Experimental Investigation of the Spread of Airborne CFU in a Research-OR under Different Air Flow Regimes using Tracer Particles

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ABSTRACT

Aim of this experimental study is to compare different types of ventilation in operating rooms (OR) regarding the highest possible patient protection against airborne germs based on particle counting. Tracer particles with the size of the airborne colony-forming units (CFU) occurring in OR shall be generated to derive representative statements about the removal of germs. In addition, they origin from aerosol generators mounted on heated person simulators to obtain a realistic dispersion of the contamination.
It can be shown that the aerosol generators designed produce particles in the relevant size classes of the airborne germs emitted by OR personnel.

INTRODUCTION

To determine the number of cases of nosocomial infections, the Robert Koch Institute carries out surveillance studies in cooperation with the Federal Statistical Office. There are 400,000 - 600,000 people made ill by nosocomial infections every year in Germany according to (Robert Koch-Institut, 2019). This affects all areas of the hospital. In Germany, up to 20,000 people die from nosocomial infections every year. Nosocomial infections that occur as a result of surgical interventions are called post-operative wound infections (POI). Here, microorganisms get into the incision of the patient during an operation (OP). These cause infections with sometimes serious health consequences. Even a successful OP can result in the death of the patient. According to the KISS study (Nationales Referenzzentrum für Surveillance von nosikomialen Infektionen, 2019), the responsible germs are usually bacterial, but fungal spores are also responsible in rare cases. For viruses, no connection has been found in the study during the investigation period January 2017 to December 2018. During revision surgery for hip arthroplasty, for example, POI occurs in 2.48% of operations. (Nationales Referenzzentrum für Surveillance von nosikomialen Infektionen, 2019, p. 25)
Surgical procedures on humans are performed in protected environments in Germany, to keep the risk of POI as low as possible. In addition to the hygienic requirements, such as prescribed and hygienic hand disinfection, a significant part of contamination control is the treatment of the room air. In many ORs, a LAF (laminar air flow) -field must be maintained, which is subject in DIN 1946-4:2018-09.
This is to ensure that, as far as possible, no infection by aerogenic pathogens occurs. A study by KISS (Brandt, et al., 2008) shows that the number of POI resulting from hip and knee operations is significantly higher with LAF than with turbulent mixed ventilation (TMV). (Breier, Brandt, Sohr, Geffers, & Gastmeier, 2011) have also found out in a study that the size of the LAF field has no influence on the number of POIs.
Since LAF also requires a significantly larger construction effort and, due to the increased air volume compared to the alternative ventilation systems displacement ventilation (DV) and TMV, it also requires significantly more energy to transport and condition the air, which also raises a considerable cost issue. This should play a subordinate role since the prevention of POI and the preservation of health and life are the most important factor.
Also, the system tests for OR lamps required in Annex E of DIN 1946-4:2018-09 could become obsolete if alternative air ducting systems are used. Unlike LAF, the latter do not depend on a directed jet, in the core of which a geometric obstacle leads to a strong influence on the flow.
To experimentally reproduce the spread of airborne CFU, aerosol generators are designed to disperse particles that represent airborne germs emitted by the personnel in an OR. These shall disperse particles with the aerodynamic properties of the airborne CFU occurring in OR. Especially density, size and electrical charge are important for the aerodynamic properties. Instead of collecting germs as it can be performed in real ORs, in the research OR these measurements are conducted with particle counting.
Also, the source strength of the aerosol generators is important to know to make the measurements representative.
As mentioned, POI occur when CFU enter the patient's incision and cause disease, such as inflammation. Pathogens of this type are usually bacteria, mostly staphylococcus. (Nationales Referenzzentrum für Surveillance von nosikomialen Infektionen, 2019) In the following, the CFU that have been detected during operations by air samplers are defined. Such germs usually occur on saliva drops or skin flakes (Lidwell, Machintosh, & Towers, 1978) but in rare cases isolated bacteria can also cause diseases such as e. g. tuberculosis. Mouth/nose protection and surgical clothing are intended to reduce the emission of germs by staff. However, this does not completely prevent the

release of saliva droplets and skin flakes (Dreller, et al., 2006), (Wenzler, et al., 2002).

In operating theatres in Chinese hospitals, in the study by (Li, et al., 1993), an Andersen cascade impactor with the preset size classes is placed in OR in Chinese hospitals. This is explicitly used for MRSA. It was placed approximately in the center of the room, one meter above the floor. Viable germs can be detected in all size classes 0.65 - 7 µm and > 7 µm.

In the study by (Nazir, Mula, Stokoe, Colbeck, & Loeffler, 2015), an Andersen cascade impactor is placed centrally in the OR. Orthopedic operations are performed. In the OR ventilated with TMV most airborne CFU precipitate in the range 3.3 - 4.7 µm, whereas in the operating room with a LAF field, the size fraction 2.1 - 3.3 µm dominates.

CFU do not occur on airborne particles < 1 µm. On larger particles, however, they can occur within a wide range, since bacteria carrying skin flakes have a size of up to 16-24 µm according to the studies of (Hughes, 1963). In conclusion, the size range of airborne CFUs in OR is spread widely, usually between 1-20 µm. Therefore, an aerosol generator that disperses particles within that size range into air shall be designed.

An aerosol generator is a device for producing a test aerosol. Typical areas of application include: Determination of the dusting behaviour of nanomaterials (solid dispersion), filter leakage tests or recovery time measurement in clean rooms with TVS. Therefore, small particles (< 1 µm) are needed. Since larger tracer particles are less common for air sampling, a new aerosol generator will be designed in this study.

The aerosol generators shall be connected to person simulators in experimental investigations to examine the spread of airborne CFU in a research-OR under different air flow regimes using the tracer particles. Hence, it is important that the construction of the device is repeatable, preferably at low cost, and that there is no hose needed to lead the particles from the aerosol generator to the emission position, since larger particles would sediment gravitational or deposit due to various mechanisms inside of the hose. Since it is difficult and flawed calculating the transport efficiency, a commercial aerosol generator was not wanted.

METHODS

As aerosol generators, de-centralized two-substance atomizers are used. A particle suspension of 50 ml double-distilled water and 0.22 g hollow glass spheres (HGS), with a median particle diameter of 10 µm, is used. The reason a suspension is used is that the particles will not be as by dispersing solid particles due to the triboelectric effect.

The aerosol is produced using a nebulizer type Pari LL. This device nebulizes the suspension according to the principle of an ejector nozzle. Compressed air creates a negative pressure, which sucks in the particle solution and disperses it into the air. The liquid droplets evaporate within a very short time since droplets < 10 µm evaporate within under a second in indoor air according to (Hinds, 1999), leaving behind the particle core of HGS. A terminal impact separator ensures that no liquid droplets larger than 50 µm are released. In addition, a droplet separator with a height of 75 mm is placed on top of the aerosol generator to prevent liquid droplets from spraying out, protecting the sensitive optics of the particle counters. In each aerosol generator, 10 ml of the suspension per test is fed.

Furthermore, compressed air is set to 1.7 bar with a pressure relief valve and connected to the nebulizer. The droplet separator prevents oil droplets from being carried out of the compressor. If it is not possible to perform a zero count of the particles in the room, a terminal HEPA filter can separate other impurities from the compressed air. The flow chart of the aerosol generator is displayed in Figure 1.

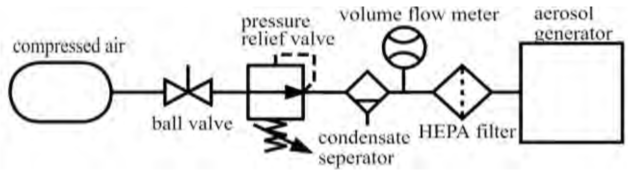

Figure 1: Flow chart of the aerosol generator, from left to right: compressed air, originating from a compressor is locked by a ball valve, the pressure relief valve enables controlling of air pressure, condensate separator removes possible machine oil particles, the volume flow meter enables control of volume flow and the HEPA filter filters remaining particles before the compressed air is led into the ejector nozzle of the aerosol generator

The measurement setup is placed in a cleanroom with particle free inlet air with laminar air flow. For the determination of the source strength, the aerosol generator is placed inside a vertical tube with a diameter of 40 cm and a length of 1.8 m on top of a filter fan unit (FFU) (see Figures 2 and 3). The ladder is needed to keep the exhaust air of the duct free of particles.

High flow velocities can be generated in the duct. This is necessary if the number of emitted particles is so large that the particle count exceeds the coincidence limit. The particle concentration in the sampling air can be reduced by increasing the volume flow in the pipe, avoiding the risk of coincidence. The laser particle counter (LPC) is placed below the aerosol generator, also inside the pipe.

The sampling probe of the LPC type Solair 3100E is located at a height of 65 cm, one meter below the aerosol generator. It has a diameter of 3.65 cm. The measurement setup is displayed in Figure 2 and Figure 3. The measurements are performed at a frequency of 1 min^{-1}. The coincidence limit of the LPC is approx. 35 000 000 particles m^{-3}. The sampling flow is approx. 1,7 m^3h^{-1}.

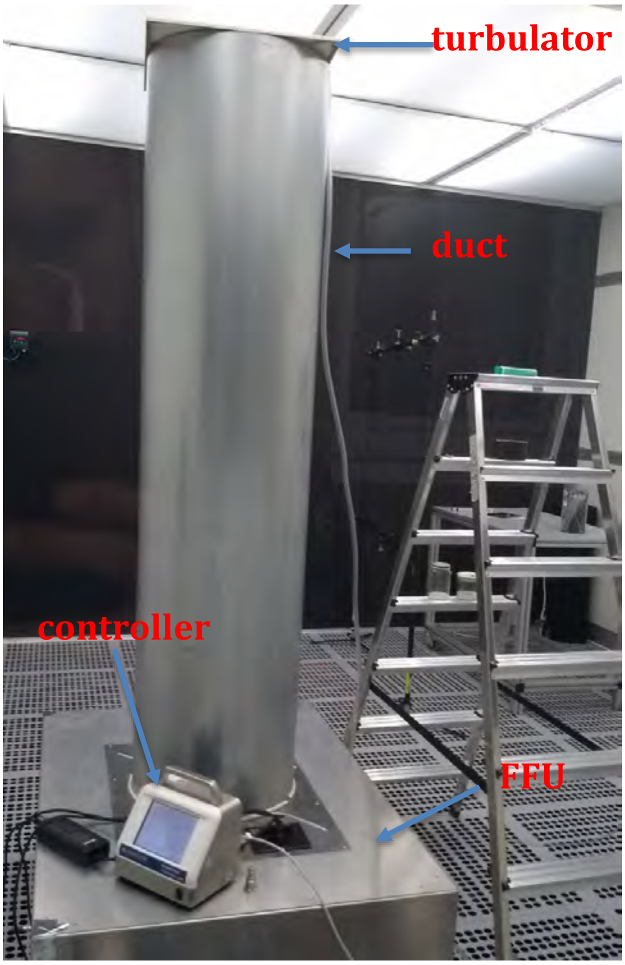

Figure 2: Experimental setup for the determination of the source strength of the aerosol generator inside the cleanroom, laminizer fabric at the ceiling and raised floor, air inlet at the top of the duct with turbulator, aerosol generator inside the duct at 1.65 m height, laser particle counter (LPC) inside with 0.65 m height of measuring probe, which is connected to the controller standing on top of the FFU

The velocity measurement and the determination of the flow profile and volume flow are carried out using a pitot tube in conjunction with a differential pressure gauge according to the median line method. A hole is drilled through the outer wall of the pipe at the level of the sampling probe to insert the pitot tube. A pressure probe consists of two oppositely directed probes that are connected to a manometer. The positive end then points against the direction of flow, while the negatively marked probe is positioned in the direction of flow. The measurement was conducted twice and both repetitions resulted in a volume flow of 1198 $m^3\ h^{-1}$.

Furthermore, it is important for particle measurement that a turbulent flow profile exists in the pipe to guarantee the best possible distribution of particles over the entire horizontal area at the sampling probe. A turbulator at the inlet of the pipe is used to generate a piston profile of the flow.

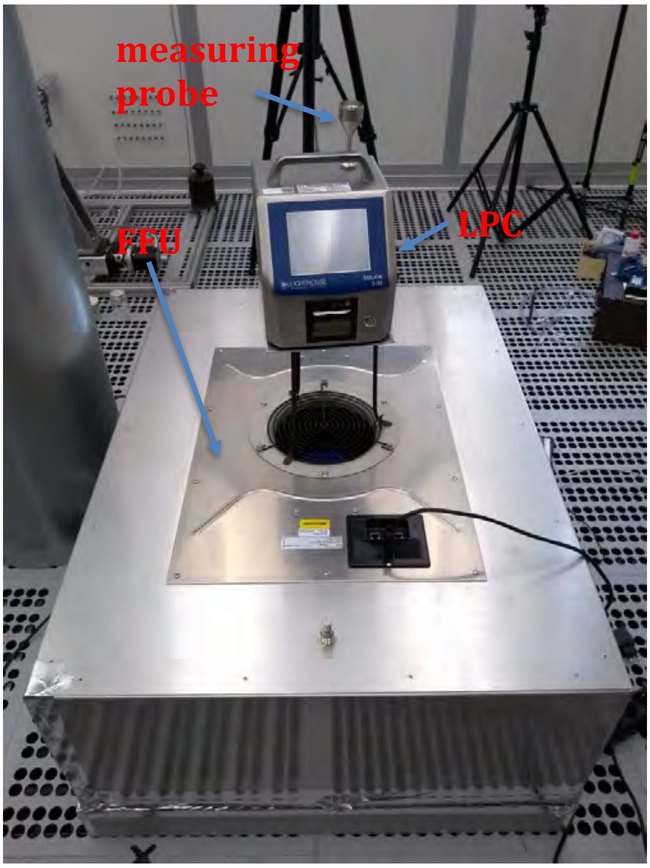

Figure 3: LPC position in the test tube on top of FFU, measuring probe right on top of LPC

The aerosol generators must be removed and cleaned after each experiment. For this purpose, an ultrasonic bath and cleaning with an antistatic cleanroom cloth are conducted.

Also, to validate the results, sedimentation plates were placed on the LPC and examined using an optical microscope. Since this process could not be automized, only a limited number of plates was examined.

Before starting each measurement, a zero count is conducted. For the measurements, the aerosol generators are kept at a constant pressure of 1.7 bar so that they are operated optimally. The aerosol generators are then filled with a dose of 10 ml of particle suspension when the researcher re-enters the OR. The measurement ends when the particle concentration at the sampling point is zero again. Then, the LPC and the compressed air supply can be deactivated. Now the room can be re-entered and the aerosol generators are dis-attached. After cleaning, the next measurement run is initialized.

The source strength of the aerosol generator per shot can be calculated according to (1):

$$P_i = \frac{P_{probe,i} * \dot{V}_{tube}}{\dot{V}_{probe}} \qquad (1)$$

P_i is the particle load emitted by the aerosol generator per measurement [-], $P_{probe,i}$ is the particle count measured by the LPC per measurement[-], $\dot{V}_{tube}$ is the volume flow inside the test tube [m³ h⁻¹] and $\dot{V}_{probe}$ is the sampling flow [m³ h⁻¹]

RESULTS

For all 9 aerosol generators examined, the measurement uncertainty in the form of the student t-distribution is calculated with the empirical rule of 68,27 %. For the calculation of the probability density function, the function stats.t.pff of the python library scipy is used.

As an example, the results for the measurement uncertainty of aerosol generator 7 are displayed in Figure 4. While the abscissa displays the count of measurements, the ordinate shows the measurement uncertainty. The different graphs show the particle size classes 1.0 - 3.0 µm, 3.0 - 5.0 µm, 5.0 – 10.0 µm and > 10 µm. It can be shown that the uncertainty is reduced greatly by adding additional measurements up to case 6. Then, the uncertainty does not variate as much as before.

The resulting mean source strength as well as the corresponding measurement uncertainty of the four aerosol generators with the lowest measurement uncertainty, which shall be used for further investigations, are displayed in Table 1 to Table 4. Since in continuing measurements particle counters type LDPC 5-10 P0 with the size classes 0.5 – 1.0 µm, 1.0 – 5.0 µm, 5.0 – 10 µm and > 10 µm are used, the particle size classes are adapted.

Since the particle size class 0.5 – 1.0 µm is not interesting for further investigations, only source strengths of particles within the size classes 1.0 – 5.0 µm, 5.0 – 10 µm and > 10 µm are represented.

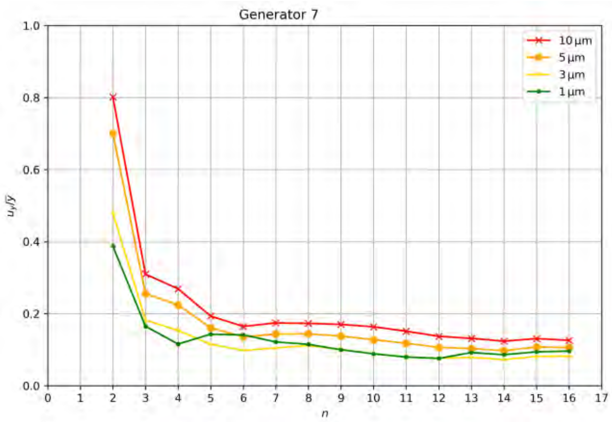

Figure 4: Measurement uncertainty of aerosol generator 7 with student t-distribution (ordinate), divided by size classes: 1-3 µm (green), 3-5 µm (yellow), 5-10 µm (orange), 10-25 µm (red). The number of repetitions is displayed on the abscissa.

The particle size class is not presented in the conventional log-normal distribution dN/dlogDP, since there are only four channels measured representing the examined size classes. Therefore, a log-normal graphing does not improve the readability of the data.

Table 1: Mean source strength and relative measurement uncertainty of aerosol generator 3 for different size classes

particle size class	mean source strength	rel. measurement uncertainty
1.0-5.0 µm	231,482,986	0.09
5.0-10.0 µm	33,279,336	0.10
> 10.0 µm	18,319,725	0.12

Table 2: Mean source strength and measurement uncertainty of aerosol generator 6 for different size classes

particle size class	mean source strength	rel. measurement uncertainty
1.0-5.0 µm	234,981,209	0.057
5.0-10.0 µm	32,487,460	0.091
> 10.0 µm	19,226,207	0.116

Table 3: Mean source strength and measurement uncertainty of aerosol generator 7 for different size classes

particle size class	mean source strength	rel. measurement uncertainty
1.0-5.0 µm	226,672,818	0.086
5.0-10.0 µm	29,849,814	0.106
> 10.0 µm	15,979,683	0.126

Table 4: Mean source strength and measurement uncertainty of aerosol generator 8 for different size classes

particle size class	mean source strength	rel. measurement uncertainty
1.0-5.0 µm	198,882,233	0.123
5.0-10.0 µm	25,118,490	0.104
> 10.0 µm	13,073,581	0.118

Regarding the sedimentation plates with an optical microscope, particles within the size range 1-12 µm could be detected. There were no particles > 12 µm found, however, the quantity of large particles was low due to the right-skewed particle distribution. Hence, the particle distribution could be validated.

In conclusion, the aerosol generator constructed generates a spectrum of polydisperse particles within a size range of 1 - 20 µm.

In further investigations, measurements will be carried out in a research OR, equipment and design of which are chosen on the base of extensive research and observation. In this room it is possible to use three different ventilation systems LAF, TMV and DV. This allows them to be compared with each other in the same arrangement. In this research OR, experiments with various occupancies are conducted with person simulators to obtain reproducible results. This will allow generic statements to be made about the ability of the airflow systems to control any contamination that occurs and the influence of OR luminaires.

ACKNOWLEDGMENTS

The project described in this article was funded by the German Federal Ministry for Economic Affairs and Energy (BMWi) under the funding code 03ET1454A. The authors assume responsibility for the content of this publication.

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