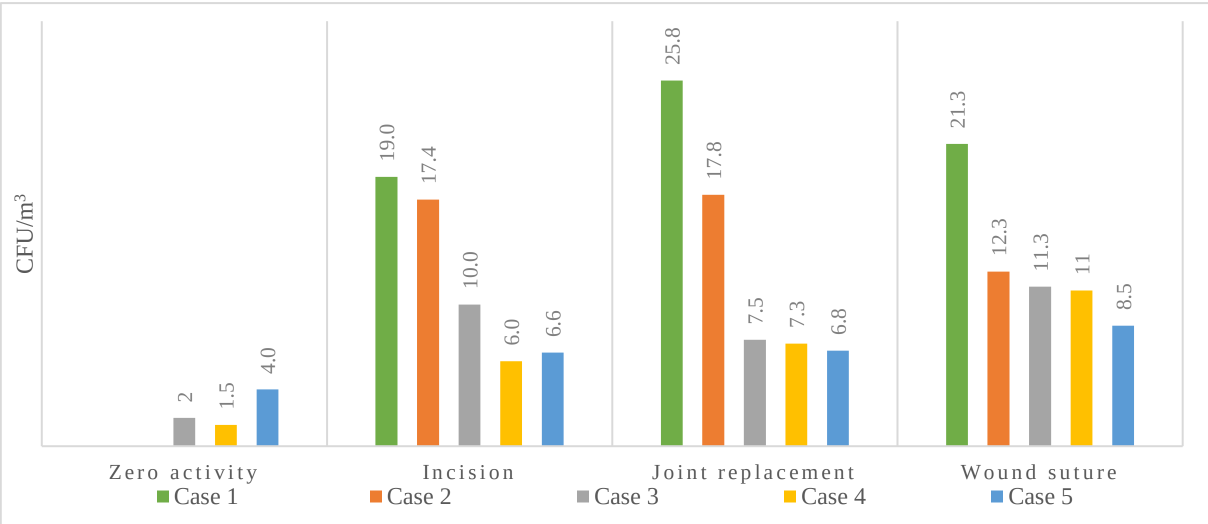


Fig. 5. The average CFU/m^3 of the different phases for the five cases

3.3 The effect of door openings on CFU level

Several studies have explored the correlation of door openings with CFU level by statistical method, as shown in Table 2. It can be seen form the results that there is a strong linear correlation between door openings and increase in CFU/m^3 for ORs equipped with displacement and MV. For UDF-system, there is an expected increase in CFU of 69.3 % if there is an operation with door openings, compared to one without door openings.

Table 2 The correlation of door openings with CFU level

Reference	Number of operations	Type of operation	Ventilation type	Correlation -door openings and increase in CFU/m^3
Andersson et al. [20]	n=30	Orthopedic trauma surgery	Displacement	r = 0.74, (P=0.001)
Smith et al. [21]	n=81	Orthopedic surgery	LAF	With door opening, the expected number of CFU increases with 69.3% (p=0.02)
Scaltriti et al. [19]	n=23	Conventional (n=12) and endoscopic(n=11)	MV	r=0.765 (p<0.01) for active samples for passive sample r=0.433(p<0.05)

In this study, After the door opening occurred in case 1, it was observed that the CFU level varied from 25 CFU/m^3 to 28 CFU/m^3. These measured values may be on the limit of detection of measuring CFU, as the accepted range for countable colonies on a standard agar plate is between 25 and 250 for most bacteria [22]. In cases 3-4, it was observed that the CFU level didn't increase immediately after the door opening occurred. However, the highest CFU/m^3 value was sampled between 1:39-1:50 hours and between 1:51-2:02 hours, in Case 3 and Case 4, respectively. It may indicate that there is a time delay from when microbial contaminant is introduced by the door opening until it reaches the surgical wound. This may be due to turbulent air flow patterns and staff movement inside the OR, as described in the study of Andersson et al. [20]. However, the current instrument to measure CFU is not able to explain accurately the possible delay of induced CFU caused by door opening. Further studies are needed to explain the transient phenomenon of transmission of CFU through door opening to the surgical environment.

4 Practical limitations

The experimental measurements performed in this study are important to understand the performance of mixing airflow regarding CFU levels in ORs. In this study, case 1-2 were conducted in a different period (in late autumn) which differs substantially from case 3-5 (in winter), which may contribute to the difference of indoor environment conditions. These might be unknown factors which will affect the measurement results of this study. However, all experimental setup in five cases were very similar and did not differ in any other substantial matter.

The level of airborne microbes occurring during surgery is a result of many factors, including ventilation design and performance, human activity, number of people, clothing, room cleanliness and so on [23-29]. As the practical limitations of the experimental measurements, we only analyze the effect of clothing and human activity on the CFU level in our study. Regarding door openings, the differences of temperature and bacterial concentration between operating room and adjoining room were not measured. With a clean corridor outside the operating room the door opening may not result in significant change of measured results. Moreover, other factors should be considered in further studies, including more combination of clothing systems, the differences of temperature and bacterial concentration between operating room and adjoining room, gender of surgical staff and surgery types. In addition, the level of CFU at the position of the instrument table is also important and this will be investigated in our further study.

5 Conclusions

It has been shown that a OR with MV may meet the ultraclean requirement, which has less than

10 CFU/m^3 of indoor air, if specific conditions, including a lower activity level and a proper clothing type, are present. However, a single operation can deviate quite substantially from this, even when these conditions are present. This study shows that MV may not meet the requirement for ultraclean operating room consistently through different operating phases, which may indicate the vulnerability of the MV systems during various phase of surgical operations. The large variation in CFU levels may be influenced by a number of factors, including activities of the surgical team, and clothing requirements of the surgical team. Our study led us to the following conclusions:

- It is possible to achieve the ultraclean air requirement ($\leq$ 10 CFU/m^3) during a surgical process with proper clothing and low surgical activities in ORs with MV.
- To achieve a lower CFU level of indoor air in ORs, all staff members should wear single-use clean air suits, preferably made of nonwoven material.
- Compared to regular OR clothing, the surgical helmet system (SHS) seems to be able to reduce the peak CFU load during a surgical procedure. However, it does not seem to further reduce the total CFU level in ORs with MV.
- A surgical team performing a surgical procedure may generate 3.4 times more microbial contaminants than a surgical team standing still in an OR with MV.

This study shows, though not desirable, that a good indoor air quality can be maintained during a surgical procedure with many surgical staff working in one OR with MV if calm intraoperative behavior is maintained. This was confirmed by another study that showed that up to 10-11 people wearing clean air suits can be present in an OR, and the ultraclean requirement can still be met [30]. To meet the ultraclean air OR requirement in a dilution ventilation OR, it is important to minimize door openings and activity level.

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