The effect of mechanical ventilation and clothing on airborne microbes and wound sepsis in hospital operating rooms, Part 2

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Editorial Note: *For 50 years, Bill Whyte has been investigating the role of mechanical ventilation in minimising airborne microbial contamination. The first 25 years were used to investigate hospital operating rooms, and the second 25 years were concerned with industrial cleanrooms. His work on operating rooms occurred at an important time in the evolution of unidirectional airflow systems, and when their effect on wound sepsis was investigated. It is common to find that the experience and judgement of scientists who have worked extensively in a particular field of science is lost, and so we have persuaded Bill to write a personal account of this time. His reminiscences are divided into two parts, this being the second.*

Abstract

This article is the second part of a review into the importance of airborne microbe-carrying particles (MCPs) as a cause of wound sepsis after surgery. The roles of mechanical ventilation and occlusive surgical clothing in reducing airborne microbe-carrying particles (MCPs) and surgical site infections (SSIs) are discussed in this part.

Introduction

This review is largely based on a commentary written prior to submitting a DSc thesis, and covers the research I carried out during the 25 years prior to about 1990 in the context of other research. It is divided into two parts. The first part was published in the previous edition of this journal and this is the second part. The author's publications are referenced as follows: (Reference 1 etc.), and a superscript number is used for the work of others.

Early research on the effect of clean air on wound sepsis

In the 1860s, Joseph Lister discovered that bacteria were the cause of wound sepsis, and he used antiseptics to kill bacteria and stop them entering the wound. Other surgeons introduced autoclaves, surgical gloves, and other methods of preventing bacteria entering the wound. Little attention was given to mechanical ventilation of operating rooms and, when used, it was mainly for the comfort of the staff. It was not until the 1950s that the roles of airborne infection, clean air, mechanical ventilation and clothing in operating theatres were investigated.

In the 1950s, investigations were made of wound infection rates after the upgrade of poorly-ventilation operating theatres. Blowers et al[1] in 1955, made various improvements to reduce SSIs, and concluded that the reduction he achieved was caused by improvements in the mechanical ventilation of his operating theatre. Shooter et al (1956)[2] showed that improvements to the mechanical ventilation of an operating theatre gave reductions in the concentration of MCPs and the occurrence of SSIs. Lowbury (1954)[3] showed in a burns dressing room that 20 air changes per hour of filtered air significantly reduced infection.

The effectiveness of clean air during surgery was investigated in the 1960s by a multi-centre trial that studied UV radiation in operating rooms[4]. UV radiation was used in half of the 15,500 operations studied, and reduced the airborne bacteria by half. Operations were divided into categories that reflected the likelihood of bacteria being introduced into the wound during surgery, this likelihood being largely dependent on whether organs that contained bacteria were entered. Thus, there were clean, clean-contaminated, contaminated and dirty categories of wounds. The clean operations were the least likely to be contaminated by bacteria, and were further divided in to 'clean' and 'clean refined', where 'clean-refined' were elective operations that were primarily closed and undrained. A statistically-significant reduction in sepsis from 3.8% to 2.9% in the cleaner air was obtained in clean-refined operations, but in no other category of operation. These clean-refined operations accounted for about half the total number of operations.

During the 1960s, MCPs were shown to be transferred to the wound by the airborne route from personnel in the operating room. Epidemics of wound sepsis, caused by unusual strains of *Staphylococcus aureus*, were shown to have come from people in the operating room who never came into contact with the open wound but worked away from the wound site[5, 6].

Burke (1963)[7] typed *Staphylococcus aureus* bacteria isolated from surgical wounds before closure, and showed that air was the largest contributor of *Staphylococcus aureus*. Bengtsson, Hambraeus and Laurell (1979)[8] studied almost 3000 operations in a conventionally-ventilated operating suite. Typing was carried out on *Staphylococcus aureus* isolated during operations from operating staff, patients, and air. There was 76 *Staphylococcus aureus* infections and 22 (29%) of them were traceable to the air in the operating room and the respiratory passages of the operating room staff.

By the early 1970s, it was generally accepted in the UK that airborne MCPs caused SSIs, and the Joint Working Party set up by the Medical Research Council and the Department of Health and Social Security (Reference 1), of which I was a member, reported their opinion that when the airborne bacterial concentration reached 700-1800/m^3 there was a significant risk of airborne infection, but when it was 35-180/m^3 the risk was slight. Total joint replacement operations were excluded from this conclusion. The Joint Working Party laid down the design principles for ventilating an operating theatre that included a supply of about 20 air changes per hour

of filtered air to dilute airborne MCPs and positively-pressurise it against entry of contaminated air from adjacent areas.

By the end of the 1970s, unidirectional airflow (UDAF) systems in operating rooms and occlusive operating room garments were available that gave further decreases in the concentrations of airborne bacteria that approached 1/m^3. This gave an opportunity to compare UDAF systems with older designs of mechanical ventilated operating rooms, and further elucidate the role of airborne bacteria and mechanical ventilation in reducing wound sepsis.

Effect of ultra-clean operating rooms on wound sepsis in orthopaedic implant operations

In 1958, Professor Sir John Charnley introduced a new operation to replace diseased hip joints with artificial joints. However, his operating room did not receive a supply of filtered air but drew air from the external corridor, and gave a very high airborne MCP concentration, and an unacceptably high wound sepsis rate in the region of 7 to 9%. In 1961 he embarked on an investigation to reduce wound sepsis that was mainly based on improvements to the mechanical ventilation of his operating theatre. Charnley also invented a total-body exhaust gown that substantially reduced airborne dispersion from the surgical team and therefore the airborne concentration of MCPs. Reductions in the airborne contamination occurred in steps, and these were associated with drops in wound sepsis. When all improvements were complete in the early 1970s, and the airborne microbial concentration was less than 1/m^3, the wound sepsis rate had fallen to less than 1%[9, 10, 11]. It is interesting to note at this point that the description and analysis of Charnley's work by Dr Lidwell[11] also showed that Charnley's results gave a similar relationship of airborne MCPs to sepsis rate that was found during the MRC trial of ultra-clean air systems. However, Charnley had introduced some improvements other than to the ventilation system, and there was scepticism that airborne infection played such a major part in wound sepsis[12].

Charnley did not use prophylactic antibiotics to protect the patient against bacteria deposited into the wound during surgery, as he was of the opinion that they 'can aggravate the postoperative infection rate'. This opinion was common at that time and backed by published research. For example, the multicentre study on UV radiation, referred to above[4], also studied the use of prophylactic antibiotics, and showed that the overall wound sepsis rate was 14.3% when prophylactic antibiotics were used, and 4.4% when they were not. This difference was found in all five hospitals in the trial, and in all categories of wound types. However, Fitzgerald et al[13], reported that during total joint replacement surgery the use of prophylactic antibiotics gave similar low sepsis rates to that reported by Charnley.

The Medical Research Council (MRC) of the UK, in consultation with the Department of Health and Social Security, agreed to run a clinical research trial to prove, or otherwise, the efficacy of ultra-clean air systems. A Steering Committee that consisted of Dr O.M. Lidwell (Chairman), Professor E.J. Lowbury, Dr R. Blowers, and I, ran the trial, with the assistance of statisticians from the MRC Statistical Unit (Stanley and Low).

Studies prior to the start of the MRC trial

Prior to the start of the MRC trial, I studied methods that could be used during the trial to help determine wound sepsis, and how to sample microbes in the wound, and air close to the wound.

The manifestation of sepsis in total joint replacement surgery was unusual. Normal wound sepsis usually occurs shortly after surgery and normally responds well to antibiotics. However, sepsis after artificial joint replacement was often located in the depth of the wound and occurred weeks, months, or even years, after operation. These infections often did not respond well to antibiotic treatment and the artificial joint had to be replaced. This type of sepsis is known as 'deep' wound sepsis. Also, it was common at that time to find failed hip operations with clinical symptoms identical to sepsis, and where no pathogenic bacteria could be isolated. Charnley called them 'sterile infections'. This caused a difficulty for the MRC committee on how to identify joint sepsis. A discussion with Mr J Graham, an orthopaedic surgeon at Gartnavel General Hospital, shed light on this problem.

Mr Graham had a patient who had undergone several unsuccessful operations, and coagulase-negative staphylococci were always isolated from the wounds. At that time, it was not accepted by hospital microbiologists that skin microorganisms, such as coagulase-negative staphylococci, *Propionibacterium acnes*, and other species, were pathogenic and could cause deep joint sepsis. Also, some of these organisms were not found within the routine incubation time used in many hospital laboratories. By means of multiple sampling, maceration of wound tissue, and longer incubation times, it was shown that low-grade pathogens could grow in the joint (Reference 2). 166 surgical procedures carried out for unsatisfactory hip or knee implants were sampled, and 51 gave growth. Nine yielded organisms regarded as pathogens, and the remaining 42 yielded organisms of low pathogenicity, including 23 *Staphylococcus epidermidis*, 12 anaerobic diphtheroids and 7 Gram-positive anaerobic cocci (*Propionibacterium* spp. and *Peptostreptococcus* spp.). A knowledge that deep wound sepsis could be caused by these low-grade pathogens ensured that the septic wounds in the MRC trial received a more thorough bacteriological examination, and there was a clearer understanding of what constituted wound sepsis.

An investigation was also carried out to determine the most appropriate microbiological methods for air and wound sampling (Reference 3). In a UDAF system, the unidirectional airflow meant that airborne MCPs sampled away from the wound could not be considered to represent the concentration at the wound, and a method was devised to sample about 20-30 cm from the wound. A wound-wash technique was also developed to determine the number of microbes in the wound after surgery. These methods were used in the MRC trial.

During the investigation of air and wound sampling methods (Reference 3), microbial counts from the air and wounds were measured during a series of total hip operations at Gartnavel General Hospital in a conventionally-ventilated operating room and a UDAF system. The airborne microbial count in the conventionally-ventilated room averaged 413/m^3, and in the UDAF system it was 4/m^3 (a 97-fold reduction). The average number of microbes washed from the wound at the end of surgery was 105

and 3, respectively, which was a 35-fold reduction. A simple mathematical model determined that 98 per cent of microbes in the patients' wounds in the conventionally-ventilated operating room originated from the air. This method of determining the percentage of airborne MCPs was subsequently used in the MRC trial.

During the investigation of air and wound sampling in both the conventionally-ventilated operating theatre and the UDAF system, an investigation was made of routes of airborne deposition of MCPs into the wound. It was found that about 30% deposited directly from air, and the remainder appeared to deposit first onto patient drapes, gloves, instruments etc. before being transferred into the wound. We had not expected so low a percentage to deposit directly into the wound, but when the large combined area of patient drapes, gloves and surgical instruments is considered, along with the high frequency these areas and the wound are touched, and the high percentage of microbes that can be transferred from one surface to another[14], the results are not so surprising. One conclusion in the case of UDAF systems is that the unidirectional airflow clean zone should be sufficiently large to contain instrument trolleys in order to prevent airborne contamination of surgical instruments.

Table 1: Airborne MCPs concentrations (/m³)

	Clothing type	
Ventilation system	**Conventional design**	**Body exhaust suit**
Conventional	164	51
Allander	49	14
Horizontal UDAF	22	1
Downflow UDAF, without walls	10	-
Downflow UDAF, with walls	2	0.4
Isolator	0.5	-

Table 2: Percentage of deep joint sepsis during different operating conditions

Operating room conditions	No prophylactic antibiotics	Prophylactic antibiotics
Control with conventional clothing	3.4%	0.85%
Ultra clean air with conventional clothing	1.7%	0.70%*
Ultra clean air with body-exhaust suit, plus isolators	0.76%	0.19%

* This percentage was originally published as 0.42% but the correct percentage is 0.70%.

The MRC ultra-clean air operating room trial

For a research study to have a reasonable chance (90%) of showing a difference between a 2% sepsis rate in a control condition, and 1% in a test condition, about 2500 operations are required in each group. In the MRC ultra-clean air operating room trial there was one control condition and two test conditions (ultra-clean air, and ultra-clean with occlusive clothing), i.e. three groups, and around 7500 operations were required. To obtain results in a reasonable time interval, a multicentre trial was required, and 19 hospitals in the UK and Sweden participated, with 8136 patients involved.

The MRC trial was a prospective and randomised study that compared modern conventionally-ventilated operating rooms with ultra-clean operating rooms, which included UDAF systems, Allander systems[15], and isolators[16]. Occlusive clothing systems, which reduced microbial dispersion from the operating team, were also included. Shown in Table 1 are the average airborne concentrations of MCPs found close to the wound.

Clinical and bacteriological records were gathered for five years, and the average time from surgical operation to the last assessment was almost 2.5 years. A series of papers (References 4 to 11) were written. It was shown that deep joint sepsis after knee and hip joint replacement could be approximately halved by use of ultra-clean air systems, and quartered by ultra-clean air systems used with total-body exhaust gowns. The results that are shown in Table 2 are those published in Reference 5. It should be noted that although sepsis rates varied between hospitals, and some reported low or zero sepsis rates, all the hospitals fitted into a consistent pattern of wound sepsis being reduced by lower airborne MCP concentrations (Reference 7).

Antibiotics were given prophylactically to about two-thirds of the patients to ensure that there were high concentrations of antibiotics in the blood stream around the time of surgery. It can be seen in Table 2 that they gave a substantial reduction in wound sepsis, and it is reasonable to assume that prophylactic antibiotics killed many of the MCPs deposited into the wound from the air. However, the MRC trial showed that prophylactic antibiotics combined with ultra-clean air systems gave an even lower rate of sepsis. Table 2 shows that the use of prophylactic antibiotics in the control ventilation systems gave a deep sepsis rate of 0.85%, but the use of ultra-clean systems reduced it to 0.42%, and the additional use of occlusive clothing reduced it further to 0.19%.

A more comprehensive analysis of the effect of ultra clean air, prophylactic antibiotics, and other factors, on wound sepsis, including a multiple regression analysis of all the results, is published in Reference 9.

The microbial counts in the wound and air were compared between the ultra-clean and control group of operating rooms, using the methods discussed in Reference 3. The percentage of airborne microbes found in the wounds of operations carried out in the conventionally-ventilated group was 95% (Reference 7), and the highest wound washout counts were associated with increased levels of wound sepsis (Reference 9).

The relationship of the deep joint sepsis rate to airborne contamination was published as a graph in Reference 7 and is reproduced in Figure 1. Figure 1, and other published information, showed that when the airborne microbial concentration at the wound was 1/m³, or less, the joint sepsis rate was close to a minimum. However, because of the limitations of some UDAF systems,

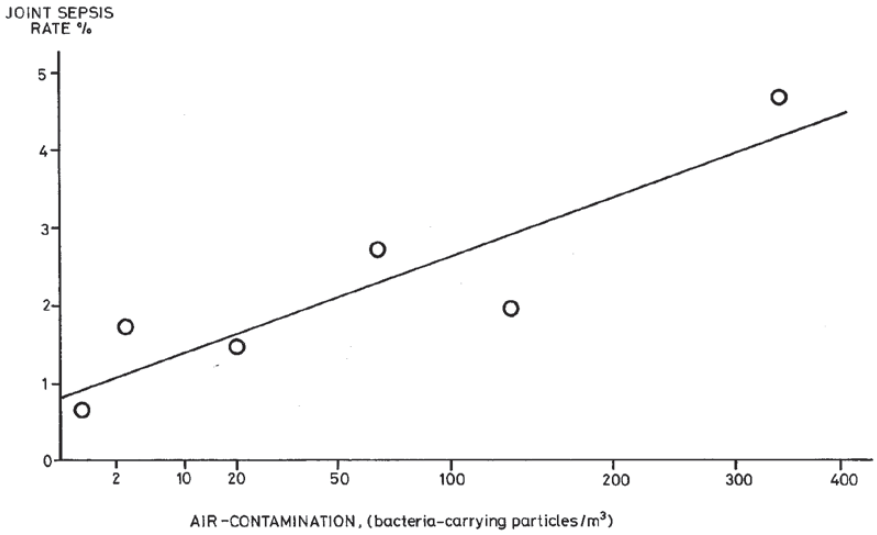


Figure 1: Relationship between late joint sepsis and airborne bacteria in the operating room.

and lack of acceptability of some occlusive clothing, achieving airborne concentrations of 1/m^3 could be difficult. When the airborne concentration is 10/m^3, a reduction of around 50 per cent in the sepsis rate is expected over that found in a conventionally-ventilated operating room, and 10/m^3 was suggested as a maximum concentration in ultra-clean air systems (Reference 8). However, it was always intended that 1/m^3 was the most desirable concentration to be achieved but, unfortunately, the concentration of 10/m^3 is most often quoted in the literature. Also included in Reference 8 were suggestions for maximum airborne concentrations in areas other than the wound, as well as methods of testing air filters, measuring air velocities, and checking the entrainment of contamination from outside to inside the ultra-clean area. These suggestions were included in a set of guidelines completed in 1986 by a committee, of which I was a member, set up by the UK Department of Health. These guidelines were not formally published, but incorporated into Hospital Technical Memorandum 2025[17], and then into the current Health Technical Memorandum 03/01[18]. Information on testing operating theatres is also given in a report from the Hospital Infection Society[19].

The follow-up of patients in the main MRC study was just short of 2.5 years. A select group of patients were followed up for 10 years, with a median of about 7 years. The results (Reference 10) suggested that only about half of the sepsis had been found during the main follow-up period of about 2.5 years.

A short article was written by Dr Lidwell to show the cost effectiveness of ultra-clean air systems compared to the costs of additional medical treatment[20]. He showed that the use of prophylactic antibiotics was by far the most cost-effective measure, but that the further reduction in the sepsis rate obtained by ultra-clean air, in addition to antibiotics, was also cost effective.

The multi-centre trial of ultra clean air systems showed the importance of occlusive operating room clothing in reducing the airborne concentration of MCPs and the occurrence of SSIs. I had been researching this topic before the start of the trial but the results of the trial encouraged me to complete it.

Surgical clothing and airborne bacterial dispersion

Microbe-carrying particles and operating theatre clothing

Microbes in hospital air are mainly found on skin cells dispersed from people[21]. Skin cells are approximately 33 µm x 44 µm in area and 3 to 5µm thick, and found in room air as whole cells or fragments[22]. Micro-organisms found in air are carried on skin particles and are therefore called microbe-carrying particles (MCPs). They will vary in size and shape, but have an equivalent particle diameter of about 12-14 µm[23] and easily deposit by gravity into surgical wounds.

The size of the interstices between the threads of fabric woven from cotton, or poly-cotton, of the type often used in operating room, is often between 80 – 100 µm, and MCPs have little difficulty in passing through the fabric. These open-weave fabrics are therefore not effective in reducing microbial dispersion in operating rooms, and a tightly-woven fabric (Ventile® cotton) was shown by Blowers and McCluskey in 1965 to be much more effective[24]. However, tightly-woven fabrics such as Ventile® cause a reduction in air and moisture exchange, and can be uncomfortable. Charnley improved the comfort of Ventile® clothing by designing a gown that used a helmet and exhaust system, this being shown in Figure 2 in the first article. However, there was little information on the effectiveness of these gowns in reducing airborne dispersion. Also, Charnley's gowns were not popular with many surgeons, and there was a need for clothing that was similar in style and comfort to conventional clothing made from open-weave fabrics, but bacteriologically effective.

Dispersion of airborne MCPs in a dispersion chamber

To investigate the effectiveness of operating room clothing, it is necessary to measure the dispersion rate of airborne MCPs from people as they exercise in a chamber. Early chambers[24, 25] were unventilated, and it was not possible to calculate a dispersion rate. A dispersion chamber (Figure 2) was therefore designed in 1976 (Reference 12) with a known supply volume of sterile air, so that the dispersion rate could be calculated from knowledge of the concentration of MCPs in the chamber air. The air flow was unidirectional, and by sampling with the upper bacterial sampler, the dispersion in a vertical UDAF was simulated, and by sampling with both the upper and lower samplers, the conventionally-ventilated operating room was simulated.

The dispersion chamber was used to investigate a variety of clothing designs and fabrics (References 12, 13, 14, and 15) and the following general information obtained:

1. Clothing should be considered as a body filter that removes airborne contamination dispersed by a person but, unless artificially ventilated, there should be sufficient air and moisture exchange across the fabric for it to be comfortable.

2. If open-weave cotton shirts and trousers of the conventional style used in an operating room are worn, a person will disperse MCPs in the range between 1 and 3500/s.

3. Dispersion rates vary over time from the same person, and between people.
4. Wearing a typical design of surgical gown made from open-weave cotton will reduce the dispersion rate by only 30%.
5. About 60-70% of the MCPs are dispersed from the skin below the waist.
6. Surgical gowns made from occlusive fabrics, such as disposable non-woven fabrics, are more effective than open-weave cotton fabrics. However, contamination still passes out from under the gown, although in unidirectional airflow this effect is not as important because of the downward airflow. Trousers made from occlusive fabrics are required to overcome this problem.
7. Charnley's total-body exhaust gown gave a 98.8% reduction in dispersion in the simulated unidirectional airflow position. When a conventionally-ventilated operating room was simulated there was an 87% reduction, this poorer result presumably being caused by dispersion from below the gown.
8. Occlusive clothing made from tightly-woven polyester fabrics used in industrial cleanrooms substantially reduced dispersion.
9. A hood designed to tuck under the neck of the gown reduced dispersion by preventing unfiltered contamination being expelled out of the neck area.

The dispersion chamber results were verified by microbial sampling in operating rooms. These results gave a similar reduction to the dispersal chamber, although the chamber results were often better.

Effect of occlusive clothing in conventionally-ventilated operating rooms

The reduction of MCPs in conventionally-ventilated operating rooms, when disposable or tightly-woven polyester clothing was worn as an alternative to open-weave cotton surgical clothing, is reported in References 14 and 15. As previously discussed, if the surgical team wears occlusive gowns, airborne contamination will be expelled from below the gowns. Also, if the rest of the staff does not wear occlusive clothing they will disperse the same amount of contamination as before, and there is little overall reduction in the concentration of airborne MCPs. Shirts and trousers of occlusive fabrics should therefore be worn by all occupants in the operating room, and surgical gowns additionally worn by the surgical team. When this was done with disposable non-woven fabric (Reference 14), the airborne bacterial counts during orthopaedic operations in a conventionally-ventilated operating room was reduced from 569 to 227/m^3 (66% reduction), and during vascular surgery from 240 to 137/m^3 (43% reduction). When the same type of experiment was carried out with polyester fabric used to manufacture industrial cleanroom clothing (Reference 15) the airborne MCP concentration dropped from 176/m^3 to 42/m^3 (a 76 % reduction).

The airborne concentrations of MCPs when wearing occlusive clothing in

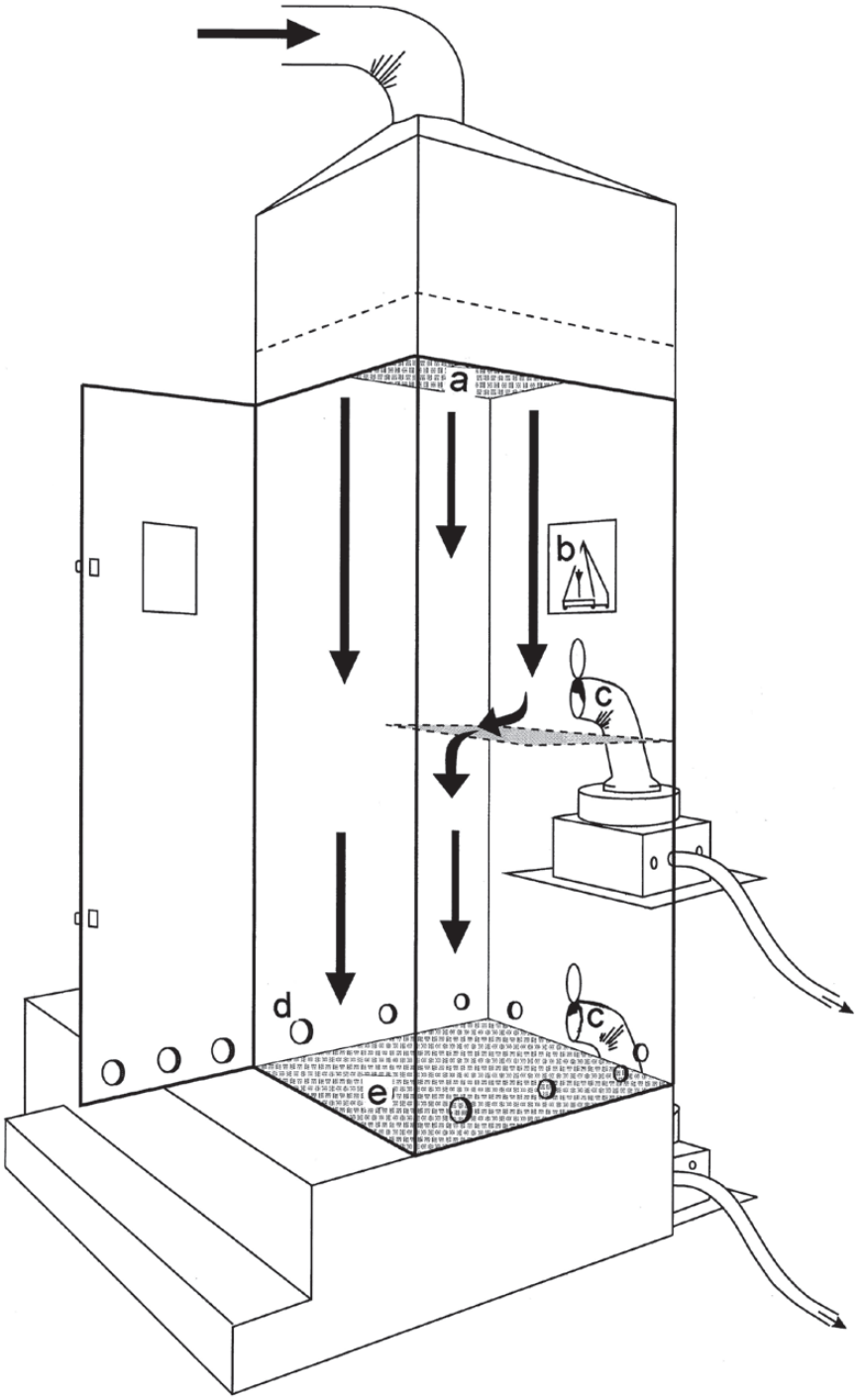
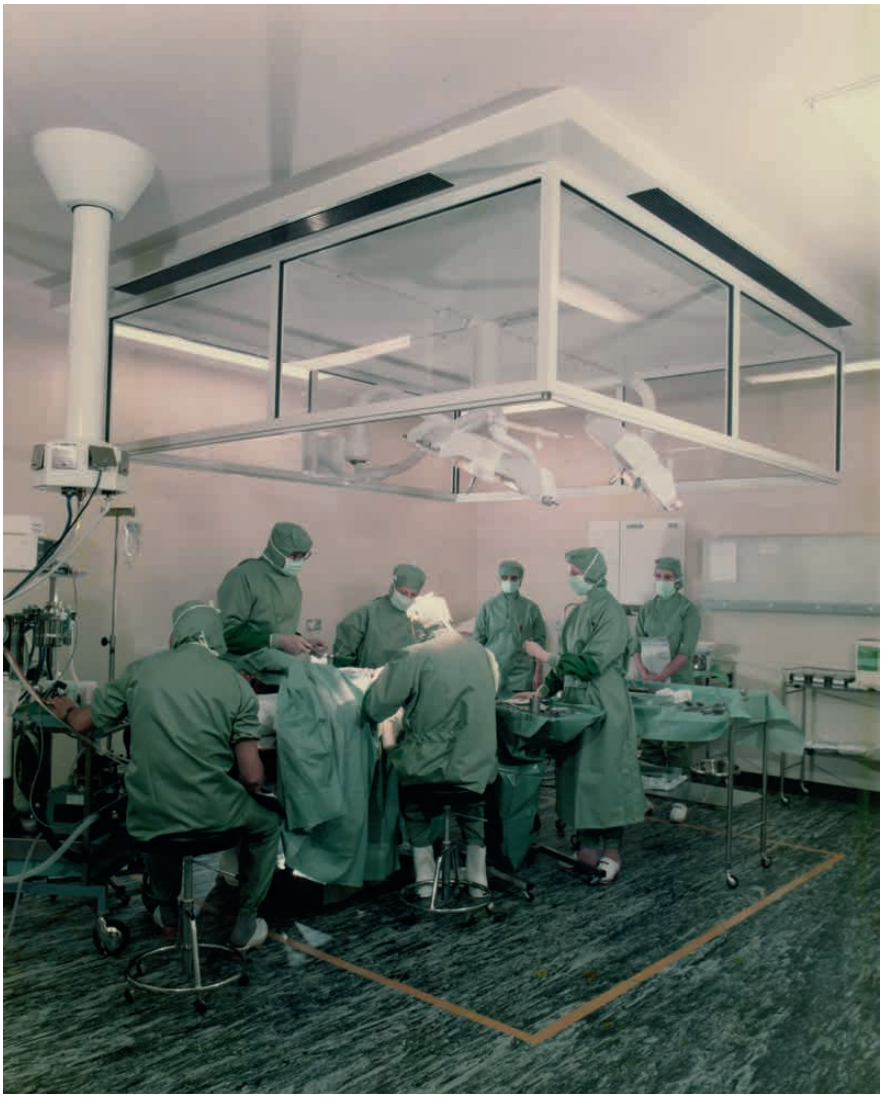


Figure 2: Dispersal chamber: a) HEPA filter, b) metronome, c) bacterial samplers, d) exhaust ports, e) control mat



UDAF ultra-clean air system with clothing made from cleanroom fabric

Table 3: Effect of clothing on the airborne MCPs count at the wound in operating rooms

Room type	Clothing type	MCP count (/m³)
Conventionally ventilated	Conventional open-weave cotton	400 - 500
Crossflow UDAF	Disposable fabric	3 and 10
	Polyester fabric	8
	Total body exhaust gowns	2.2
Downflow UDAF	Open-weave cotton	8 and 16
	Open-weave cotton shirt and trousers + disposable gown	2.5
	Disposable fabric	0.7 and 1.5
	Polyester fabric	0.7
	Total body exhaust gowns	0.6, 0.7 and 0.7

Table 4: Wound sepsis (%) in operating rooms during the MRC trial

Grade of superficial sepsis	Type of ventilation	
	Conventional	Ultraclean
major	1.1	0.5
minor	4.1	3.5

conventionally-ventilated operating rooms were large in comparison to the airborne concentrations that could be achieved in UDAF systems.

Effectiveness of occlusive surgical clothing in UDAF systems

The results of clothing experiments carried out in a UDAF system at Gartnavel General Hospital, Glasgow are reported in References 12 to 16, and summarised in Table 3. Also included are results from an adjacent conventionally ventilated operating room. The results are averages of airborne MCPs measured in the area of the wound during a number of total joint replacement operations and, although assembled over several years, the observations were of the same surgeons and senior nursing staff.

Except for the total-body exhaust gowns, almost all of the clothing worn within the UDAF system was a conventional-style with trousers, shirt-top, and surgical gown made from the same fabric. The exception was a set of observations in the downflow UDAF, where a disposable gown was worn over conventional-style, open-weave, cotton trouser and shirt-top.

Additional observations were made in a UDAF system at the West Cumberland Hospital. When all the surgical clothing was made from polyester cleanroom fabric, an average count of 0.48/m³ was obtained at the wound, and when total-body exhaust gowns were worn, the average count was 0.43/m³.

Two reviews of the bacteriological effectiveness of operating room clothing, as well as masks, gloves and drapes are given in References 17 and 18.

Reduction in wound contamination and sepsis in operations other than total joint replacement

Deep joint sepsis was the most important type of wound sepsis that occurred after total joint replacement surgery, and the MRC trial concentrated on this type. However, SSIs that occurred shortly after surgery in the superficial layers of the wound and therefore similar to other types of operations were also studied. It was established (Reference 11) that major superficial sepsis after total joint replacements was significantly reduced by ultra-clean air systems (Table 4), and although minor sepsis was lower, the difference was not statistically significant.

These results suggested that ultra-clean air systems may reduce wound sepsis in other branches of surgery.

The MRC study showed that the incidence of sepsis was related to the number of bacteria washed from the wound (Reference 7). Wound washouts could therefore be used as an indicator of the effect of sources of bacteria, including air, on wound sepsis. A study was therefore carried out using gall bladder operations (Reference 19 and 20), which were a clean/contaminated category of operation, i.e. clean when the bile was sterile and contaminated when the bile was infected. An efficient wound sampling method, previously devised by Benediksdottir and Hambraeus[26], was used. A method for sampling the patient's skin was developed (Reference 21) along with a method to calculate the efficiency of sampling methods (Reference 22).

The experiment was organised to find the effect of various sources of microbial contamination and their control measures. Cotton or impervious gowns were alternated between operations, as were incision drapes. Measurements were made of the microbial concentration of the skin next to the wound, of microbes in bile, of punctures in gloves, and of airborne microbial concentrations. The relationship of these risk factors (excluding airborne MCP concentrations) to wound counts is reported in Reference 19, and it was found that infected bile and incision drapes significantly affected the count of bacteria in the wound.

To study the effect of airborne bacteria on wound counts (Reference 20) it was necessary to obtain different airborne microbial concentrations in the operating room. Low airborne counts were achieved by a small unidirectional airflow system that passed HEPA filtered air over the instrument tray and wound. The relationship of the wound washout count to all of the measured risk factors, including air concentrations, was analysed. It was found that in wounds where bile was not infected and the wound washout count was less than 100, the wound count was related to the airborne concentration. When the airborne bacteria were reduced by 13-fold the wound contamination was reduced by about 50%. However, where the bile was infected and the wound count was above 100, no relationship was found.

Discussion and conclusions

This article reviews the research that I (and others) have been involved with, until 1990, into SSIs caused by airborne MCPs, and its reduction by mechanical ventilation and occlusive clothing.
The following evidence was presented to show the importance of airborne infection in conventionally-ventilated operating rooms.

a. Early studies in operating rooms and a burns dressing room showed that airborne concentrations of MCPs and wound infection were reduced by improved mechanical ventilation, or UV radiation[1, 2, 3, 4];

b. Epidemics of wound sepsis caused by unusual types of *Staphylococcus aureus* dispersed by a person working in the operating theatre but never in contact with the open wound, demonstrated airborne infection[5, 6].

c. Isolating *Staphylococcus aureus* from wounds at the end of surgery, or from septic wounds, and correlating the isolated types with sources in the operating room, demonstrated the importance of the airborne route of infection[7, 8];

It has been accepted since the 1970s in the UK that surgical operations should be carried out in operating rooms with 20 air changes per hour of filtered air used to dilute airborne MCPs dispersed by the operating room staff, and to pressurise the room against entry of MCPs from adjacent areas (Reference 1)[17, 18].

Research into the additional contribution of ultra-clean systems in reducing airborne MCPs and wound infection has been discussed in this article. Charnley reduced airborne MCPs in his operating theatre by improving the mechanical ventilation and clothing system until an ultra-clean system with unidirectional airflow and total-body exhaust gowns had evolved. These improvements were carried out in stages, and drops in airborne MCP concentrations were paralleled with reductions in the wound sepsis rate from about 7 to 9% to below 1% when he completed his improvements[9, 10, 11].

The multi-centred MRC trial of ultra-clean air systems (References 4 to 11) compared operating theatres using good conventional ventilation with those using ultra-clean air systems. Ultra-clean air systems were shown to be capable of giving large reductions in the concentration of airborne MCPs (Reference 4). Airborne MCPs were shown to account for between 95% and 98% of the bacteria found in the wound after surgery in the conventionally-ventilated operating rooms (References 3, 7). Ultra-clean air systems approximately halved the deep sepsis rate in total joint replacement operations, and when lower airborne MCP concentrations were obtained by additional use of occlusive clothing, the rate was quartered (Reference 4, 5, and 11). These results were accepted by the UK Department of Health and the large majority of total joint replacement operations in the UK are now carried out in ultra-clean systems, this decision being mirrored throughout much of the world.

The use of ultra-clean air systems still remains a controversial subject, with a surprising report in 2008 showing an increase in SSIs when UDAF systems were used[27]. However, such claims must be examined critically and the following aspects considered:

1. The findings were not the product of clinical trials set up in a prospective and randomised manner to show that the effect of clean air is consistent in multiple centres, as was the case in the MRC trial. If clinical trials are not set up scientifically this can lead to confounding factors such as allocating difficult surgical cases to the best operating conditions, and other possible biases, which might affect the results. A sufficient length of time must also be left after surgery to ensure that a reasonable proportion of the incidence of deep (not minor superficial) sepsis is found; in the MCR trial it was over 2 years.

2. Ventilation systems designated as 'ultra-clean' may not achieve ultra-clean performance, and fail to give low rates of wound sepsis. The problems of the poor design of UDAF systems and occlusive clothing have been discussed in this and the previous article, and to obtain ultra-clean air conditions, it is necessary to consider the following:

   a. Downflow systems are more effective than crossflow systems;

b. Some UDAF systems do not achieve the UK minimum average of 0.38m/s for a partial-walled system (0.3m/s for a full-wall) when readings are taken 2m above the floor, and 0.2m/s when 1m from the floor. They are therefore less effective in clearing contamination dispersed by the surgical team and give higher airborne MCP concentrations;

c. A sufficiently large ultra-clean area is required to protect surgical instruments laid out on trolleys from airborne deposition of MCPs;

d. Full walled systems will ensure that the air supply reaches the wound, and a high enough velocity is obtained to ensure the removal of airborne MCPs. However, full walls are inconvenient and are now seldom used in UDAF systems. UDAF systems without full walls must be designed to ensure the correct downward airflow and the velocity at the wound is that given in (b). This is a particular problem if warm air is supplied, as buoyancy of the air prevents the clean air supply reaching the wound.

e. Airborne MCPs generated external to the ultra-clean zone should be prevented from being entrained into the zone and depositing into the wound, this being a particular problem when the ultra-clean zone is much smaller than an area of about 3m by 3m. The test method used in the HTM 03-0118 should be used to check for entrainment problems.

f. Clothing systems used as an alternative to total-body exhaust-system gowns may not be as effective in reducing airborne MCP dispersed from the surgical staff.

If UDAF systems are not designed to the above principles, which are more fully discussed in the first article, and effective occlusive clothing not used, the MCP concentration is likely to exceed 10/m^3, and will certainly fail to reach the 1/m^3 required to minimise airborne infection (Reference 7 and 8). A recent multi-centre study carried out in 29 operating rooms in 14 hospitals[28] showed that about half the air samples in a UDAF system with a large ultra-clean zone failed to achieve an MCP concentration of ≥10/m^3, and UDAFs with a small ultra-clean area had higher airborne concentrations than conventionally ventilated operating rooms. Any clinical trials that compare UDAF systems with ultra-clean systems must include airborne MCP concentrations measured at the wound to confirm that the ultra-clean system achieves ultra-clean performance.

3. Since the MRC trial, the use of prophylactic antibiotics has become universal. This ensures that many of the airborne bacteria deposited into wounds during surgery are killed, and low sepsis rates are obtained, but makes it more difficult to show the positive effect of ultra-clean air. However, the MRC study demonstrated that although prophylactic antibiotics gave a substantial reduction in wound sepsis, an additional reduction was obtained when clean air was additionally used (References 4, 5 and 9).

These three aspects add to the difficulty of showing the advantages of ultra-clean air systems, and may explain the failure to do so.

Using UDAF systems increases the cost of installing and maintaining an operating room suite, and the use of prophylactic antibiotics is an attractive cheaper option for controlling wound sepsis. However, the development of antibiotic resistance of bacteria in hospitals is a serious and continuing problem and, to combat it, bacterial transfer must be controlled by aseptic techniques. For that reason, ultra-clean systems should be used to prevent pathogenic bacteria from being deposited into the wound, as not all bacteria are sensitive to the prophylactic antibiotic selected and wound sepsis may occur. Also, as the more effective and modern antibiotics are used as prophylactic antibiotics it is better to avoid any antibiotic-resistant bacteria depositing in the wound, as they may survive and cause wound sepsis and a future antibiotic-resistant problem. It is better to ensure that the fewest number of bacteria are deposit into the wound i.e. prevention is better than cure. A combination of both ultra-clean air systems and prophylactic antibiotics seems sensible, and even if the additional reduction in infection by the combination is small, the consequences to a patient of deep sepsis after total joint replacement are serious enough to merit the extra effort and cost.

The research reviewed in this article shows that airborne bacteria are the cause of wound sepsis, and a UDAF system with occlusive clothing is a useful control method, particularly in total joint replacement operations. At present, the use of UDAF systems is usually confined to total joint replacement operations, but it seems sensible to use ultra-clean air systems in other operations that are likely to be susceptible to airborne contamination. Clean operations with a large wound area exposed during a long operation, especially implant operations, and those where the consequences of infection are more serious, are strong candidates for the use of ultra-clean systems. It is hoped that the information given in the two articles provide evidence for the adoption of this suggestion.

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