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Influence of different ventilation systems on contamination of medical devices

Translation of the article "Einfluss von unterschiedlichen Lüftungssystemen auf die mikrobiologische Instrumentenreinheit" published in German in Hygiene & Medizin 2013, volume 38, issue 4, pages 142 to 146.

Keywords

Surgical site infections

LAF

Ia-OR

Ib-OR

Medical device contamination

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Summary

Background: The sterility of the medical devices used in an operating room (OR) is one main aspect to avoid surgical site infections. This study analyzed the influence of different ventilation situations with regard to contamination of the medical devices. Method: We analyzed laminar airflow (LAF) ceilings, size 3.2 m x 3.2 m (Ia-OR), and turbulent ventilation systems (Ib-OR). The Ia-OR was successfully qualified with degree of protection measurement according to DIN 1946-4: 2008. The Ib-OR was qualified with a recovery test. Within the Ia-OR additional measurements were done out-side of the protected area of the LAF to show the importance of this area.

Results: The results show a relationship between medical device contamination and the kind of ventilation system used. The medical devices in the Ib-OR and outside the protected area were contaminated more often and with more microbes than within the protected area under the LAF.

Discussion: The extent to which the provisions of the medical devices guideline (KRINKO/BfArM Recommendation) are being fulfilled under such ventilation conditions is questionable. The Recommendation explicitly states that medical device sterility must be maintained until the point of use. The aim of the present study was to focus on one, hitherto frequently overlooked, aspect of intraoperative instrument contamination.

Introduction

Some four years on from the amendment of DIN 1946-4:2008-12 on the use of heating, ventilation and air-conditioning (HVAC) systems in buildings and rooms used in the health care sector, the potential benefits of large airflow ceilings in OR rooms continue to elicit animated discussion (Table 1) [1]. This is due to the unclear study results. The findings of the studies carried out are contradictory with regard to infection prophylaxis [2-4]. Nor has light been cast on this situation by the commentary made by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) on DIN 1946-4:2008-12 [5]. While assignment of this matter to the category of 'unresolved issues' is scientifically comprehensible, the resultant conclusion, advocating discontinuation of the use of Ia-OR rooms is less understandable.

Table 1: Supply air systems as per DIN 1946-4:2008-12 for OR rooms with 'high' (room class Ib) and with 'particularly high' air purity (room class Ia).

Room Class Ia	Room Class Ib
LAF air supply ceilings $\geq 3.2 \times 3.2$ m (standard size)	Turbulent mixed airflow (TMA), individual outlets
Protected area with low-turbulence displacement ventilation (flow) extending approx. 3 m x 3 m at working height and encompassing OR team, OR table and instrument tables	or
or	LAF air supply ceilings 3 to < 9 m ² with low-turbulence displacement flow which may not fully encompass the OR team and instrument tables
LAF air supply ceilings < 9 m ² with proof for each individual position analyzed that the low-turbulence protected area encompasses the OR team, OR table and instrument tables and the protectively isolated patient	

The greatest challenge when investigating the efficacy of ventilation systems derives from the fact that the impact of the ventilation system in the OR cannot be viewed in isolation. Among other influence factors is, in particular, the role of perioperative antibiotic prophylaxis, which is now a standard procedure, especially for endoprosthetic operations. However, all other risk factors mentioned in the KRINKO Recommendation for Prevention of Postoperative Surgical Site Infections play a role [6]. But many of these factors are dependent on the surgical team or patient, hence it is very difficult to assess their individual impact.

However, this situation can be greatly remedied by focusing exclusively on contamination of sterile instruments during an operation. Contaminated instruments can be the source of surgical site infections. Hence the KRINKO Recommendation for Prevention of Postoperative Surgical Site Infections cites observance of strict aseptic practices as being one of the most important measures of infection prevention [6]. Since instruments come into direct contact with the surgical site, they can cause post-operative wound infections. Therefore, the procedures used to reprocess such instruments are subject to stringent requirements. The legislation governing medical device reprocessing is set out in the Medical Devices Directive and in associated regulations, and applies to medical devices that should be sterile, or at most harbour only a low microbial count, when put to use [8]. Appropriate cleaning, disinfection, packaging and sterilisation of med-

ical devices are assured through the use of validated processes. The aim here is to ensure maintenance of the sterility of the instruments until the tray or other items of packaging are opened. Next, the instruments are placed on the instrument table, where they remain until they are used on the patient. To date, there are in most cases no rules on how long instruments can be left on the table until they are used on the patient. The KRINKO Recommendation for Prevention of Postoperative Surgical Site Infections does not address this matter [6].

But the RKI Recommendation on Hygiene during Operations and Other Invasive Procedures states that the instruments and instrument tables should be positioned beneath the laminar airflow (LAF) ceiling [7]. This area is called the protected area and comprises the OR table with patient, sterile-gowned surgical staff as well as the instrument tables. The topic of protected area and definition of this area are elaborated on in greater detail in DIN 1946-4:2008-12 [2]. However, there are no scientific data to corroborate the need for such measures.

The present study aimed to investigate whether contamination of instruments in the OR occurred during surgery and, if so, to gain insights into the microbial count on instruments exposed to different ventilation systems (Room class Ia and Ib) as well as outside the protected area in Ia operating rooms.



Figure 1: Sampling table with test setup. A) Air sampler, B) Sedimentation plates, C) Crile clamps

Materials and Methods

To ascertain the microbial count on OR instruments in relation to the ventilation system used, a test setup was devised. It was possible to implement this experimental procedure during routine working practices, without any interference with these. Since endoprosthetic knee and hip operations make stringent demands on hygiene, our investigations were confined to these operations.

To establish whether there is a relationship between the ventilation system used and instrument contamination, three ventilation situations were investigated using measurement technology methods:

1. Within an LAF protected area, which had been successfully qualified with degree of protection measurement as per DIN 1946-4:2008-12 (room class 1a),
2. Outside the LAF protected area,
3. Within an OR with turbulent ventilation as per DIN 1946-4:2008-12 (room class Ib) in the vicinity of the real instruments, which had been successfully qualified as room class Ib with a recovery test.

The boundary conditions were virtually identical in both operating rooms: the rooms were under positive pressure, the doors remained shut during operations, the number of persons in the OR as well as average operating times (Ia protected area:

mean value 70 min; Ia outside area: mean value 69 min; Ib: mean value 65 min) were identical.

An additional instrument table, designated in the following as the 'sampling table', was positioned in the immediate vicinity of the actual instrument tables (Figure 1). Both the airborne microbial count concentration and microbial sedimentation were measured on this sampling table.

The airborne microbial count was determined by means of impaction methods (impactor FH 5, manufacturer: Klotz). Microbial sedimentation was measured with two sedimentation plates as per DIN 1946-4:2008-12 Annex F. In addition, real instruments, represented by five sterile Crile clamps were arranged on the sampling table. The Crile clamps were chosen for two reasons. First, clamps and scissors are part of the basic instrument complement needed in several operations. Second, clamps are not unduly demanding when it comes to determining the bioburden.

Columbia blood agar plates were used for the impaction method and for sedimentation. After sampling, the plates were incubated in the laboratory at 36 °C for 48 hours and then the colony forming units (cfus) were determined. The bioburden on Crile clamps was measured as per DIN EN ISO 11737-1: 09-2009 [8]. Each clamp was

swivelled in a vessel containing trypticase soy broth (TSB). The broth was then passed through a membrane filter. Next, the filter was incubated for 48 hours at 36 °C and evaluated. The transport and sample preparation conditions were monitored by means of a transport control facility.

For the endoprosthetic operations chosen, an approximate incision-suture time of 70 minutes can be expected. During that time, the sampling table was positioned in a designated manner.

Ten measurements were performed for each ventilation system, amounting to a total of 30 airborne microbial concentration measurements, 60 sedimentation plates and 150 Crile clamps. All measurements were commenced after making the incision. The sedimentation plates as well as the Crile clamps were exposed throughout the entire incision-suture time. It was not possible to evaluate three of the Crile clamps since they were unsterile at the time of sampling.

Results

The results obtained for the three test series showed that there were marked differences in the microbial counts between the various ventilation systems (Table 1, Figure 2). The mean value for the airborne microbial count measurements was based on 10 measurements using, in each case, 1000 l. The mean value for the sedimentation plates was obtained from 20 plate measurements. The number of Crile clamps investigated varied according to the test series since, as mentioned before, it was not possible to evaluate some of the clamps.

The mean value for the airborne microbial count within the Ia LAF-protected area was 0.4 cfu/m³, and was the lowest measured. There was a 55-fold increase in the number of airborne cfus outside the protected area. And in the Ib-OR with turbulent ventilation, values were more than 150-fold higher than in the Ia-OR protected area.

For the sedimentation plates the same trend was observed as for the airborne microbial count measurements. The lowest contamination level was detected in the Ia-OR, and the highest in the Ib-OR.

A similar situation was observed as regards the contamination levels on the Crile clamps. Here, too, the number of cfus on instruments was higher in the Ib-OR than in the protected area of the Ia-OR.

Table 2: Results of the airborne microbial count measurements, of sedimentation plate and Crile clamp contamination levels subject to different ventilation systems

		la-OR protected area	la-OR outside protected area	Ib-OR
Impaction method	Mean value [cfu/m ³]	0.4	23	63.5
	Standard deviation	0.7	15.6	36.6
	Variation coefficient	1.66	0.68	0.58
	Minimum [cfu]	0	2	24
	Maximum [cfu]	2	50	147
Sedimentation plates	Mean value [cfu/m ³]	0.5	3.2	3.8
	Standard deviation	1.0	4.0	2.7
	Variation coefficient	2.27	1.26	0.71
	Minimum [cfu]	0	0	0
	Maximum [cfu]	4	12	12
Crile clamps	Mean value [cfu/m ³]	0.8	3.5	3.9
	Standard deviation	1.9	10.1	8.0
	Variation coefficient	2.4	2.9	2.0
	Minimum [cfu]	0	0	0
	Maximum [cfu]	8	64	48

Figure 2: Comparison of airborne microbial count determination, of sedimentation plate and Crile clamp contamination levels for the various ventilation systems

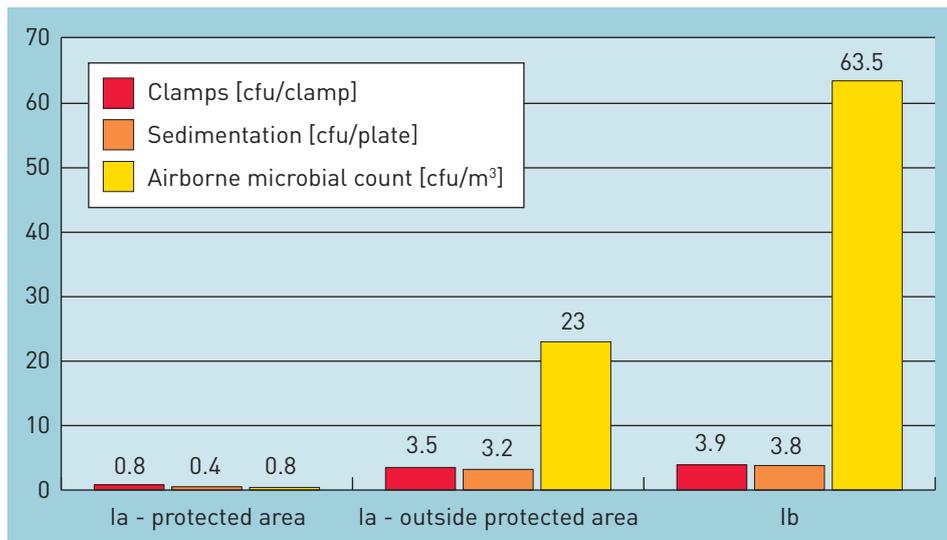


Table 3: Comparison of contamination levels on sedimentation plates and Crile clamps, of an equivalent size surface area, for the different ventilation systems

	la-OR protected area	la-OR outside protected area	Ib-OR
Sedimentation plates [cfu/50 cm ²]	0.4	2.8	3.4
Crile clamps [cfu/50 cm ²]	1.6	7.0	7.8

Table 4: Individual results for Crile clamp contamination levels with the different ventilation systems

	la-OR protected area	la-OR outside protected area	Ib-OR
Number of clamps	48	49	50
Clamps with 0 cfu	33	26	17
Proportion of contaminated clamps	31 %	47 %	66 %
Mean value [cfu]	0.7	2.8	3.6
Maximum value [cfu]	7.4	64.0	44.3

Direct comparison of the cfus on sedimentation plates and on Crile clamps is not possible in this state. To that effect, the results must first be converted on the basis of an equivalent sized surface area (Table 3). The sedimentation plates employed had a total surface area of 56.7 cm². The surface area of the Crile clamps was estimated to be around 25 cm². Here, the supporting surface of the sterile surgical drape on which the instruments were placed was not taken into account. These calculations revealed that the cfus on the instruments were considerably higher than on the sedimentation plates.

Table 4 gives a summary of the individual results for instrument contamination for the respective ventilation type.

There are two conspicuous findings with respect to these values. The absolute number of contaminated instruments is twice as high in the Ib-OR as within the protected area of the la-OR. Furthermore, the maximum number of cfus on individual instruments under both turbulent ventilation conditions is much higher than beneath the LAF flow.

Discussion

The results show that the airborne microbial count within the protected area of an la-OR is much lower than outside the protected area or in a Ib-OR. That also reflects the general expectations. Thanks to the high air change rate and unidirectional airflow in the la-OP, microorganisms are being effectively eliminated.

Nor is the link seen between the airborne microbial count and microbial sedimentation anything new. But, contrary to expectation, that relationship does not appear to be linear. While the mean value of the airborne microbial count in the Ib-OR is around 150-fold higher than in the protected area of the la-OR, the number of cfus on the sedimentation plates or instruments does not rise to the same extent. One possible explanation for this is that sedimentation rate beneath the LAF ceiling is higher because of the top to bottom unidirectional flow than under turbulent ventilation conditions. In the latter setting, there is no unidirectional flow; instead, there is transverse airflow and, accordingly, a lower probability of hitting the instrument table.

One interesting observation in this study is the higher number of cfus on in-

struments compared with sedimentation plates. At first glance, this appears difficult to explain. One reason could be the structure of the sedimentation plate. The blood agar plates normally used have an outer synthetic rim with a height of around 1.5 cm. The air hits against the nutrient medium but, because of the rim, it is unable to spread out to the sides. This gives rise to an air cushion, which impedes further air exchange. To put that theory to the test, using the experimental setup described above the sedimentation rate was investigated also using rimless agar plates (contact plates). The number of cfus was markedly higher on the rimless plates than on the normal sedimentation plates (data not illustrated).

That contaminated instruments pose a risk of infection is beyond doubt [9]. This is why instrument reprocessing is regulated by the Medical Devices Directive and regulations based on this [10].

The investments needed to assure the technological and hygiene aspects of medical device reprocessing are enormous. This commences immediately after the medical device is used on a patient and the entire reprocessing circuit must be traversed until the instrument is reused again [9]. Our findings have clearly demonstrated that the entire reprocessing chain is being jeopardized by exposing the instruments under uncontrolled environmental conditions in the operating room.

During the test phase, the instruments were left for 60 to 70 minutes on the instrument table. But many operations take much longer. There are hygienic prescriptions whereby oronasal masks or sterile gloves should be exchanged intraoperatively. But, in the majority of cases, there are no recommendations on how long sterile instruments may be left exposed within the OR until they are reprocessed.

To date, it was always assumed that airborne microbes entered the surgical wound directly. Our results suggest that an indirect entry route via contaminated instruments plays a more important role than hitherto believed. Since qualitative determination of the microorganisms involved was not the focus of this paper, the implications of our findings for onset of postoperative surgical site infections are difficult to estimate. In view of the unexpectedly high level of contamination on the

instruments, a second study will be conducted to identify, in particular, the microbial spectrum on the instruments.

Conflict of interest

The authors declare that they have no conflict of interests as understood by the guidelines of the International Committee of Medical Journal Editors.

References

1. DIN 1946-4:12-2008. Raumluftechnische Anlagen in Gebäuden und den Räumen des Gesundheitswesens. Beuth Verlag, Berlin.
2. Brandt C, Hott U, Sohr D, Daschner F, Gastmeier P, Rüden H. Operation room ventilation with laminar airflow shows no protective effect on the surgical site infection rate in orthopedic and abdominal surgery. *Ann Surg*; 246: 695-700
3. Lidwell OM, Lowbury E, Whyte W, Blowers R, Stanley SJ, Lowe D. Effect of ultraclean air in operating rooms on deep sepsis in the joint after total hip or knee replacement. *Br Med J (Clin Res Ed)*. 1982;285(6334):10-14.
4. Breier AC, Brand C, Sohr D, Geffers C, Gastmeier P. Laminar airflow ceiling size: no impact on infection rates following hip and knee prosthesis. *Infect Control Hosp Epidemiol*. 2011;11: 1097-102.
5. Kommentar der KRINKO zur DIN 1946-4 (2008), Raumluftechnische Anlagen. *Epid. Bull.* 2010;4:35.
6. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention beim Robert Koch-Institut. Prävention postoperativer Infektionen im Operationsgebiet. *Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz* 2007;50:377-393.
7. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention beim Robert Koch-Institut. Anforderungen zur Hygiene bei Operationen und anderen invasiven Eingriffen. *Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz* 2000;43:644-648.
8. DIN EN ISO 11737-1:09-2009; Sterilisation von Medizinprodukten – Mikrobiologische Verfahren - Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten. Beuth

Verlag, Berlin.

9. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM). Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. *Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz* 2012;55:1244-1310.
10. Gesetz über Medizinprodukte, Medizinproduktegesetz, MPG, Erstfassung vom „Medizinproduktegesetz in der Fassung der Bekanntmachung vom 7. August 2002 (BGBl. I S. 3146), zuletzt geändert durch Artikel 1 des Gesetzes vom 14. Juni 2007 (BGBl. I S. 1066)“ Stand: Neugefasst durch Bek. v. 7.8.2002 | 3146; zuletzt geändert durch Art. 1 G v. 14.6.2007 | 1066