A mobile laminar airflow unit to reduce air bacterial contamination at surgical area in a conventionally ventilated operating theatre

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Operating theatre; Laminar airflow; Air contamination; Colony count; Particle count

Summary The aim of this study was to evaluate the efficacy of a mobile laminar airflow (LAF) unit in reducing bacterial contamination at the surgical area in an operating theatre supplied with turbulent air ventilation. Bacterial sedimentation was evaluated during 76 clean urological laparotomies; in 34 of these, a mobile LAF unit was added. During each operation, settle plates were placed at four points in the operating theatre (one at the patient area and three at the perimeter), a nitrocellulose membrane was placed on the instrument table and an additional membrane near the wound. During four operations, particle counting was performed to detect particles ≥0.5 μm. Mean bacterial sedimentation on the nitrocellulose membrane on the instrument table was 2730 cfu/m²/h under standard ventilation conditions, whereas it decreased significantly to a mean of 305 cfu/m²/h when the LAF unit was used, i.e. within the suggested limit for ultraclean operating theatres (P = 0.0001). The membrane near the wound showed a bacterial sedimentation of 4031 cfu/m²/h without the LAF unit and 1608 cfu/m²/h with the unit (P = 0.0001). Particle counts also showed a reduction when the LAF unit was used. No significant difference
was found at the four points in the operating theatre between samplings performed with, and without, the LAF unit. Use of a mobile LAF unit with turbulent air ventilation can reduce bacterial contamination at the surgical area in high-risk operations (e.g. prosthesis implant). © 2007 The Hospital Infection Society. Published by Elsevier Ltd. All rights reserved.

Introduction

Surgical site infection (SSI) is a major complication following surgery. Microbial contamination of the surgical site is a necessary precursor for infection. For most SSIs, the source of pathogens is the endogenous flora of the patient’s skin, mucous membranes, or hollow viscera. However, it is generally accepted that the main factor causing SSI after clean operations is bacterial contamination of the operating theatre air, predominantly caused by contaminated skin scales shed from the surgical team. The dose of contaminating micro-organisms required to produce infection is very low when foreign material is present at the site. As few as 10 colony-forming units (cfu) are estimated to be the safe bacterial content per cubic meter of air in an operating theatre where prosthetic replacement arthroplasties are performed. Appropriate staff theatre dress and good theatre discipline to minimise the spread from operators, associated with a controlled ventilation system, are means of reducing air microbial contamination. The installation of laminar airflow (LAF) is very costly and may be difficult in existing premises; hence, an interesting proposition is the addition of a mobile LAF unit which is independent and can be added to conventional operating theatre ventilation to decrease the microbial count at the surgical area. In Sweden, Friberg et al. tested the additional LAF unit both in sham operations and during groin hernia operations, and found a significant reduction in sedimenting bacteria, to the levels achieved with laminar airflow.

The aim of this study was to test the bacteriological efficiency of the mobile LAF unit in a conventional operating theatre where urological operations are performed.

Methods

Operating theatre

The study was performed in the operating theatre at the Urology Unit of the University Hospital of Parma. The theatre (154 m²) is supplied with a turbulent ventilation system with 15 air changes per hour.

LAF unit

The additional LAF unit (TOUL Meditech AB, Västerås, Sweden) used in the experiment has a 0.5 × 0.4 m screen with a central zone of airflow at 0.6 m/s and a peripheral zone with 0.4 m/s (manufacturer’s data), producing exponential airflow preventing entrainment of operating theatre air outside the LAF unit. The air supplied by the unit passed through a high-efficiency particulate air filter (HEPA), HP 14, with an efficiency of 99.995% (EN 1822). The LAF unit was positioned at the foot-end of the operating table with the airflow directed over the instrument table towards the surgical area.

Operations

The study was performed during 76 clean laparotomies, 42 performed in ordinary conditions and 34 performed while the LAF unit was functioning. The mean duration of operations was 172 min in the first case and 187 min in the second case (P = 0.4).

All patients received antibiotic prophylaxis half an hour before general anaesthesia and followed up for a one-month period to detect any surgical wound infections.

Operating team

The operating team ranged between six and eight in number (three or four surgeons, one scrub nurse, one circulating nurse, and one or two anaesthetists). The mean number of people in the operating theatre was 7.07 during operations performed in ordinary conditions and 7.38 during operations while the LAF unit was functioning (P = 0.2). Conventional cotton gowns were used for all operations.

Monitoring method

Aerobic bacterial sedimentation was evaluated by using settle plates and nitrocellulose membranes,
starting at the moment of the first surgical incision. During each operation, Petri dishes 90 mm in diameter containing plate count agar (PCA) were left exposed to the air according to the 1/1/1 standard (for 1 h, 1 m from the floor and about 1 m from any obstacles) to determine the index of microbial air contamination (IMA) at four points in the operating theatre (one at the patient area and three at the perimeter of the operating theatre) (Figure 1).\(^{10}\) The plates were incubated at 36 °C for 48 h; the number of cfu is the IMA. The results were expressed in cfu/m²/h, as suggested by Friberg et al.\(^ {11}\)

At the same time, a nitrocellulose membrane 47 mm in diameter (Type 114 06, Sartorius SpA, Florence, Italy) was positioned on the instrument table and, after 1 h of exposure, was transferred to a Petri dish containing PCA; in 47 operations (19 performed with and 28 without the LAF unit) an additional membrane was located near the wound (Figure 1). The plates were incubated at 36 °C for 48 h. The results were expressed in cfu/m²/h for an easier comparison with the results obtained by settle plates.

For the interpretation of the results, the value of 350 cfu/m²/h was considered an acceptable level for operating theatres with an ultraclean system and 3930 cfu/m²/h as a limit for those with a conventional system.\(^{10,11}\)

Particle count was performed during four operations (two with and two without the LAF unit) at 14 points of the operating theatre (four at the patient area, near the patient’s head, and 10 at the perimeter of the operating theatre, subdivided into three areas) (Figure 1). CLIMET CI 500 Asco-tec, positioned 70 cm from the floor, with an aspiration volume of 0.1 m³, successively normalized at 1 m³, was used. ISO values for ≥0.5 μm particles were considered for the interpretation of the results.\(^ {12}\) A particle sampling was performed at the operating table while the LAF unit was functioning, after the patient had been removed.

**Statistical analysis**

SPSS (Statistical Package for Social Sciences) was used for statistical evaluations. Analysis of variance was used to establish significant differences between variables. \(P\)-Values of \(\leq 0.05\) were regarded as significant.

**Results**

The mean bacterial sedimentation on nitrocellulose membrane at the instrument table was 2730 cfu/m²/h in standard ventilation conditions, whereas when the LAF unit was functioning it decreased significantly, reaching a mean value of 305 cfu/m²/h (\(P \leq 0.0001\)) (Table I), a reduction of 89%. The nitrocellulose membrane near the wound also showed significantly lower bacterial counts while the LAF unit was functioning: from 4031 cfu/m²/h in ordinary conditions it fell to

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![Figure 1](image.png)  
*Figure 1*  
Diagram of the operating theatre showing the position of the LAF Unit and the sampling points.
1608 cfu/m²/h with the LAF unit (P = 0.0001) (Table I), although the decrease was less (60%) than at the instrument table.

Table II shows the mean values of bacterial contamination detected by the settle plates positioned at the four points in the operating theatre. In ordinary conditions the mean values ranged from 2007 cfu/m²/h at perimeter 1 to 3276 cfu/m²/h at perimeter 3, with a mean value in the operating theatre of 2429 cfu/m²/h. While the LAF was functioning, air bacterial contamination ranged from 1911 cfu/m²/h at the patient area to 3433 cfu/m²/h at perimeter 3, with a mean value in the operating theatre of 2398 cfu/m²/h. No significant difference was found at any point investigated between samplings performed with and without the LAF unit.

No correlation was found between bacterial contamination on the settle plate at the patient area and on the membrane at the instrument table when the LAF unit was used (P = 0.637, $r^2 = 0.07$), whereas without the LAF unit a significant correlation was found (P = 0.006, $r^2 = 0.178$). The correlation between bacterial contamination on the settle plates at the patient area and on the membrane near the wound was not significant without LAF (P = 0.306, $r^2 = 0.04$), whereas it was significant (P = 0.02, $r^2 = 0.279$) with the LAF unit in place.

Table III shows the mean values of ≥0.5 µm particle count at the four points in the operating theatre. Without the LAF unit, the mean values ranged from 1727 268 particles/m³ at perimeter 2 to 2 425 577 particles/m³ at perimeter 3. While the LAF unit was functioning, particle contamination ranged from 1 141 600 particles/m³ at the patient head area to 1 707 681 particles/m³ at perimeter 1. A significant difference was found at the patient head area and perimeter 2 sampling points, with and without the LAF unit. The sampling performed at the operating table after the removal of the patient registered 233 034 particles/m³. No surgical site infections were observed during the follow-up period in any patient.

**Discussion**

Since Lidwell et al. demonstrated a correlation between airborne bacteria contamination levels and the incidence of postoperative wound infections, the use of ultraclean operating theatres with LAF ventilation has been recommended in orthopaedic implant surgery, to reduce postoperative SSI.1–3,7,13 The need for low levels of airborne contamination should always be taken into account, particularly when foreign material is used for prosthetic and other surgical procedures.13

According to the UK National Health Service (NHS), ultraclean operating theatres sampled close to the wound site during operations should contain <10 cfu/m³ of air when using conventional cotton clothes.14 Considering the EC GMP correlation, based on Whyte’s findings, this value corresponds to 5 cfu/plate/h (786 cfu/m²/4 h) on settle plates of 90 mm in diameter left exposed for 4 h, which means 1.25 cfu/plate/h (196 cfu/m²/h) (Table IV).15,16 Recently, similar values using settle plates, although slightly higher, have been proposed in addition to the current British bacteriological standard. Friberg et al. suggested a value of 350 cfu/m²/h and Pasquarella et al. a maximum value of 5 cfu on settle plates 90 mm in diameter (standard IMA), which corresponds to 786 cfu/m²/h.10,11

In our study, we chose passive sampling instead of active sampling, since this method appears to be a clinically relevant indicator of bacterial contamination, to estimate airborne bacteria sedimenting onto the surgical wound.10,11,13–19 We used settle plates at the four points of the operating theatre and nitrocellulose membranes at the instrument table and near the wound. The settle plates in the theatre were used for giving an indication of the bacterial contamination levels in the operating theatre in ordinary conditions and

<table>
<thead>
<tr>
<th>Table I</th>
<th>Bacterial sedimentation values (cfu/m²/h) on nitrocellulose membranes at the instrument table and near the surgical wound with and without mobile laminar air flow (LAF) unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling points</td>
<td>Without LAF unit</td>
</tr>
<tr>
<td>Instrument table</td>
<td>2730 (1778)</td>
</tr>
<tr>
<td>Near the wound</td>
<td>4031 (2509)</td>
</tr>
</tbody>
</table>

Values are mean (SD).

<table>
<thead>
<tr>
<th>Table II</th>
<th>Bacterial sedimentation values (cfu/m²/h) on settle plates at the four points in the operating theatre with and without mobile laminar air flow (LAF) unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling points</td>
<td>Without LAF unit</td>
</tr>
<tr>
<td>Patient head</td>
<td>2347 (1114)</td>
</tr>
<tr>
<td>Perimeter 1</td>
<td>2007 (994)</td>
</tr>
<tr>
<td>Perimeter 2</td>
<td>2084 (963)</td>
</tr>
<tr>
<td>Perimeter 3</td>
<td>3276 (2187)</td>
</tr>
</tbody>
</table>

NS, not significant.

Values are mean (SD).
for pointing out the reduction between LAF and non-LAF areas. The nitrocellulose membranes could be used to measure the bacterial contamination directly at the critical points (instrument table and surgical wound); in fact, they had the advantage of being sterile and light enough to be located on the drapes near the wound. In addition, particle count was carried out for comparison with ISO standard and as an additional means to evaluate the effect of the mobile LAF unit.

The results of bacterial contamination positioned at the instrument table and near the wound suggested that the LAF unit was able to reduce bacterial contamination at the surgical area; the low number of cfu achieved at the instrument table during the operations performed while the LAF unit was functioning was similar to that expected in the patient area in an ultraclean operating theatre. The contamination at the instrument table while the LAF unit was being used (305 cfu/m²/h) was similar to that obtained by Friberg et al. on the chest of the patient (355 cfu/m²/h), even though in the absence of an LAF unit they registered a value (775 cfu/m²/h) lower than ours (2730 cfu/m²/h). While the LAF unit was functioning, the mean cfu value at the wound area was greater than at the instrument table; however, the reduction in cfu value was statistically significant. This could be explained by considering that the membrane was positioned downstream of the wound area; the bacteria spread by the operating team probably accumulated on the membrane; also, the membrane was sometimes at a lower level than the wound level. Moreover, it may be that the airflow was not perfectly directed towards the wound; in fact, the new LAF unit model has a sensor to direct the airflow correctly.

The theatre in which the experiment took place is conventionally ventilated, and air bacterial contamination values obtained at the four points in the operating theatre are consistent with this kind of ventilation system. According to the NHS, in conventional operating theatres during surgical operations the number of airborne bacterial cfu should not exceed 180 per cubic metre. Referring to the EC GMP correlation between active and passive sampling, the 180 cfu/m³ value given by the NHS, which is about 200 cfu/m³, may be considered as corresponding to 25 cfu (3930 cfu/m²/h) on settle plates 90 mm in diameter (Table IV). The highest values were obtained at perimeter 3, where anaesthetists usually stay; the latter were one or two in number and often spoke and moved about. At this point, the cfu values were still below 3930 cfu/m²/h, it would seem that

<table>
<thead>
<tr>
<th>Sampling points</th>
<th>Without LAF unit</th>
<th>With LAF unit</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient head</td>
<td>1813 535 (669 116)</td>
<td>1 141 600 (449 460)</td>
<td>0.015</td>
</tr>
<tr>
<td>Perimeter 1</td>
<td>2 074 199 (567 029)</td>
<td>1 707 681 (649 625)</td>
<td>NS</td>
</tr>
<tr>
<td>Perimeter 2</td>
<td>1 727 268 (546 823)</td>
<td>1 500 198 (797 740)</td>
<td>0.003</td>
</tr>
<tr>
<td>Perimeter 3</td>
<td>2 425 577 (1 203 325)</td>
<td>1 592 732 (462 227)</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS, not significant.
Values are mean (SD).

<table>
<thead>
<tr>
<th>ISO classes</th>
<th>EC GMP</th>
<th>Microbial contamination</th>
<th>IMA</th>
<th>NHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade</td>
<td>Particle count</td>
<td>≥0.5 μm</td>
<td>CFU/m³</td>
<td>Settle plates a</td>
</tr>
<tr>
<td>5</td>
<td>A</td>
<td>3500</td>
<td>&lt;1</td>
<td>&lt;1 (&lt;157)</td>
</tr>
<tr>
<td>7</td>
<td>B</td>
<td>350 000</td>
<td>10</td>
<td>5 (786)</td>
</tr>
<tr>
<td>8</td>
<td>C</td>
<td>3 500 000</td>
<td>100</td>
<td>50 (7860)</td>
</tr>
<tr>
<td>—</td>
<td>D</td>
<td>ND</td>
<td>200</td>
<td>100 (15 719)</td>
</tr>
</tbody>
</table>

ND, not defined.
Values in parentheses represent cfu/m²/h.

a Colony-forming units (cfu) on settle plates 90 mm diameter after 4 h of exposure.
b Colony-forming units on settle plates 90 mm in diameter after 1 h of exposure, calculated as a quarter of the cfu value indicated by EC GMP after 4 h of exposure.
c Colony-forming units on settle plates 90 mm in diameter after 1 h of exposure.
the threshold values of 3930 cfu/m²/h and 180 cfu/m³/h are too high; at the other points in the operating theatre, the mean values were below 2358 cfu/m²/h. Particle count at all the points in the operating theatre was within ISO Class 8 (3 500 000).12

The fact that no significant difference in air bacterial contamination was found at any point investigated in the operating theatre, either under normal conditions or while the LAF unit was functioning, and no correlation between bacterial contamination on the settle plate at the patient area and on the membrane on the instrument table, means that the action of the LAF unit is limited to the surgical area and does not influence other sites of the operating theatre. Friberg et al. found no significant correlation between contamination on the chest of the patient and in the periphery when the LAF unit was being used.9 Particle count measured at the patient head area while the LAF unit was functioning was lower than at all the other sampling points in the operating theatre. The significant difference found for ≥0.5 μm particles at the patient area and perimeter 2 could be explained by the influence of the LAF at these areas.

As regards the infection rate, no conclusion can be drawn as to the efficacy of the LAF unit in reducing wound infections. A higher number of patients should be followed up to evaluate this point. However, bearing in mind the study by Whyte et al., which estimated that about 98% of the bacteria in the joint replacement wounds of patients operated on in a conventionally ventilated operating theatre derived from the air, we can suppose that a lower number of bacteria sedimented in the wound while the LAF unit was functioning and a lower number of wound infections should be expected in operations at risk of airborne infections.3

The results of our study confirm the efficacy of the LAF unit in reducing bacterial and particle contamination. However, the decision to apply the LAF unit should depend on a series of considerations: 'Is the operation at risk of airborne infection? Should the operation be performed with low air microbial contamination?' If the answer is yes, the next question is: 'Is the air microbial contamination at the surgical area under the limit proposed for surgery at high risk of airborne infections?' The easiest way to verify this point is a bacteriological sampling by using the active or passive method. Bacterial contamination levels <10 cfu/m³ with active sampling or <786 cfu/m²/h (ideal value 350 cfu/m²/h) with passive sampling should be considered as acceptable values.10,11,14

If the results of microbiological controls are not satisfactory for operations with a high risk of airborne infection, and the ventilation system present is not able to lower microbial contamination, the LAF unit can be a suitable remedy.

In conclusion, we can suggest the use of the LAF unit when procedures with a high risk of airborne infection (e.g. prosthesis implant) have to be carried out in circumstances where ultraclean air facilities are not available. Further, a mobile LAF unit might also be useful in any field of activity where there is a risk from air bacterial contamination e.g. field surgery, food or pharmaceutical industries.

Conflict of interest

None.

Funding

No external funding. Institutional activity.

References

11. Friberg B, Friberg S, Burman LG. Inconsistent correlation between aerobic bacterial surface and air counts in operating rooms with ultraclean laminar air flows: proposal of