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Can clothing systems and human activity in operating rooms with mixed flow ventilation systems help achieve the ultraclean air requirement (≤10 CFU/m^3) during orthopaedic surgeries?

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SUMMARY

Objectives: The level of airborne microbial contamination in operating rooms (ORs) is an important indicator of indoor air quality and ensures a clean surgical environment. The main objective of this study was to clarify the possibility of achieving the requirement for an ultraclean operating room (≤ 10 CFU/m^3) with mixed flow ventilation based on clothing and human activity.

Methods: Experimental measurements during mock surgeries were conducted in an actual OR with mixed flow ventilation in the Emergency, Heart and Lung Centre at St. Olavs Hospital in Trondheim. The bacterial concentration close to the surgical site was measured during five mock-up surgeries. All five mock-up surgeries followed real surgical procedures which could represent similar conditions in the OR.

Results: The experiment results verified that the average CFU/m^3 of three of the five mock-up surgeries was 8.5, which was below or equal to the ultraclean requirement, while the other two mock-up surgeries did not meet the ultraclean requirement. Surgical activity together with the type of clothing worn by surgical staff in ORs seem to be the most significant reason for the high CFU level during surgery.

Conclusions: It is possible to achieve the ultraclean air requirement (≤ 10 CFU/m^3) during a surgical process with proper clothing and low surgical activity in ORs. This study clarifies

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the effect of clothing and human activity on the CFU level in the surgical micro-environment in ORs, and contributes to developing new products for the surgical team.

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 infection. A previous study has shown that airborne microbial contaminants are an important source of SSIs in clean operations [3]. Today, many countries measure the level of colony-forming units (CFU) per m^3 in operating rooms (ORs) during surgery as a measure of microbial standards. For an OR with ultraclean requirements, a value of $\leq$10 CFU/m^3 within 30 cm of the surgical wound is often used [4]. To fulfil the ultra-clean requirement, most ORs built today utilize a unidirectional airflow system (UDF system), also known as a laminar air flow system, as this type of system has been shown to deliver a cleaner operating environment compared with the traditional mixed flow ventilation (MV) system [5,6]. However, very few clinical studies have found clear correlation between decreased SSI rates and the use of a UDF system. In fact, one recent study showed that postoperative SSI rates increased in ORs using a UDF system [7]. A few studies have shown significantly higher SSI rates after knee prosthesis surgery and hip prosthesis surgery in ORs with a UDF system [8,9]. Due to ambiguity of the UDF system to decrease the SSI rate, this system is not recommended by the World Health Organization for patients undergoing total arthroplasty [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 spreads the contaminant source throughout the entire room, reaching the surgical wound and sterile instrument table following the turbulent air pattern. In ORs with MV, the requirement for air cleanliness is $\leq$100 CFU/m^3 in many countries [11]. However, studies have shown that it is possible to achieve microbial concentrations $\leq$10 CFU/m^3 during surgery in ORs with MV [12,13].

Most previous 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 micro-environment [11]. The air quality of the operating micro-environment could have a direct impact on SSI. The main objective of this study was to clarify the possibility of achieving the requirement for an ultraclean OR ($\leq$10 CFU/m^3) with MV based on clothing and human activity. To achieve this, the bacterial level of the operating micro-environment was measured in St. Olavs Hospital through five mock surgeries.

Methods

Operating room for mock surgeries

The mock surgeries were conducted in an actual OR with MV in the Emergency, Heart and Lung Centre at St. Olavs Hospital in Trondheim, Norway. The OR has an area of 53 m^2 and a height of 2.9 m. The OR is equipped with four radial air diffusors located in the ceiling in each corner of the room (Figure 1). There are four exhaust grills in this OR. Two exhaust grills are 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 are 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 pressure in the OR was 5 Pa higher than that in adjacent rooms to avoid any leakage of contaminated air. The room temperature for all experiments was set at 23 °C.

Clothing systems used in mock surgeries

Five different types of OR clothing (A–E) were used in mock surgeries (Figure 2). A clean air two-piece disposable non-woven polypropylene suit fulfilling the requirements of EN13795-2:2019 was worn by the patient (Clothing A) [14]. Members of the surgical team wore one of the following:

- Clothing B: a non-woven polyester/polyethylene surgical gown, fulfilling the requirements of EN13795-2:2019, worn over a clean air suit, together with a surgical face mask (EN 14683 type II approved) [15].
- Clothing C: a surgical helmet system (SHS), made of a three-layer liquid-proof fabric. A surgical cap was worn underneath the helmet, but no face mask was worn.
- Clothing D: a clean air suit and surgical face mask, and an incorrectly positioned surgical hood.
- Clothing E: a clean air suit and surgical face mask, and a correctly positioned surgical hood.

The surgical hoods had a flexible strap securing a tight fit around the exposed parts of the face.

Mock surgery

Five mock surgeries were conducted to simulate typical real operating conditions that occur during orthopaedic surgeries (Figure 3). The mock surgeries were divided into three main phases according to the activity level: incision (50 min); joint replacement (33 min) and wound suture (37 min). In addition, zero activity (20 min) was added before the start of three mock surgeries. During this phase, the patient and surgical members kept still with no talking. Activities relating to incision and wound suture were similar. Joint replacement differed from the two other phases by hammering and arm shaking performed by the main surgeon (simulating hammering and drilling), squatting action by the assistant surgeon (simulating the manoeuvring of the patient's leg), and an arm shaking action by the sterile nurse (simulating mixing of cement). During the mock surgery, talking was performed by the surgical members reciting the alphabet (A–Z) loudly every seventh minute. All

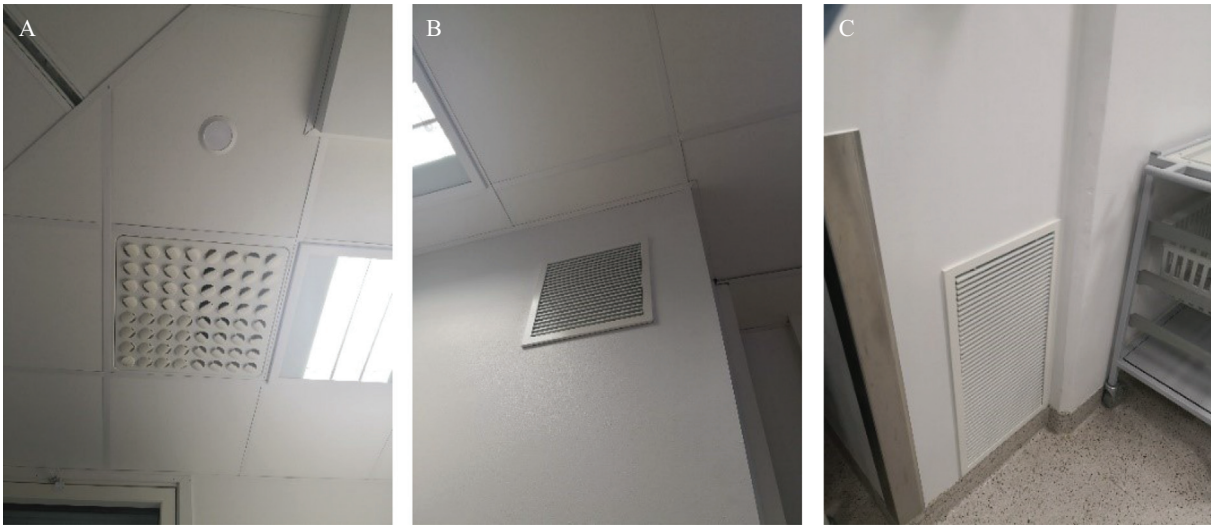

Figure 1. Air diffusors and exhaust grills: (A) Radial air diffusor. (B) Exhaust grill close to the ceiling. (C) Exhaust grill close to the floor.

five mock surgeries were performed by five surgical members with a female patient. Most participants in the mock surgeries were the same, with a change of one female and one male participant in Cases 1—2 and Cases 3—5, respectively. Detailed information on the five cases is presented in Table I.

Microbial contaminant measurements

To measure the CFU/m^3 in the OR, an active air sampler (AirIdeal 3P, bioMérieux, Marcy l'Etoile, France) was placed on the upper abdomen of the simulated patient, and air samples were collected at 10-min intervals. After the experiment, the agar plates were incubated at 35 $\pm$ 2 °C for 2 days and then for 1 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, an MV system with 20 ACH removes 99% of the contaminants in an empty room in 14 min [16]. Hence, a delayed starting time of 15 min was used to allow any bacteria-carrying particles (BCPs) 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 containing 5—7% cattle blood with external and internal diameters of 90 mm and 85 mm, respectively, were used.

Results and discussion

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 with regular scrub suits by showing reduced airborne BCP concentration

Figure 2. Operating room clothing for 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.

Figure 3. Set-up for mock surgery (photograph taken during Case 1).

Table I
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

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 BCPs 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 Figure 4. It can be seen that the CFU levels of Cases 1–2 were higher than those for Cases 3–5. In these five mock surgeries, the surgical team and the patient wore clean air suits with double tie-on masks, folded under the chin. In Case 1, where an SHS was used, the surgical staff did not wear a surgical hood, and in Case 2, the surgical hood was not tucked under the clean air suit (the surgical hood should be tucked under the clean air suit to improve the seal, preventing the dispersal of airborne BCPs). 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 with Cases 1–2. The use of a SHS does not reduce the CFU/m^3 level in a dilution ventilation OR compared with the use of regular OR clothing [18]. If the ultraclean requirement is to be met in a dilution ventilation OR, it seems that the surgical team need to wear clean air suits with the surgical hood tucked under the clean air suit.

Effect of human activity on CFU level

The distribution of average CFU/m^3 at each phase for the five cases is shown in Figure 5. Many studies have suggested that activity level is an important mechanism that influences the CFU/m^3 level during surgery. In the present 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 CFU/m^3 level increased by a factor of 3.4 for a surgical team performing procedures compared with the same team standing still. In Cases 3–5, the average CFU/m^3 level was 8.5 CFU/m^3, which is below or equal to the ultraclean requirement. The average CFU/m^3 level 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 factor influencing the CFU/m^3 level, and that the activity level is more important than the number of people present in the OR [19]. According to the present results, one person moving can disperse as many bacteria as three to four people standing still.

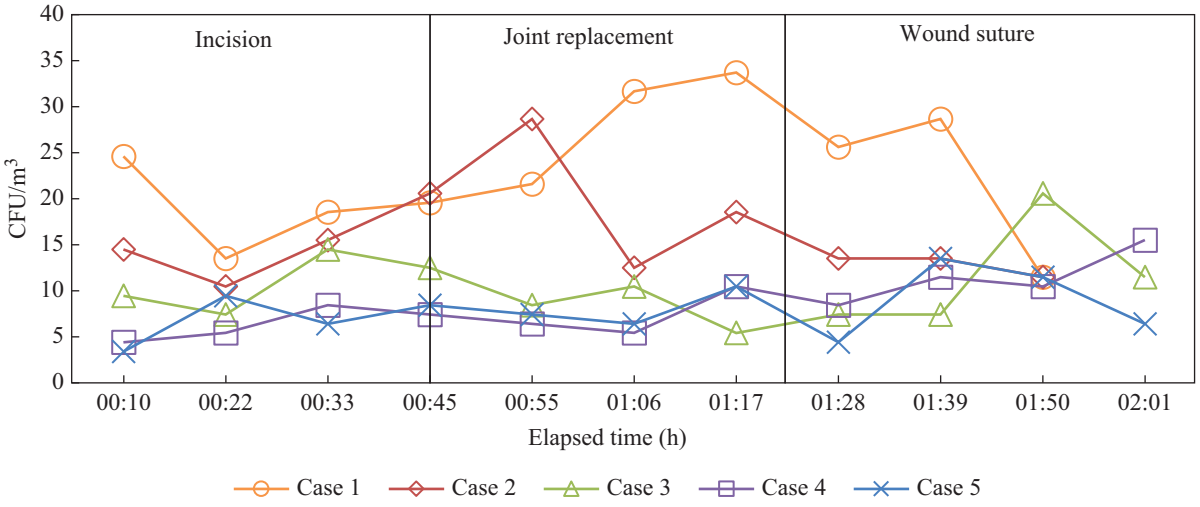

Figure 4. Colony-forming unit (CFU) values of five mock surgeries.

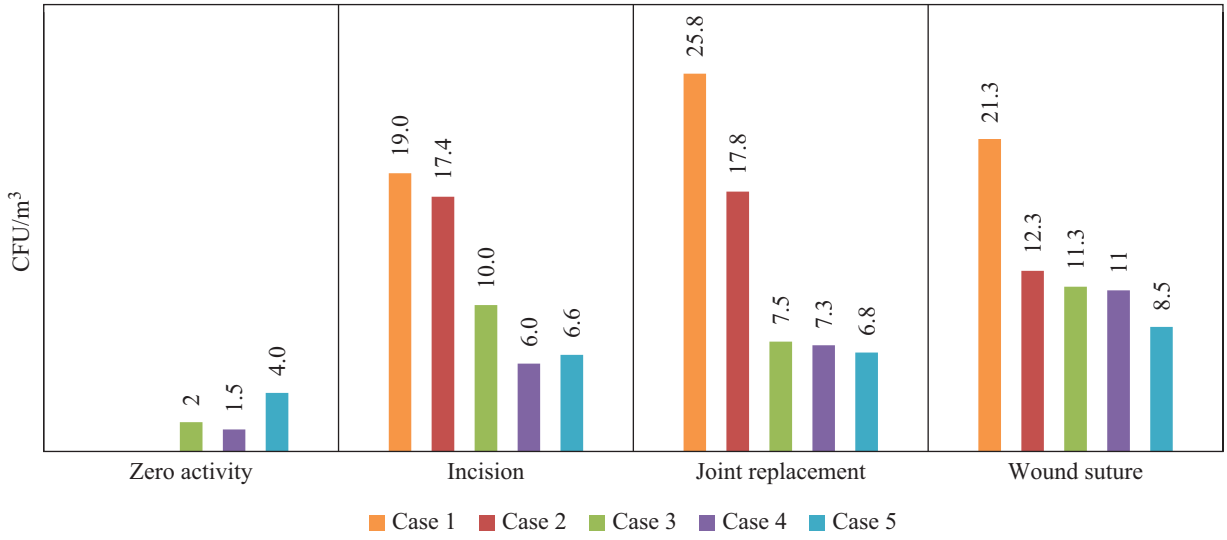

Figure 5. Average colony-forming unit (CFU) level/m^3 in each phase for the five cases.

Effect of door openings on CFU level

Several studies have explored the correlation between door openings and CFU level, as shown in Table II. It can be seen from the results that there is a strong linear correlation between door openings and increased CFU/m^3 level for ORs equipped with displacement ventilation and MV. For ORs with a UDF system, an expected increase in the CFU level of 69.3% was observed for operations with door openings compared with those without door openings.

In this study, after the door opening occurred in Case 1, the CFU level increased from 25 CFU/m^3 to 28 CFU/m^3. These 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 did not increase immediately after the door opening. However, the highest CFU/m^3 value was sampled between 1:39 and 1:50 h and between 1:51 and 2:02 h in Cases 3 and 4, respectively. This may indicate that there is a time delay from when a 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 by Andersson *et al.* [20]. However, the current instrument to measure CFU is not able to explain the possible delay in CFU increase caused by door opening. Further studies are needed to explain the transient phenomenon of transmission of CFU through door opening to the surgical environment.

Practical limitations

The experimental measurements performed in this study are important to understand the performance of mixing airflow regarding CFU levels in ORs. Cases 1–2 were conducted in late autumn, whereas Cases 3–5 were conducted in winter; this may have contributed to the difference in indoor environment conditions. In addition, there may be unknown factors affecting the measurement results of this study. However, all experimental set-ups in the five cases were very similar.

Table II
Correlation of door openings with colony-forming unit (CFU) level

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

LAF, laminar air flow; MV, mixed flow ventilation.

The level of airborne microbes during surgery is a result of many factors, including ventilation design and performance, human activity, number of people, clothing, room cleanliness etc. [23–29]. Due to practical limitations of the experimental measurements, this study focused on the effects of clothing and human activity on CFU level. Regarding door openings, differences in temperature and bacterial concentrations between the OR and the adjoining room were not measured. With a clean corridor outside the OR, door opening may not result in a significant change in CFU level. Moreover, other factors should be considered in further studies, including more combinations of clothing systems, differences in temperature and bacterial concentrations between the OR and the adjoining room, gender of surgical staff, and types of surgery. In addition, the CFU level at the instrument table is also important, and this will be investigated in a further study.

In conclusion, this study showed that an OR with MV may meet ultraclean requirements (<10 CFU/m^3) under specific conditions, including lower human activity and appropriate clothing. However, a single operation can deviate quite substantially from this, even when these conditions are met. This study shows that MV may not meet the requirement for ultraclean ORs consistently through different operative phases, which may indicate the vulnerability of MV systems during various phases of surgical operations. The large variation in CFU levels may be influenced by a number of factors, including human activity and clothing worn by the surgical team. This study led to the following conclusions:

- It is possible to achieve ultraclean air requirements (≤10 CFU/m^3) during surgery in ORs with MV with appropriate clothing and low surgical activity.
- To achieve a lower CFU level of indoor air in ORs, all staff members should wear single-use clean air suits, preferably made of non-woven material.
- Compared with regular OR clothing, the SHS may 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. Therefore, calm behaviour should be maintained during surgery.
- Although not desirable, good indoor air quality can be maintained with many surgical staff present in one OR with MV. This supports another study which showed that 10–11 people wearing clean air suits can be present in an OR and the ultraclean requirement still 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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Conflict of interest statement
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