Performance assessment and clinical validation of OR ventilation systems

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ABSTRACT

Microbiological burden of room-air in operating theatres is a known risk factor for surgical site infections. However, it is unclear how to best evaluate efficacy and efficiency under routine clinical conditions. Moreover, there still is a lack of data to assess the impact on infection rates.

To date there still is substantial discussion in the scientific community which ventilation system provides the most effective and economical respectively efficient control of microbial risk factors during surgery. This is especially important as most standards do not require a performance assessment of the operating room ventilation, but rather rely on tests “at rest” in empty rooms. This might be an explanation for the conflicting results regarding infection preventive effects of different OR ventilation systems as well as the ambiguous data for infection rates.

Since the release of the latest version of DIN 1946-4 in 2018 in Germany [DIN, 2018] a positioning analysis (worst-case scenario with the largest space requirement) for determining the required protected area in class 1a (highest standard) operating rooms is also mandatory. Therefore, another key point of this investigation was to use typical workflow scenarios to assess existing installations regarding the match of the required and the built size of the protected area. Positioning analyses were done together with the on-site staff for various clinical procedures in different hospitals. In all cases, the positioning analysis revealed that required protected areas need to be significantly larger than provided by the existing setup. The size of the protected area that is actually required can only be determined by individual positioning analysis. Most existing installations of unidirectional flow systems (UDF) are likely to be too small. The larger protected areas actually require significantly larger rooms in order to maintain proper thermodynamics. Furthermore, significantly higher volumetric flow rates are required. Finally, the current mismatch between actual and necessary protected area would be a possible explanation for the controversial data situation regarding the infection preventive effects of UDF systems.

Thus, we aimed to evaluate how different widely used qualification techniques as well as several operational parameters impact OR ventilation performance assessment. We specifically studied the desired effect of reducing microbiological air burden and infection rates under routine clinical conditions. Therefore, we evaluated the performance of a temperature controlled ventilation system (TcAF) during surgery and its impact on surgical site infections. This was done under routine clinical conditions in 10 clinical installations of the TcAF system Opragon (Avidicare AB, Sweden) during live surgeries according to the Swedish SIS TS 39: 2015 standard. Furthermore, a retrospective analysis of 1,000 consecutive cases of primary total joint arthroplasty (hip, knee) before and 1000 after installation of the TcAF system was performed. Endpoints for clinical outcome were length of stay and infection rates.

Our results show that performance testing is essential for a proper assessment of OR ventilation systems. Moreover, we demonstrated that TcAF systems are able to reliably and robustly ensure "ultra-clean" air (<10 CFU/m3) in the entire operating room demonstrating its capability to reduce the risk of airborne microbial transmission during surgery. The retrospective analysis of clinical patient data shows positive impact of TcAF on key clinical outcome parameters in line with previous research by Charnley and Lidwell.

INTRODUCTION

Background

Surgical site infections (SSI) are among the most frequent hospital associated infections (HAI) and thus have long been the focus of scientific research. The airborne transmission of infections is an important mechanism in the development of infectious diseases. Already in the 19th century (Joseph Lister) there was the hypothesis that airborne microorganisms are a cause of postoperative wound infections. The use of ventilation systems is a known measure to reduce intraoperative microbiological contamination of room air. Moreover, these systems create a physiological room climate and remove harmful gases from the operating room. The relevance of an adequate ventilation system to reduce SSI was demonstrated as early as 1959 by Sir John Charnley, who showed a correlation between colony forming units (CFU) and SSI. Using a ventilation system, the CFU level was reduced from 600 CFU/m^3 to <1 CFU/m^3 reducing the infection rate during hip prosthesis surgery from 8.5% to 0.7%. [CHARNLEY, 1964; CHARNLEY; Eftekhar, 1969] The Lidwell study from 1980 with 19 hospitals in three countries confirmed the connection between

the air and subsequent wound infections and is most frequently cited in all ventilation-related discussions [Lidwell et al., 1982]. At the same time, other studies [Gastmeier et al., 2012; Bischoff et al., 2017] have questioned the clinical benefit of unidirectional flow (UDF). Still there is few data available regarding efficacy and efficiency of different ventilation systems under routine clinical conditions with respect to minimizing airborne microbial contamination and subsequent SSI rates. Numerous factors influence the design of such systems, including the area of application. Therefore, ventilation technology in the operating room has been an important topic of discussion for a long time. This confronts the operators of health care facilities with the question of finding the best ventilation and air conditioning system for the operating room in order to achieve the goals of air quality, climate management and infection prevention effectively and economically efficiently. This decision is thus not easy, since a ventilated room, including all furnishings and persons who spend time in it, represents a complex thermodynamic system in which all subsystems influence each other. The influence or the benefit for infection prevention, however, is difficult to investigate and evaluate, not least because of the multifactorial genesis of infections. The perioperative antibiotic prophylaxis for the prevention of postoperative wound infections, which has been established as standard for many years due to numerous study results, makes comparative studies difficult. In addition, the patient's own body flora as an endogenous cause is the main source of postoperative wound infections (>50%). [P. Gastmeier, 2010] The evaluation of exogenous factors, which play an important role in the development of postoperative wound infections, is therefore difficult. Nevertheless, it is known that personnel as an exogenous source of pathogens (approx. 15-30%) can be a relevant cause. The influence of secondary airborne pathogens depends on the type and duration of the operation. However, despite the work of Charnley and Lidwell, the relevance is still being discussed controversly, especially since a differentiation from endogenous causes by the similar germ spectrum would be very difficult to achieve.

Nevertheless, it is obvious that microbiological contamination of the air in the immediate vicinity of the operating table and instrument table by skin flakes carrying microorganisms from the staffs' skin flora will result in direct or indirect contamination of the operating field (Figure 1). The extent to which this is relevant has not yet been conclusively clarified by clinical and microbiological studies.

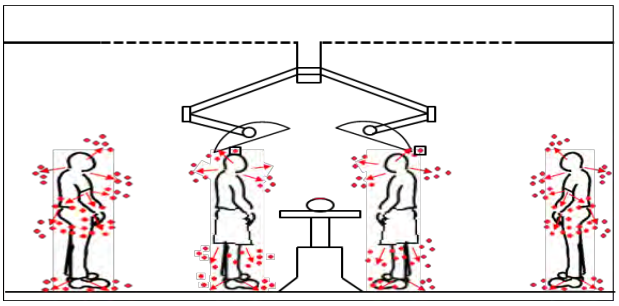

Figure 1: Release of skin scales into the environment (according to Lüderitz Krankenhaushygiene up2date 3/2008)

In this context, surgical clothing is of particular importance. Adequate surgical clothing with cuffs on the arms and legs, as well as the insertion of the upper part into the trousers and the wearing of appropriate surgical caps can significantly reduce the release of skin flakes and thus an important risk factor (Figure 2).

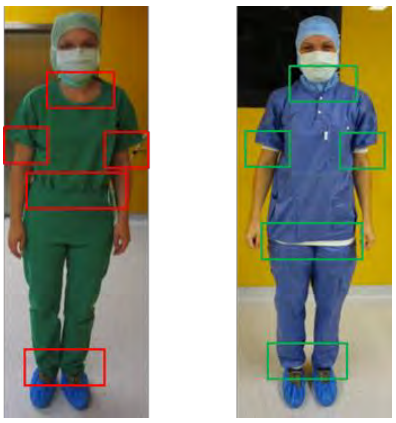

Figure 2: OR clothes with (right) and without (left) cuffs

All in all, a multidimensional package of measures is certainly required to minimize the risks of airborne postoperative wound infections. Due to the increasing resistance to antibiotics and the continuing high number of postoperative wound infections, this certainly includes ventilation and air-conditioning concepts. The aim here is to minimize the number of microorganisms in the air, especially in the area of the operating field. For this purpose, convection currents caused by the heat of people and equipment as well as possible flow obstacles such as surgical lights must be taken into account. In order to counteract e.g. body convection, an air speed of approx. 0.25 m/s is required, as otherwise the particles contained in the air could rise. If the speed is too high (above 0.35 m/s), however, there is a feeling of draught and thus an impairment of the well-being of the personnel. By means of different technologies of permanently installed air handling units, an attempt is being made to control the air flow in the operating room similar to that in clean rooms of the manufacturing industry in order to prevent the airborne entry of particles into the operating field either by directed or non-directed air flows. In both cases high purity HEPA filtered air is blown into the room. However, since there are different temperature zones in an operating room depending on the number of heat sources and

personnel, sufficient mixing must be ensured in all cases. This is often not sufficiently the case with purely laminar flows. In sum, not all "disturbances" can be controlled (Figure 3). Depending on the insertion and removal of air into or from a room, different flow forms are created depending on air velocities, air temperature and the position of supply air outlets and exhaust air ducts. Still this repeatedly leads to controversial debates, which are also reflected in the different technical solutions available as well as in a heterogeneous set of technical standards for ventilation technology. The most important concepts are briefly outlined below. With the worldwide valid standard EN ISO 14644 for technical and pharmaceutical cleanrooms, there is currently an internationally uniform standard, but this does not apply to ventilation technology in operating rooms or health care facilities. Although a European standardization process is currently underway, there are still rather different regulations and specifications, for example, the German DIN 1946-4, the Swedish SIS-TS 39 and the British HTM 03-01A.

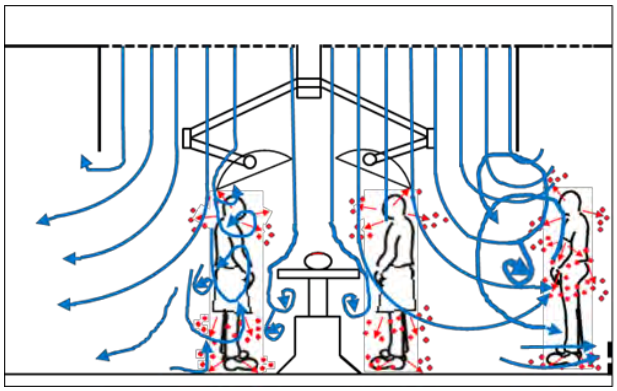

Figure 3: Interferences with ventilation systems, example low-turbulence displacement flow (according to Lüderitz Krankenhaushygiene up2date 3/2008)

UDF systems (unidirectional flow) [Behnke, 2017; R. Külpmann]

In order to ensure the lowest possible pollution of the air with particles, pollutants or microbial organisms, an essentially parallel unidirectional flow form is used that creates a protected area under the UDF outlet (supply air ceiling). This should be large enough to include not only the operating field and surgical team but also the instrument tables [T. Benen et al., 2013]. Even with a high supply air volume, often 10,000 m^3/h depending on the size of the room and the supply air ceiling field, a low turbulence level of less than 5% is aimed for. The average flow velocity is between 0.2 and 0.5 m/s. If possible, an air velocity of 0.35 m/s should not be exceeded in order to meet the climatic-physiological comfort criteria according to EN ISO 7730. This is not always possible. Especially in the case of a so-called differential flow, where is a central area of the supply air field with a higher flow velocity to ensure a better displacement effect. Furthermore, this usually leads to higher noise levels. Despite the use of differential flow, the flow directed in this way is susceptible to disturbing factors such as operating room lights, personnel and medical equipment (Figure 4,5).

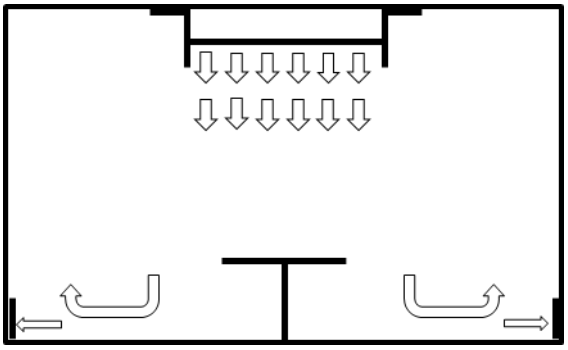

Figure 4: Diagram UDF

Figure 5: Example UDF system

TMV systems (turbulent mixing ventilation) [DIN, 2018; Behnke, 2017]

In contrast to the UDF, here the supply air is not introduced over the entire surface, but through evenly distributed individual small air outlets at a few positions. It is essential to avoid areas without air movement. Swirl diffusers on the ceiling are used to generate mixed air flows as efficiently as possible. The mixing of the supply air with the room air is ensured by appropriately high flow velocities. Depending on the size of the operating room, an air volume of 2,400 to 3,600 m^3/h is therefore usually introduced turbulently and undirected into the operating room as supply air. Air exchange rates between 10 and 60 times per hour achieve the dilution effect and thus a reduction of the polluted room air (Figure 6,7).

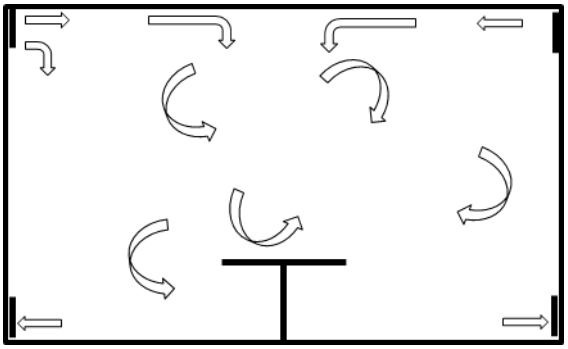

Figure 6: Diagram TMV

Figure 7: Example TMV system

TcAF (Temperature Controlled Airflow) [Alsved et al., 2018; Buhl et al., 2016]

The TcAF system provides on the one hand a protection area by displacement similar to the UDF and on the other hand areas with correspondingly high air mixing as in a TMV. This leads not least to savings in installation and operating costs. In this system, air flows into the operating room from above through special hemispherical outlets made of a non-flammable polyurethane foam (Air-Shower = air shower outlets). This air requires only a very small impulse due to the use of gravity for the outflow, which is minimized by the nature of the air showers. This results in a correspondingly directed outflow behaviour in the sense of a unidirectional flow. By arranging a central area of typically eight circularly arranged outlets, a protected area is generated. This is created by using gravity, as the air blown in is approx. 1.5 K cooler than the air at operating table height. This results in an air velocity of more than 0.25 m/s, which leads to a corresponding displacement flow. By installing separate air-showers outside the protection zone, the room temperature is kept constant and the remaining air in the room is mixed accordingly. Furthermore, unfavourable turbulences (rolls) outside the protection zone can be effectively prevented. This ensures optimal control of the air flows in the entire room (Figure 8,9).

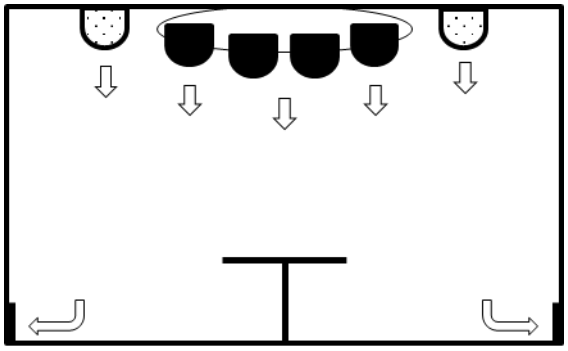

Figure 8: Diagram TcAF

Figure 9: Example TcAF system (Source: Avidicare)

All solutions show differences which are briefly summarized in the table in a qualitative comparison (Table 1).

Table 1: technical properties of three different solutions

Properties	UDF	TMV	TcAF
defined protection area	yes	no	yes
fast particle	yes	no	yes
bacterial contamination < 10 CFU/m³	yes	no	yes
noise	high	low	low
feeling of draught	high	low	low
Increased cooling of the patient	no	no	no

In studies from our research group it could be shown that the TcAF technology achieves comparable results to a UDF system [Buhl et al., 2016]. Air velocity and temperature measurements, as well as results from CFD simulation and degree of protection measurement according to DIN 1946-4 confirm this. The system fulfils the requirements for the degree of protection according to DIN 1946-4:2008, the specifications according to SIS-TS 39: 2015 and also achieves ISO class 5 or at least GMP class B. From the CFD simulation there are further indications that the system is obviously more stable and less susceptible to interference introduced into the flow. This also applies to persons in the "protected area". In a recent study of the University of Lund [Alsved et al., 2018], comparative investigations of three systems (UDF, TMV and TcAF) were carried out in one and the same clinic. The aim was to evaluate the systems in terms of air purity (CFU/m^3), energy consumption and working environment (noise level and draught sensation) from the perspective of the surgical team. For this purpose, measurements of the microbiological load were taken at 3 locations (in the operating field, < 40 cm distance from the operating field, on the instrument table and in the periphery of the room) in an operating room during 45 orthopaedic interventions. The surgical team evaluated the work situation with a

questionnaire. As a result, it could be shown that UDF and TcAF but not TMV reached a value below 10 CFU/m^3 in all measurements at all measuring points. The values in the periphery were lowest for the TcAF system. The CFU concentration was not proportional to the air volumes of the different systems. Compared to the UDF solution, the energy consumption of the TcAF system was 28% lower and showed significantly less adverse effects from noise and drafts in the staff surveys. The authors conclude that both UDF and TcAF are an effective and efficient solution to minimize airborne microbial contamination. In contrast to full-area UDF, the installation of other ceiling-mounted components (ceiling supply units, surgical lights, etc.) and room lights is more flexible with TcAF solutions than with UDF systems.

SCIENTIFIC WORK AND RESULTS

To further clarify the impact on bacterial air burden, we assessed 10 clinical installations of the temperature-controlled ventilation system (TcAF) Opragon (Avidicare AB, Sweden) during live surgery according to the Swedish SIS TS 39: 2015 standard [SIS, 2015] using active air sampling (Figure 10). Measurements were taken at the OR table/surgical site, instrumentation tray and in the periphery. The spectrum of procedures included general surgical interventions and trauma/orthopaedic procedures. For the active air sampling the impaction method on blood agar plates was used (Klotz Impactor FH6, Figure 11). Blood agar plates were incubated 72 hours at 35 °C. Colonies were counted as colony forming units per cubic meter of air (cfu/m^3). Moreover, a retrospective case control study of 1,000 consecutive cases of primary total joint arthroplasty (hip, knee) before and 1,000 consecutive cases after the installation of an ultraclean airflow ventilation system (temperature controlled Airflow TcAF System Opragon AB, Avidicare Sweden), in the same operating room was performed. Clinical outcome was evaluated using length of stay and infection rates as endpoints. The proper function of the TcAF system was checked by intraoperative measurement using active air sampling (blood agar plates, Klotz Impactor FH6).

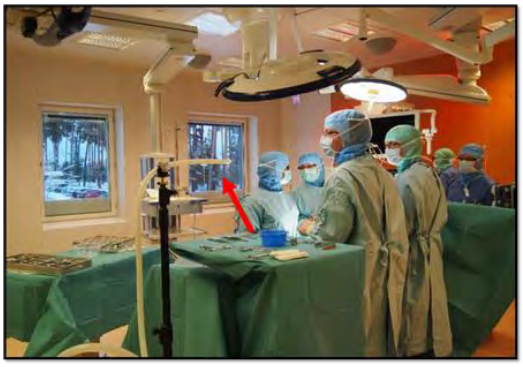

Figure 10: Set-up for the measurement of bacterial air burden with the active air sampling procedure (red arrows indicate the tube-tip for air sampling)

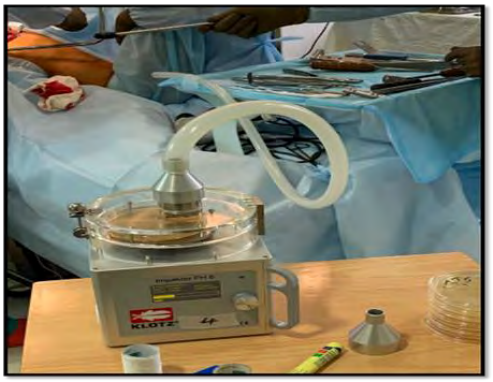

Figure 11: Klotz Impactor FH6 for active air sampling

The retrospective analysis of 1000 consecutive patients undergoing total joint replacement (hip, knee) in an operating room with a TcAF system compared to 1000 consecutive cases in an operating room with mixing ventilation showed that TcAF was associated with a decrease in mean postoperative hospital stay, a decrease in percentage of hospital length of stay, and a decrease of infectious complications from 3% to 1%.

During the intraoperative measurements there were on average 6 persons in the room with a median (M) 6, mean (MW) 6.2 and standard deviation (SD) 1.3. The measurements showed values of median (M) 0 cfu/m^3 over all measuring points in the room, mean value (MW) 1.8 cfu/m^3, standard deviation (SD) 4.5 cfu/m^3. In detail, the following germ counts were obtained: In the area of the surgical field median (M) 0 cfu/m^3, mean value (MW) 0.4 cfu/m^3, standard deviation (SD) 0.8 cfu/m^3, in the range of the instrument table median (M) 0 cfu/m^3, mean (MW) 1 cfu/m^3, standard deviation (SD) 1.9 cfu/m^3 and in the periphery median (M) 2 cfu/m^3, mean (MW) 4 cfu/m^3, standard deviation (SD) 6.7 cfu/m^3. (Figure 12)

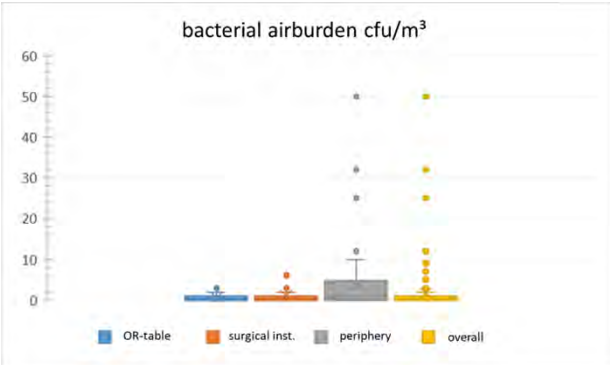

Figure 12: Measurement results active airsampling

For the retrospective study the measurements of the TcAF system were always within the limit demanded by the Swedish SIS TS39: 2015 requirements for infection sensitive surgery, which proved proper function of the TcAF system. Ultraclean air provided by the TcAF system was associated with a decrease in mean postoperative hospital stay from 11,0 to 8,64

days, a decrease in percentage of patients who stayed inpatient over 14 days after surgery from 7,3% to 2,2% and a decrease of infectious complications from 3,3% to 1,1%. (Figure 13) The data analysis of the disease histories shows that only two repeat hospitalizations (0,2%) were registered in the test group (ultraclean air) due to infectious complications after primary arthroplasty. Another nine patients (0,9%) with superficial postoperative wound infection were treated on an outpatient basis. Analogous values in the control group were eight rehospitalizations (0,8%) and 25 patients (2,5%) treated on an outpatient basis for superficial postoperative wound infection (Figure 14). Univariate logistic regression analysis revealed that the use of TcAF was statistically significantly associated with the reduction of infectious complications with an OR of 0,3259 (95%CI, 0.16-0.65, p<0,05).

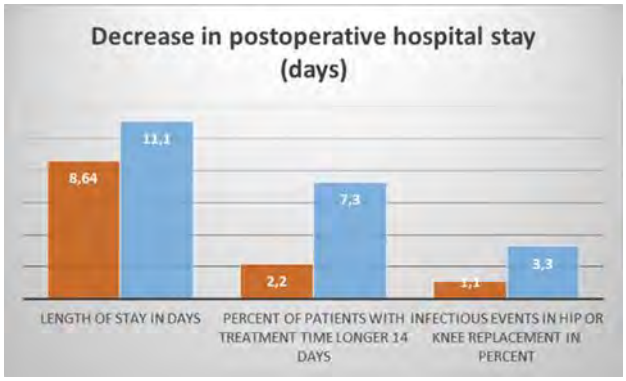

Figure 13: Decrease in length of stay for hip and knee replacement by TcAF-system (orange bars) vs. conventional mixing ventilation (blue bars)

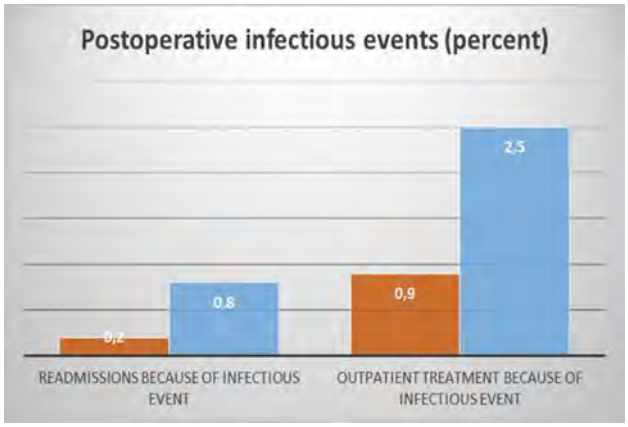

Figure 14: Decrease in length postoperative infectious events by TcAF-system (orange bars) vs. conventional mixing ventilation (blue bars)

DISCUSSION AND CONCLUSION

Adequate ventilation technology in the operating room is required with regard to the control of the room climate (including management of thermal loads) and the guarantee of aspects of work safety (removal of toxic substances). There is still a need for clarification and research regarding the infection-preventive effect of ventilation technology. It is undisputed, however, that microbiological pollution of indoor air is a risk factor and it is desirable to keep it as low as possible. Since an operating theatre in operation is a complex thermodynamic system, all influencing factors must be sufficiently considered when planning an air conditioning system. Only then is it ensured that the ventilation system implemented generates a benefit and no harm, especially from the point of view of infection prevention. A poorly planned system can, at worst, lead to a higher microbial load in the room air and thus to correspondingly higher infection rates. This is probably also one of the main reasons why the studies and meta-analyses carried out to date, which have not taken this aspect sufficiently into account, have not been able to demonstrate any advantages of systems with a low-turbulence displacement flow. Nevertheless, it is precisely these UDF systems that are particularly "prone to failure", so that alternatives are required. With the Temperature Controlled Airflow (TcAF) such a solution seems to be available, although further aspects still need to be investigated. Requirements of the Swedish standard were met or significantly exceeded by the TcAF system. The median cfu counts for the whole room, the area around the surgical field and the instrument table were 0 cfu/m^3. The temperature controlled airflow reliably and robustly ensures "ultra clean" air <10 cfu/m^3 in the operating theatre and therefore is capable to reduce the risk of airborne microbial transmission under routine clinical conditions.

In principle, it would be desirable to develop a uniform international standard for ventilation systems in the operating theatre that focuses on the goals of occupational and patient safety. In terms of risk management, it would therefore be appropriate to focus on the normative specifications not only in terms of the technical design of ventilation systems. The "what" should be achieved should be more important than the "how" it is achieved. This would also provide room for innovation. With EN ISO 14644 and the GMP guidelines, there are, in addition to the specific but internationally non-uniform standards for ventilation and air-conditioning technology, actually specifications that could meet these requirements. These include the definition of high-purity indoor air <10 CFU/m^3 or <5 CFU/m^3. Regardless of this, a ventilation and air-conditioning system can only work effectively if the appropriate conditions are in place and the personnel adhere to certain "rules of conduct". Starting, for example, with the positioning of the instrument tables, the correct surgical clothing, the opening of doors and movements in the room. It would therefore certainly make sense and be desirable to investigate the existing solutions even more precisely and systematically within the framework of clinical studies through further research work. Research into

fundamentally new ventilation concepts for the operating room also seems necessary. At present, the decision is ultimately up to the operator, together with the responsible hospital infection control department. The respective utilization concept current scientific data and information needs to be taken into account. A risk management based approach should be applied to define which ventilation and air-conditioning system should be used in each specific case depending on the clinical spectrum of interventions and operations. If one pays special attention to the avoidance of risk factors, one should choose a solution that reduces the microbiological load of the room air. Taking current publications into account, the UDF and the TcAF are certainly suitable for this purpose. However, the results presented suggest that the TcAF system could provide the economically most efficient and clinically most effective solution under routine clinical conditions.

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