The design and testing of unidirectional airflow operating theatres

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Abstract

This article discusses the design of unidirectional airflow systems used to ventilate operating theatres and provide low concentrations of airborne micro-organisms during surgical operations. Also described are tests that can be used to confirm that unidirectional airflow systems are well designed and perform correctly when installed and during their lifetime. Reasons are given for the failure of unidirectional airflow systems to provide low concentrations of airborne micro-organisms and reduce joint infection rates after total joint arthroplasty when compared to conventional mixed-airflow operating theatres.

Key Words: operating theatres, ventilation, airborne micro-organisms, infections

1 Introduction

In the 1960s, Professor Sir John Charnley developed a surgical operation to replace diseased hip joints with an artificial joint. However, this operation was sensitive to microbial contamination, and the joint infection rate of his early operations was in the region of 7% to 9% [1, 2]. Charnley was working in a poorly-ventilated operating theatre (OT) and as he improved the mechanical ventilation and surgical clothing he obtained reductions in airborne microbe-carrying particles (MCPs) that were associated with reductions in infection rates[1, 2]. When the airborne MCP concentration was reduced to about 1/m^3, the infection rate was about 0.5%. He concluded that low concentrations of airborne MCPs were needed to minimise joint infections.

Criticisms were made of Charnley's studies, and the UK Medical Research Council (MRC) set up a large, multi-centred, prospective, and randomised study, which compared the infection rates after total joint replacement operation carried out in conventional mixed-flow OTs and in ultra clean OTs (mainly UDAF systems). This study showed air to be the main source of deep infections and that ultra-clean air systems significantly reduced these infections [3, 4]. It was found that conventionally ventilated OTs gave an average airborne MCP concentration of 164/m^3, and when the average airborne concentration in an ultra-clean system was about 1 MCP/m^3, the infection rate of deep joint infections caused by airborne contamination was close to the minimum [5]. However, because of the limited acceptability and availability of the most effective ultraclean air systems, an average airborne concentration of 10 MCP/m^3 was suggested as a maximum value to give a worthwhile reduction of joint infections [6].

Both Charnley and the MRC showed that to obtain the lowest concentrations of MCPs it is necessary to use occlusive clothing to control dispersion of MCPs from the surgical team, as well as an ultra-clean ventilation system to remove the MCPs. Only the design of the ventilation system is discussed in this article; information about occlusive clothing is given elsewhere [7, 8, 9].

The most common OT ventilation system is the conventional mixed-airflow type. About 20 air changes per hour of filtered air is supplied through ceiling air diffusers, and this mixes and dilutes airborne MCPs in the OT and removes them through low-level exhausts. This dilution method is not as efficient as unidirectional airflow (UDAF) systems. UDAF systems use a bank of high-efficiency

air filters in the OT ceiling to provide a downward flow of air towards the wound and sterile instruments in approximately parallel streamlines. This type of airflow is shown in Figure 1. UDAF systems use more air than conventional mixed-airflow systems but typically produce a microbial air concentration that is 100-fold less than conventional mixed-airflow systems [5]. UDAF systems are also designed so that the air is supplied from filters in the wall and flows across the operating theatre. However, these crossflow systems are uncommon.

A UDAF system is often called a 'laminar airflow' (LAF) system in the medical literature. However, we consider this is a mistake, as the air velocity is too high to be laminar in the scientific sense; Thomas and Symonds have explained this in more detail [10]. It is called 'unidirectional airflow (UDAF)'in this article, which is the name used in manufacturing industry and in the ISO 14644 series of cleanroom standards [11]. However, the term 'LAF' is used in the next paragraph as it was the name used in the papers that are discussed.

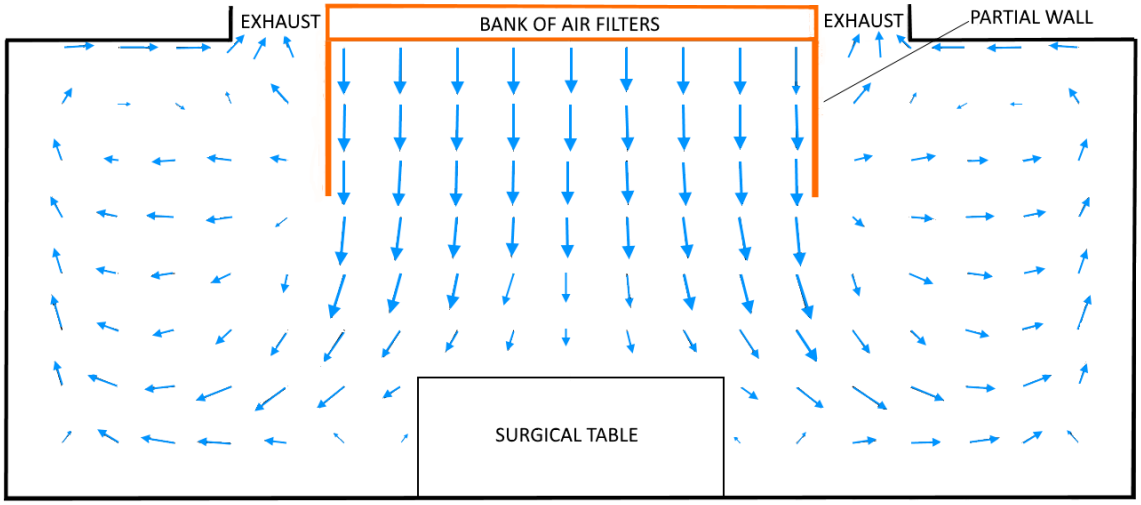

Figure 1 Airflow in a UDAF system in an operating theatre

In 2016, the WHO produced guidelines for the prevention of surgical site infections [12] and it contained a conditional suggestion that 'LAF' systems were unnecessary for total joint replacement operations. This suggestion was largely based on an article written by Bischoff et al [13]. However, Bischoff et al's critique has been criticised and refuted [14, 15]. One problem with Bischoff's et al's conclusions is that little, or no, information was supplied about the LAF systems they included in their study. This is important, as Agodi et al [16] has surveyed LAF systems in 14 hospitals and found that many failed to provide an acceptable MCP concentration of below 10/m^3, and some were no better than conventional mixed-airflow OTs. Vonci et al [17] showed that the five 'LAF' systems they studied gave an average MCP concentration of 12/m^3. If UDAF systems are poorly designed, or badly maintained, or both, then they will be much less effective that those studied by Charnley and the MRC study, and unlikely to obtain average airborne concentration of 1 MCP/m^3. It should, therefore, not be concluded that 'LAF' systems are ineffective in reducing deep joint infection, without demonstrating that they are able to achieve the correct clean air conditions.

This present article considers design difficulties that will lead to ineffective UDAF systems and discusses how they should be designed to achieve the performance required for ultraclean surgery. Tests to confirm the effectiveness of UDAF systems are also discussed.

Information was obtained about the design and testing of UDAF systems by studies commissioned by the UK MRC and the Department of Health around the time of the main MRC clinical study. Some

of this information was published in scientific journals [18-22] but some was the subject of internal reports which were not publically available. This information was incorporated into Hospital Technical Memorandum 2025 [23], which evolved into the current UK Health HTM 03-01 [24]. However, HTM 03-01 is relatively unknown outside the UK, and the reasons for the design and test requirements have been largely forgotten. Knowledge of this information, along with more recent research, is discussed in this article and should lead to more effective UDAF systems.

2 Design of unidirectional airflow (UDAF) systems

To design an effective UDAF system, information is required on:

- Whether the unidirectional airflow should be downflow or crossflow;
- The required velocity of the unidirectional airflow, and its disruption by staff movements;
- Disruption of unidirectional airflow by thermals and physical obstructions such as operating theatre lamps;
- Control of airflow from the air supply filters down to working height to achieve low concentrations of airborne MCPs;
- The need to protect sterile instruments, in addition to the wound, from airborne contamination;
- Removal efficiency of air filters against airborne contamination.

2.1 Direction and air velocity of unidirectional airflow and disruption by staff movements

An investigation has been carried out during surgery into whether the airflow in a UDAF system should be downflow or crossflow, and what is its optimum air velocity [19]. This was carried out in a full-walled UDAF enclosure where the air velocity could be changed during the operation from 0.1m/s to 0.6m/s, in steps of 0.1m/s, as well as the air direction from downflow to crossflow. These changes were carried in a randomised manner during total joint replacement operations, without compromising asepsis.

Shown in Figure 2 are the airborne concentrations of MCPs found within 30 cm of the wound. It can be seen that the downflow system was more effective than crossflow and that the air velocity should not be less than 0.3m/s. It was considered that at low velocities, the unidirectional airflow was disrupted by movements of the surgical team and changed to a mixed airflow which was less effective in removing airborne MCPs. More recent experiments have confirmed this [25].

Based on these results, it was suggested that a minimum velocity of 0.3m/s is required in UDAF systems that use full-walled enclosures. However, as will be discussed later, when a partial-walled system is used, the air velocity needs to be increased to a minimum velocity of 0.38m/s. It should be noted that the required air velocity in pharmaceutical cleanrooms is between 0.35m/s and 0.54 m/s [26] and that almost all of their UDAF systems are full walled.

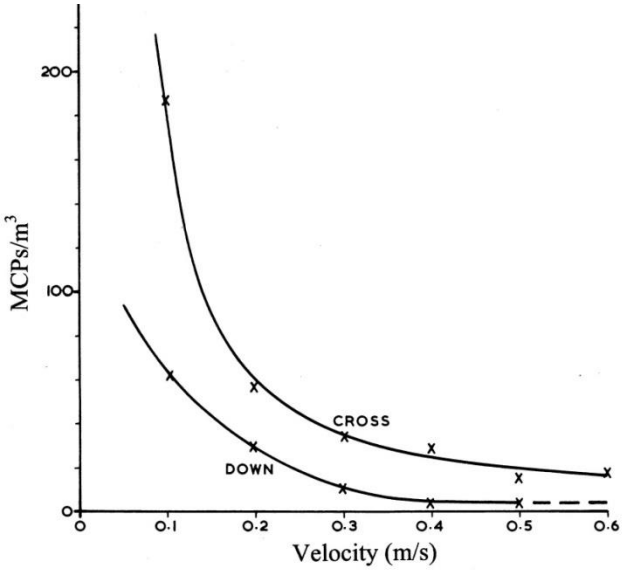

Figure 2: Airborne MCP counts with respect to unidirectional air velocity and direction.

2.2 Effect of obstructions and thermals

In conventional mixed-airflow OTs, the surgical lamp is often large, with a diameter of 1 metre. If this lamp is installed in unidirectional airflow it will obstruct and disrupt the airflow to the sterile area, and MCPs will not be efficiently swept away. Shown in Figure 3 is such a surgical lamp in unidirectional airflow, with the airflow pattern round it obtained by time-elapsed photography of neutral-buoyancy helium-filled detergent bubbles [20]. This shows the problem area after the lamp, where the lower velocity and mixed airflow will produce a higher concentration of MCPs. Additional experiments were carried out using a test particle challenge to obtain quantitative information about this problem [20]. These experiments showed that surgical lamps and other obstructions should be as small and aerodynamic as practical to provide good unidirectional airflow conditions.

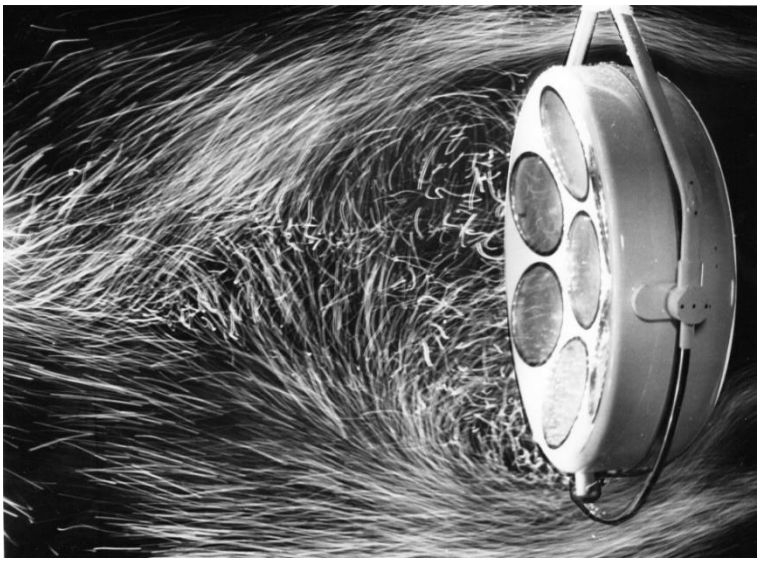

Figure 3: Helium-filled detergent bubbles showing disruption of unidirectional airflow passing a large operating theatre lamp

Hot air rising from surgical lamps and other hot surfaces can disrupt unidirectional airflow. Schlieren photography was used to establish what air velocity is required to control this [20]. An

operating lamp pod with an unusually high surface temperature was investigated and it was shown that the thermal currents are prevented from rising by a downward unidirectional airflow velocity of 0.3m/s. It was considered that this type of surgical lamp produced the worst thermal problem likely to be encountered and any thermal problems will be fully controlled when the unidirectional air velocity is 0.3m/s, or greater.

2.3 Control of airflow down to working height

The best airflow to achieve low concentrations of airborne MCPs in UDAF systems is achieved by full-walled enclosures. These walls are round the perimeter and made of glass or plastic sheets, or plastic flexible strips, and come to within about 30cm of the floor. As shown in Figure 4, full walls constrain the air from the filter bank down to the level of the wound and surgical instruments. They prevent the sideways movement of the supply air towards high level exhausts as well as preventing the penetration of less-clean air from outside the enclosure. However, full walls reduce communication as well as access of large pieces of equipment, and most current UDAF systems are designed without full walls, and use no walls, partial walls, or an air curtain. However, lack of full walls reduces the control of airflow down to working height, and how this control can be maximised is now discussed.

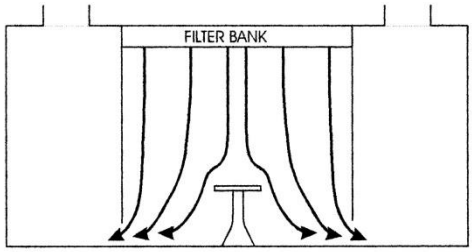

Figure 4 Airflow in full-walled UDAF system

2.3.1 Loss of air velocity: In full-walled UDAF systems, the air supply is constrained downwards to the wound and instruments (Figure 4). However, without full walls (Figure 5), some of the supply air is likely to move sideways to the air exhausts and this causes a reduced air velocity at working height.

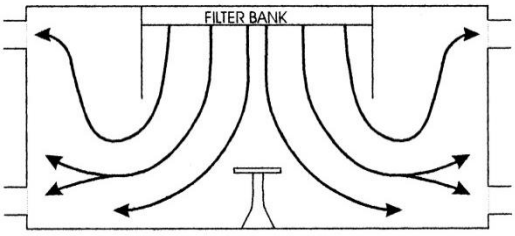

Figure 5 Airflow in partial-walled UDAF systems.

The loss of air velocity in a partial wall system is shown in Figure 6, which gives the reduction in air velocities from supply filters to table height. When these results are compared to a full-walled system, it is found that there is an additional loss of about 25% of the air velocity at working height [21] As previously discussed, when measurements were carried out in a full-walled UDAF system, a minimum air supply velocity of 0.3m/s was considered satisfactory. However, if this additional drop in air velocity is taken into consideration, partial-walled system should have a minimum air supply velocity of 0.38m/s, and this is the velocity suggested in HTM 03-01.

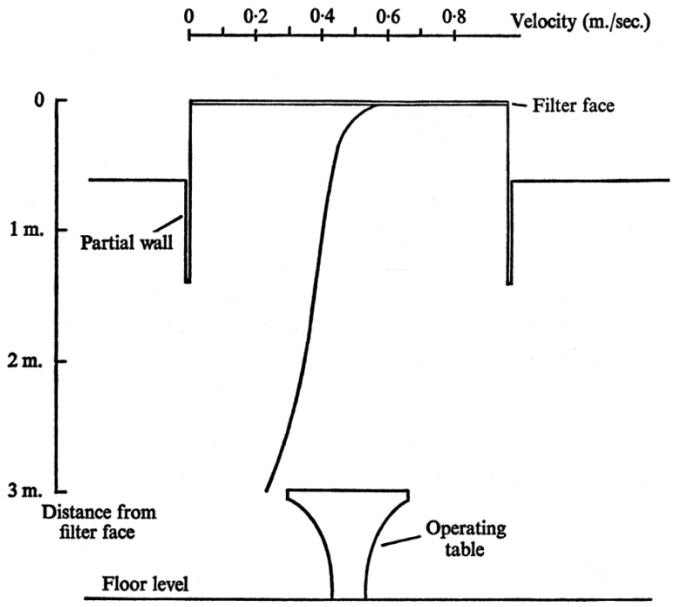

Figure 6 Air velocity in partial walled system from filter face to operating table.

2.3.2 Short circuiting of supply air to exhausts: If a UDAF system has no walls and the air exhausts are in the ceiling then, as shown in Figure 7, there can be a short circuit of the supply air to exhausts that will reduce the availability of filtered air at the working area [21]. However, it has been demonstrated that if partial walls are provided that stop about 2 metres above the floor to provide good access, then this problem is substantially reduced [21].

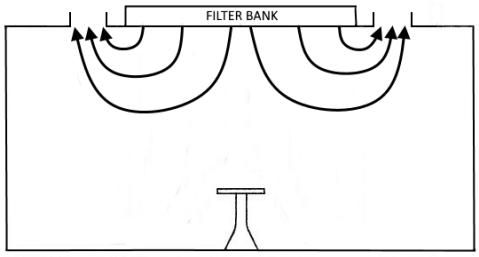

Figure 7 Short circuiting between air supply and ceiling exhausts

2.3.3 Effect of air supply temperature: If UDAF systems do not have full walls, a problem will occur if the air supply is hotter than room air. This is illustrated in Figure 8 where hot buoyant air (hatched area) is shown not to pass the table on its way to the exhausts.

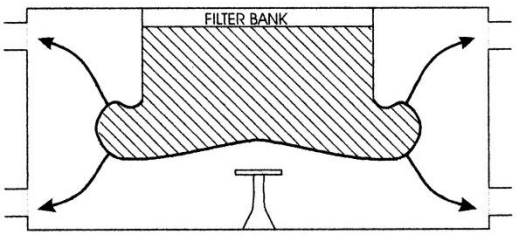

Figure 8 Effect of hot buoyant air in UDAF

The results of an investigation of two partial-walled UDAF systems [22] are shown in Figure 9. When the air supply temperature was about 1°C warmer than the surrounding room, little or no supply air reached the wound. However, as the air supply became colder, the air velocity at wound height

increased, and when it was 1.4ºC lower than the surrounding room air, the velocity was about twice the condition when the supply and room temperature were the same.

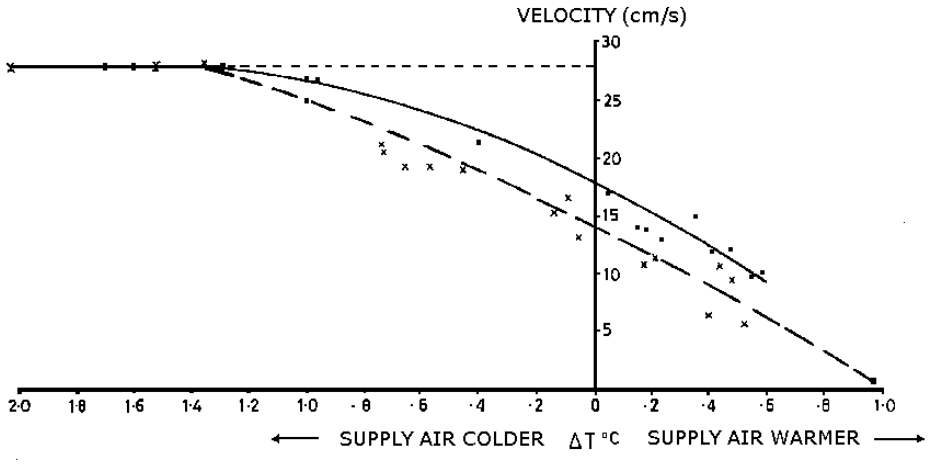

Figure 9 Effect of the temperature difference between supply air and surrounding room air on air velocity at wound height.

Experiments were also carried out to show the penetration of test particles into the UDAF clean air zone and the effect of a temperature differential [22]. Figure 10 shows that only a small amount of particles seeded outside the clean zone were entrained into the clean zone of a partial-walled UDAF system when the air supply had the same temperature as the surrounding room. However, Figure 11 shows a greater penetration when the supply air was 0.65°C hotter than the surrounding room.

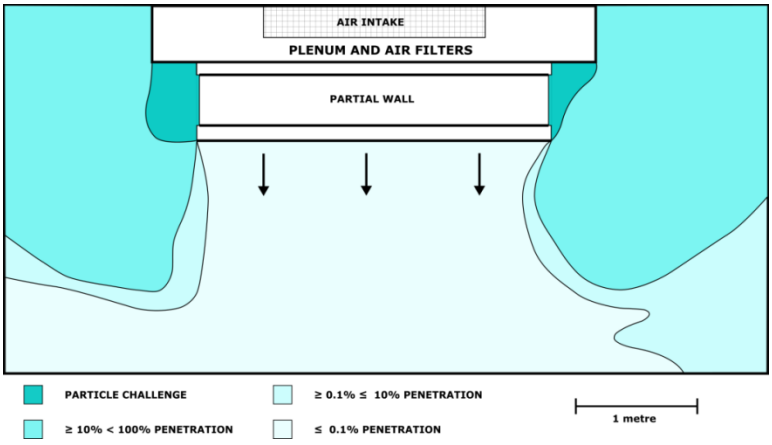

Figure 10 Penetration of particles into clean zone of partial-walled system: iso-thermal conditions

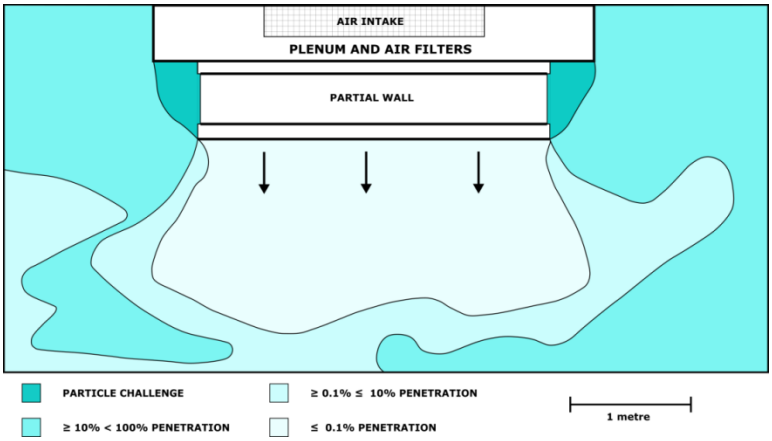

Figure 11 Penetration of particles into clean zone of partial-walled system. Supply air 0.65°C hotter than surrounding room.

In some UDAF systems, the OT air is recirculated to an external air handling unit, where it is conditioned and returned to the UDAF system for use as supply air. In normal situations, the heat gain from people, lights, and machinery in the OT requires cold air to be supplied, and this should result in good unidirectional airflow down to working height. However, it has been found that if heat losses through the room's walls and floor are high, such as occurs in an OT with outside walls during a cold day, then warm supply air is required and air buoyancy reduces the amount of supply air that reaches the sterile area.

Some designs of modular UDAF systems draw air from the OT and, after filtration, use it as supply air. The heat gain from the fans in the modular system causes the air temperature of the supply air to increase by about 0.5ºC to 0.7°C. If there is no cooling within the UDAF system then buoyancy problems can occur. These buoyancy problems should be considered when designing the ventilation system.

2.3.4 Entrainment of air from outside the sterile zone: If full-walls are not used in UDAF systems, microbial contamination in the area outside the clean zone may enter and reach instrument trolleys and, possibly, the wound area. This is shown in Figure 12, as well as in Figures 10 and 11. The area outside the clean zone is normally more heavily contaminated with MCPs than the UDAF clean zone [27] and entrainment should be minimised; this should be demonstrated by the test method that is discussed later.

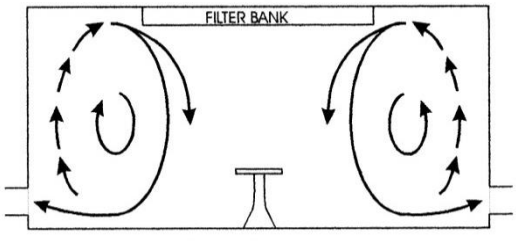

Figure 12 Entrainment into clean zone

2.4 Area of sterile zone provided by the UDAF system

The size of the bank of air supply filters, and hence the sterile area round the wound and instruments, varies between types of UDAF systems. Smaller systems provide an area sufficient to protect the wound, while larger systems will additionally protect the sterile instruments on trolleys.

An experiment was carried out in two adjacent OTs, one room having conventional mixed-airflow ventilation and the other a UDAF system [28]. TJR operations were studied and the airborne count in the conventional mixed-airflow OT averaged 413 MCPs/m^3, and in the UDAF system it was 4 MCPs/m^3 (a 97-fold reduction). Microbes were also washed from the surgical wound before closure and the count shown to average 105 and 3, respectively, which was a 35-fold reduction. These results showed that 98% of microbes in the wounds exposed in the conventional mixed-airflow OT came directly and indirectly from the air. Also investigated was the contribution of surfaces such as instruments and drapes, where MCPs could deposit from air and be transferred to the wound by surface contact. It was found that this source contributed the majority of the microbes in the wound. This was unexpected, but if consideration is taken of the much larger surface area of the drapes, gloved hands, and instruments compared to the wound area exposed to airborne deposition, and that about 10% to 20% of surface microbes can be transferred by touch [29], the result is not so surprising. These experiments showed the UDAF system needs to not only protect the wound but the whole sterile area.

2.5 Particle removal efficiency of high efficiency filters

UDAF systems have a bank of high efficiency filters that supply a unidirectional flow of sterile air. These air filters have removal efficiencies that are specified according to EN 1822-1 [30] and ISO 29463-1 [31]. Both standards use the filter's most penetrating particle size (about 0.3 μm) to determine the removal efficiency. High removal efficiencies are unnecessary to remove MCPs from both recirculated and outside air, as the average equivalent particle size is about 12 μm [32]. It has been shown that filters about 90% efficient are sufficient to provide MCP-free air [33] and 85% is the minimal removal efficiency specified in HTM 03-01.

Lower-efficiency filters usually have a much smaller pressure drop across the filters than higher-efficiency filters, and this lack of resistance to airflow can cause an uneven and undesirable airflow distribution across the face of the air supply filters. Also, testing for leaks in the installed filters by the normal manner described in ISO 14644-3 [34] is difficult if the overall filter efficiency is less than 99.95%. Therefore, the removal efficiency of filters used in UDAF systems is usually between ≥99.95% and ≥99.995%, which is achieved by H13 and H14 type of filters, respectively, according to EN 1822, and 35H, 40H and 45H type of filters, respectively, according to ISO 29463-1.

3 Design, testing and monitoring of UDAF systems

Surveys have been carried out in UDAF systems during surgery [16, 17] and it was found that many gave MCP concentrations above the acceptable count of 10/m^3. To avoid such an outcome, the following is suggested: (a) when developing new designs of UDAF systems, they should be correctly designed using information in this article and their likely performance ascertained and improved by Computational Fluid Dynamics (CFD), and (b) tests should be used to ensure UDAF systems function correctly when first installed and over their lifetime.

3.1 CFD analysis

When a new UDAF system is being designed, its likely airflow performance can be investigated by means of computational fluid dynamics (CFD) and its design developed and improved. Using this approach, the direction and velocity of airflow can be determined by numerically solving the Navier-Stokes equations. However, when applying CFD, various challenges are encountered such as numerical convergence, modelling and meshing, as well as selecting the correct turbulence model, boundary conditions, and turbulent intensity of the air [35]. As well as these inherent problems in CFD analysis, there is a major problem with personnel movements, as CFD analysis cannot effectively deal with the unpredictable movements of the surgical team. This results in UDAF systems having a poorer performance than shown by CFD analysis, especially when the air velocity is low and the

airflow is less stable. These difficulties may create some doubt about the usefulness of CFD analysis in predicting the airflow pattern in a UDAF system. To investigate this, a comparison was made in a typical UDAF system of a CFD analysis and actual measurements.

The OT studied had a floor area of 7m x 7m and height of 2.8m. In the middle of the room was a UDAF system that had a 3m x 3m bank of high efficiency air filters in the ceiling that provided a unidirectional flow of air. Round the perimeter of the filter bank was a partial wall that came down to within 1.9m of the floor. The air supply velocity was 0.38m/s and the temperature of the air supply was within 0.1°C of the temperature outside the UDAF system. The air exhausts were located at ceiling height and outside the partial walls.

The UDAF system was analysed using ANSYS (version 2019 r2) software suite, where Design Modeller, Mesher, and CFX were used to model the geometry, build the mesh, and solve the simulation, respectively. The symmetry of the OT was used to reduce the size of the computational domain, which resulted in a quarter of the geometry being modelled. The mesh was 1.35 million elements (0.387 million nodes), which consisted of elements that were a mixture of hexahedral, tetrahedral and prisms. The problem was solved using a SST k-ω turbulent model with a turbulent intensity of 5%. The analysis was considered to have achieved convergence when 1) the residuals were less than 5×10^{-6} and 2) when the velocity at a monitoring point within the middle of the domain reached a steady-state.

Shown in Figure 13 is a cross section of the UDAF system that gives the airflow velocities and directions produced by CFD analysis. The unidirectional air flows downwards from the air supply filters but cannot pass through the surgical table, and the area above the table has a low velocity. The air then turns and circles upwards to the high level air exhausts.

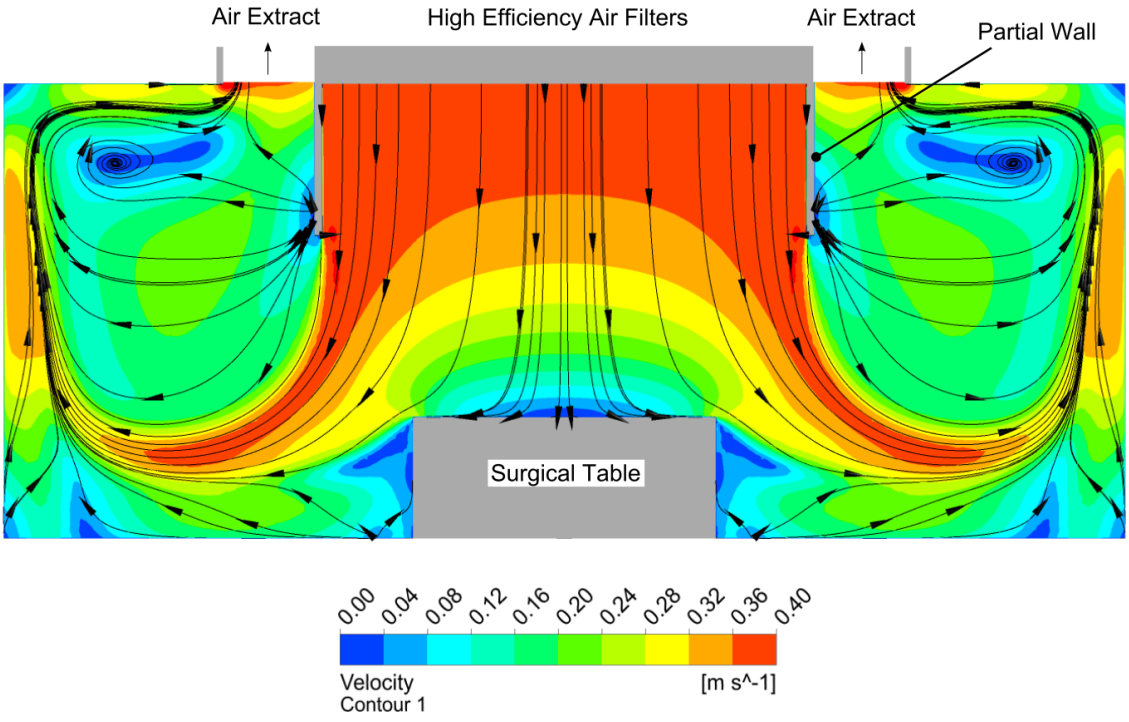

Figure 13 CFD analysis of partial-walled UDAF system showing air velocities and streamlines

Shown in Figure 14 are the results obtained from measuring the air velocities and air directions in the actual UDAF system when the room was empty. Only half the area of the UDAF system was investigated as it was assumed that the other side of the system was a mirror image. The air velocities were measured by a vane anemometer that had been previously calibrated in a low-speed wind tunnel.

No velocities below 0.24m/s are given in Figure 14 as it was considered that measurements below this velocity were unreliable. Included in the figure is a contour line of equal velocities of 0.25m/s, which can be seen to correspond reasonable well to that found by the CFD analysis given in Figure 13. Unfortunately, the OT that was studied was not square and the distance the UDAF system was from the wall varied, and the distance in Figure 14 is slightly less than in Figure 13. However, a comparison of Figure 13 and Figure 14 shows that the CFD results gave a similar airflow pattern to the actual.

Alsved et al [36] have also carried out a CFD analysis on a similar design of UDAF system with an air supply velocity of 0.4m/s, and a similar airflow pattern was obtained.

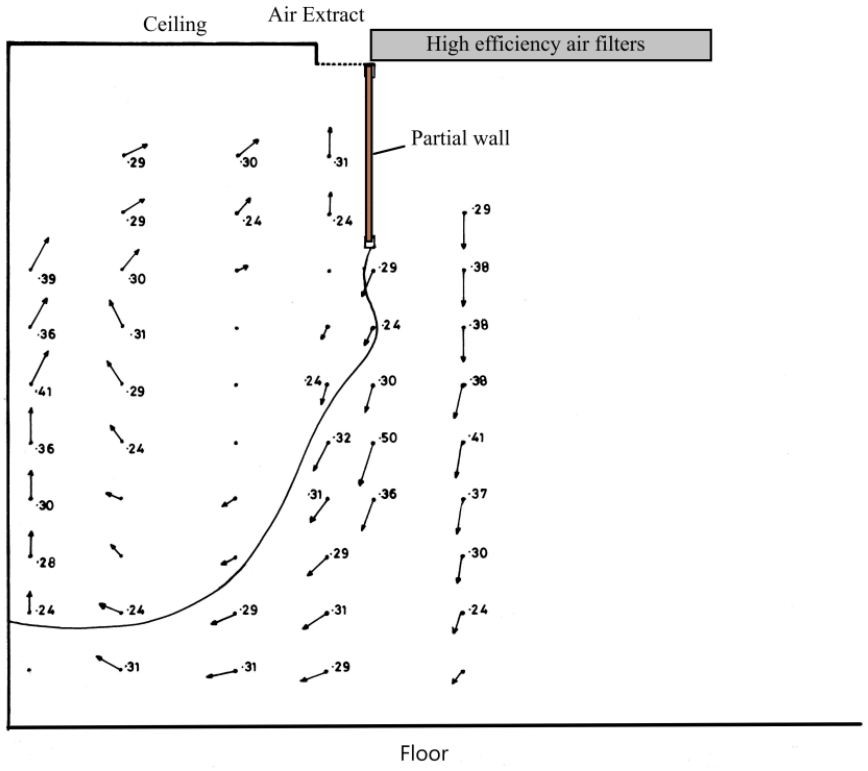

Figure 14 Actual velocities and direction of airflow in UDAF system. Dot indicates that the air velocity was <0.24m/s

Microbial air sampling was also carried out at the wound during total joint replacement surgery in this design of UDAF system, when the surgical team wore occlusive clothing, a satisfactory average concentration of 0.5 MCPs/m^3 was obtained [27]. Alsved et al, who studied a very similar UDAF system, found an average airborne concentration during surgery of less than 1 MCP/m^3 [36]

3.2 Routine physical tests

The following physical tests are suggested in HTM 03-01 for the routine testing of UDAF systems. They are usually carried out when UDAF systems are first installed and on an annual basis. A positive result shows that the UDAF system has been well designed and overcome the problems discussed in this article.

3.2.1 Air filter tests: It is necessary to demonstrate that the final air supply filters in a UDAF system are free of leaks. This should be carried out using the test method described in ISO 14644-3 [34]. A test aerosol of small particles (about 0.5 μm) is introduced and well mixed before the filter system.

The supply side of the filter system is scanned for leaks that are greater than 0.01% of the challenge concentration with a sampling probe attached to an airborne particle counter or photometer. As the number of inanimate airborne particles used to challenge the filters is several million per m^3, the technique is much more sensitive than one where a leak of airborne MCPs is sought. The particle detection method is also much more rapid than microbial sampling and is the preferred method of testing filter systems.

The pressure drop across air filters should be monitored to ensure that they are not being blocked by an accumulation of particles and fibres, and the air supply velocity reduced. A record should be kept of the pressure differentials over time.

3.2.2 Air velocity test: As previously discussed, and shown in Figure 2, the microbial air concentration in UDAF systems is directly related to air velocity and this should be measured. The test is normally carried out without the presence of a surgical table. Air turbulence at the filter face causes velocities greater than the true velocity to be recorded [37], and air supply velocity readings should be taken more than 15cm from the filter face. HTM 03-01 suggests two metres from the floor, which usually coincides with the bottom of the partial wall. HTM 03-01 gives a grid of test positions where the air velocities should be measured. The average air supply velocity should not be less than 0.3m/s in a full-walled system and not less than 0.38m/s in a system without full walls.

Because of the airflow control problems previously discussed, the air velocity should also be measured at working height i.e. 1 metre from the floor. In this case, the air velocity should not be calculated as an average, but each velocity should be $\geq$0.2m/s.

A drop in the air velocity over time gives information as to when filters may need replacing. A record of the air velocities should be kept, and used with the record of the differential pressures across the filters to plan filter replacements.

3.2.3 Entrainment of contamination from outside the clean area: If a UDAF system is built without full walls, then some contaminated air from outside the clean zone will be entrained into the clean zone. To ensure that the amount of entrainment is acceptable, small test particles are released outside the clean zone and their penetration into the clean zone is measured by a particle counter or photometer. To carry this out, a measuring grid is provided in HTM 03-01 and penetration into the outer zone of the sterile area of the UDAF should be less than 10%, and penetration of the inner zone is less than 1%. At the centre point it should be less than 0.1%.

3.3 Non- routine physical test

3.3.1 Visualisation of airflow by smoke: The visualisation of airflow in a UDAF system by smoke is suggested in HTM 03-01. This test is unnecessary as part of routine monitoring but is valuable for demonstrating airflow problems and their potential causes, especially the effects of short-circuiting and entrainment that are illustrated in Figures 8, and 10 to 12. The test is usually carried out in an empty and newly installed system, or where routine testing has revealed problems with the airflow. However, it should be noted that smoke visualisation results are not quantitative and do not provide physical measurements or results and, therefore, the interpretation of the effectiveness of the airflow is subjective.

Visualisation methods are described in ISO 14644-3, and a suitable method for a UDAF system is the use of streams of test smoke. A plastic pipe of about 4.5cm diameter with 2mm to 3mm holes bored, in line, about every 10cm can be used. This pipe is sealed at one end and set up on support stands so that it spans the UDAF system below the partial wall. A smoke generator of the type used to test for leaks in air filter systems, or the type used in theatres and music venues can be used to generate smoke that is fed it into the pipe. An air pump is likely to be needed to push the smoke through holes in the tube. If a record required, a video can be taken of the flow of the smoke. Light beams and dark background will enhance the visualisation.

Discussion

A multicentre, prospective, and randomised study run by The UK Medical Research Council found that airborne MCPs are the main source of joint infection after total joint replacement surgical operations [3, 4, 5]. It was shown that conventional OTs, which had mixed-flow ventilation system similar to ordinary mechanically-ventilated rooms but with about 20 air changes per hour, gave an average airborne concentration of MCPs of 164/m^3. Clean air systems that gave an average airborne concentration of about 10 MCPs/m^3 were found to significantly reduce joint infections, and systems that gave an average of about 1 MCPs/m^3 reduced airborne infections close to a minimum [5, 6].

Some more recent clinical studies have failed to repeat the conclusions of the MRC study [13]. However, these studies have been criticised for the poor quality of the results and, of particular importance to this article, a lack of information about the design and testing of the UDAF systems that were studied [14, 15]. Published articles have shown that some UDAF systems can fail to achieve an average concentration of airborne MCPs of 10/m^3, let alone 1/m^3, and some systems performed no better than conventional mixed-airflow OTs [16]. It is, therefore, reasonable to consider that unless UDAF systems are shown to be superior to the conventional mixed flow OTs to which they are compared, they cannot be reported as ineffective.

It is the experience of the authors of this article that the principles of designing, testing, and operating UDAF systems are poorly understood. Information about these principles is given in an article written by the steering committee of the MRC study [6] and HTM-03-01 [24], but these documents are not well known outside the UK, and the scientific basis of this guidance may be unclear. In addition, articles about the clinical effectiveness of UDAF systems usually fail to provide information about their design or routine testing. There appears to be a lack of understanding about the design and testing of UDAF systems and clarification is given in this article.

Conclusions

Information is needed about the design of UDAF systems and the rationale behind the design requirements. The ability of a UDAF system to provide satisfactorily low concentrations of airborne MCPs in operating theatres has been shown in this article to depend upon several design criteria, namely, (1) the air supply must be as free as possible of microbial contaminants (i.e. appropriately filtered), (2) the airflow should be vertical, and possess sufficient velocity to efficiently remove microbial contaminants generated by the surgical team, (3) the effect of obstructions and thermals should be minimised, (4) the air supply should not be warmer than the air in the OT, (5) a minimum amount of contaminated air should enter the unidirectional airflow from outside the system (entrainment), (6) the UDAF system should be large enough to protect not only the surgical wound from airborne contamination but surgical instruments that make contact with the wound. This article gives information on the importance and reasons for employing such design criteria.

Tests are required to confirm that UDAF systems are correctly designed and work well when first installed, and over their lifetime. Such tests are provided by a MRC report [6] and in HTM-03-01 [24] and these tests are described, along with the reasons for their use.

If a UDAF system is designed to fulfil the requirements given in this article, it will pass the physical tests described in this article. It is the experience of the authors, and others who routinely carry out these tests, that if a UDAF system passes these tests, the average airborne concentration during surgery will be below an acceptable average concentration of 10 MCPs/m^3. However, to achieve the more desirable average concentration of 1 MCP/m^3, it will be usually necessary to wear occlusive surgical clothing that reduces dispersion of MCPs from the surgical team [7, 8, 27]. Demonstrating this additional reduction needs to be ascertained by measuring the concentration of airborne MCPs during surgery. This aspect of testing is not discussed in this article.

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