Mobile zoned/exponential LAF screen - a promising new concept in ultra-clean air technology for additional operating room ventilation

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Summary: A new concept in the form of a mobile screen (0.5 x 0.4 m) producing ultra-clean exponential LAF (air-flow central zone 0.6 m/s and peripheral zone 0.4 m/s) was investigated as an addition to conventional turbulent/mixing operating room ventilation. The evaluation was performed during strictly standardised sham operations reflecting conditions during major surgery. The study consisted of a pilot experiment (n=2) designed to give high counts of sedimenting aerobic colony forming units. In a second main study (n=10), recording dust particles, air-borne and sedimenting aerobic cfu the screen was challenged with optimal operating room clothing.

In the pilot experiments the use of the screen resulted in a substantial reduction of sedimenting bacteria from 3835-4940 to 0-390 cfu/m²/h. In the main study and measured up to 1.6 m from the screen the use of the additional LAF reduced the surface contamination from 416-314 to 7-78 cfu/m²/h in the different areas important for surgical asepsis (P=0.001-0.0001). Measured in the wound area the screen reduced the air counts of bacteria from 9-14 to 0.2-0.4 cfu/m³ (P=0.008-0.0001). In the same area a marked reduction of air-borne dust particles was registered (P=0.007-0.009).

In conclusion and compared to an optimal situation in turbulent operating room ventilation the additional mobile LAF screen reduced the counts of aerobic air-borne and sedimenting bacteria-carrying particles as well as dust particles to the levels gained with complete ultra-clean LAF room ventilation (operating box). Thus, the screen might prove a valuable addition in operating room ventilation technique as well as in other areas were asepsis is essential.

Keywords: Operating room; laminar air flow; clothing; colony counts; microbiology; particle counts.

Introduction
It is generally accepted that the main factor causing surgical site infection (SSI) is bacterial contamination of the operating room (OR) air either directly contaminating the wound or indirectly by contaminated sterile equipment. It is also accepted that the origin of this contamination is contaminated skin scales shedded from the surgical team. There are in principal three ways to reduce this contamination. The first is OR ventilation in order to dilute and evacuate the contamination. The second is operating clothing enclosing the personnel in order to
reduce spread of skin scales to the OR air. The third principle is to kill the germs either by ultraviolet light in the OR after contaminating the wound by antibiotics. 6, 7

The prime principal has resulted in development of ultra-clean laminar air flow (LAF) systems for ventilation of operating rooms (operating box). 8, 9, 10, 11 This concept is today mainly used for implant surgery and is costly and requires space for installation, which is often difficult to impossible in already existing premises.

A new concept introducing a mobile screen supplying ultra-clean exponential LAF has been developed. The system is designed to work independently as an addition to basic OR ventilation and contains HEPA filter as well as closed UVC for ultimate bacterial control.

The purpose of the present study was to evaluate the novel mobile screen supplying ultra-clean exponential LAF as an addition to conventional turbulent or mixing OR ventilation.

Methods

Operating room (OR) and ventilation systems

All experiments were performed in the same OR. The air streams in both systems were tested using smoke. Illumination was provided using two streamlined cross-shaped operating lights positioned at 45° to minimise disturbance of the airflow.

OR ventilation The OR was equipped with a conventional turbulent or mixing ventilation system (16 air changes/h, temperature 20°C) supplying filtered outdoor air to the OR using a positive (plenum) pressure and an inclined perforated screen at the ceiling along one side wall and evacuated at the opposite side at floor level.

Additional LAF unit In half of the experiments in addition to the basic OR ventilation a mobile unit producing ultra-clean exponential LAF was introduced (TOUL Hospital AB, Västerås, Sweden). The LAF unit consisted of a stainless steel box on wheels equipped with a fan and High Efficiency Particulate Air Filter (HEPA type MGEA 600) and closed ultraviolet light (UVC 254 nm). The OR air was sucked into the box, filtered and sterilised before passing through a tube to a movable screen. The screen (0.55 x 0.4 m) had a central zone of air flow at 0.6 m/s and a peripheral zone with 0.4 m/s producing zoned or exponential air-flow preventing entrainment of OR air outside the LAF. The screen was placed at the foot-end of the OR table with the air-flow directed along the table (Figure 1).

Sham surgery

To compare bacterial and dust particle contamination system with and without the mobile LAF screen an experimental model with strictly standardised sham operations was chosen. The model has earlier been described in detail 12 and here only information relevant to this study is given. The study consisted of a simple pilot experiment (1+1) designed to yield high counts of bacterial surface contamination. This was followed by a main study (5+5) where the screen was challenged with optimal OR clothing.

The experimental model used in the main study consists of three phases. With the OR empty only one person performing the sampling (10 min) was present in the room. During preparation (10 min) the operating table was dressed with a disposable non-woven sterile sheet (Mölnlycke Health Care AB) and the members of the surgical team were dressed and positioned in the room. During surgery (30 min) the surgical team every minute performed a 15 sec routine of standardised movements and commands mimicking the oral and physical activities during a two-hour major orthopaedic operation. In the pilot experiment only the surgical phase was used.

Operating team and clothing

The pilot experiments (1+1) was done during one separate occasion. In the main study the sham operations (5+5) were performed during two days by the same mock team. In both instances the team consisted of six individuals. Four acted as operating team and one as anaesthetist and one as circulating nurse.

In both parts of the study the whole team wore basic operating theatre clothing in the form of shirts tightly fitted around the arms and trousers tightly fitted around the ankles, all made of nylon and cotton (30/70 domestic Mercan P-3467), sterile gloves (Biogel Regent Medical UK) and facemasks (special Mölnlycke Health Care AB Sweden). In the pilot experiments this
was only supplemented with a small head cap as head cover. In the main study the surgical team in addition used sterile gowns (standard C) and a surgical hood helmet model (Glenn) covering the neck, reaching out on shoulders and well tucked under the sterile gown all from (Möllycke Health Care AB, Sweden). All clothing was changed before each experiment.

**Sampling methods and experimental set up**

Aerobic bacteria were studied using agar plates incubated for 48h at 37°C before counting the number of bacteria-carrying particles, i.e. colony forming units (cfu). The two control plates not exposed to the air used in each experiment were all without contamination.

**Air counts of bacteria** The number of colony forming units in the air was measured only in the main study using an MD8 Air Sampler (1m³/10min) placed in the wound using gelatine membrane filter (AKA AB) transformed to 9cm/diameter agar plates (Figure 1). The air was measured during five 10 min periods, before preparation (10min), during preparation (10min) and during sham surgery (3x10 min).

**Bacterial sedimentation rates** Surface contamination was studied using 14cm diameter agar plates Columbia II Agar Base (BBL) enriched with 5% horse blood (Figure 1). Four plates were placed outside the surgical zone but at the same level as the operating table and were exposed during main study to air during 40 min both during preparation (10min) and during sham surgery (30min). In the pilot experiment the exposure time was only during surgery. The other plates were placed in the instrument area (0.30 m from screen), in the wound area (0.75m from screen) and patient area (1.10 to 1.60m from screen).

**Air counts of dust particles** Dust particles were sampled in the wound area with a laser particle sampler (Met One Model 217 Inc OR USA capacity 0.028/m³/min). The sampler recorded particles sized >0.5-5 and >5 μm during one minute in the middle of each 10 minutes during the experiments. During sham surgery physical activity was avoided during measurements.

**Statistics**

In the main study the type of ventilation was randomised to morning and afternoon. SPSS was used for statistical calculations and differences between means were analysed with Mann-Whitney U-tests. The relations between sedimenting and air-borne colony forming units as well as the relations between air-borne colony forming units and dust particles were studied using regression analyses. P<0.05 was chosen as a significant difference.

**Results**

**Pilot study (n 1+1)**

**Bacterial sedimentation rates** The use of the LAF screen with ultraclean exponential air streams markedly reduced the surface contamination (cfu/m²/h) with bacteria-carrying particles in the "instrument", "wound" and "patient" areas compared to the experiment without the screen (Table I). With the screen no contamination was registered in the "instrument" and "wound" areas. In the periphery of the operating room no major difference in sedimenting colony forming units could be seen using the extra LAF or not.

**Air counts of dust particles** In the "wound" area and compared to the experiment without the screen the addition of laminar air-flow reduced the number of air-borne dust particles/m² >5μ by a factor of 3.5 and for particles >0.5-5μ by a factor of 2.6 (Table I).
Table 1. Sedimenting bacteria-carrying particles (cfu/m$^2$/h) and air counts of dust particles/m$^3$ in the two pilot experiments with and without an additional LAF screen with ultraclean exponential air streams. For particle counts (n10+10) means and (SD) are given.

<table>
<thead>
<tr>
<th>Variable and sampling site (distance to screen in m)</th>
<th>With screen (n 1)</th>
<th>Without screen (n 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedimenting bacteria (cfu/m$^2$/h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instruments (0.30)</td>
<td>0</td>
<td>3835</td>
</tr>
<tr>
<td>Wound (0.75)</td>
<td>0</td>
<td>3835</td>
</tr>
<tr>
<td>Patient (1.10)</td>
<td>390</td>
<td>4940</td>
</tr>
<tr>
<td>Periphery (&gt;2)</td>
<td>715</td>
<td>520</td>
</tr>
<tr>
<td>Particle air count/m$^3$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound (0.75)</td>
<td>&gt;5μ</td>
<td>383 (336)</td>
</tr>
<tr>
<td></td>
<td>&gt;0.5-5μ</td>
<td>10396 (4218)</td>
</tr>
</tbody>
</table>

Table 2. The air contamination (cfu/m$^3$) in the wound area (0.75m from screen) with bacteria-carrying particles during sham surgery with and without an additional LAF screen with ultraclean exponential air streams. Means and (SD) and significant differences between groups are given.

<table>
<thead>
<tr>
<th>Air counts cfu/m$^3$</th>
<th>Sampling period</th>
<th>With LAF screen (n 5)</th>
<th>P-value</th>
<th>Without LAF screen (n 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No activity</td>
<td></td>
<td>0.2 (0.5)</td>
<td>0.04</td>
<td>1.6 (1.1)</td>
</tr>
<tr>
<td>Preparations</td>
<td></td>
<td>0.4 (0.5)</td>
<td>0.008</td>
<td>8.8 (2.6)</td>
</tr>
<tr>
<td>During surgery</td>
<td></td>
<td>0.2 (0.6)</td>
<td>0.0001</td>
<td>14.0 (4.9)</td>
</tr>
</tbody>
</table>

Main study (n 5+5)

Air counts of bacteria Using the LAF screen the air contamination with cfu/m$^3$ in the wound area before sham surgery, during preparations and during surgery was minimal and well below the accepted limit for operating units with ultraclean laminar ventilation, i.e. <10 cfu/m$^3$. Compared to experiments without the screen the additional ventilation significantly (p=0.008-0.0001) reduced air contamination during the phases of activity by a factor of 22-70 (Table II).

Bacterial sedimentation rates In all areas important for surgery the additional screen significantly (p=0.001-0.0001) reduced the surface contamination to a level well under the limit for what is acceptable for operating units with ultraclean laminar ventilation, i.e. <350 cfu/m$^2$/h. In the periphery of the operating room no difference was found using the LAF screen or not. The results are given in Table III.

Surface to air ratio (SAR) With screen the relation between sedimenting and air-borne colony forming units in the wound area was 33/1 (P=0.77, R$^2$=0.03). Without screen the relation was 24/1 (P=0.055, R$^2$=0.0.76).

Type of cultured bacteria The cultured bacteria colonies were mainly coagulase negative staphylococci and micrococcus.
Table III. Sedimentation of bacteria-carrying particles during sham surgery with and without an additional LAF screen with ultraclean exponential air streams. Means and (SD) and significant differences between groups are given.

<table>
<thead>
<tr>
<th>Sampling site (distance to screen in m)</th>
<th>With screen (n 5)</th>
<th>P-value</th>
<th>Without screen (n 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instruments (0.30)</td>
<td>65 (92)</td>
<td>0.001</td>
<td>416 (228)</td>
</tr>
<tr>
<td>Wound (0.75)</td>
<td>7 (29)</td>
<td>0.0001</td>
<td>364 (201)</td>
</tr>
<tr>
<td>Patient 1 (1.10)</td>
<td>61 (67)</td>
<td>0.0001</td>
<td>329 (176)</td>
</tr>
<tr>
<td>Patient 2 (1.60)</td>
<td>78 (52)</td>
<td>0.0001</td>
<td>416 (130)</td>
</tr>
<tr>
<td>Periphery (&gt; 2)</td>
<td>309 (185)</td>
<td>ns (0.9)</td>
<td>314 (204)</td>
</tr>
</tbody>
</table>

Table IV. The air contamination with dust particles >5μ and >0.5-5μ in the wound area (0.75m from screen) during sham surgery with and without a mobile LAF screen with ultraclean exponential air streams. Means and (SD) and significant differences between groups are given.

<table>
<thead>
<tr>
<th>Particle size and sampling period</th>
<th>With screen (n 5)</th>
<th>P-value</th>
<th>Without screen (n 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;5 μ</td>
<td>0</td>
<td>ns (0.1)</td>
<td>28 (38)</td>
</tr>
<tr>
<td>No activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparations</td>
<td>7 (16)</td>
<td>0.007</td>
<td>1119 (358)</td>
</tr>
<tr>
<td>Surgery</td>
<td>2 (16)</td>
<td>0.007</td>
<td>424 (89)</td>
</tr>
<tr>
<td>&gt;0.5 - 5μ</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Empty</td>
<td>317 (437)</td>
<td>0.009</td>
<td>45549 (19440)</td>
</tr>
<tr>
<td>Preparations</td>
<td>472 (369)</td>
<td>0.009</td>
<td>68584 (15315)</td>
</tr>
<tr>
<td>Surgery</td>
<td>324 (258)</td>
<td>0.009</td>
<td>66317 (11546)</td>
</tr>
</tbody>
</table>

Air counts of dust particles. Using the LAF screen the air contamination with dust particles/m³ in the wound area before sham surgery, during preparations and during surgery was minimal and compared to experiments without the screen the additional ventilation significantly (p=0.009-0.007) reduced this air contamination (Table IV).

Relation between air count of colony forming units and dust particles. During surgical activity with (n 15) and without screen (n 15) each 10 minutes air borne colony forming units was correlated with the corresponding measurements of dust particles (0.5-5μ and >5μ). No significant correlation (R²=0.01-0.03) was found with or without the screen. When both ventilations were considered together significant correlation (P=0.001, R²=0.71-0.74) existed between both sizes of dust particles and air borne bacterial contamination. The equations for the linear regression were for dust particles $0.5-5\mu = 106.19 \text{ cfu/m}^3 + 196.3$ and for $>5\mu = 0.7283 \text{ cfu/m}^3 + 0.919$.

Discussion

The novel mobile ultra-clean LAF screen with exponential airflow was first tested...
in a simple pilot experiment designed to give high counts of sedimenting aerobic colony forming units. The result form the pilot study prompted us to a main study using optimal OR clothing. With regard to ethical considerations the LAF screen was evaluated in experimental situations with sham operations earlier proved to reflect actual activity during major surgery. In the pilot experiment the extra screen was challenged with a situation where the team members did not use operating gowns, just small head cap and face masks. Without the screen this resulted in a very high surface contamination with bacteria carrying particles. The contamination was almost totally obliterated when the screen was used.

In the main study optimal operating clothing in the form of squire hood reaching out on shoulders and disposable non-woven gowns was used. It can be noted that in the experiments without the screen this clothing resulted in a very low bacterial air and surface contamination. In fact, the contamination in the wound area during surgery was just above the suggested acceptable limits for ultra-clean LAF units, i.e. 10 cfu/m³ and 350 cfu/m²/h. Also in this situation the addition of the screen significantly reduced both types of bacterial contamination to very low levels completely comparable to those found in different types of complete ultra-clean LAF units. The screen proved to supply the operating table with ultra-clean air in the areas studied, i.e. up to a distance of 1.6 m from screen.

The idea to supplement conventional OR ventilation with clean-air spot ventilation is not new (e.g. Weiss Technik GMBH D-6301 Reiskirchen Germany). However, this has not been shown to be as efficiently as complete LAF units and is today a method not generally used. A problem with extra spot ventilation with uniform airflow is the entrapment of OR air from outside the extra air stream. We tested a similar screen to the one described here supplying uniform airflow. This screen could only supply ultra-clean air up to a distance of 0.5m and smoke tests clearly showed inflow of OR air into the ultra-clean air stream. The exponential airflow produced by a higher velocity of the air stream in the central part of the screen than in the peripheral part results in an air pressure gradient giving an airflow deviating out in the remaining part of the OR. This graded outflow of air efficiently prevents inflow of OR air into the ultra-clean air. This principle is earlier a well documented technique used in operating box air technology where the exponential air flow makes extra walls in OR unnecessary.

As an additional observation no relation between surface contamination and air contamination of bacteria carrying particles was found when the screen was used. Without the screen a week correlation existed with a ratio in the range that was earlier demonstrated in similar experimental conditions. Recently the use of bacterial air counts as the most reliable indicator for the risk of contamination of sterile areas in the OR environment has been questioned by several authors. Our results further supports the view that surface contamination is a better indicator of bacterial contamination in the OR and especially so when an ultra-clean airflow is used.

The efficiency of modern operating garments to reduce bacterial contamination is well documented. However, the levels of contamination found here was very low and about half of that earlier found in similar experiments. Compared to that in the earlier experiments the difference in clothing consisted of a tight fit around the upper arm of the working dress and a surgical hood reaching out on shoulders and worn under operating gown. Although, not to be proven here, these changes in clothing designed to prevent the known risk for dispersal of skin scales from the upper part of the body at the neck area seems to be of importance for an optimal function of modern operating clothing.

In OR surroundings dust particle counts are generally accepted as a method to assure tightening material and filter efficiency but have not been proven to reflect bacterial air contamination. Also in this study no correlation between particle counts and air-borne cfu’s was found when the experiments with and
without the additional ventilation were studied separately. However, when the two different conditions were considered together a strong correlation existed between the two parameters indicating that in a specific situation particle counts can give an estimate of the efficiency of a ventilation system to reduce bacterial air contamination. A similar result has been reported in a study of air contamination in different ventilation conditions in a laboratory. 26

In conclusion the additional LAF screen reduced the counts of aerobic air-borne and sedimenting bacteria-carrying particles as well as dust particles to the levels gained with complete ultra-clean LAF OR ventilation units (operating box). Especially in implant surgery operating boxes are today widely used for prevention of air-borne bacterial contamination to wound and sterile equipment. A complete ultra-clean LAF OR unit is expensive and needs a building that have room for the large ventilation unit, air ducts and filter ceiling or wall in the OR. This is often cumbersome to impossible in existing premises without extensive rebuilding. In this situation the mobile LAF screen can be seen as a valuable addition to operating room ventilation technique used as a complement to existing conventional OR ventilation. Especially in situations with insufficient ventilation and/or clothing facilities the screen might prove to be an easily applied tool to reduce the risk for surgical site infection. The next step is now further evaluation during real surgical activity.

References


