

Can we meet the requirement for ultra-clean operation room (10CFU/m³) with dilution ventilation?

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Abstract. The objective of this study is to analyse what conditions may, and may not take place during surgery in a dilution ventilated operating room (OR), to fulfil an ultra-clean requirement (10 CFU/m³). To achieve the objective, literature review and a mock surgery with air sampling was performed. Colony forming unit (CFU) measurements were conducted to estimate the bacterial concentration in the air. During the mock surgery, the following conditions was present: a clean air suit, surgical gowns, double-tie-on masks and surgical hoods was used by all surgical members, except for the non-sterile members whom did not wear surgical gowns. 5 surgical members + 1 patient were present, 0 door openings occurred and a predefined movement and action plan set the activity level. The average CFU/m³ for the mock surgery was 15,4(SD:5,4). The CFU/m³ during a high activity period was about 21,5% higher than in low activity periods. With the conditions simulated in the mock surgery, and the clothing used, the OR were not able to fulfil the ultra-clean requirement. To reduce the CFU/m³ the activity level needs to be reduced. The literature shows that to meet the ultra-clean requirement all staff members should wear single-use clean air suits made of non-woven fabric, surgical masks, and a surgical hood. Traffic level needs to be minimized and a calm intraoperative behaviour needs to be maintained by the surgical staff. The amount of people present seems less important compared to the activity level taking place during surgery.

1. Introduction

Studies have shown that bacteria carrying particles (BCP) finding its way to the surgical wound by the airborne route is an important source of surgical site infections (SSI) in clean operations(1). The BCP-level occurring during surgery is a result of many factors, including; ventilation design and performance, number of people present, occupant behaviour, traffic in and out of the OR, type of clothing used, obstacles for air distribution, convective air currents, and room cleanliness (2-8).

Today many countries use the colony forming unit per cubic metre of air (CFU/m³) as a parameter to classify ORs regarding their expected bacterial performance. For an OR with an ultra-clean requirement a value of 10 CFU/m³, within 30cm of the wound is often used after being suggested by (9).

To fulfil the ultra-clean requirement, most ORs built today utilizes a laminar air flow (LAF) ventilation system, as it has proven to deliver a cleaner operating environment compared to the dilution ventilation principle(1, 10-13). However,

recent studies have shown that there is little difference in the prevalence of SSI between the designs(14-16), and as a consequence WHO in their guideline *Global guidelines for the prevention of surgical site infection* do not recommend the use of LAF as a measure to reduce the incidence of SSI(17).

Stated by these facts, and given the higher investment and operation cost of the LAF system(18), it is interesting to analyse the dilution ventilation principle to achieve an ultra-clean OR.

Studies have shown that it is possible to get bacterial concentration below 10 CFU/m³ during surgery in a dilution ventilated OR(3, 19-22). The main goal of this article is to analyse the perimeters present to as; *what conditions may and may not take place during surgery in a dilution ventilated OR to fulfil an ultra-clean requirement*. To evaluate this, findings from the literature is used together with aero microbiologically counts during a mock surgery.

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1.1 Source of bacteria in the operating room

In clean operations, such as orthopaedic and vascular implant surgery, it has been proven that bacteria living on the skin of the staff and the patient is an important source of causing SSI(1, 23). The human skin is continuously renewing itself, and in the process, skin scales are shed in a magnitude of 10^7 per day (24, 25). Around 10% of the shed scales inhabits bacteria(25), and if dispersed into the air they may strike or settle in the wound, on instruments or a surgeons hands, forming both a direct and indirect route of wound contamination(1).

1.2 Dilution ventilation

The dilution ventilation principle achieves its workings by introducing high speed air from diffusors placed in the ceiling, which forms a chaotic turbulent flow pattern inside a room. This turbulent behaviour causes the inlet air to mix with the existing air in the room, thus dilute whatever the contaminants that are present in the air. The diluted air is then exhausted through strategically placed grills. The nature of this principle is such that whatever the placement of a contaminant source in the room, its contaminants may reach the surgical wound following the chaotic air pattern. Thus, to achieve a low airborne BCP level in the vicinity of the surgical wound, it is essential to limit the bacterial source strength from all sources in the room, not only near the surgical field.

1.3 OR clothing

To protect the wound and surgical field from airborne BCP, different OR clothing and gear can be used to limit bacterial dispersion. Most of these products achieves their working by containing the BCP. Commonly used products are; surgical masks, surgical hood/cap and scrub suits. Scrub suits are distinguished between two types; regular scrub suit and clean air suit. Clean air suits are designed to limit bacterial dispersion from the wearer to the OR air, which is not the case for regular scrub suits(26). Many studies have confirmed the protective effect of a clean air suit compared to regular scrub suits, by showing reduced airborne BCP concentration during surgery or in dispersal chamber tests(19, 21, 27). When looking at the chaotic air pattern of the dilution ventilated principle, it is important that all members of the surgical team is wearing clean air suits to minimize the BCP concentration.

1.4 Ultra-clean air quality in a dilution ventilated ORs

Many studies in the literature have shown CFU levels below 10 CFU/m^3 for operations performed in dilution ventilated ORs(3, 19-22). These studies are

generally concerning the evaluation of bacterial dispersion of clean air suits compared to regular scrub suits.

Some common factors seem to be present in these studies to achieve the low bacterial counts, and that is; the use of clean air suits and to limit traffic flow.

In (3) 10 to 11 people were present during the surgeries and still a mean value of 7 CFU/m^3 was achieved. It is thinkable that the calm nature of the cardiac operations, compared to for example a total hip and knee arthroplasty, where hammering, drilling, sawing and manoeuvring of the patient's leg is occurring, leads to reduced bacterial dispersion. This was also one of the conclusions from the author of the article; that the staff should adjust their activity level during the entire operation to minimize wound sepsis, thus underlining the importance of reducing the activity level in order to achieve low CFU/m^3 .

(28) suggested a similar conclusion in a study which involved passive and active bacterial sampling of 23 operations of different nature. It was found that both passive and active microbiological samples correlated with door-opening frequency, which the authors used as an index of staff and visitor movement, but not with the number of people present during surgery.

Based on these findings the authors suggested that human movement inside the OR was a more important factor than the number of people present during surgery in keeping low BCP concentrations.

To meet the ultra-clean requirement with dilution ventilation it seems important to keep OR traffic and activity level to a minimum. Further, it seems to be possible to have up to 10-11 persons present during surgery, if a calm intraoperative behaviour is maintained by the surgical staff. Although most of the studies in which the surgical staff wore clean air suits quite consistently showed CFU/m^3 values below the ultra-clean requirement, some operations in some of studies did not meet the requirement.

2. Materials and methods

2.1 Operation room layout and ventilation

A dilution ventilated OR in the emergency and hearth-lung centre at St.Olavs hospital in Trondheim was used for performing the mock surgery(Figure 1). The OR is equipped with four radial diffusors located in the ceiling in each corner of the room, and four exhaust grills, where two is placed near the ceiling and two near the floor. The OR has around 22,5 ACH and a positive pressure relationship of 5Pa to the adjacent rooms.



Figure 1: Showing the layout of the OR used in the mock surgery. One of the diffusers can be seen in the upper left corner of the figure



Figure 2: Showing the setup for the mock surgery

2.2 Mock surgery

A standardized mock surgery has been composed to simulate typical real-operating conditions that can occur during a total hip arthroplasty. The parameters being controlled is shown in Table 1.

Table 1: Showing some of the parameters which are known to affect the BCP concentration in the OR air during surgery, and how these are controlled in the composed mock surgery.

Controlled parameters:	Control measure:
Movements and activity level	A predefined movement and action plan for each member of the staff
Number of persons	5 staff members and 1 patient
Door openings	0
Talking	All staff members say the alphabet out loud every 7 th minute
Electrocautery	No use of electrocautery
Operation length	2 hours

A predefined movement and action plan for each member of the staff was made, based on the authors observations during a real hip arthroplasty surgery. The experiment can generally be divided in three main phases according to the activity level:

1. incision phase (0-50min), 2. joint replacement phase (50-83min) and 3. wound closure phase (83-120min). The incision and wound closure phase have a very similar activity distribution. The joint replacement phase differs from the two others by a hammering and shaking of arms action performed by the main surgeon (simulating hammering and drilling), squatting action by the assistant surgeon (simulating the manoeuvring of the patients leg), and shaking of arms action by the sterile nurse (simulating mixing of cement). The setup for the mock surgery is shown in figure 2:

2.3 Operating room clothing

The *base layer* for the staff and patient consisted of a non-woven two-piece disposable clean air suit made of polypropylene, approved according to the EN 13796 standard. The following additional clothing was worn: Sterile members wore disposable surgical gowns, double-tie-on masks and surgical hoods. The non-sterile members used the same clothing, with the exception of the surgical gown. Specifications/description of the different clothing/gear;

-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.

-Surgical hood had folds that stretched down the upper body

-Gowns were made of nonwoven polyester/polyetylen and were approved according to the EN13795:2011 standard. They were equipped with flexible cuffs which the gloves were pulled tightly over to secure an airtight fit.

2.4 Sampling method

To measure the CFU/m³ in the OR air an active air sampler, simulating the surgical wound, was placed on the patients stomach and gathered BCP in 10 minutes intervals. It took about one minute to change agar plate in the active sampler between measurements. All surgical activities were centred around the sampler, approximately 10-20cm away from it. Sampling was done around 1,1m above the floor. After experiment end, the agar plates were brought to incubation and was first stored at a temperature of 35 +/- 2°C, for two days, then for one day at room temperature before counting.

The bacterial level of the empty OR(at rest state) was measured using the active sampler before the experiment. The sampler was placed on the same location as it would have during the experiment. According to (29) a dilution ventilation system with perfect mixing and 20 ACH, removes 99% of the contaminants in an empty room in 14 minutes.

Hence, a delayed starting time of 15min was used to allow any BCP being introduced when placing the sampler to be either ventilated or to settle before the empty room measurement.

2.5 Instruments

2.5.1 Active air sampler

An active air sampler (*AirIdeal 3P, Biomerieux*) was used to measure the BCP level in the air. The sampler has a constant suction volume of air of 100L/min, and uses the impaction principle for particle collection. Air is drawn through a perforated plate, and any particles passing the holes impacts on an agar plate with a speed of less than 20m/s. The device was set to draw air for 10 minutes for each sample, meaning a suction volume of 1000 l. The device was calibrated 8 months prior to experiment start. Bacterial counts were converted to most the probable number of microorganisms collected per plate (MPN) following FELLER's law. This statistical correction is used since a single organism may enter the same orifice in the suction plate, making it difficult to evaluate if the colony emerged from a single or multiple BCP's. 85mm agar plates enriched with 5-7% cattle blood, which maintains a pH of 7,4 was used for the measurements. 5% of the used plates were controlled for sterility

2.5.2 Manometer

To measure the pressure differential between the OR and the adjacent areas, the device "DPM TT570 C" was used. The device has a resolution of 1 Pa and an accuracy of ± 2 Pa. The device was calibrated 7 months prior to the experiment.

3. Results

The CFU readings from the active sampler is shown in Figure 3. Average CFU/m³ was 15,4(SD:5,4).

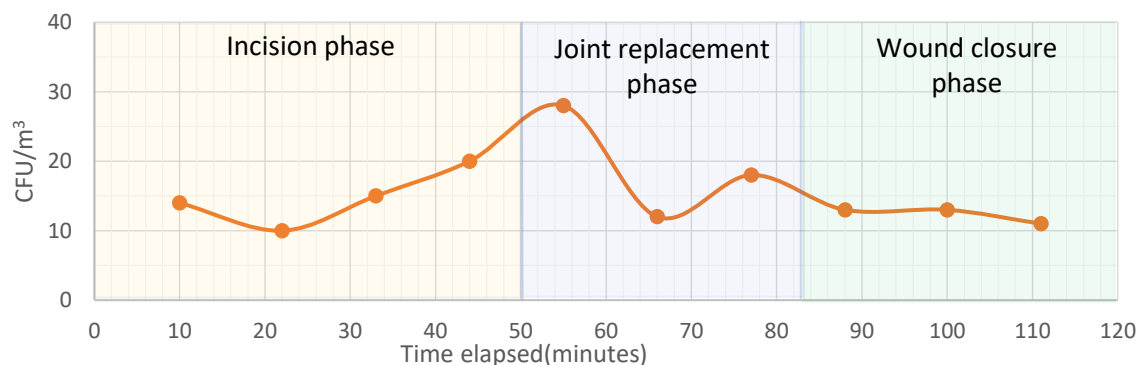


Figure 3: Showing a graphical view of the CFU/m³ values from Table 2. The x-axis shows at which time during the experiment the samples were taken. Y-axis shows the amount of BCP collected from the OR air by the active sampler. The graph is divided in the three phases of the mock surgery: Incision phase (0-50 min), joint replacement phase (50-83 min) and wound closure phase (83-120 min).

4. Discussion

By looking at the average CFU/m³ value, we can see that with the clothing used and the conditions which emerged by the mock surgery, the OR did not manage to meet the ultra-clean requirement of 10CFU/m³.

For the sample curve (figure 3) we can observe a high first reading for the joint replacement phase (sample nr 5, figure 3) which is expected due to the increased activity level. Then for the second reading (sample nr 6) a decrease is seen, followed up by an increase on the following reading (sample nr 7). A possible explanation for this "dimp" in the curve during the joint replacement phase is that the inserting and removal of the 6th agar plate(sample nr.6) from the active sampler interfered with two "shaking of arms" activity performed by the main surgeon, and hence any BCP that was dispersed during these activities was not collected by the sampler. Therefore the actual average CFU/m³ value for the joint replacement phase is probably higher than what the readings show. Consequently, the CFU/m³ values for the experiment is probably somewhat higher then what the results shows.

4.1 Activity level and airborne BCP level

It is interesting to analyse how much the increased activity level during the joint replacement phase affected the airborne BCP level, compared to the calmer incision and wound closure phase. By calculating the average CFU/m³ for each of the phases in the experiments, the distribution in figure 4 can be seen. Generally, a higher average CFU/m³ can be seen during the joint replacement phase, compared to the two other phases. The mean CFU/m³ increased by 11% from the incision phase to the joint replacement phase, and then decreased 32% when going from joint replacement phase to wound closure phase. By taking into account that the readings for sample nr.6 probably should be higher, it is likely that the effect of the increased activity

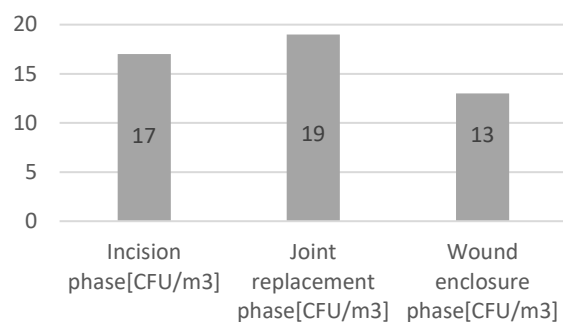


Figure 4: Showing the average airborne BCP concentration (CFU/m³) for the different phases of the experiment.

level should also be higher. The increased activity during the joint replacement phase, compared to the two other phases, resulted in an average increase of 21,5% in the airborne BCP level. This indicates that the activity level is of great importance to reduce the bacterial load on the surgical wound.

4.2 The OR

In one of the corners of the OR, a large robotic x-ray machine is placed. It is possible that the machine blocks some of the air flow from one of the diffusers, leading to a possible stagnant zone near the operating table. If this is the case, the stagnant zone could have affected the BCP concentration near the surgical field and further led to elevated BCP counts during the experiment. The CFU readings from the active sampler of the empty room, showed 0 CFU/m³. This confirms that there is no infiltration of polluted air from the adjacent rooms. It is uncertain if the OR used in the experiments reflects the optimum case.

4.3 Ultra-clean air quality in a dilution ventilated OR

It is clear that the conditions emerging from the mock surgery, with the clothing being worn, was too rough for the ventilation system to handle for the OR to meet the ultra-clean requirement. The clothing which were worn, is the same type which were used in many of the operations from the literature that managed to meet the ultra-clean requirement.

One of the common denominators in the literature for low CFU/m³ level was to keep traffic level in and out of the OR to an absolute minimum.

In our study this condition was fulfilled by keeping the doors closed during the experiments. Following this reasoning one should imagine that the experiment carried out should suppress 10 CFU/m³, especially when considering that many of the used studies from the literature had more people present in the OR, and still managed to meet the ultra-clean requirement

The analysis of the CFU/m³ related to the different phases of the mock surgery clearly shows that increased activity level leads to increased

bacterial dispersion. It is therefore quite clear that the activity level which emerged from the mock surgery was too high, and if an ultraclean OR is to be achieved, the activity level has to be reduced. The idea that activity level has a big influence on the CFU/m³ level, is supported by some (3, 28).

5. Conclusion

Earlier studies shows that a dilution ventilated OR can meet the ultra-clean requirement quite consistently if the right conditions are present (3, 19-22). However, single operations can deviate quite substantially from this, even when the right conditions are present.

With the simulated conditions in the mock surgery, the OR clothing used were not able to ensure an indoor air quality that met the ultra-clean air quality requirement. To reduce the bacterial concentration in the air during the mock surgery, the activity level needs to be reduced.

To meet the ultra-clean requirement in a dilution ventilated OR, all staff members should wear single-use clean air suits, preferably made of non-woven material. Surgical masks and hoods should be worn by the entire staff. The amount of people present seems less important compared to the activity level taking place during surgery. 10-11 people wearing clean air suits can be present and the OR can still fulfil the ultra-clean requirement, if the activity and traffic level is minimized(3). Activity level together with traffic in and out of the OR seems to be the most significant reason for high airborne BCP concentration during surgery in ultra-clean operations.

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