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Evaluating the effect of Novarerus NV800 air purifier units during orthopaedic surgery to reduce bioburden in the air

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SUMMARY

Background: A locally installed air purifier unit (Novaerus Protect 800) has been shown to reduce the air bioburden in an intensive care unit and the incidence of healthcare-associated infections.

Aim: To explore whether this type of air purifying unit could reduce bacterial concentrations in the air of an operating room (OR) during orthopaedic surgery, thereby reducing the risk of surgical site infections.

Methods: In this prospective experimental study, undertaken in 2018, three air purifying units were installed in an OR in a Swedish hospital in 2018. The air was actively sampled during 11 operations by a slit-to-slit agar impactor with the air purifying units either switched on or switched off. Air movements were visualized with the aid of smoke in mock-up studies.

Findings: No significant difference in bacterial concentrations in air was found between the two conditions (air purifying units switched off or on) (P=0.54). Air movements around and above the surgical wound were disordered and resembled those of dilution mixing air.

Conclusion: The three air purifying units installed in the OR did not reduce the airborne bacterial levels in the critical zone during orthopaedic surgery.

Introduction

Orthopaedic surgical site infections are devastating complications that are difficult to treat with antibiotics due to biofilm formation around prosthetic material, often in combination with antibiotic resistance [1]. Preventive measures to block bacteria from entering the wound during surgery are multi-faceted and often bundled, including, for example, appropriate use of surgical prophylaxis, surgical site preparation, limiting the number of people and movements in the operating room (OR), limiting door openings and traffic into the OR, and tight clothing for staff [2]. Airborne transmission of bacteria-carrying skin scales from surgeons and staff into the surgical wound can be blocked by effective heating, ventilation and air conditioning (HVAC) systems, which dilute airborne bacteria and sweep them away from the surgical wound and instruments [3].

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Many ORs in Sweden have HVAC systems with relatively low air supply rates compared with modern ORs. This makes it difficult to meet the strict requirements of infection-prone surgery, such as total hip and knee joint replacements. It is costly to build new and more effective HVAC systems, so cheaper solutions to achieve clean air in the OR are preferred.

It was recently shown that a locally installed air purifier unit was able to reduce the air bioburden in an intensive care unit (ICU) and the incidence of healthcare-associated infections [4]. Logically, air purifier units could reduce the bacterial concentration in OR air during surgery, thereby reducing the risk of surgical site infections. The aim of this study was to explore whether local air purifying units could reduce bacterial concentrations in the air of an OR during orthopaedic surgery, in addition to the existing HVAC system.

Methods

Study design and ethics

A prospective experimental study was set up in an orthopaedic department in a Swedish university hospital. This study was part of the randomized multi-centre EPOS study described elsewhere [5], which was approved by the Swedish Ethical Review Authority (2015/1139–31/4). The study was approved by the Head of the Department of Orthopaedic Surgery, and performed in accordance with the Declaration of Helsinki [6].

Setting

This study was udnertaken at Danderyd's University Hospital, Sweden over a 3-week period in autumn 2018. The selected OR had high-efficiency particulate air (HEPA)-filtered air supplied through an inclined screen with air flow of 0.6 m^3/s, providing approximately 20 air changes per hour. The inclined screen was situated along one of the side walls near the ceiling, and exhaust air devices were located close to the floor on two opposite walls.

Surgical clothing

The surgical team wore high-performance, disposable clean air suits (Mölnlycke, Gothenburg, Sweden) which met the requirements of European Standard EN-13795–2:2019 [7]. The clean air suits had known source strength of 1.15 colony-forming units (CFU)/s during orthopaedic surgery [8]. The clean air suits met the Swedish requirement for infection-prone orthopaedic surgery of source strength $<$1.5 CFU/s [9].

Air purifying equipment

Three Novaerus Protect 800 (NV800; DCU Alpha, Dublin, Ireland) air purifier units were used in this study. These are commercially available recirculation air cleaners, intended to decrease the concentration of micro-organisms in the air when in operation. The unit is designed to be wall mounted or fixed on a mobile rail, and has a size of 366 mm (height) x 365 mm (width) x 114 mm (depth). The technology (NanoStrike) inactivates airborne bacteria and viruses by bursting cells and inactivating nucleic acids by plasma. The air is sucked into the unit from underneath, and is emitted after the purification process from the vertical sides of the units. The units were installed on two opposite-facing side walls, next to the wall with the inclined screen. Each unit had an airflow rate of 0.07 m^3/s, and the total air flow passing through the three units was 0.21 m^3/s.

Active air sampling

The OR air was actively sampled during orthopaedic surgery using a slit-to-slit agar impactor FH3™ [10] with $d_{50} \leq 2$ μm, in accordance with SS-EN 17141 2020 and Swedish guidelines [9]. The air was sampled as blind tests with the air purifying units either switched on or switched off. The slit sampler was placed approximately 1 m above the floor, adjacent to the instrument table, at the same level as the operating wound. Each operation lasted for $>$45 min, enabling four to six samples to be taken during each operation in accordance with Swedish recommendations [9].

Laboratory analysis

The microbiological growth medium for all tests was standard medium tryptic soy agar (TSA) in 90-mm Petri dishes. The TSA plates were incubated for $\geq$72 h at 32 °C, followed by $\geq$48 h at room temperature (22 ± 2 °C). After incubation, the number of CFUs was counted and recorded as aerobic CFU/m^3.

Visualization of air movements by smoke test

The visualization of air movements was performed with the aid of smoke using Dräger air current tubes. These tests were carried out in the OR without staff, but the influence of staff movements was determined with mock-up studies.

Statistical analyses

Maximum, minimum and mean bacterial concentrations were calculated for each operation, and expressed as mean (min–max) CFU/m^3. The Mann-Whitney two-sided *U*-test was used to compare the results from the two conditions (air purifying units switched on or off). $P \leq 0.05$ was considered to indicate significance.

Results

The air was sampled during 11 orthopaedic procedures in autumn 2018, with the three air purifier units switched off during five operations and switched on during six operations (Table I). Surgical characteristics and the results of active air sampling are shown in Table I. The difference in the bacterial concentration in the air between the two conditions (air purifying units switched on or off) was not significant (P=0.54) (Figure 1).

The smoke test visualized air movements in the 'critical zone', which was taken to be the area around and above the surgical wound and the operating table in this study. Air movements were also studied in the periphery around the air supply screen and the exhaust devices. The observed airflow pattern in the 'critical zone' was disordered, and resembled that of dilution mixing air due to the movements of the surgical team and their convection flows.

Table I
Surgical characteristics and results of active air sampling when the air purifying units were switched off (Operations 1–5) or on (Operations 6–11)

Operation	Type of operation	Purifying unit switched on or off	Number of staff present (mean)	Bacterial concentration (CFU/m^3), min–max	Bacterial concentration (CFU/m^3), mean
1	Biceps fracture	Off	9.6	6–20	10.2
2	Shoulder fracture	Off	7.2	6–18	9.8
3	Knee stabilization	Off	7.0	2–12	7.0
4	Ankle fracture	Off	7.3	4–22	14.8
5	Extraction knee plate	Off	8.0	2–28	14.0
Mean		Off	7.8		11.2
6	Revision wound – lower leg	On	6.0	1–14	6.2
7	Revision wound – lower leg	On	7.0	10–22	17.0
8	Revision wound	On	6.0	4–22	10.7
9	Ruptured Achilles ligament	On	6.7	1–18	7.3
10	Ankle	On	7.0	20–22	20.6
11	Ankle	On	7.8	8–42	21.0
Mean		On	6.8		13.8

CFU, colony-forming units.

Discussion

This study investigated whether three air purifier units mounted on walls in an OR could reduce the airborne bacterial concentration in the 'critical zone' during orthopaedic surgery. The air was sampled during five operations with the air purifying units switched off and during six operations with the air purifying units switched on. The mean bacterial concentration was 11.2 CFU/m^3 when the three units were switched off, and 13.8 CFU/m^3 when the three units were switched on. This concentration is just above the Swedish recommendation of 5–10 CFU/m^3 [9]. There was no significant difference in the bacterial concentration between the two conditions. There are two main reasons for this finding.

Air flow through the inclined screen was 0.60 m^3/s, while total air flow passing through the purifying units, recommended to be installed in mid-size rooms, was 0.21 m^3/s. This means that the total volume of purified air only represented one-third of the total air volume of the OR. Theoretically, this gives a reduced purifying capacity when the air in the 'critical zone' is dilution mixing air, and does not achieve the desired effect of cleaning the air in the 'critical zone' just above the operating wound and above the instruments. The air passage rate (m^3/s) and the duration of plasma treatment should theoretically be doubled to reduce the bacterial concentration in the OR to <5 CFU/m^3 under the same conditions. On the other hand, mobile air purifying units with increased velocity could cause undesired air turbulence and disrupt the ventilation above the 'critical zone'.

Furthermore, the purified air from the three units did not seem to reach the 'critical zone'. This could be explained, in part, by the positions of the surgical team in relation to the air purifying units, as the surgical team blocked the dispersion routes of the purified air, which thus failed to reach the 'critical zone'.

The results of this study, although limited by its small size, are similar to the results of a study in an adult respiratory ward by Fennelly *et al.* [11]. One Novaerus NV800 unit and four smaller Novaerus NV200 units installed in a four-bedded bay did not have any effect on airborne bacterial and fungal concentrations over a 14-day period with the units in operation compared with a control period [10]. However, the findings by Fennelly *et al.* [11] and the results of the present study are in contrast to the results of a study by Arikan *et al.* [4], which found that the bacterial concentration in an ICU was reduced when three Novaerus air purifying units were in operation. One possible explanation for the different and conflicting results of

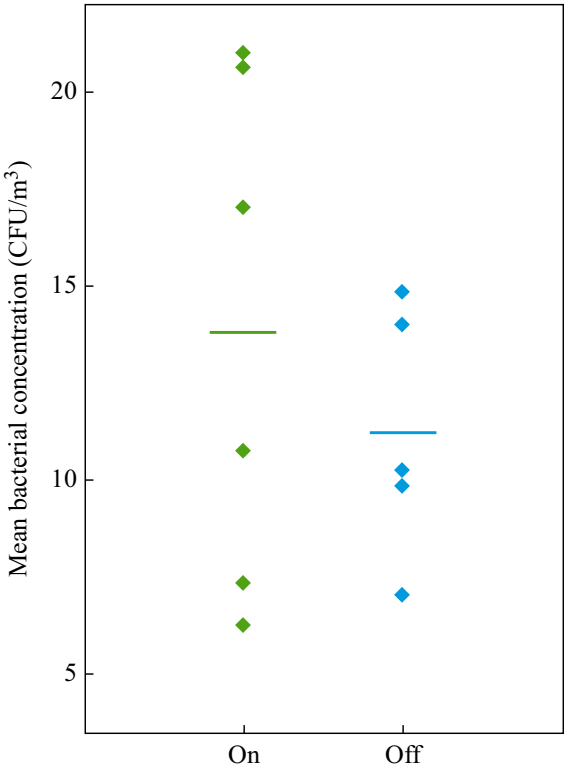

Figure 1. Mean bacterial concentration [colony-forming units (CFU)/m^3] for each operation when the air purifying unit was switched on or off. The overall mean value is shown as a line for each of the two conditions.

the present investigation in an OR and the results of Arikan *et al*. [4] could be that the air turnover is much higher in an OR than in an ICU, so the proportion of purified air is higher in an ICU than in an OR. Another possible explanation for the conflicting results could be that the study by Arikan *et al*. [4] used one NV1050 and two NV800 devices, instead of three NV800 devices as in the present study. The antibacterial effects of NV800 and NV200 are based on plasma treatment of the air, whereas NV1050 incorporates a HEPA H13 filter in addition to the plasma technology. Although the three investigations (Arikan *et al*. [4], Fennelly *et al*. [11] and the present study) were conducted in different healthcare environments using different protocols, it is possible that the differing results reflect the inclusion/exclusion of active HEPA H13 filtration.

In conclusion, the three air purifying units installed in the OR did not reduce the airborne bacterial levels in the 'critical zone' during orthopaedic surgery in this investigation.

Conflict of interest statement
None declared.

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