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Major article

Traffic flow in the operating room: An explorative and descriptive study on air quality during orthopedic trauma implant surgery

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Background: Understanding the protective potential of operating room (OR) ventilation under different conditions is crucial to optimizing the surgical environment. This study investigated the air quality, expressed as colony-forming units (CFU)/m^3, during orthopedic trauma surgery in a displacement-ventilated OR; explored how traffic flow and the number of persons present in the OR affects the air contamination rate in the vicinity of surgical wounds; and identified reasons for door openings in the OR.

Methods: Data collection, consisting of active air sampling and observations, was performed during 30 orthopedic procedures.

Results: In 52 of the 91 air samples collected (57%), the CFU/m^3 values exceeded the recommended level of <10 CFU/m^3. In addition, the data showed a strongly positive correlation between the total CFU/m^3 per operation and total traffic flow per operation ($r = 0.74$; $P = .001$; n = 24), after controlling for duration of surgery. A weaker, yet still positive correlation between CFU/m^3 and the number of persons present in the OR ($r = 0.22$; $P = .04$; n = 82) was also found. Traffic flow, number of persons present, and duration of surgery explained 68% of the variance in total CFU/m^3 ($P = .001$).

Conclusions: Traffic flow has a strong negative impact on the OR environment. The results of this study support interventions aimed at preventing surgical site infections by reducing traffic flow in the OR.

The prevention of surgical site infection (SSI) after orthopedic implant surgery is a hot topic for politicians, hospital administrators, and clinicians, given the enormous amount of resources these infections consume in terms of extra costs of medications, reoperations, and extended length of hospital stays.[1-4] Adding the human perspective, a recent study indicated that afflicted patients suffer deeply, both physically and emotionally, from the consequences of a deep SSI for a prolonged period.[5]

Strategies to minimize the risk of SSI can be focused on 3 major areas: the patient, the surgical technique, and the surgical environment. Optimizing the patient preoperatively by applying current knowledge about the risks associated with smoking, malnutrition, ongoing infections and wounds, diabetes, and other underlying diseases and conditions compromising immunologic defense systems can improve postoperative outcomes significantly.[6-9] Optimizing the surgical technique by not exceeding the estimated 75th percentile of surgery time based on the type of surgical procedure reduces the risk of SSI and also minimizes blood loss, thereby avoiding the need for (allogeneic) blood transfusions and eliminating postoperative hematomas.[10-15]

The present study focused on strategies aimed at optimizing the surgical environment, in particular the air quality in the operating room (OR). Enhancing air quality by reducing airborne contamination has been shown to be of great importance, especially in relation to implant surgery.[16-18] It has been suggested that levels be maintained at <10 CFU/m^3 during implant surgery, and that clinical

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benefits can be expected by reducing it to 1 CFU/m^3,[18] given that very low levels of clinically relevant coagulase-negative staphylococci can initiate a device-related infection.[19] A landmark study found a strong linear relationship between the level of bacterial air contamination and the prevalence of deep SSI.[20]

The most common ventilation systems in use today are turbulent, displacement, and laminar airflow (LAF) systems. Whereas turbulent and displacement ventilation systems differ primarily in the methods used to supply clean air, both are incapable of opposing heat emissions from people and lamps. Both types of systems are sensitive to movement, leading to the formation of local eddies.[21] The most important source of airborne contamination is related to the dispersal of particles from persons present in the OR and their movements.[22-24] Clothing OR staff in scrubs with lower air permeability compared with conventional scrubs can reduce the dispersal of microorganisms by the OR staff, thereby significantly reducing the airborne contamination.[23,25,26] An experimental study has indicated that the protective ability of tightly woven clothing systems can deteriorate after repeated washing and sterilization.[27] Another study concluded that unnecessary conversation in the OR can contribute to an increased risk of airborne contamination,[28] and a pilot study indicated a possible association between high levels of noise during surgery and SSI.[29] The impact of OR door openings on air quality has been investigated in several studies,[30,31] but clinical tests of this have proven difficult. Ritter et al[32] found no significant difference in OR airborne bacterial counts between closed doors (mean, 15.2 CFU) and swinging doors (mean, 14.5 CFU). Stocks et al[13] reached the same conclusion. Only one study to date has reported a correlation between OR door openings and elevated airborne bacterial counts[33]; however, that result was based on 69 passive samples (on settle plates) and only 13 active samples (single-stage slit impact) placed outside the surgical wound area. The aims of the present study were to investigate the air quality, expressed as CFU/m^3, during orthopedic trauma implant surgery in a displacement ventilated OR; to explore how traffic flow and the number of people present in the OR affect the air contamination rates in the vicinity of the surgical wound; and to identify reasons for door openings in the OR.

METHODS

Setting

The study was performed at a Swedish university hospital that performs approximately 9,000 surgical procedures annually. Data was collected in 3 parallel ORs of equal size (39 m^2), each equipped with an upward air-displacement system supplying cool air (2-3°C below room temperature) above the floor in each of the 4 corners of the room. By thermal convection, the air is evacuated via 4 exhaust fans installed in the ceiling. Each OR is supposed to be maintained at positive air pressure by adjusting the inflow rate to exceed the outflow rate; however, the desired difference in pressure between the outer hall and the OR is not specified. Normally the pressure difference is ~3 kPa, and an alarm is activated if the pressure falls so that the difference is neutralized. Each OR has only a single entry point, with the door opening inward, leading directly to the outer hall. The OR teams wore conventional cotton/polyester 50/50 mix shirts and trousers, long surgical hoods tucked in, and private shoes and socks. The scrubbed team also wore reinforced disposable sterile gowns, facemasks (RII), and double-sterile gloves. Adherence to this practice was recorded for every operation. During almost half of the operations, at least one of the air inlet supply devices was partially blocked by medical equipment.

Data were collected during 30 consecutively selected full-length orthopedic trauma operations involving different types of closed-fracture surgery using plates and screws, intramedullary nails, or hemiarthroplasty. Sampling and data collection were done during the daytime and in most of the cases once a week, over a 7-month period from April to November 2010, with the exception of the holiday month of July.

Air sampling method

A Sartorius MD-8 air scanner (Sartorius Mechatronics, Göttingen, Germany) was used to collect airborne microorganisms. Air was sampled at a flow rate of 3 m^3/hour (0.83 L/second) in 20-minute periods continuously during the operations. The instrument was placed outside the sterile zone, and a sterilized flexible hose was extended to reach the wound area, with a filter holder attached to the end. The filter holder with a gelatin filter (3 μm pore size; 80 mm diameter) was placed 20-40 cm from the wound. The filters were placed vertically (n = 60), slightly upward (n = 23), slightly downward (n = 17), or horizontally (n = 3). In those cases in which the OR nurse had problems attaching the filter holder close to the wound (n = 13), the holder was placed on the Mayo stand. Data on filter placement was absent in 4 cases. The filter was changed every 20 minutes by the scrub nurse or the assistant and given to the researcher, who immediately placed it on a nonselective Colombia agar base plate with 5% horse blood. Agar plates were incubated at 30°C for 4 days, after which the total aerobic bacterial count was measured. Microbiological results are expressed as CFU/m^3. A total of 116 samples were analyzed; 4 samples were accidentally contaminated and thus excluded from the analysis. Filters and plates were handled using strict aseptic technique. To evaluate the technique, filters that had not been used for air sampling were placed on agar plates and incubated in the same way as the used filters; no bacterial growth was detected.

Observational method

Data was collected using a pretested, structured observation form. The following variables were included: date and time, OR, room temperature, type of surgery and fixation method. The period from incision time to wound closure was divided into 20-minute intervals corresponding to the ongoing air sampling. During 119 intervals (each interval corresponding to 20 minutes of air sampling), traffic flow was measured, as well as the reasons for door openings, and the current step in the surgical procedure was recorded. The number of people present in the OR, patient and researcher excluded, was recorded.

Data analysis

Primary analyses showed that CFU/m^3 could not be considered a variable with a normal distribution. For this reason, the linear relationship between CFU/m^3 per 20-minute interval and traffic flow per 20-minute interval was investigated using Spearman's rho. To investigate the strength and direction of the linear relationship between the total traffic flow per operation and the total CFU per operation, partial correlations were conducted, enabling the removal of duration of surgery as a potentially confounding variable and thereby giving a more accurate description of the relationship between the variables. Investigations of correlations between normally distributed variables (ie, traffic flow, duration of surgery, and number of people present) were performed using Pearson's product-moment correlation coefficient. Significance was defined as $P < .05$. All tests were 2-tailed. In relation to hierarchical multiple regression analysis, preliminary analyses were conducted to ensure no important violations of the assumptions of normality, linearity, and multicollinearity.

One-way between-group analysis of variance with post hoc tests found no significant difference in mean CFU counts among the 3 ORs. However, applying the same test on sampling device positioning indicated that these variations can lead to differences in mean CFU/m^3 values. The mean difference between vertically placed filters and filters placed on the Mayo stand was significant (P = .01) (Table 1). In 2 operations involving tibia fractures fixed with an intramedullary nail, the sampling filters had been placed vertically on the opposite leg. During surgery, the injured leg was flexed at 90 degrees, thereby partially or completely blocking the sampling filters with the sterile drape during most of the operation. For this reason, further analysis of air quality in the vicinity of the wound area, samples obtained on the Mayo stand and during the 2 operations for tibia fracture were excluded, leaving 92 samples for analysis. Four operational phase were defined: 1, incision phase; 2, dissection phase; 3, implantation phase; and 4, wound closure phase. Content analysis was used on observational data.[34]

Ethics

The study was approved by the University of Gothenburg's Ethics Committee (157-10). Written and oral information was provided in line with the 4 principal requirements of the Helsinki Declaration (autonomy, beneficence, nonmalfeasance, and justice).[35] Accordingly, informed consent was obtained from all of the OR teams before observations and sampling.

RESULTS

Air sampling was performed during 30 orthopedic operations in a total of 120 air sampling intervals. The distributions of surgical procedures were 73 plates and screws (60.8%), 26 intramedullary nails (21.7%), and 21 hemiarthroplasties (17.5%). The variations in CFU/m^3 values were found between operations rather than during operations (P = .001). In 52 of 91 samples, the CFU/m^3 values exceeded the recommended level of <10 CFU/m^3. In 14 of 24 operations, the mean values exceeded 10 CFU/m^3; in 5 of these operations, the mean values exceeded 25 CFU/m^3. The highest mean values were 37.5 and 44.3 CFU/m^3. Qualitative analysis revealed high activity levels (ie, movements within the OR as well as traffic flow) during these operations, along with other potentially negative variables, such as hair hanging outside the surgical hood, the presence of a sneezing person, and more than 5 people present in the OR. In 5 operations, mean values were <5 CFU/m^3, with the lowest values being 1.6 and 2.3 CFU/m^3, and notes written during these operations reveal that there was no traffic flow and low activity. Basic results on air quality, expressed as CFU/m^3, and related variables are provided in Table 2.

Traffic flow

The relationships between the total traffic flow rate per operation and the total CFU/m^3 sampled per operation and between traffic flow rate per 20-minute interval corresponding to 20 minutes of air sampling were investigated. A positive correlation was found between CFU/m^3 and traffic flow rates when measured in 20-minute intervals (r = 0.309; P = .003). The data show a strong, positive correlation between the total CFU/m^3 per operation and total traffic flow rate per operation (r = 0.74; P = .001; n = 24 operations). Because duration of surgery correlates to the total CFU and traffic flow rates, duration of surgery was controlled for in the analysis.

A total of 529 door openings were recorded. Reasons for OR entries and exits were grouped into categories, as shown in Table 3. No reason could be identified in relation to 93 entries and exits. To exemplify, this could mean that a staff member would enter the OR, take a look around, and then walk out.

Table 1
CFU/m^3 values and sampling positions

Position	n	Mean	SD	95% confidence interval for mean: Lower bound	Upper bound
40-20 cm from wound					
Vertically	60	15.8	13.9	12.2	19.4
Downward	17	15.2	10.2	10.0	20.5
Slightly upward	23	13.0	13.4	7.1	18.8
Horizontally	3	8.6	3.7	−0.74	18.0
Mayo stand					
Vertically	13	6.6	4.4	3.9	9.4
Total	116	13.9	12.6	11.6	16.3

n, number of samples.

Table 2
Air quality and related variables

Variables	n (missing)	Mean (SD)	95% CI for mean	Median (range)
CFU/m^3	91 (1)*	15.9 (13.4)	13.1-18.7	13 (0-55)
Total CFU/m^3 per operation	24†	60.4 (55.9)	36.8-84	33.5 (7-187)
Number of people	111 (9)‡	5.4 (1)	5.2-5.6	5 (3-10)
Traffic flow rate	119 (1)‡	4.3 (2.9)	3.8-4.8	4 (0-14)
Traffic flow rate per operation	30†	17.4 (13.5)	12.4-22.4	14 (0-67)
Duration of surgery, minutes	29 (1)§	83.5 (39.7)	68.4-98.5	60 (20-200)

*Number of air samples.
†Number of operations.
‡Measured in 20-minute intervals.
§From incision time to end of closure in minutes.

Traffic flow rates in relation to the previously mentioned 4 phases of the operation were analyzed by one-way analysis of variance with post hoc tests showing no significant difference in mean traffic flow rate per 20-minute intervals. In addition, no significant differences in mean CFU/m^3 values were found among the different phases. No correlation was detected between the number of people present and traffic flow rates in the OR.

Number of people and the effect on air quality

A minor correlation was found between CFU/m^3 and the number of people present in the OR (r = 0.22; P = .04; n = 82).

Duration of surgery and type of surgical procedure

No correlation was found between CFU/m^3 rates measured in 20-minute intervals and duration of surgery measured in minutes. A positive correlation was found between the total CFU/m^3 per operation and duration of surgery (r = 0.62; P = .01; n = 23). No correlation was found between traffic flow rate per 20-minute interval and duration of surgery, but a strong correlation was noted between total traffic flow rate per operation and duration of surgery (r = 0.79; P = .01; n = 23). Differences in mean CFU values in relation to type of surgical procedure are presented in Table 4.

Predictors of CFU

Hierarchical multiple regression was used to assess the ability of traffic flow and number of people present in the OR to predict CFU/m^3 levels after controlling for duration of surgery. Duration of surgery was entered in step 1, explaining 36% (adjusted R^2 = 0.359)

Table 3
Reasons for traffic flow

Necessary door openings*	n	Semi-necessary door openings	n	Unnecessary door openings	n
Expert consultations (eg, help needed from senior surgeons, expert nurses, or anesthesiologists)	40	Surgical team members entering after incision or leaving before closure	76	Logistic reasons planning next or other operation	30
Instruments or other material needed	137	Lunch and coffee breaks	108	Social visits	45
				No detectable reasons	93
Total	177		184		168
					529

*The need assessed in relation to patient safety and ongoing procedure.

Table 4
Relationships among CFU, surgical procedures, and traffic flow, analysis of variance

	n	Mean	SD	95% CI	*P* value
Mean CFU/m^3 value in relation to surgical procedure*					.001
Plates and screws	69	18.7	13.3	15.5-21.9	
Hemiarthroplasty	11	4.73	9.87	1.1-18.6	
Intramedullary nails	11	4.73	3.1	2.6-6.8	
Mean traffic flow rates in relation to surgical procedure†					.004
Plates and screws	69	4.5	2.7	3.8-5.1	
Hemiarthroplasty	11	2.3	1.4	1.3-3.3	
Intramedullary nails	11	2.2	2.3	0.6-3.77	

*Number of air samplings corresponding to type of surgical procedure.
†Number of surgical procedures corresponding to traffic flow rate per 20-minute interval.

of the variance in total CFU/m^3 per operation. After entering traffic flow and number of people present, the total variance explained by the model as a whole was 68% [F(3,16) = 14.32; *P* = .001]. The 2 control measurements, traffic flow and number of people, explained an additional 34% (adjusted $R^2 = 0.336$) of the variance in CFU/m^3 when controlling for duration of surgery (R^2 change = 0.34; *F* change (2,16) = 9.91; *P* = .002). In the final model, only traffic flow was statistically significant (standardized β = 0.95; *P* = .001).

DISCUSSION

In orthopedic surgery, large-scale efforts and research activities have focused on infection control, mainly in relation to elective primary joint replacement surgery. The findings of the present study show that the recommended limit of >10 CFU/m^3 was exceeded in 57% of the samples analyzed. Patients with orthopedic trauma carry an extra burden of preoperative soft tissue and skeletal damage, and have minimal opportunities to be optimized in relation to comorbidities that are known to be major risk factors in this group of patients.[36] Adding smoking habits and old age (the latter of which is common in patients with osteoporotic hip fracture), a picture of a highly vulnerable group of patients emerges. Reducing risk factors in the surgical environment clearly would be beneficial for this group of patients. One of the most important findings of the present study is the highly negative impact of traffic flow in the OR on bacterial contamination of the air close to the wound; that is, a high rate of door openings was associated with high rates of CFU/m^3 values. This correlation is weaker when analyzing CFU/m^3 per 20-minute interval compared with the total CFU/m^3 per operation, which may be related to the unorganized manner in which bacterial dispersion reaches the wound area after an OR entry or exit because of turbulent air flow patterns as well as movement of people in the OR. Analysis of the factors affecting traffic flow found that only 7% of the door openings were related to the need for expert consultation. Supply issues represented the largest category (26%); improving preoperative planning and communication between the surgeon and OR nurse in charge could possibly reduce these door openings. Staff breaks accounted for 20% of door openings; surgical team members entering or leaving the OR when the wound was open, for 14%. Reductions in all of these large categories of traffic flow are possible. Door openings for logistic reasons could all be avoided by telephone communication. Door openings related to social visits and for no detectable reasons together accounted for 27% of the traffic flow, possibly reflecting an OR culture that accepts door openings for no special reason. Although it is reasonable to think that an individual who enters an OR always has a good reason for doing so, in those cases we could find no link to the ongoing procedure. Blaming individuals for lack of discipline is not be a fruitful way to address this problem, given that the cause probably extends the individual level. In addition, merely counting exits and entries while failing to analyze the reasons behind traffic flow behavior could lead to misdirected interventions.[37]

Directing the focus of change at an organizational level, including enhanced knowledge, logistics, and perioperative planning, would give the OR staff the necessary tools to minimize door openings in the OR. This would not only minimize traffic flow, but also likely reduce the duration of wound exposure. Lynch et al[38] reported a mean rate of 40 door openings per hour for orthopedic total joint surgery, and Young et al[39] reported a mean rate of 19.2 per hour for cardiac surgery, compared with the rate of 12.9/hour in the present study. The traffic flow patterns reported in these 3 studies must be considered in light of the high correlation between door opening rate and elevated CFU levels, representing a major patient safety problem.

The large variation in CFU values among operations in the present study is in line with previous reports.[13,20,33] This supports the perception that CFU/m^3 level should not be discussed as an independent variable with a presumed normal distribution in the OR, because it is highly dependent on other variables and can be reduced to almost nondetectable levels under optimal conditions. The importance of the duration of surgery in relation to CFU/m^3 levels measured at 20-minute intervals was of minor importance. However, the duration of surgery is of clinical relevance, given that the total CFU level increases with increasing duration of surgery, thereby exposing the wound to an increased total number of CFUs and increasing the risk of SSI.[10,40] In addition, longer duration of surgery was associated with in higher total OR traffic flow rates. In this sample, only very small variations in relation to the number of people present in the OR were observed; as a result, the effect of the number of people present in the OR on CFU level could not be investigated thoroughly. The differences in CFU levels related to type of surgery, with fixation with plates and screws associated with the highest levels, can be explained by the fact that these procedures were associated with 50% more door openings. The fact that in almost half of cases, at least one of the air inlet supply devices was partially blocked by medical equipment might suggest that the staff has poor knowledge of how the ventilation system works and how to deal with the reality of underdimensioned operating rooms. To investigate the consequences of blockage of air inlets, it would be necessary to control for how close the medical equipment was placed in relation to the inlet device and also for how large an area of the inlet supply was blocked. These data were not registered in the present study, precluding analysis of the possible impact on air contamination rates. Given that our regression model explains 34% of the variance of total CFU/m^3 per operation, future research should aim at developing a clinically relevant predictive model for estimating bacterial contamination under different environmental and behavioral conditions, taking into account clothing systems and activity levels in the OR.

Methodological considerations

Conducting representative air sampling in the OR in live conditions proved highly challenging, and many methodological and technical issues had to be addressed both before and during the present study. The choices of sampling velocity, time, and culture media were based on recommendations from infection control practitioners performing surveillance sampling on a regular basis. Studies have reported that the viability of microorganisms might be affected by prolonged sampling times and high airflow rates.[41,42] Evaluation of the Sartorius air sampler demonstrated no reduction in the viability of cocci after drawing 2.6 m^3 for 20 minutes, but negative effects for *Escherichia coli*.[43] Various cocci were the main relevant species found in the OR,[24] and these bacteria also are the leading cause of infections related to implanted medical devices.[44] Based on this, we believed that the sampling time was an acceptable compromise between the purpose of the study and the need to avoid being overly intrusive during the procedures. However, we consider the wide variety of sampling positions in this study a limitation, which might have led to underestimation of CFU values. The literature typically reports on the distance from the wound to the sampling device (striving to be as close as possible), sampling velocity, and time; unfortunately, methodological issues are rarely studied or discussed. Further studies addressing the positioning of sampling filters, the angle between filters and air flow, sampling velocity in relation to air flow patterns produced by different ventilation systems, and their impact on outcome data are needed. Standardizing an optimal air sampling method would produce reliable data and facilitate comparisons between studies to provide insight into the protective capacity of different ventilation systems during operations. Upward- displacement ventilation systems have been demonstrated to more effectively remove particles compared with conventional systems.[45,46] An experimental study[47] comparing conventional ventilation and upward-displacement ventilation confirmed that the upward displacement system was more efficient in removing particles <10 μm, but found no difference between the 2 ventilation systems for particles >10 μm.[47] More importantly, the bacterial air counts were generally higher in the displacement systems than in conventional systems. Considering this in the present study, it is possible that the displacement system produced higher mean CFU/m^3 values than what would have been registered under the same circumstances in a conventionally ventilated OR. However, the present study demonstrates that even in a displacement ventilated OR, very low CFU/m^3 levels could be obtained by keeping the doors closed and reducing the number of people present.

Even structured observations can be susceptible to bias.[48] Human perceptual errors can affect the obtained information, as well as behavioral distortions, due to the presence of an observer. Several measures were taken to address potential bias: (1) The observational form was pretested and modified, (2) the observer had no previous connection with the ward under observation, and (3) the observer underwent self-training sessions to maximize accuracy. Concealed observations to reduce reactivity were not feasible and were considered a possible source of distrust between the observed and the observer. To estimate the effect of the presence of an observer, the traffic flow rates at the beginning of the study period (May) were compared with rates measured after 6 months (November); no statistically significant differences in traffic flow rates were detected.

CONCLUSION

This study has clearly linked elevated airborne bacterial counts in the surgical area to door openings in conventionally ventilated ORs, thereby providing the scientific evidence needed to initiate interventions aimed at preventing SSI by reducing traffic flow in the OR. In addition, analyzing the reasons for door openings seems to be of great importance to the success of any intervention implemented.

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