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Major article

Comparison between mixed and laminar airflow systems in operating rooms and the influence of human factors: Experiences from a Swedish orthopedic center

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Background: The importance of laminar airflow systems in operating rooms as protection from surgical site infections has been questioned. The aim of our study was to explore the differences in air contamination rates between displacement ventilation and laminar airflow systems during planned and acute orthopedic implant surgery. A second aim was to compare the influence of the number of people present, the reasons for traffic flow, and the door-opening rates between the 2 systems.
Methods: Active air sampling and observations were made during 63 orthopedic implant operations.
Results: The laminar airflow system resulted in a reduction of 89% in colony forming units in comparison with the displacement system ($P < .001$). The air samples taken in the preparation rooms showed high levels of bacterial growth ($\approx$ 40 CFU/m^3).
Conclusions: Our study shows that laminar airflow-ventilated operating rooms offer high-quality air during surgery, with very low levels of colony forming units close to the surgical wound. The continuous maintenance of laminar air flow and other technical systems are crucial, because minor failures in complex systems like those in operating rooms can result in a detrimental effect on air quality and jeopardize the safety of patients. The technical ventilation solutions are important, but they do not guarantee clean air, because many other factors, such as the organization of the work and staff behavior, influence air cleanliness.

The importance and role of (unidirectional) laminar airflow ventilation systems (LAF) in operating rooms (ORs) designed to provide protection from surgical site infections (SSI) have been questioned.[1,2] A retrospective cohort study based on routine surveillance revealed that higher rates of SSI following total hip arthroplasty (THA) are associated with the use of LAF compared with conventional ventilation systems.[3] Moreover, the 10-year results from the New Zealand joint register[4] reported a significant increase in early deep infection following THA and total knee arthroplasty in ORs equipped with LAF compared with conventional ventilation systems. A recent review article[2] recommends that the installation of LAF systems should be stopped.

Our study was performed in a hospital where comprehensive organizational changes were carried out during 2006. Financial investments were made to convert 3 displacement-ventilated ORs into 3 larger ORs equipped with LAF to enhance quality. However, the results from the Swedish Hip Arthroplasty Register in 2010[5] showed an unexpected and worrying increase in infection rates following THA. Moreover, compared with the national average, the hospital had more than twice the risk of reoperations following THA.[5] The aim of our study was to explore the differences in air contamination rates between displacement ventilation systems (DV) and LAF during planned and acute orthopedic implant surgery of bone and joint. A second aim was to compare the influence of the

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Table 1
Technical specifications of the ventilation system

	Laminar airflow system	Displacement	Preparation room
Airflow, m^3/h	9,160	2,430	3,900
Supply vent size, mm	3,600 × 3,600	*	2,000 × 2,000
Air velocity, m/sec	0.25 ± 0.02	0.09-0.15	0.27 ± 0.02
Filter class	EN 1822, H 14	F9	EN 1822, H 14
Room size, m^2	46	39	5
Operating room lamp size, mm	640 × 640	640 × 640	
Temperature	20°C ± 1°C	20°C ± 2°C	22°C

*The displacement ventilation operating rooms were equipped with an upward system, supplying cool air approximately 2°C-3°C below room temperature above the floor by thermal convection. The air is evacuated via exhaust outlets installed in the ceiling.[6] Filter classes are according to the European classification system. The EN779:2002 standard is used for the classification of fine filters as F9. The EN1822:2009 standard classifies HEPA filters. H 14 is the highest standard for clean rooms.

number of people present, the reasons for traffic flow, and the door-opening rates between the 2 systems. Moreover, we aimed to describe how surgical instruments are prepared and protected from airborne contamination before surgery.

METHODS

Data collection

Our study was set in an orthopedic teaching hospital in which more than 10,000 surgeries are performed every year. During April-November 2010, the research group studied air quality and traffic flow in DV ORs during 30 orthopedic trauma implant procedures at this hospital.[6] Data from the above-mentioned study were used for comparison with the data collected in LAF-ventilated ORs in our study. The data collection periods in the prior study and ours overlapped and the same researcher used the same study protocol. Data in the LAF ORs were consecutively collected during 33 orthopedic implant operations conducted April 2010-May 2011. Four samples taken behind the surgeon during 1 operation were removed from further analysis because this sampling point was not included in the study protocol. The sample size was based on theoretical assumptions because the data necessary to conduct a proper power calculation did not exist before our study. The ward has 3 ORs equipped with vertical LAF ventilation systems and 3 ORs equipped with DVs. The LAF ORs have 2 entry/exit points; 1 leads directly to an unsterile corridor. This entry/exit point is a sliding door with 2 options: a large door opening for the passage of large equipment, and a smaller opening used by people. The other entry/exit point leads through a swing door into a preparation room. The DV ORs have only 1 entry/exit point, a swing door leading to the same nonsterile corridor described above.

For technical specifications and projected settings for the 2 ventilation systems, see Table 1.

Conventional cotton/polyester 50/50-mix shirts and trousers, long disposable surgical hoods tucked in, and private socks and shoes were the clothing regimen in all of the observed operations. In all cases, the scrubbed members wore reinforced surgical gowns and facemasks. Nonscrubbed members of the team did not wear facemasks.

Air sampling in the LAF-ventilated ORs

The study methodology relating to the air sampling technique and onsite observations was similar to the one used and previously described.[6] In short, a Sartorius MD-8 Air Scanner (Göttingen, Germany) was used for the active collection of aerobic airborne microorganisms. Air was sampled continuously during surgery at a flow rate of 3 m^3/h (0.83 L/s) in 20-minute periods. The air scanner was placed outside the sterile zone and a sterilized flexible hose reached the surgical wound area, with a filter holder attached to the end. The filter holder with a sterile gelatin filter (pore size 3 μm and diameter 80 mm) was placed approximately 30 cm from the wound. When this was not feasible, the filter holder was placed on the Mayo stand. The scrub nurse changed the filter every 20 minutes, after which the filters were placed directly on a nonselective Colombia agar base plate with 5% horse blood. The agar plates were incubated at 30°C for 4 days before the total aerobic bacterial count was measured. Microbiology results were expressed as colony forming units/$meters^3$. Filters and plates were handled using a strict aseptic technique. For evaluation, unused filters were placed on agar plates and incubated in the same way as the used filters. Analysis showed no bacterial growth.

Onsite observations

The included observational variables were date; time; OR identification number; the positioning of the air sampling filter (angle and place); air temperature; type and length of operation; number of persons present (researcher and patient excluded); preparation of sterile instruments; door-opening rates; and, when possible to detect, reasons for doors being opened. All data were recorded in 20-minute periods in accordance with the air sampling periods. In addition, field notes based on participant observations were taken throughout the study period.

During the observations it was brought to our attention that there appeared to be "something wrong" with the ventilation in the adjacent preparation rooms. We carried out preliminary tests that revealed airflow rates of about 0.00-0.03 m/s in the 3 existing preparation rooms. Active air samples were taken during 3 standardized sham preoperative preparations of sterile instruments and equipment needed for a regular THA operation. To mimic normal conditions, the hospital's standardized sets of instruments (12 instrument trays) and equipment for THA procedures were used, as was the standard clothing regimen. The sampling filters were placed <10 cm from the instrument table, 100 cm above the floor. Two control measurements were made during instrument preparation after technical revisions of the ventilation system.

Statistical analysis

In the analysis of colony forming units and related variables, the mean, or the total count over the 20-minute blocks of observation per surgery, was used for the different outcomes. For the number of persons in the room, the mean number was used and, for colony forming units and door openings, the total numbers were used. The summary statistic per surgery could then be analyzed as independent between the cases and overdispersion was avoided. Poisson regression was used. For differences in colony forming unit density between different stages of surgery and different sampling positions, the Kruskal-Wallis one-way analysis of variance by ranks was used. Significance was defined as $P < .05$.

Ethics

Our study was approved by the Regional Ethical Review Board, Gothenburg, Sweden (Drn: 157-10). Informed consent was obtained from all OR teams before observations and sampling.