THESIS FOR THE DEGREE OF LICENTIATE OF ENGINEERING

Practical Safety Ventilation in Ultraclean Air Operating Rooms

PEDRO GANDRA

CHALMERS
UNIVERSITY OF TECHNOLOGY

Department of Architecture and Civil Engineering,
Building Services Engineering
CHALMERS UNIVERSITY OF TECHNOLOGY
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PEDRO GANDRA

Department of Architecture and Civil Engineering,
Division of Building Services Engineering
Chalmers University of Technology
SE-412 96 Gothenburg
Sweden
Telephone + 46 (0)31-772 1000

Cover:
Airflow visualisation by smoke during a mockup-operation in the CHOPIN-project.
Photo: Thomas Tell. See Figure 6.3, p. 78.

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ABSTRACT

PRACTICAL SAFETY VENTILATION IN ULTRACLEAN AIR OPERATING ROOMS

When planning new ultraclean air operating rooms, often the first question is which is the preferred room air distribution system and what system is the best to meet the requirements of microbiological air cleanliness. Today, in Sweden, the requirement is a target level of 5 CFU/m^3during the design phase, in order to ensure that the level of Ò10 CFU/m^3during infection prone surgery is maintained.

This study is based mainly on the analysis of published scientific reports and other documentation. The focus is to compare the main principles for room air distribution systems, mixing and displacement principle and to see whether the requirements of microbiological air cleanliness can be fulfilled during ongoing surgery. Three different distribution systems available in Sweden have been compared.

The room air distribution systems studied are:

- Mixing airflow/partly displacement
- Unidirectional airflow (UDF)
- ñTemperature controlled airflow (TAF)ò - A specific Swedish room air distribution system.

The result of the comparison shows that in operating rooms for infection prone surgery all three studied room air distribution systems could achieve the target level of 5 CFU/m^3 when the air volume flows are above 2 m^3/s provided that the total microbiological source strength does not exceed 10 CFU/s.

The total microbiological source strength depends upon the number of people in the operating room, their chosen surgical clothing system, and their activity level.

Keywords: Ultraclean operating room, room air distribution system, airborne bacteria-carrying particles, microbial source strength, surgical clothing system

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PREFACE

For more than fifteen years I worked for Locum AB, as a technical manager and specialist on construction and building services. Locum is the Stockholm County Council company assigned to manage and build hospitals and healthcare buildings.

From the start in the Technical Committee SIS/TK 527 Cleanliness in operating rooms, I had the privilege to participate. Swedenôs first guideline document (SIS-TS39:2012) was published by this Technical Committee and gave guidance on microbiological air cleanliness in operating rooms. The work in the committee raised my interest for further studies on a licentiate level.

Another major factor behind my decision was that Locum was planning several major hospital building projects, all of them including surgical units with more than 70 new operating rooms in total. This contributed Mrs. Saija Thacker, BSc, Locumôs former Technical Director, to approve and economically support my project.

Furthermore, one third of the project cost was supported by the Healthcare Administration of the Stockholm City Council, after recommendation of Dr. Jan Forslid, MD, Ph.D., due to their interest in the reduction of surgical site infections.

Before the publishing of guideline SIS-TS39:2012, there were only short and general regulations for determining the necessary airflow to operating rooms. Furthermore, they were based on the idea that a determined number of room volume air changes per hour (ach) viz. 17-20 ach, would ensure the required level of microbiological air cleanliness independently of the number of persons in the room and their clothing. SIS-TS39 explains which parameters are fundamental to ensure the patient safety and states that every system for the room air distribution, that meets the requirements, can be chosen, i.e. there is more than one single acceptable system.

The logical question from members of ongoing projects was therefore which room air distribution system should be preferred. Todayôs designs on the Swedish market are primarily three, viz. mixing airflow, unidirectional airflow and a Swedish hybrid of those two marketed as ñTAF (Temperature controlled airflow).ò A comparison among those three solutions became the goal of my research.

This thesis is based on the study of several aspects within the field of Safety Ventilation, which I have performed from 2014-2018, at Chalmers University of Technology, Department of Architecture and Civil Engineering, Division of Building Services Engineering.

To my examiner Professor Jan Gustén, that made this project possible by accepting me at Chalmers University of Technology, I am most grateful. I also want to thank Mr. Göran Dalaryd, MSc and Mr. Thomas Tell, BSc, from AF-Infrastructure AB who have participated in one of my articles, and generously discussed different questions with me. Furthermore, special thanks to Mr. Russell E. Madsen, MSc, President of The Williamsburg Group, Gaithersburg, Maryland, for his linguistic support.

I am most grateful to my supervisors Professor Bengt Ljungqvist and Assoc. Professor Berit Reinmüller that made one of my long-time wishes come true. Without their support, patience, generosity and enthusiasm throughout this project, I would not been able to complete this thesis.

Stockholm, November 2018
Pedro Gandra

CONTENTS

A.1 ï Gandra, P., Ljungqvist, B., Reinmüller, B., Tell, T., Dalaryd, G., (2016), Swedish comparative study of three principally different surgery room ventilation systems by experimental measurements and CFD calculation. ICCCS International Symposium on Contamination Control, Sao Paulo, Brazil; 157-160.

A.2 ï Gandra, P., Ljungqvist, B., Reinmüller, B., (2017), Unidirectional air flow systems with low velocities in operating rooms ï a comparison between measured values of airborne viable particles and theoretical calculated values with the dilution principle. European Journal of Parenteral and Pharmaceutical Sciences, 22(3), 82-86.

ABBREVIATIONS AND ACRONYMS

ach	Air changes per hour
CFD	Computational Fluid Dynamics
CFU	Colony Forming Units
HEPA	High Efficiency Particulate Air
LAF	Laminar Air Flow, earlier expression for UDF
NKS	New Karolinska Solna
SSI	Surgical Site Infection
PTS	Program för Teknisk Standard - A Swedish national network
TAF	ñTemperature controlled AirFlowò - A specific Swedish room air distribution system.
UDF	UniDirectional Flow

TERMS AND DEFINITIONS

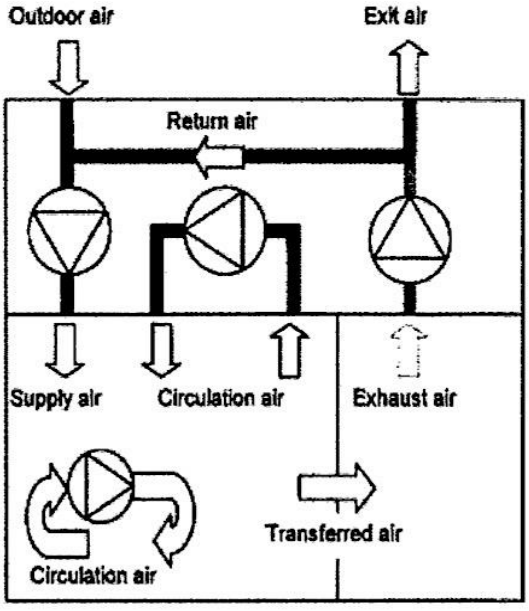
Active air sampling
Collection of bacteria-carrying particles from a specified volume of air, through collection on a filter or impaction on an agar surface.

Aerobic bacteria
Bacteria, which in order to live and grow, require access to free oxygen.

Air change rate
The ratio between the air volume flow into or out of a room and the volume of the room.

Note: Usually expressed in number of air changes per hour, ach.

Airflow nomenclature



Air volume flow
Volume of air transported per unit of time, specified in the unit m^3/s, l/s, or m^3/h, also called airflow rate or shortened airflow.

Note: In this thesis, room air distribution systems with an air volume flow of Ò1.5 m^3/s (1500 l/s) are called low air volume flow systems and room air distribution systems with an air volume flow of >1.5 m^3/s (1 500 l/s) are called high air volume flow systems.

Air velocity
The velocity of the air expressed in meters per second (m/s).

Air terminal device
A device located in an opening provided at the boundaries of the treated space to ensure a predetermined motion of air in this space. Also Supply/Exhaust air (terminal) devices or diffusers.

CFU (Colony Forming Unit)
Bacteria-carrying particle, which gives rise to a colony on a culture plate.

Clean air suit
Suit shown to minimize contamination of the operating room air from skin scales originating on the skin of persons.

Note: Clean air suits are medical technical products that meet the requirements set out in SS-EN 13795 and are designed to reduce the risk of airborne contamination.

Critical zone
Dedicated space in the operating room, which covers the critical areas, including operating table and tables with the sterile instruments, in which the concentration of contamination (microbiological, gaseous and particulate) is controlled.

Differential pressure
Difference in air pressure between rooms.

Note: Specified in SI unit Pascal, Pa.

Dispersal chamber (ñBody-Boxò)
HEPA-filtered supply air test chamber with exhaust air in which the concentration of the total number of particles and bacteria-carrying particles from test subjects is measured in order to calculate the source strength.

Endogenous infection
Infection caused by patient's own bacteria.

Exogenous infection
Infection of the patient from other people or the surroundings.

Final filter
Air filter used to separate particles and microorganisms in the final filtration stage.

HEPA-filter
High Efficiency Particulate Air filter in accordance with SS-ISO 29463. As a rule, it is mounted as final filter.

Mixing airflow
Principle based on dilution of the contaminants by mixing the contaminated air with clean air, also called dilution mixing air or mixing air.

Non-unidirectional airflow
Air distribution where the supply air entering the clean room or clean zone mixes with the internal air by means of induction.

Operating room (Operating theatre)
Room, which is primarily intended for surgical operations.

Recovery time/cleanup period
The time it takes to reduce the concentration of airborne particles to one hundredth of the original concentration (100:1).

Safety ventilation
Safety ventilation is the interaction between air movements and the dispersion of contaminants in environments and the control of these environments, both regarding human safety and product or process safety/cleanliness.

Scrub suit
Working garment for operating room staff, made from materials that do not meet the requirements of EN 13795-2 for clean air suits.

Note: Scrub suit is not intended to prevent airborne dispersal from staff. Scrub suit is not a medical technical product.

Source strength
The average number of CFU or total number of particles released per second from one person wearing a specified clothing system.

Supply/Exhaust air devices
A device located in an opening provided at the boundaries of the treated space to ensure a predetermined motion of air in this space. Also, air terminal device.

Surgical operation
Surgical intervention which penetrates the skin or mucous membrane and is performed by an operating team.

Sweeping action of air
Transport of airborne contaminants by convective transport.

Total airflow
Outdoor airflow plus any circulation flow that is added to the room.

TAF
ñTemperature controlled airflowò - A specific Swedish room air distribution system with two temperature zones, where the temperature difference is kept constant.

UDF system
Unidirectional airflow system is a room air distribution system aiming to displace contaminants by the sweeping action of the air.

Note: In this thesis, UDF systems with an airflow velocity of <0.3 m/s are called low air velocity UDF systems and UDF systems with an airflow velocity of >0.4 m/s are called high air velocity UDF systems.

Unidirectional airflow
Controlled airflow through the entire cross-section of a cleanroom or a clean zone with a steady velocity and air streams that are considered to be parallel.

Note: Principle based on transport of contaminants out of the critical zone by the sweeping action of the air.

Ultraclean air
Operating room air cleanliness during ongoing surgery of less than 10 CFU/m^3 of air.

Visualization
Characterization of air movement by visualization, e.g. using smoke tests.

SYMBOLS

c	concentration of bacteria-carrying particles (CFU/m^3), total number of particles (number/m^3)
c_o	initial concentration; bacteria-carrying particles (CFU/m^3), total number of particles (number/m^3)
D	diffusion coefficient (m^2/s)
n	number of people (number)
N	air change rate (1/s also 1/h)
q	outward particle flow from point source (number/s)
q_l	outward particle flow per unit length from line source (number/(s, m))
q_s	source strength: mean value of the number of bacteria-carrying particles per second emitted from one person (CFU/s), mean value of the total number of particles emitted from one person (number/s)
Q	total air volume flow (m^3/s)
S	total source strength: bacteria-carrying particles (CFU/s), total number of particles (number/s)
t	time (s)
T	time constant (s, also min)
v_0	constant velocity in the x-direction (m/s)
V	volume of operating room (m^3)

1 INTRODUCTION

General

In 2016 the World Health Organization estimated that more than 300 million people underwent surgery in 2012 within the organizationôs 194 Member States. This was an increment of almost 40% from 2004, see Weiser et al. (2016). The surgical volume can be expected to continue to grow, particularly in very-low and low-expenditure Member States, according to the same report. In spite of all benefits that it represents for the patients in years of saved lives or improved life quality, one major drawback is the potential risk of surgical site infections. Such infections implicate a significant financial and capacity burden for the healthcare system and causes an unacceptable suffering for the patient, see e.g., Erichsen Andersson (2013) and Parvizi et al. (2017).

It is known since more than half a century that the microbiological air cleanliness in the operating room is fundamental for avoiding post-operative deep wound infections. This is especially relevant for infection prone surgery, such as procedures involving greater prosthesis like knee and total hip replacement. Such surgery requires specially designed room air distribution systems, preferably in combination with special clothing systems and controlled number of people present in the operating room during the surgical procedure.

Before World War II, most surgical procedures were performed in operating rooms ventilated naturally. After the war, mechanical ventilation was used to secure a microbiological clean and safe air environment. The development in prosthetic surgery combined with increased life expectancy has resulted in a substantial increment of infection-prone surgery.

Since the late 70s, it has been generally accepted that infection-prone surgery should be performed in rooms using unidirectional airflow, which is mandatory in some countries although not in Sweden. This rule of thumb has been challenged in recent studies, see Gastmeier et

al. (2012), which has led to the World Health Organization, WHO, showing some reservations on the benefits of using UDF systems for total arthroplasty surgery in ñNew recommendations on intraoperative measures for surgical site infection preventionò by Allegranzi et al. (2016).

Parvizi et al. (2017) comments on this unexpected reassessment of LAF/UDF ventilation stating that ñ*Although it appears that LAF may not be needed, the role of positive ventilation systems and the efforts to reduce the number of particulate matters in the OR cannot be questioned.***ò**

The purpose of this thesis is to discuss important points to consider from an engineerôs point of view when selecting room air distribution system for todayôs ultraclean air operating rooms.

This study is based mainly on the analysis of published scientific reports and other documentations. The focus lies on comparing the main principles for safety ventilation, mixing and displacement, applied in three different room air distribution systems available in Sweden today, and whether they can fulfill the Swedish requirements of microbiological air cleanliness during ongoing surgery.

The room air distribution systems that will be studied are:

- Mixing airflow, partly displacement
- Unidirectional airflow (UDF)
- ñTemperature controlled airflow, (TAF)ò - A specific Swedish room air distribution system.

The principle of mixing airflow is the most common in general building ventilation and even the most used in common operating rooms all over the world.

For decades, unidirectional flow (UDF) has been named laminar airflow (LAF), even though it is not strictly laminar not even in well-controlled environments, why the term UDF is internationally preferred. UDF room air distribution systems are today the first choice in operating rooms for orthopedic surgery.

The third distribution system in this study claims to be a hybrid of the two fundamental airflow concepts with two temperature zones.

The Design Process

The process of building a new surgery building or ward may differ slightly in different county councils and regions in Sweden. After the project has been decided, the main stages are, firstly to establish a Programme Plan thereafter a more specified System Plan and finally a Construction Plan. The task of selecting the room air distribution system is the subject of this thesis and is a part of the System Plan.

The Stockholm County Council, which supervises the healthcare services, is also the owner of the public company Locum, whose mission it is to build and manage healthcare buildings. Therefore, a task for the project managing group to select systems for room air distribution to the operating rooms is led by personnel from Locum and includes representatives from the affected healthcare wards.

In the operating room, the number of people staying during the surgery and the number of bacteria-carrying particles slipping through their garments is important to the calculation of necessary total air volume flow needed in order to meet the air cleanliness requirements during ongoing surgery. It is necessary that these two parameters, number of people, and grade of occlusiveness of their clothing system, are decided during the elaboration of the System Plan.

In its mission, Locum is expected to explain the advantages and disadvantages of the room air distribution systems for operating rooms, assisting the healthcare representatives in the project to select the best option out of several criteria, including space limitations (in reconstruction projects), type of surgery, flexibility requirements and also general cost analysis.

The authorôs role at Locum has been to answer questions from the project management group, which often means, specifically, explaining the differences between different room air distribution systems available on the Swedish markets.

Purpose

The purpose of this thesis is to gather background material of room air distribution systems for ultraclean air operating rooms and discuss critical parameters important when selecting such an air distribution system. The work should also assist the healthcare representatives and others in projects concerning ultraclean air operating rooms.

Delimitation

This thesis is limited to operating rooms with ultraclean air, defined as room air cleanliness during ongoing surgery of less than 10 aerobic bacteria-carrying particles (CFU) per cubic meter.

Comparing and ultimately choosing a room air distribution principle, and often a specific system for new operating rooms, consists of more than just the efficiency to ensure the microbiological air quality.

Project economy, life cycle cost, maintenance conditions and durability, flexibility for new surgery routines, work environment and energy efficiency area other important selection criteria that will not or only superficially be assessed in this work.

Structure

This thesis begins with definitions and a description of todays room air distributions systems followed by a literature survey. After that, the dispersion of airborne contaminants is explained by mathematical expressions. Previous studies of recent CFD simulations and an experimental study called "CHOPIN project"are discussed continued by some calculations on UDF-systems with low air velocties. The thesis ends with discussion and conclusion.

2 DESCRIPTION OF TODAYS ROOM AIR DISTRIBUTION SYSTEMS

2.1 Air Distribution Principles

There are two main airflow principles when choosing room air distribution system for operating rooms. One principle is based on dilution of the contaminants by non-unidirectional airflow and the other principle is based on displacement of contaminants by unidirectional airflow from a protected zone within the room to the periphery of the room. In the following, existing room air distribution systems for operating rooms on the Swedish market will be discussed.

For all room air distribution systems one commonality is that the supply air is HEPA-filtered and that the temperature is a few degrees lower than the room air temperature in order to stabilize the airflow pattern.

The contamination level, e.g., microbiological contamination from people, heat from equipment and particle contamination from surgical smoke, affects the air volume flow necessary to achieve a controlled cleanliness during ongoing surgery.

2.2 Mixing Airflow

Room air distribution systems using mixing airflow are designed and intended to dilute contaminated air with cleaner air to decrease and thereby control the level of contaminants in the air of the room. Supplying a room with mixing airflow to reach an accepted contamination level at steady state (during activity) is the most common method. Low air volume flow systems often distribute around 0.6-0.7 m^3/s and have no recirculation of air. These room air distribution systems are used in most of the rooms in hospitals including operating rooms for common surgery, i.e., with lower level of air cleanliness (Ò50 CFU/m^3) than the operation rooms for infection

prone surgery (Ò10 CFU/m^3). High air volume flow systems often distribute 2 m^3/s or more and a major part of the air is recirculated trough HEPA-filters.

To reach total mixing in every part of the room, although it is almost impossible to achieve, it is in practice enough to accomplish dilution to a predetermined cleanliness level in critical zones, provided that it is achieved within a specified time. Critical zones are usually the surgical site area and all instrument tables.

Low air volume flow systems

For decades, mixing airflow for operating rooms has been achieved with many different designs regarding the location of the inlet air devices. Two common versions are the symmetrically located inlet air devices in the ceiling and the inclined screen along the ceiling/wall angle at one side of the room, see Figures 2.1 and 2.2.

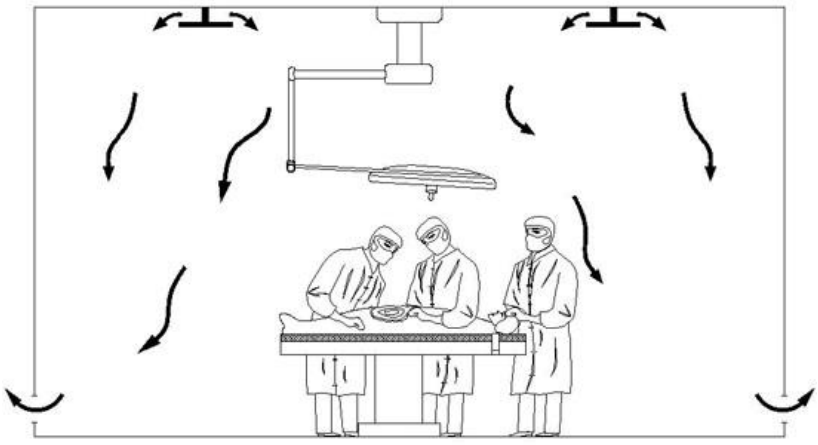


Figure 2.1 Room air distribution system with mixing air and its idealized airflow pattern. (Retrieved from Nilsson (2002)).

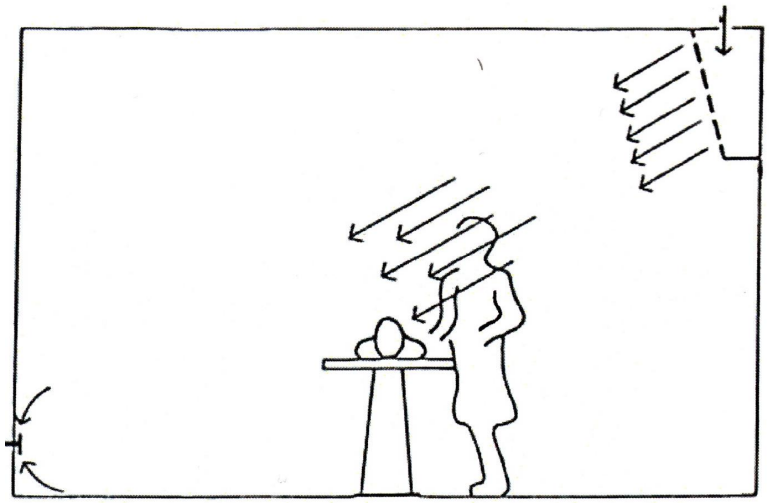


Figure 2.2 Idealized airflow pattern using the one-side inclined inlet air screen design. (From Ljungqvist and Reinmüller (2013)).

The symmetrically located inlet air devices in the ceiling are intended to generate a vertical downward turbulent pattern, while the inclined screen is intended to generate a main airflow pattern moving diagonally across the room, see Ljungqvist and Öhlund (1983).

These two solutions have traditionally been dimensioned for supply airflows related to the number of the room volume air changes per hour which has resulted in airflow volumes from around 0.6 m^3/s up to 1 m^3/s, (600-1000 l/s) based on Ó17 ach.

High air volume flow systems

The first operating rooms using a mixing air system with high air volume flow (Ó1.5 m^3/s) and circulation air have recently been built in Stockholmôs hospital, the New Karolinska Solna (NKS). Similar systems are now being built in other hospitals in Sweden. In these rooms, the inlet air devices are ceiling-mounted in a square shape above the surgical site. Each device has several rows of nozzles pointing obliquely downwards and can be rotated in order to tune the direction of the airflow for the best mixing effect, see Figure 2.3.

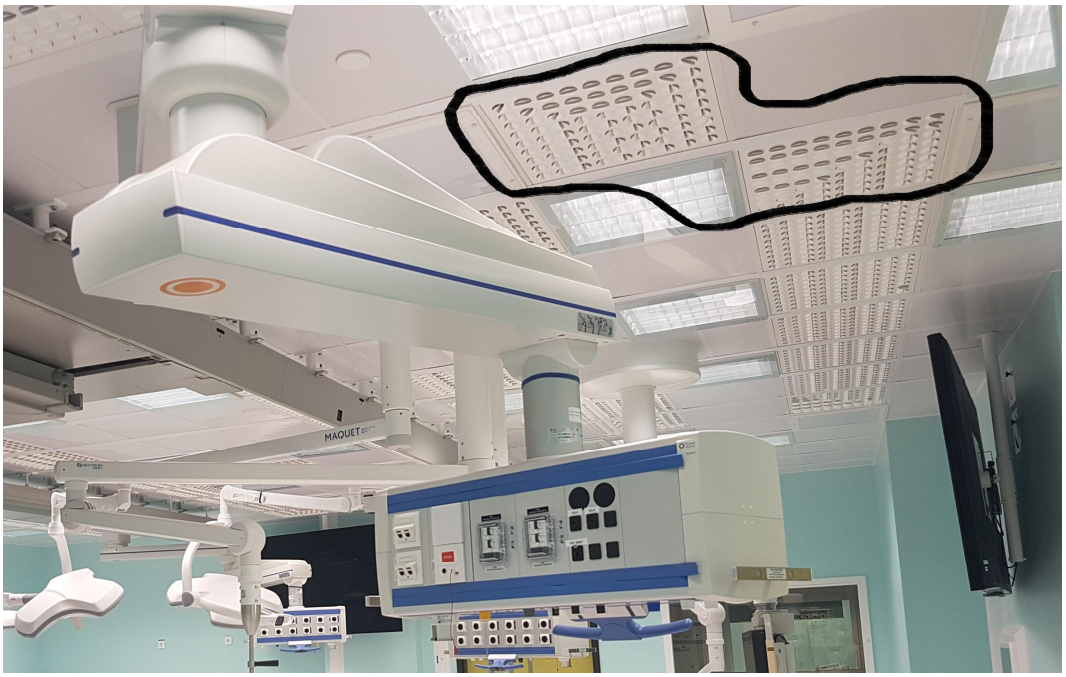


Figure 2.3 A mixing air system at the NKS-hospital. Note that the direction of the supply air nozzles can be readjusted (Photo: J. Nordenadler).

2.3 Unidirectional Airflow UDF

Using the concept of protecting the critical areas by sweeping away airborne contaminants, sweeping action by HEPA-filtered air, the basic parameter is the supply airflow velocity. One basic difference from mixing room air distribution systems is that UDF-based distribution systems for operating rooms are considered as two-zone solutions. Here, three types of UDF can be distinguished, viz. high velocity systems with sweeping action of the air and a uniform air velocity of 0.4 m/s to 0.5 m/s, systems with varying air velocities over the distribution surface, and systems with uniform low velocity <0.3 m/s.

UDF distribution systems are often grouped according to air velocity (high and low air velocity). However, the same grouping related to air volume flow as in part 2.2. Mixing Aiflow can also be applied to UDF distribution systems (low and high air volume flow).

In operating rooms that apply unidirectional airflow, there are two main alternatives for the geometry of the inlet air direction, viz. either horizontal or vertical. In both cases, the challenge for the inlet air is to, undisturbed, reach the surgical site area and instrument tables, and overcome buoyancy from heat sources, disturbance from objects in the airflow and movements of the staff, with retained protecting efficacy.

High air velocity UDF systems

The UDF zones had long sidewalls in the 70s, but, in order to enhance the surgery process, the full room height walls surrounding the surgical site were reduced to partial height walls about 700 mm high hanging from the ceiling around the inlet air device. The air velocity was around 0.45 m/s and the air volume flow was mostly in the range of 4-5 m^3/s. In Sweden, this kind of solution is still available on the market and can be found in older operating rooms.

Varied air velocity UDF systems

One version of varied air velocity system by Howorth (1985), was marketed as Exflow because the theoretical airflow pattern resembles the shape of an exponential function, see Figure 2.4.

In the mid-70s there was also wall-free variants available. Such solutions are still on the market. Such a wall-free solution was the Allander air curtain system, named after its Swedish inventor, see Abel and Allander (1966). In this concept the material sidewalls were replaced by a continuous curtain-shaped airflow around the central airflow from the supply air device, see Figure 2.5.

There are nowadays other UDF-systems on the market with variable inlet air velocity.

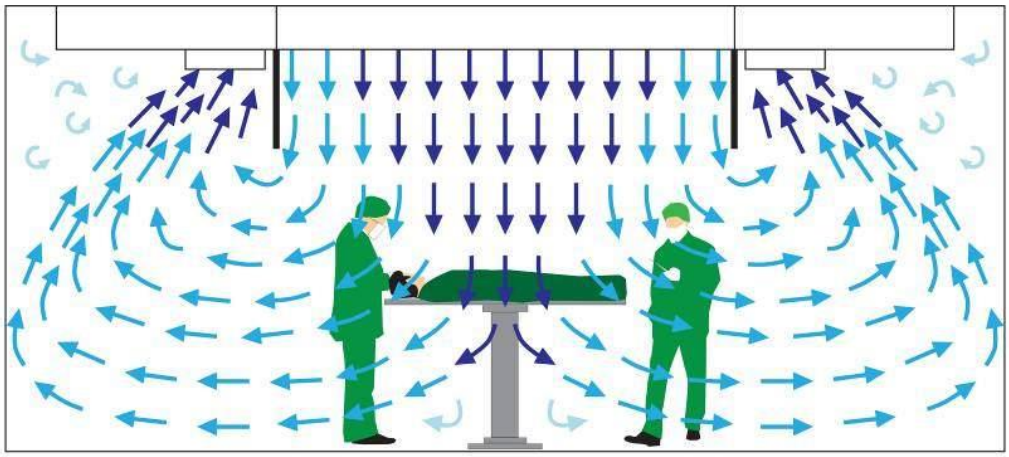


Figure 2.4 The Exflow UDF-ceiling with short walls controlling the airflow near the supply air diffusers.(Retrieved from howorthgroup.com).

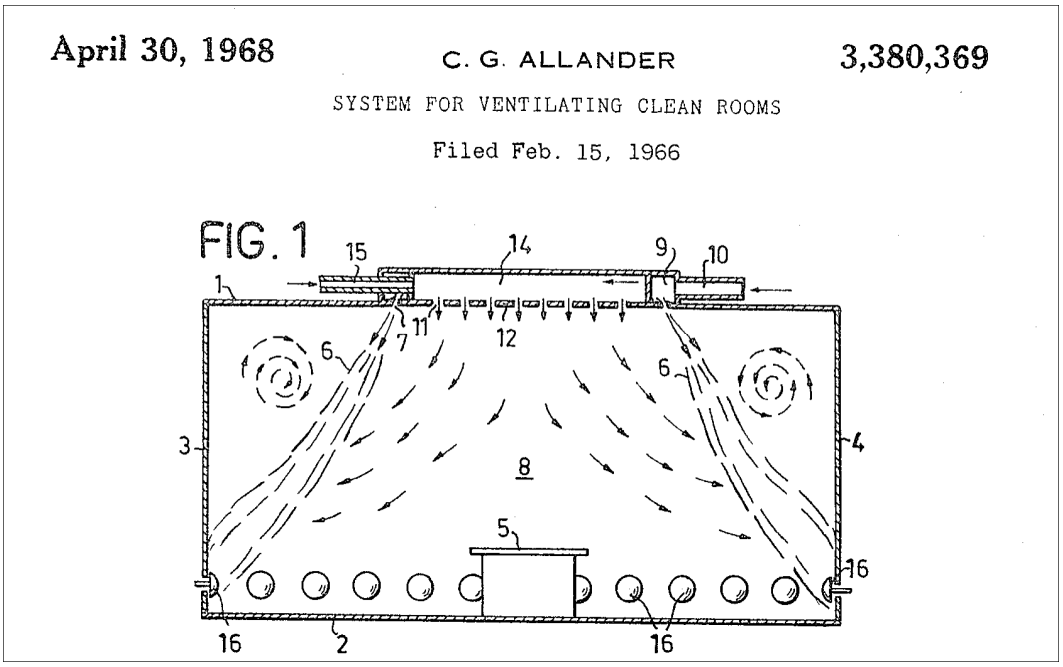


Figure 2.5 Detail from Allanderõs application for US-Patent 3380369 with the air curtains on (6). Note that, the operating room was seen as a ñclean roomò at that time. (Retrieved from google.com/patents).

Low air velocity UDF systems

Many UDF systems are built with HEPA-filtered supply air diffuser covering an area of about 10 m^2 in the middle of the room. In Sweden, the supply airflow velocity is usually at least 0.25 m/s, which means that the air volume flow is approximately 2.5 m^3/s. UDF-ceilings with larger filter areas give conditions for supply of larger air volume flows, and are used in so called intervention or hybrid rooms. This type of UDF systems is not discussed here.

Low air supply velocities are usually combined with low supply air temperature.

This design of the room air distribution system will theoretically result in a central zone of the room supplied with HEPA-filtered UDF airflow and a surrounding zone supplied by the airflow from the critical areas with an uncontrolled mixing airflow of expected more contaminated air during activity, see Figures 2.6 and 2.7.

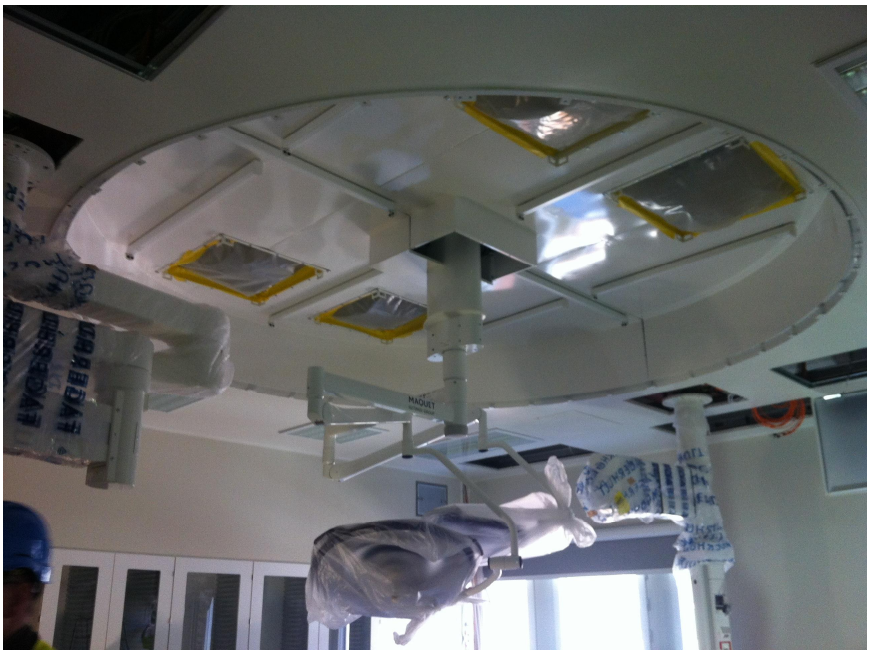


Figure 2.6 Contemporary UDF-ceiling without sidewalls, under construction at Kalmar hospital, in Sweden. (Photo: P. Gandra).

Figure 2.7 UDF ceiling as in Figure 2.6 completed with final HEPA-filters and diffuser. Circular shape is often preferred in Sweden for UDF-ceilings corresponding to a circular critical zone, marked on the floor. (Photo: P. Gandra).

2.4 Other Systems

In the following, two different designs are described based on combining two principles for room air distribution.

The ñTAFò design

Today, in Sweden, there is one hybrid system delivered by one single manufacturer. This solution intends to create two different temperature zones in the room, for the surgery and the anesthesiology team respectively, as they traditionally prefer different temperatures in their work environment. Surgeons, especially in procedures with high physical activity or warmer attire, prefer an air temperature <20^{o}C, preferably 18^{o}C. In contrast, the anesthetic team prefers a temperature >20^{o}C, as they wear light clothing and stays relatively still during most of the surgical procedure.

Technically, the inlet air is supplied by one fan using one duct divided in two branches at the end, with the branch supplying the surgical site

fitted with a cooling battery. In this system, the inlet air devices are designed as half spheres and located in the ceiling evenly over the room configured in two groups. One group is in a ring above the surgical site and supplies this site with cooled air, intended to flow in a parallel pattern vertically driven by the combination of fan energy and gravity. The other inlet air devices are evenly distributed above the periphery supplying that zone with warmer airflows.

Figure 2.8 shows an operating room equipped with the ñTAFò-room air distribution system.

Figure 2.8 The hybrid ***ñ****TAF****ò****-system has a central zone with cooler displacing airflow and a peripheral zone (the rest of the room) with warmer mixing air supply. (Retrieved from avidicare.com).*

It should be noted that this design does not allow the HEPA-filters to be mounted as final filters that the standard ISO 14644-3 (2005) requires. This increases substantially the demands on duct tightness after the fan.

In this solution, the inlet air temperature is kept around 2 degrees below the air temperature in the periphery of the room, i.e., 19^{o}C in the surgical site and 21^{o}C in the periphery. This room air distribution system is therefore marketed as ñTemperature controlled airflow, TAF.ò The special feature of this system is claimed to be that the temperature difference between the two zones is kept constant. The ñTAFò system for operating rooms is relatively new on the market and has therefore been described in a limited number of papers.

The vertical upward displacement system

By displacement ventilation, it is commonly meant downwards unidirectional-airflow room distribution systems, as described in part 2.3. However, mainly in Sweden, there is an earlier system, branded as Floormaster, invented around 1980 by a Swedish company. The system can still be found in some operating rooms, see Erichsen-Andersson et al. (2014). The ventilation principle is based on supplying the air impulse free at low temperature, close to floor level. This cold air, being heavier than the room air, will initially spread along the floor, building up a stratum of clean air from the floor and upwards. As this air warms up by the heat load in the room, the inlet air will rise towards the ceiling, carrying and diluting the contaminants on its way up to the exhaust devices.

This concept and its idealized airflow pattern can be schematically seen in Figure 2.9.

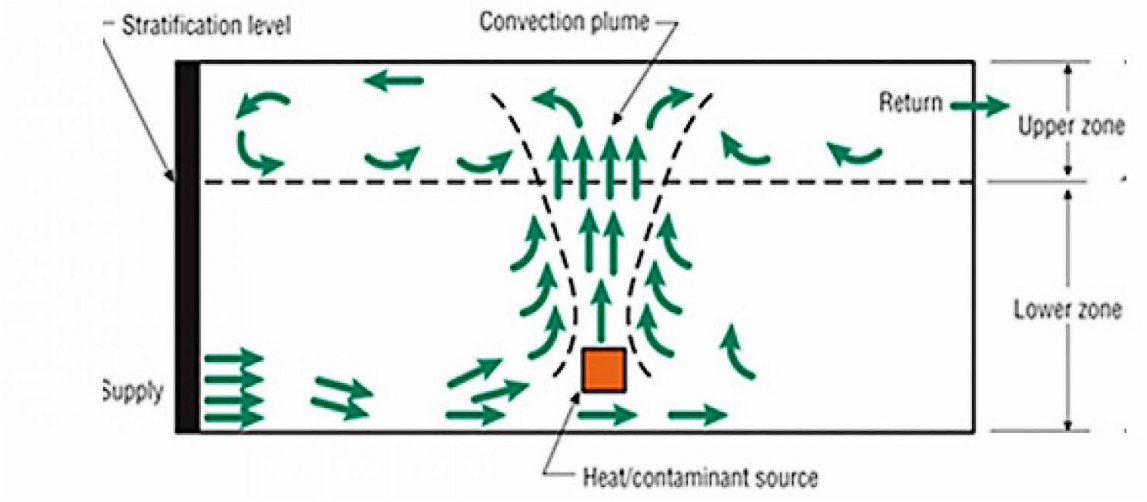


Figure 2.9 Theoretical airflow patterns with vertical upwards displacement distribution system. (Retrieved from Costello, 2013).

Hillerbrant and Ljungqvist (1990), performed full-scale tracer gas tests in operating rooms with room air distribution systems with total mixing airflow, inclined screen, (1900 m^3/h, 16 ach), and displacement airflow (2000 m^3/h, 17 ach). A comparison between the two room air distribution systems showed that no decisive difference could be noted from a contamination standpoint, when persons are moving in the operating room.

Friberg et al. (1996, 1998), describe measurements of bacteria-carrying particles during standardized simulated operations in the same two operating rooms used by Hillerbrant and Ljungqvist (1990). The room air distribution system with displacement airflow resulted in a two- to three-fold increase in the wound area and on the instrument table in the number of airborne bacteria-carrying particles and of surface counts, compared to the conventional system with mixing airflow.

Today, in Sweden, the room air distribution system with this kind of displacement airflow is not commonly chosen for new operating rooms but is still in use in some hospitals.

3 PREVIOUS STUDIES

3.1 Room Air Distribution Systems

It was mainly after the World War II that mechanical ventilation for infection control during operations was introduced, see e.g. Ljungqvist and Reinmüller (2013), and Whyte (2015a, 2015b).

Bourdillon and Colebrook (1946) were probably the first to recognize the importance of supplying the operating room with, "copious amounts of filtered airò, but also to create a positive pressure in the room in order to prevent contaminated air to be sucked in from outside.

Lowbury (1954) had shown that burns dressed in rooms with positive-pressure and plenum ventilation, suffered less frequently from sepsis compared with rooms without such ventilation. Therefore, he recommended the use of positive-pressure ventilation with filtered air to be extended ñto operating theatres and shock rooms.ò

At this time, the first exhausting fans were mounted in the outer wall creating negative pressure in the operating room, thus deteriorating the air quality instead of enhancing it. Shooter et al. (1956) measured as much as 1400 CFU/m^3 in a negative-pressurized operating room!

Concerning the air volume flow needed for sufficient protection of the patient, Bourdillon and Colebrook (1946) suggested early a minimum of 10, but rather 20-30 air changes per hour and a minimum of 5 minutes recovery time between operations. The recovery time (10:1) of 5 minutes indicates an air change rate of about 30 ach for a common room size of that time.

By the early 1960s, the mixing principle was well known and the basic principle was used for room air distribution systems by mechanical ventilation during surgery.

The first attempts to compare differently designed room air distribution systems were made by Blowers and Crew (1960). By this time, there were still operating rooms in the UK ventilated by exhaust ventilation and not all rooms were ventilated by over-pressurized (plenum) ventilation that would perform acceptably well.

In a comprehensive and thorough combined experimental and field study, Blowers and Crew (1960) established a proportional relation between the supply airflow and the reduction of the mean level of contaminants in the room. Comparing ñturbulent and downward-displacement ventilationò over the whole room, they stated that, among other aspects, the operating room ñshould be pressurized by a flow of filtered airò and besides that, ñall openings between the rooms of an operating-suite should be fitted with doors.ò At this time, operating rooms (often called theatres) consisted of several rooms with open communication in between, used for several functions like sterilization, scrub, anesthetic room, and sink room.

Comparing mixing ventilation with displacement ventilation, they wrote:
ñ*If a displacement system using the convenient ceiling diffusers is used, there is little advantage in exceeding a ventilation rate of 1200 cu.ft./min (equal to 17-20 ach) for the main room.****ò***

This corresponds to about 2000 m^3/h in a 6mx6mx2.7m room. It is noteworthy that these values, 2000 m^3/h and 17-20 ach, are still used as guidelines for operating rooms in many countries, although in different contexts.

Starting in the early 60s and through all that decade, John Charnley, an innovative British orthopedic surgeon, devoted himself to the mission of lowering the rate of surgical site infections by airborne contamination. Trough more than ten years of extensive research with measurements including 5,800 total hip replacements, he succeeded to reduce the rate of postoperative wound infection from around 8% to less than 1% without using prophylactic antibiotics, see Charnley (1972).

Todayôs knowledge of how to achieve sufficient air cleanliness during infection-prone surgery was developed in particular by his historical

enhancement of hip arthroplasty. In Charley's last published words the year he died, he wrote:
ñ*If postoperative infection continues at a level 1%-5% there are grounds for believing that this operation can be justified only for elderly and grossly disabled patients*;ò see Lidwell, (1993).

With the assistance of Hugh Howorth, an air engineer, Charnley enhanced the room air distribution system in several steps, achieving eventually substantial improvements, see Whyte (2015a, 2015b). These improvements will be described later in this work.

Another important study comparing different ventilating systems for operating rooms was made by Lidwell et al. (1967). In their project ñ*ventilation equipment was installed in one of the twin operating rooms in the suit so that it was possible to select, from within the operating room itself, any of three alternative systems of air supply*.ò

Available room air distribution systems in that study were:

- Downward displacement, trough six diffusers
- Moderate velocity turbulence (0.13 m/s, 0.66 m^3/s)
- Low velocity turbulence, the air being introduced vertically downward trough three large grilles along one side of the ceiling.

No significant differences could be detected between the three ventilating systems regarding the contaminant levels. What could be seen was, instead, a variation of those levels when varying the supply air volume flow.

Despite the extensive research by Charnley (1972) and several others, mainly British researchers during the 60s, ten years later, in late 70s, there was still skepticism about the importance of operating room ventilation combined with occlusive garments to avoiding surgical wound infections. This motivated the implementation of a large multicenter study in 19 surgery centers, 15 in the U.K. and in 4 in Sweden (Huddinge, Lund, Malmö and Uppsala), see Lowbury and Lidwell, (1978). Several types of ñultraclean air systemsò were included: Five hospitals used the Charnley system (three ñgreenhousesò and two downflow UDF without walls), three had horizontal UDF airflow distribution systems and another three had

Allander's óair curtainsô combined with body-exhaust-ventilated operation suits (the same as in the ógreenhouseô). Three of the hospitals used a so-called Trexler isolator system, that is not a room air distribution system but an isolator where the surgeon operates through glove ports, see Lowbury and Lidwell, (1978).

The first report of the results from that so far, largest study ever made, with over 8000 total hip or knee replacements, was published by Lidwell et al. (1982), and Lidwell (1983), with the conclusion that: ñ*These results are strong evidence that ultraclean air in operating rooms reduces the incidence of deep sepsis after total joint-replacement operations and that this reduction is enhanced when the operating teams wear whole-body exhaust suits.*ò

Thus, this study confirmed the results by Charnley that there is a correlation between the rate of postoperative infections and the number of aerobic bacteria in the room air during surgery.

The unidirectional airflow system was invented in the early 1960s and described by Whitfield (1967), becoming generally adopted as a standard solution in the more cleanliness-demanding industrial cleanrooms. From the 70s, this room air distribution system has also been considered a safe system for infection-prone surgery. This system was called ñlaminar airflow ventilationò, LAF, although it was not ñlaminarò scientifically speaking but rather ñunidirectionalò or ñparallelò by its airflow pattern.

Surgery rooms with UDF systems started to be built during the 70s. In Sweden, surgery wards often included a few operation rooms with a UDF system for infection prone operations, i.e., surgery processes demanding so-called ultra-clean air, i.e.,<10 CFU/m^3. Later, many studies concluded that such type of room air distribution system provided lower CFU levels than the corresponding systems based on dilution mixing airflow.

Mixing air systems for common, sometimes called ñgeneral surgeryò and UDF systems for infection-prone surgery were thus seen as standard solutions until Nordenadler (2010) in his doctoral thesis showed that UDF systems installed in several hospitals in Sweden occasionally act by mixing rather than displacement at times during ongoing surgery. The reason was that many UDF ceilings had low

inlet air velocity (<0.3m/s) and, therefore, the airflow pattern was easily disturbed by common circumstances during the surgical process. However, even with that disturbed unidirectional airflow pattern, the systems were able to achieve low rates of airborne bacteria at the surgical site.

These observations led to the conclusion that the air volume flow rate delivered from a UDF ceiling at $<3 m^3/s$ is enough for decreasing the level of airborne contaminants to an acceptable level even without the displacement effect but instead with the mixing dilution effect.

Recently, epidemiological and multi-center studies, see Allegranzi et al. (2016) and Bishoff et al. (2017), show a certain skepticism about the advantages of using UDF-based air distribution systems. Allegranzi et al. (2016) describe the new WHO recommendations and write:
"*Meta-analyses showed that laminar air flow ventilation has no benefit compared with conventional ventilation in reducing the SSI incidence in total hip or knee arthroplasty. The quality of evidence was rated as very low. Considering these results and associated costs, the experts panel decided to suggest that laminar airflow ventilation systems should not be used as a preventive measure to reduce the risk of SSI in patients undergoing total arthroplasty surgery*."

3.2 Microbiological Requirements

Between microorganisms and disease the connection was established by Robert Koch in 1876, see Lidwell (1987). Robert Lister, a contemporary surgeon considered to be the ñfatherò of antiseptic surgery, was well aware of the importance of protecting the surgery wound from contamination causing infections, see Lister (1890).

Lister therefore introduced several routines for an aseptic process during surgery like sterilizing the instruments and mandatory hand wash with ñcarbolic acid,ò i.e., phenol, before and after the procedure, see Lister (1890). The results of using this strong antiseptic were so encouraging that he designed a device that sprayed phenol over the incision, see Figure 3.1.

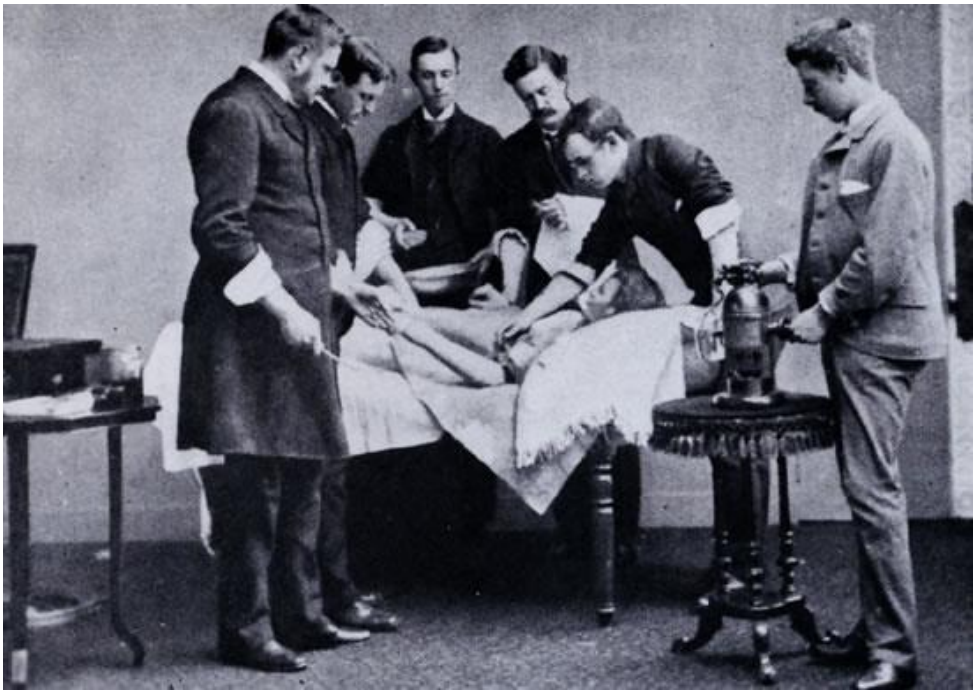


Figure 3.1 Listerôs antiseptic spray being used during surgery at Aberdeen about 1880. (Retrieved from ScienceDirect).

However, to the teamôs health this routine was detrimental, which is why Lister, in 1887, ended its use and wrote later:
ñ*As regards the spray, I feel ashamed that I should have ever recommended it for purpose of destroying the microbes of the air*ò.

Noteworthy, in the same article, Lister confesses that he, for some time, believed the spray to be efficient and with ñan atmosphere free from living organismsò he could even omit ñvarious other precautionsò which he previously had supposed to be ñessential,ò see Lister (1890).

At this time, the concern of infection source focused mainly on endogenous infection, i.e., infection caused by the patientôs own bacteria and therefore the struggle to convince old-school surgeons about the advantages of aseptic procedures in surgery.

With the invention in 1941 of the Casella air sampler by Bourdillon et al. (1941), there was as a practical basic tool available for measuring and assessing microbiological air quality during surgery. After 1945 mechanical ventilation for infection control started to be used in operating rooms.

With the Casella air sampler, Bourdillon and Colebrook (1946) were able to show that the source of bacteria found in the patientsô wounds originated from the skin of a staff member who had not been in direct contact with the patient. Thus, they concluded that microbes in the room air can cause post-surgery infections and that a substantial reduction of such infections could be achieved by room air distribution systems with ña supply of fairly filtered air equal to 10 changes per hourò but added that ñan air-supply of 20 to 30 changes per hour is considered preferable, where practicable.ò

Blair and Williams (1961) discovered a significant tool for the start of modern investigation in this field viz. ñphage typing,ò a method of identifying bacteria species. With this method, it could now be established that surgical wound infection can be caused by microbes not only from the patient (endogenous infection), but also from an external source, i.e., microscopic contaminants in the room air (exogenous infection). Endogenous infection is usually controlled by conventional routines and is especially relevant when the incision is in non-sterile parts of the body, e.g. the abdomen.

When operating in sterile tissue and especially when introducing larger prosthetics made of body-foreign materials, the infection source is predominantly exogenous, mostly the room air: ñThe need to investigate the airborne route as a source of surgical infections was

prompted by certain experiences when using massive prosthetic implants in the hip-joint,ò see Charnley (1964).

Lidwell et al. (1982) reported in the early 1980s after the multicenter study, there was a need to set limit values for airborne contamination in operating rooms. Based on their findings, Whyte et al. (1983) wrote: ñThe results suggest that a substantial benefit can be obtained if the average concentration of airborne bacteria-carrying particles at the wound does not exceed 10 m^{-3} (i.e. 10 CFU/m^3), and that a great benefit will result from even cleaner air (down to 1 m^{-3} or less).ò Still today, Ò100 CFU/m^3 and Ò10 CFU/m^3 are the worldwide-accepted safe levels for common surgery and infection-prone surgery, respectively.

The Swedish Standard Institute, SIS, provides a Technical Specification, SIS-TS39 (2015), with the English title ñMicrobiological cleanliness in the operating room ï Preventing airborne contamination- Guidance and fundamental requirementsò. It was first published 2012 and revised 2015 and it recommends that for infection-prone surgery the CFU-level of the room air in the surgical site should be less than 10 CFU/m^3. Due to inevitable variation in CFU-level during the surgical procedure, the document recommends the airflow volume to be dimensioned assuming mixing air movements as the ruling principle and aiming for a level of 5 CFU/m^3 combined with the use of clean air suites and a limited number of people in the room, except the patient.

SIS-TS39 (2015) also give guidance on locations for CFU measurements during ongoing surgery and the choice of microbiological air sampling equipment.

Equivalent level for less infection-prone surgery, in SIS-TS39 called ñother surgery,ò is 50 CFU/m^3.

This document is now seen generally in Sweden as an informal standard for operating rooms in public hospitals. However, when included in a building project contract, it becomes a formal requirement.

3.3 Surgical Clothing Systems

In Listerôs (1867) classical work ñOn the Antiseptic Principle in the Practice of Surgeryò, the question of surgery clothing for infection control is not mentioned at all. At this time surgeons used common street clothing, normally not even washed between the operations. In 1890, in his updating article "The present position of antiseptic surgery," this question is still not mentioned although the medical products company Johnson & Jonson published 1888 a booklet entitled, "Modern methods of Antiseptic Wound Treatment." where they recommended that ñThe operator and assistants should wear a clean white coat or apron.ò under the part Important General Directions and Precautions, see Gurowitz (2011).

Figure 3.2 shows the lack of common surgery attire before the principles of aseptic procedures were understood and applied in surgery and Figure 3.3 shows some enhancement of aseptic precautions some years later. The lack of gloves and masks suggests that the concern was more about protecting the surgeon than the patient.

In the beginning of the 20th century, we can see that masks (and gloves) had been introduced in the attire for surgery for almost the whole staff, see Figure 3.4.

Figure 3.2 Orthopedic surgery about 1880. (Retrieved from Gurowitz, (2011)).

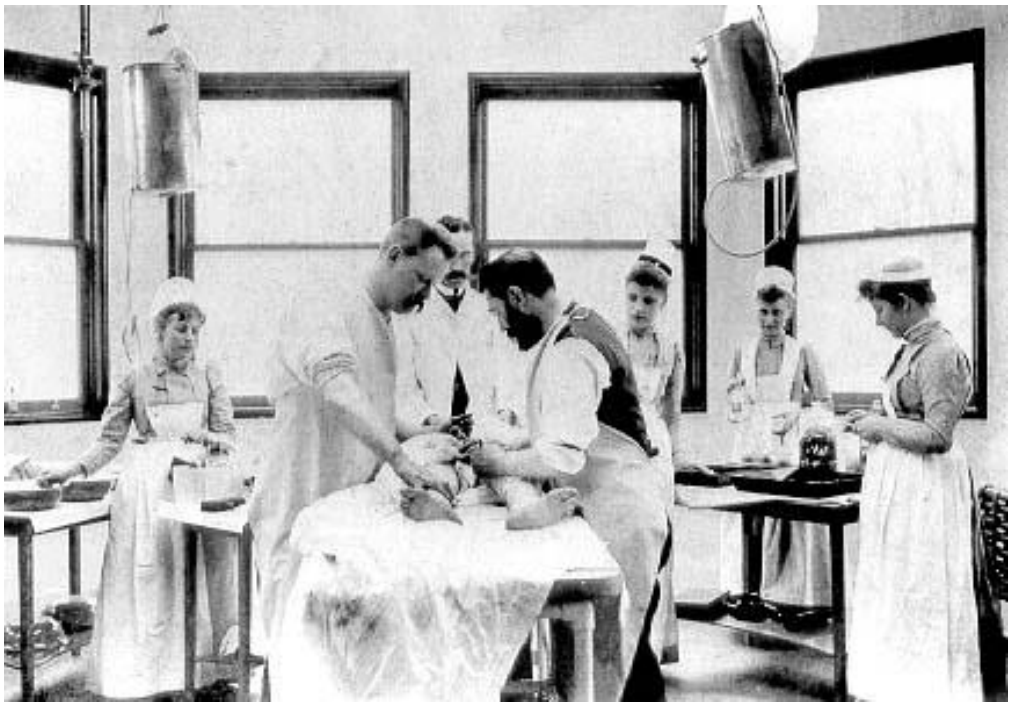


Figure 3.3 Orthopedic surgery in mid-1890s. (Retrieved from rochesterregional.org).

Figure 3.4 Surgery clothing 1922, now including mask and gloves with exception of the anesthesiologist, Washington. (Retrieved from Library of Congress Prints and Photographs Division Washington, D.C.ôs website).

In an unconventional study of the historical use of operating room attire by Adams et al. (2016), based on the systematic analysis of a large number of photographs a suggestion of timeline is as follows:

For surgeons, gowns were consistently worn during surgery from 1901, caps from 1930, masks and gloves from 1937. Anaesthesia providersô timeline lagged beginning with 1919 for gowns, 1948 for caps and 1957 for masks. Despite the studyôs substantial limitations, it gives a good idea of fundamental aspects of the evolution of important parts of intraoperative measures to avoid surgical site contamination.

One of the earliest studies concerning the effect of surgical gowns for controlling the emission of bacteria-carrying skin scales was done in the end of 1940s by Duguid and Wallace (1948). Using a slit sampler in a specially constructed chamber they concluded that:

ñ*Air contamination with dust-borne bacteria from clothing was reduced only a little ï e.g. to about a half ï when a sterile loose cotton gown of the surgical pattern was worn over the ordinary clothing, but it was reduced very greatly ï e.g. to a tenth or a twentieth ï when a sterile dust-proof gown was worn.ò*

Also, Charnley was a pioneer in this field. After his successful attempts to reduce the contaminant rate in the room air by mainly displacement ventilation, he started to look at creating a barrier around each emission source, i.e., each staff member, by increasingly occlusive clothing systems. According to Lidwell (1993), Charnley made the first attempts to work in tightly woven fabrics. Eventually, he created a mechanically ventilated (exhausted) whole-body impervious suit, called ñbody exhaust systemò which routinely was introduced in the end of the 70s for infection prone surgery, see Charnley (1972).

Figure 3.5 shows Charnley and his co-surgeons operating inside a clean-air operating enclosure wearing body exhaust suits. Figure 3.6 shows two drawings of Charnleyôs body exhaust suit.

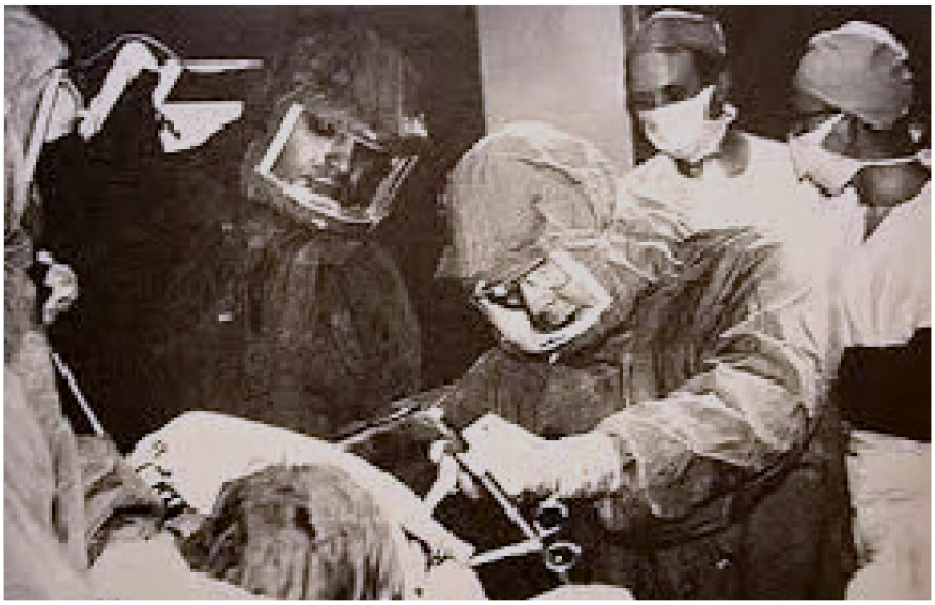


Figure 3.5 Orthopedic surgery with John Charnley wearing his body- exhaust suit (Retrieved from johncharnleytrust.org).

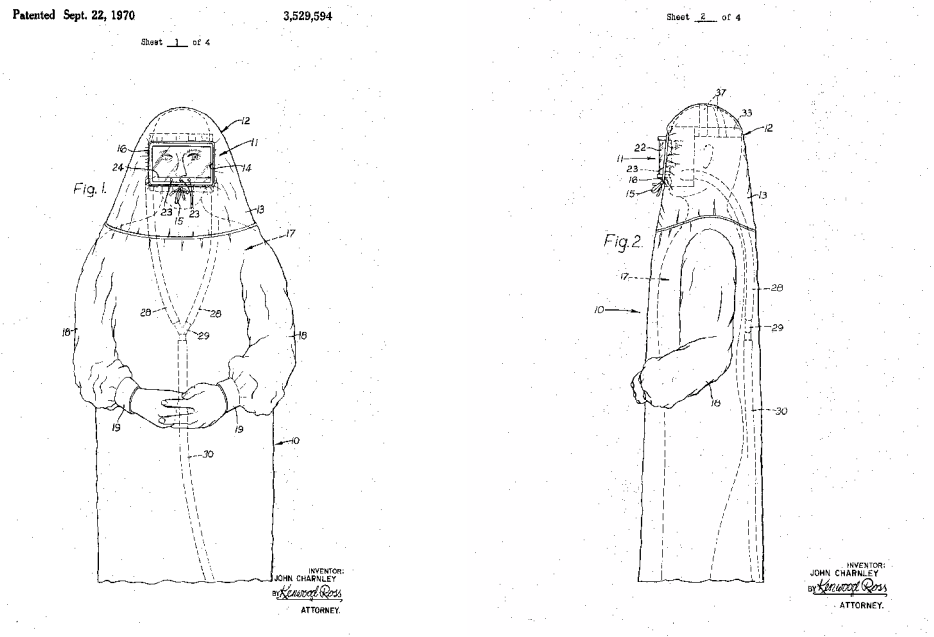


Figure 3.6 Detail from Charnleyôs US-patent application concerning the exhaust ventilated body suit 1970. (Retrieved from google.com/patents).

This concept was later completed with the helmet and landed in an exhaust ventilated whole body suit with expected total barrier effect on air contaminants from the staffsô body.

The conclusion was that combining his room air distribution solution in his special clean-air operating enclosure, the infection rate decreased from 1.5% to less than 1%, (Charnley 1972). Although sturdy and not very comfortable, this kind of ñspace suitsò were still used locally in Sweden in the eve of the 80s, see SPRI report 71 (1981).

Charnley-type body exhaust suits are still used in some countries and in a recent systematic review by Young et al. (2016), ñSurgical Helmet Systemsò and ñBody Exhaust Suitsò were compared. The Body Exhaust Suits were reported, in contrast to Surgical Helmet Systems, to be effective in reducing infection rates in arthroplasty.

Figure 3.7 shows one of todayôs models of body exhaust suit being tested before an operation of a presumptively infectious tuberculosis patient in Stockholm 2017.

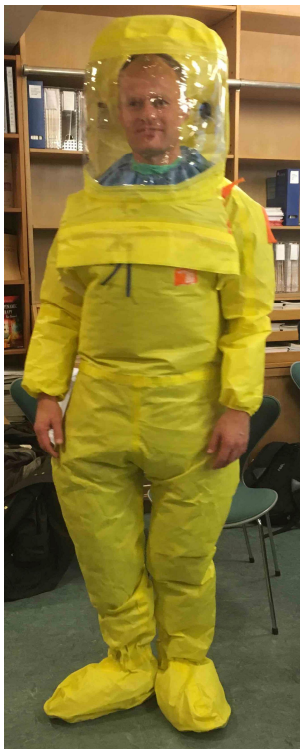


Figure 3.7 *Testing a body-exhaust-suit before being used for a contagious patient. Ventilation is provided by two HEPA-filtered small fans mounted on the backside and can be reused after disinfection. The suit is disposable. (Photo: P. Gandra).*

Earlier clothing systems for surgery were made of cotton fabrics like common healthcare clothing. Today, the most common surgical clothing systems in Sweden consists of a mix of cotton and synthetic fibers, commonly polyester, with 1% of carbon fiber to avoid electrostatic discharge.

In industrial cleanrooms, it was early decided that fabric made of cotton or mixed cotton and synthetic fiber should not be used in environments of high cleanliness. Firstly, because it was difficult to achieve sufficient tightness and secondly, because cotton fibers would partially fall out after laundry, decreasing the required level of occlusiveness.

The combined filtration efficacy of fabric, construction and design of the clothing, can be evaluated in a dispersal chamber or ñBody-Box,ò Such Body-Boxes have been used for studying cleanroom garment protection efficiency by, e.g., Whyte et al. (1976), Hoborn (1981),

Whyte and Bailey (1985), Ljungqvist and Reinmüller (2004, 2013, 2016), Whyte and Hejab (2007) and Romano et al (2016).

The Body-Box is still a reliable method for comparing the efficacy of different clothing systems. The evaluation is based on sampling of airborne particles in the exhaust air. The particles being emitted by a test subject wearing the clothing system to be evaluated and performing standard movements inside the test chamber. The aerobic bacteria carried by those particles are collected on an agar media, incubated, and counted. From the mean concentration of CFU/m^3 the source strength can be calculated. The source strength value can be used for comparison among clothing systems tested identically. The average number of bacteria-carrying particles released per second from one person wearing a specified clothing system is called source strength.

Figure 3.8 illustrates the principle of a dispersal chamber, ñBody-Boxò designed by Ljungqvist and Reinmüller, (2004).

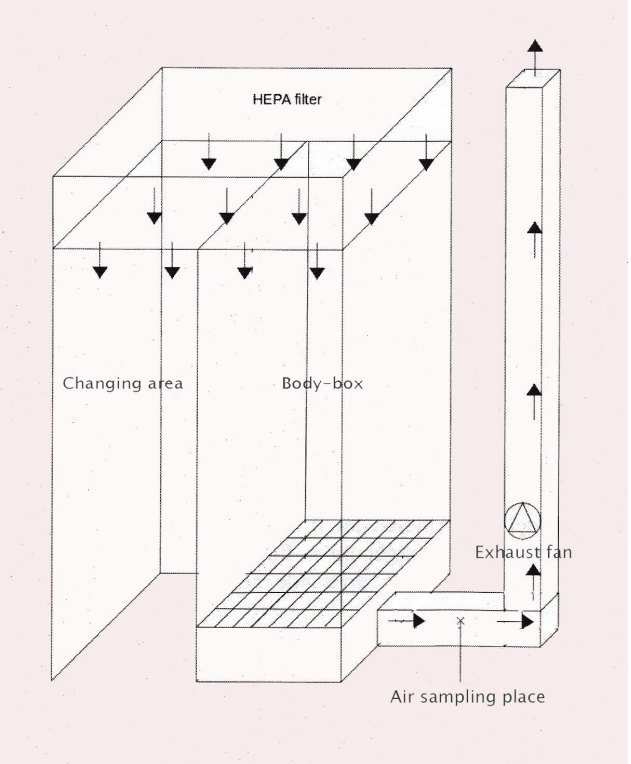


Figure 3.8 Principle of a dispersal chamber, óBody-Boxô, designed by Ljungqvist and Reinmüller, used for measuring the source strength of a test person wearing a clothing system (drawing by Hallberg Borgqvist, 2010).

Comprehensive research and measurements of the average emission rate of bacteria-carrying particles from the test person, the source strength, have been extensively performed by Ljungqvist, et al.(2004, 2011, 2013, 2014, 2015, 2016).

In those studies, it has been shown that the source strength varies both between individuals and occasions. Knowing the total airflow of clean air supply, the source strength value can be used for estimation of the expected mean concentration of aerobic bacteria in a room air at steady-state, depending on the number of persons in the room and the used clothing system.

Another parameter in this context is the physical activity level, as the emission of shedded skin flakes increases with increasing body movements. As shown by Ullmann, et al. (2017), during ongoing orthopedic surgery, the source strength in a procedure with low staff activity can be approximately a quarter of the value of the source strength measured in the dispersal chamber. Comparing the dispersal chamber values from the same clothing system with the measured mean source strength from the surgical staff during a high physical activity, the value is half the chamber value. This is the case during hip joint surgery.

In more demanding infection-prone surgery and also in general surgery, it is not unusual that part of the staff in the operating room wear clothing system made of mixed material (cotton/polyester) with a corresponding source strength around 4-5 CFU/s, which will increase after many laundering cycles.

Ljungqvist and Reinmüller (2013), have shown that fabric of mixed material with cotton is more open to skin scales and less resilient to wear of the fabric by the washing process than fabric made from polyester or (poly-) olefin (polyethylene). The difference between woven mixed material with cotton and tightly woven polyester (without any cotton fiber) can be seen in Figure 3.9.

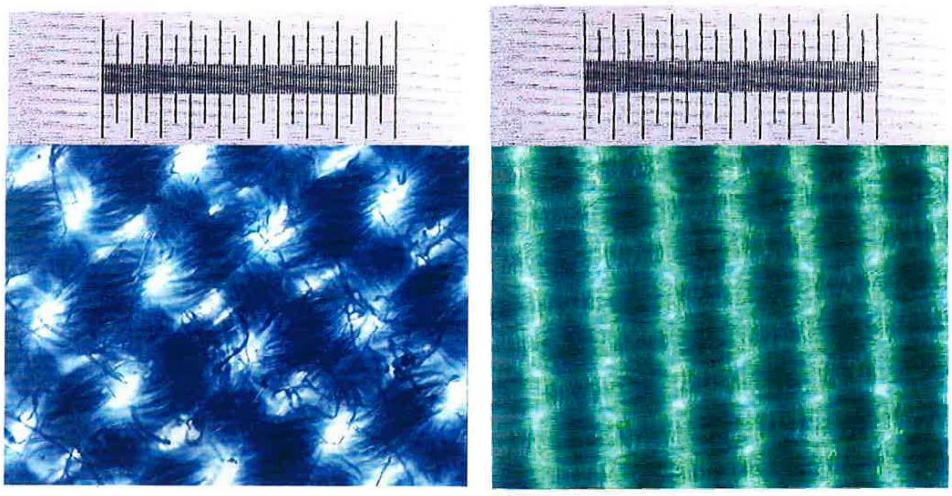


Figure 3.9 Mixed cotton/polyester fabric (left side) and polyester woven fabric (right side) seen under a microscope with the same magnification. The scale is 1 mm long (1000 microns). (From Nordenadler (2010)).

The following Figures, 3.10 and 3.11, show clothing made with the mentioned type of fabrics.

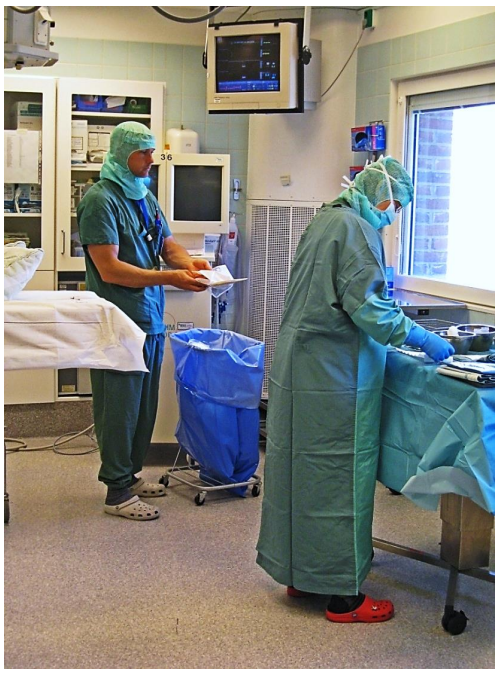


Figure 3.10 Today's conventional clothing system (cotton/polyester) for common surgery, made of mixed material cotton/polyester as shown in Figure 3.9, left side. (From Nordenadler, 2010).

Figure 3.11 Clothing system (polyester and 1% carbon fiber) of the same type as shown in Figure 3.9, right side. (From Nordenadler, 2010).

Initiated by the project for the Swedish NKS-hospital, a special clothing system was developed made by synthetic olefin fiber (98% olefin and 2% carbon fiber). The surgical system includes textile hood and a pair of textile knee-length boots to be worn over the shoes.

A study published by Ullmann et al. (2017) compares a conventional mixed material clothing system with the olefin system, with and without boots. The results confirmed the long-known better protective effect of the special clothing compared with the mixed material system. As for the olefin clothing system with and without boots, the use of knee-length boots lowered the source strength to more than half, both in the dispersal chamber and during ongoing surgery. Figure 3.12 shows the olefin special surgery clothing system and Figure 3.13 the textile boots.

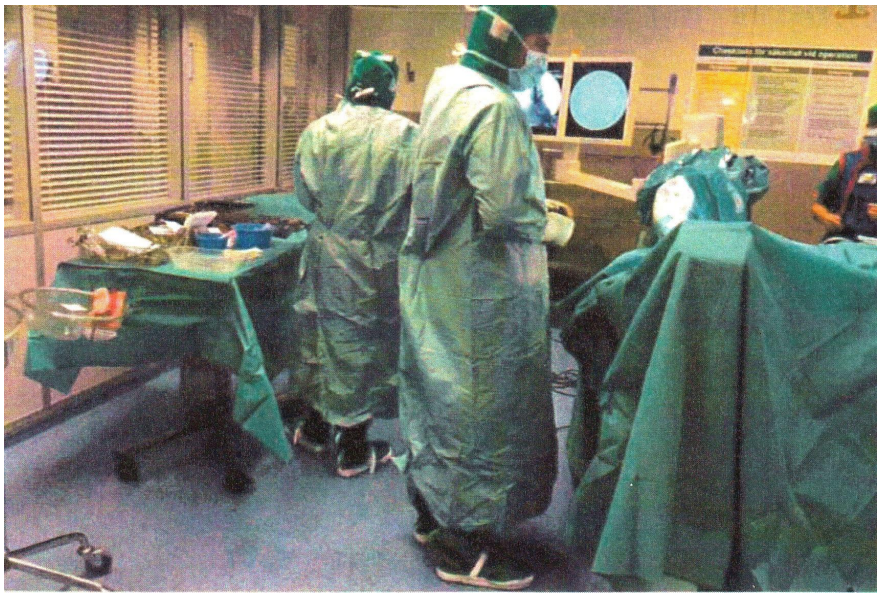


Figure 3.12 The olefin clothing system being assessed during an ongoing operation. (From Ullmann et al., 2017).

Figure 3.13 Detail of the textile boots in Figure 3.12, to be worn over common shoes. (Retrieved from textilia.se).

4 DISPERSION OF AIRBORNE CONTAMINANTS

4.1 General

The air may move in two different ways. One of these is characterized by a smooth flow, free from disturbances, such as small and temporary vortices or eddies. This is known as laminar flow. The other type of flow is characterized by small and temporary fluctuations caused by instabilities. The flow is no longer constant but fluctuates more or less around an average level. This is known as turbulent flow and the disturbances are often interpreted as being small temporary eddies.

To estimate the problems associated with the transport of contaminants by air, we must understand how this transport occurs. With the assumption that, with traditional room air distribution systems and rules we apply, the air in the rooms is more or less turbulent.

The aim is to arrange the room air distribution system in such a way that there is a basic flow of air. An organized basic flow implies that the flow can be characterized by means of streamlines, i.e., the paths taken by weightless particles in the room as they follow the air stream, if the turbulent fluctuations are ignored. The transport of contaminants due to the streamline flow is often described as convective transport.

The simplest system for an analysis of the transport of contaminants by ventilation/air is, therefore, convective transport along the streamlines. The disturbances caused by turbulence (turbulent diffusion) are superimposed on this. Obviously, if there is no turbulence, turbulent diffusion is replaced by molecular diffusion or Brownian motion. It can generally be assumed in regions with well-defined airflow fields that the settling velocity of contaminants is negligible, which implies that gravitation plays an inferior role.

In laminar flows, gases and particles have different dispersion patterns, where the dispersion of gases is faster than that of particles. On the other hand, in turbulent flows due to the turbulence, gases and particles have similar patterns, which are wider than that of laminar flows.

A vortex is characterized by the fact that the streamlines are closed within a region, which in the followings is referred as the vortex region. According to the laws of aerodynamics, tangential velocity in the vortex region should increase as the center of the vortex is approached. However, systematic investigations by Ljungqvist (1979) show that this is not always the case in vortices formed in ventilated rooms. Everything indicates that the air mass within the vortex region moves as a rigid body under the influence of powerful turbulence. A certain amount of energy is, therefore, needed to maintain a vortex, and in most cases, this energy is obtained from the kinetic energy of the air on its entry into the room. The greater the kinetic energy of the air in the room, the greater the chance of vortices occurring with closed streamlines.

Owing to the fact that the streamlines are closed, there is no convective removal of contaminants emitted within the vortex region. It is only turbulent diffusion within the vortex that causes the removal of contaminants. In a room where contaminants are emitted within a vortex region, the average concentration of contaminants inside the vortex region can be 10 times higher than in the air extracted by ventilation. This allows us to use the concept of contaminant accumulation in the context of vortices.

In operating rooms with unidirectional airflow, obstacles such as operating lamps and other equipment, below the unidirectional airflow ceilings, will cause disturbances of the air movements. This gives that wakes and vortex streets can occur in regions above the operating tables.

The air movements can be visualized by using isothermal smoke. Figure 4.1 shows undisturbed smoke dispersion in an operating room with vertical unidirectional flow.

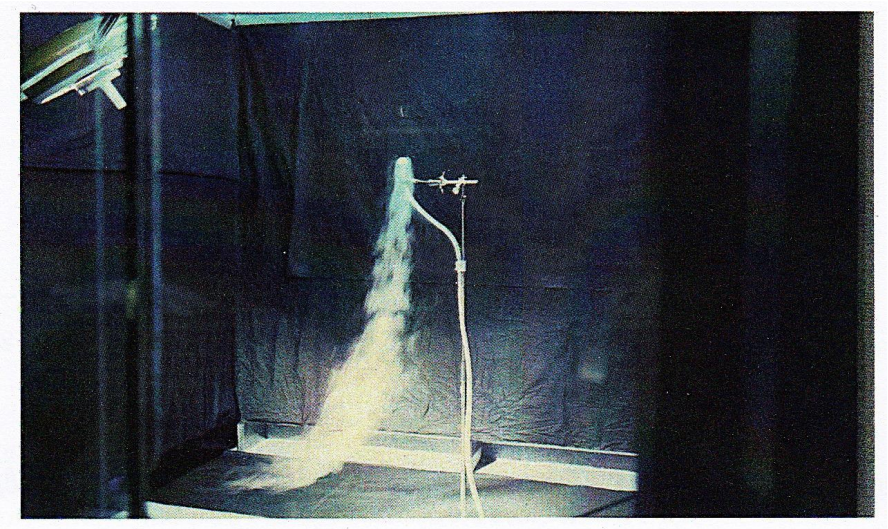


Figure 4.1 Dispersion of smoke in an undisturbed vertical unidirectional airflow system. (From Ljungqvist and Reinmüller, (2013)).

If an operating lamp with large surface is placed over the point of smoke emission shown in Figure 4.1, a wake is easily created, see Figure 4.2.

Figure 4.2 Dispersion of smoke downstream an operating lamp with large surface showing a wake region in the unidirectional airflow system shown in Figure 4.1. (From, Ljungqvist and Reinmüller, (2013)).

It has also been shown by using visual illustrative methods, that accumulation can occur in the wake region of both people and objects; provided that the contaminants are emitted in the wake region, characterized by eddies or vortices, which entrain air into the reverse flow near the obstacle, see Ljungqvist (1979, 1987).

With their need for energy-demanding turbulence, stable vortices are unusual. When they occur, it is mostly in the form of wakes, which are set up behind obstacles in a high energy, more or less parallel airflow. Vortices are generally unstable, i.e., they have limited duration. Such vortices are often periodic, i.e., they are formed and decay, die out, and are formed again, and so on. The frequency can be uniform but may vary. This is obviously the case when it is the movements of a person that give rise to a vortex.

With visual illustrative tests (Ljungqvist (1979, 1987)) in which emitted contaminants are replaced by isothermal smoke and the dispersion is recorded by means of photographs and film, it has been shown that the presence of a person in a unidirectional airflow can give rise to wakes that may be stable or unstable. The unstable situation is, in most cases, caused by the influence of arms and hands. A simulation study by Chow and Wang (2012) indicates that the surgeonôs bending movement can have an identical effect.

For a more thorough description of the interaction between air movements and dispersion of contaminants and contamination risks, see Ljungqvist and Reinmüller (2006, 2013).

4.2 Mixing Airflow

If an operating room with supply and exhaust air has completely turbulent mixing, the dilution principle is applicable. Furthermore, if the contamination sources are in the room with a constant total generation rate, source strength, the supply air is without contaminants and gravitational settling plays an inferior role, the expression for concentration, *c*, at any time, becomes:

$$c = \left(c_o - \frac{S}{Q} \right) e^{-\frac{Q}{V} \cdot t} + \frac{S}{Q} \qquad (4.1)$$

where c_o = initial concentration; bacteria-carrying particles (CFU/m^3), total number of particles (number/ m^3)
S = total source strength; bacteria-carrying particles (CFU/s), total number of particles (number/s)
Q = total air volume flow (m^3/s)
V = volume of operating room (m^3)
t = time (s)

When the total source strength, *S*, only has reference to bacteria carrying particles, the contamination source mainly is the operating team and the following expression is valid:

$$S = n \cdot q_S \qquad (4.2)$$

where n = number of people (number)
q_s = source strength, mean value of the number of bacteria-carrying particles per second emitted from one person (CFU/s)

In the following, airborne contaminants have reference to the operating team and its activities.

Case 1, Build up, ($c_o = 0$, $S>0$)

When the operating team enters an empty room, the initial concentration c_o is assumed zero and the expression for concentration in Equation (4.1) becomes:

$$c = \frac{S}{Q}\left(1 - e^{-\frac{Q}{V}\cdot t}\right) \tag{4.3}$$

Case 2, Steady-state, (*t*Ÿ Ð, *S*>0)

The concentration rises rapidly when the contaminant generation first starts and then levels off. The exponential term exp(-*QĀ/V*) of Equation (4.3) and Equation (4.1) approaches zero after sufficient time, and the concentration asymptotically approaches a maximum steady-state concentration (c_{max}) given by:

$$c = c_{max} = \frac{S}{Q} \tag{4.4}$$

Case 3, Decay, (*S=0*)

When the operating team leaves the operating room, the contaminant generation stops. This can be calculated by setting the contaminant generation to zero (*S*=0) in Equation (4.1). The concentration becomes:

$$c = c_o \cdot e^{-\frac{Q}{V}\cdot t} \tag{4.5}$$

where $c_o =$ *S/Q*

The expression Q/V is called the air change rate and is the inverted time constant of the room:

$$N = \frac{Q}{V} = \frac{1}{T} \tag{4.6}$$

where N = air change rate (l/s, also l/h)
T = time constant (s, also min)

It should be noted that the concentration in steady-state only depends on the total source strength S and the air volume flow Q, while the air change rate Q/V only has influence during increasing and decreasing concentration.

Equation (4.5) shows that the concentration decays exponentially with time. The decay time, also called recovery time, can with aid of Equations (4.5) and (4.6) be expressed as:

$$t = T \ln \frac{c_o}{c} \tag{4.7}$$

According to ISO 14644-3 Test methods (2005) and SIS-TS39:2015 (2015), cleanliness recovery performance is evaluated by using the 100:1 recovery time, which is defined as the time required for decreasing the initial concentration by a factor of 0.01.

For example, two operating rooms with turbulent mixing air distribution and air change rates of 20 changes per hour and 15 changes per hour respectively, will get the following theoretical recovery times:

20 air changes per hour (T=3 min) gives 13.8 minutes
15 air changes per hour (T=4 min) gives 18,4 minutes

Figure 4.3 illustrates the principal graphs of cases 1-3 (build-up, steady-state, decay) in form of dimensionless concentration in an operating room with 20 air changes per hour (ach). The dimensionless concentration is described as the quotient between concentration and the maximum concentration.

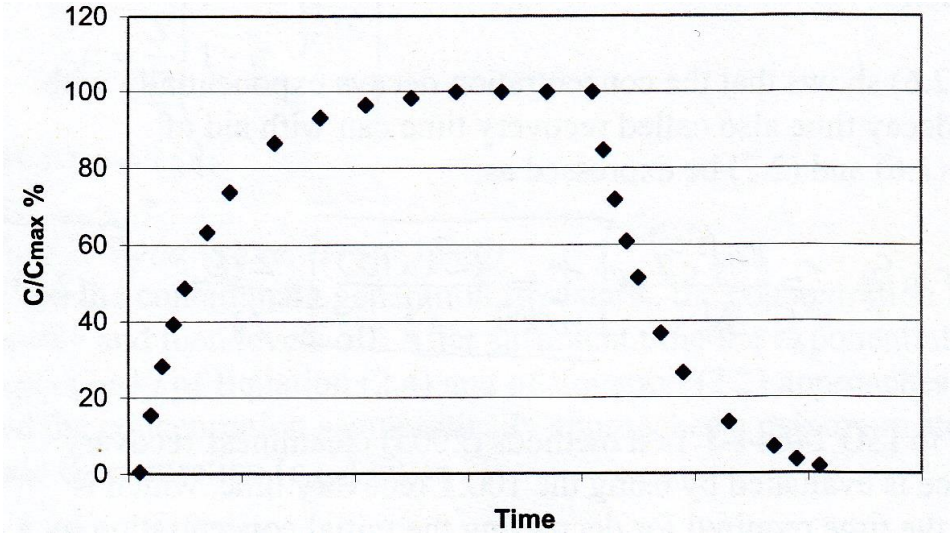


Figure 4.3 Principal graphs of cases 1-3 (build-up, steady-state, and decay). The dimensionless concentration, (the quotient between concentration and the maximum concentration) as function of time in an operating room with 20 ach.

A commonly used formula for microbiological cleanliness, is Equation (4.4) in combination with Equation (4.2), see SIS-TS39.

$$c = \frac{n \cdot q_s}{Q} \tag{4.8}$$

When estimating the total supply airflow needed for an operating room, Equation (4.8) is used in the following form given the cleanliness level required for the planned type of surgery.

$$Q = \frac{n \cdot q_s}{c} \tag{4.9}$$

In the same manner source strength can be calculated with Equation (4.8) written in the form

$$q_s = \frac{c \cdot Q}{n} \tag{4.10}$$

4.3 Unidirectional Airflow

Dispersion from a fixed source in a uniform parallel flow is described theoretically and experimentally inter alia by Bird et al. (1960), Fuchs (1964), Hinze (1975), Ljungqvist (1979) and Ljungqvist and Reinmüller (2006). For a continuous point source situated in the origin in a parallel flow with constant velocity v_o in the x-direction, the concentration after simplification becomes:

$$c = \frac{q}{4\pi Dx} \cdot e^{-\frac{v_0(y^2+z^2)}{4Dx}} \tag{4.11}$$

where q = outward particle flow from point source (number/s)
v_0 = constant velocity in the x-direction (m/s)
D = diffusion coefficient (m^2/s)

Figure 4.4 shows schematically the dispersion pattern in the x, y-plane (z=0).

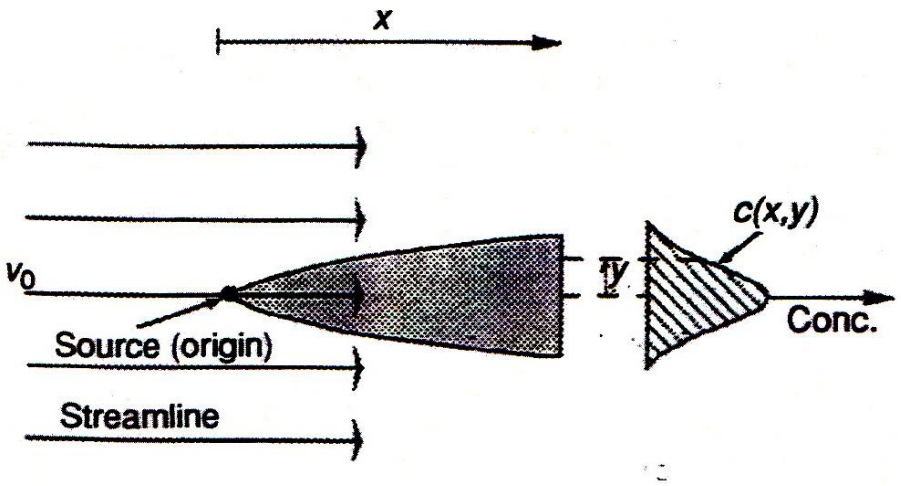


Figure 4.4 Schematically dispersion pattern caused by a continuous point source in a unidirectional flow with constant velocity in the x-direction.

The concentration for a continuous line source situated along the *z*-axis in a parallel flow with constant velocity v_o in the *x*-direction can, in a simplified form, be expressed as:

$$c = \frac{q_l}{2(\pi D v_0 x)^{\frac{1}{2}}} \cdot e^{-\frac{v_0 \cdot y^2}{4Dx}} \qquad (4.12)$$

where q_l = outward particle flow per unit length from line source (number/(s, m)).

5 PREVIOUS STUDIES OF CFD SIMULATIONS

Computational Fluid Dynamics, CFD, is a branch of fluid mechanics that uses numerical analysis and data structures to solve and analyze problems that involve fluid flows. With increased processor capacity in computers, it can be expected that CFD simulations would come closer to the reality.

Since the late 1980s, CFD-simulation has been a fast-developing tool used in the prediction of room air distribution and contaminant dispersion and it is commonly used for designing industrial cleanrooms and laboratories. Examples of early articles assessing operating rooms were published in the beginning of the 90s, by Buchanon and Dunn-Rankin, (1998) and thereafter by Colquhoun and Partridge, (2003) and Chow and Young, (2004).

One of the major advantages of this tool is the possibility of inexpensively assessment of different designs before the room is built but also when studying different layouts needed by new process requirements.

In all CFD simulations, it is crucial that the boundary data are accurate and relevant. Boundary data are influenced, by e.g., pressure differences, thermal loads from light sources and release rate of contaminants. When selecting the calculation model, it is inevitable that simplification of all relevant parameters is made. Simulation of the air movements and the dispersion of bacteria-carrying particles in the air of a cleanroom ISO class 5 or cleaner, allows the assumption of controlled air movements and processes. However, during activity in an operating room, the air movements differ substantially from those in the more controlled conditions in a cleanroom.

Physical objects in the operating room have long been known for generating eddies and vortices leading to local accumulation of contaminants. This could be seen when using smoke to visualize the

air movements but visualization does not give information of the CFU concentration. Using CFD-technology those concentrations levels can be illustrated and estimated.

Orthopedic surgery, particularly the most infection-prone procedures like total hip replacement, involves high physical activities from both the surgeon and other staff members. This means not only high emission of bacteria but also frequent disruption of the airflow near the open wound area.

Presently, there are no validated models for simulating e.g. the effect of the surgeonôs bending forwards and back. Such situations have been studied by Chow and Wang, (2012), using a model of a unidirectional unit with high air velocity (0.4-0.5 m/s) and equipped with 0.7 m constraining walls. They concluded that when the surgery team stands upright and still, the bacteria level nearby the wound is less than 1 CFU/m^3. It could even be foreseen that the surgeon bending over the work zone would contribute to eddies and wake vortices and thus higher concentration of particles in the critical zone.

Less predictable was that the worst case is when the surgeon leans back to upright position. In fact, their calculation predicts a CFU-level well above the accepted requirement of max10 CFU/m^3, near the wound. One limitation with this study is that the authors have assumed higher source strength from the surgeon during his bending movement. Although plausible, the increase has not yet been verified and therefore that studyôs increased contaminant levels are assumptions to be validated.

Figure 5.1 shows the standard strictly upright position of the whole surgery team when modeling a CFD-calculation.

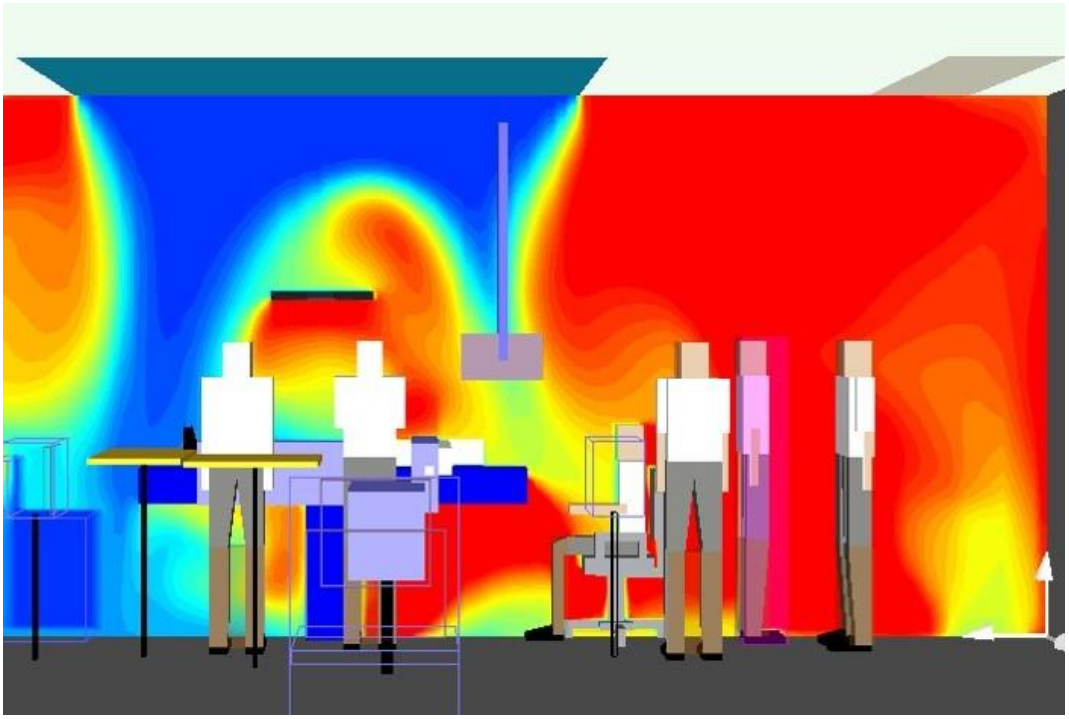
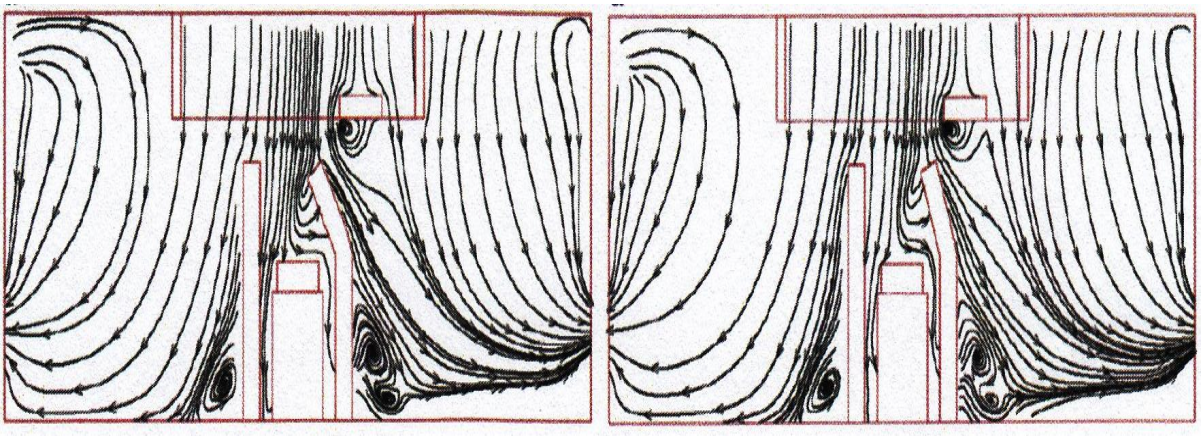
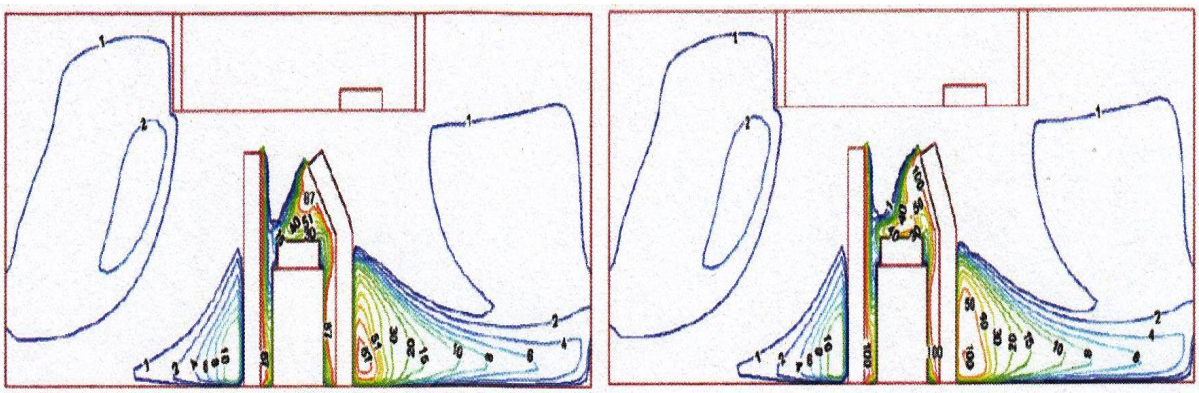


Figure 5.1 Common CFD modeling with the surgeons standing strictly upright during surgery. The colors simulate particle concentration increasing from blue to red, analogous with color temperature. (Unpublished CFD-picture from the CHOPIN project).

A part of the results from the study by Chow and Wang (2012), simulating the bending movement of the surgeonôs upper body causing increased concentrations is shown in Figure 5.2.



a b



c d

Before bending After bending

Figure 5.2 Calculated streamlines, (a and b), and calculated values of contaminant concentration, (c and d), before (a and c) and after (b and d) the surgeonôs bending back of the upper body under an UDF-ceiling. The colors simulate concentration increasing from blue to red (Adapted from Chow and Wang, 2012)

Note that the high particle levels shown in the turbulence zones are based on an assumed increase of the particle emission, (source strength), from the surgeon during his bending movement, which has not been validated.

Another issue of concern is the position of the surgery lamps, which during surgery need to be moved in an unpredictable way, potentially affecting the unidirectional flow. Actually, several researchers using numerical simulations point out the disturbing role of movements of persons or equipment within the unidirectional flow, see Balocco et al.

(2015), Brohus et al. (2006, 2008a, 2008b), Chow and Wang., (2012), Sadrizadeh et al. (2014a, 2014b), and Romano et al (2015).

Wang et al. (2014) showed that the walking impact of the scrub nurse moving faster than 0.25 m/s, (in the study, 0.5 m/s or faster), could contaminate the instrument table or the upper side of the patient. This study had assumed UDF air distribution system ventilation with sidewalls and higher supply inlet air speed, which is a safer UDF design than those commonly installed in Sweden.

The surgeonôs movements but also the movements of the scrub and circulating nurse could be an important part of the explanation of Nordenadler's (2010) findings suggesting that a great part of UDF-systems in Sweden during activity often tend to show a transition from unidirectional to mixing air distribution functions, and can be treated as mixing air room distribution systems.

Sadrizadeh et al. (2014a, 2014b) used CFD simulations to compare air movements and dispersion patterns of bacteria-carrying particles at several room air distribution systems in one model with the characteristics of an updated large operating room (around 60 m^2) with high air volume flows (2.2 m^3/s equivalent to approximately 45 ach). He compared horizontal versus vertical downflow design when using displacement room distribution airflow in the operating room. He could show that unidirectional horizontal flow provided a greater level of cleanliness at the surgery site than that of vertical downflow, being more resilient to the effect of heat sources.

However, this was only true when the horizontal supply airflow reached the surgical site area without any interferences of staff members or equipment. When an obstacle was placed in the airflow, e.g. a staff member stood between the inlet air device and the wound area, wake vortices were generated and contaminants were accumulated with the risk of reaching wound area. The undisturbed vertical unidirectional airflow showed lower CFU-levels in the operating room than that of mixing airflows, but when the vertical flow was disturbed by obstacles, the CFU concentrations became close to those of mixing.

Sadrizadeh et al. (2015) also showed that separate emission regions of viable particles, head or ankle region respectively, did not give any significant differences in the CFU concentration found in the wound area.

Two of the principal researchers in numerical analysis by CFD, Chow and Yang, (2005) states that ñdirect measurement and numerical computationò are the main approaches when assessing the airflow pattern in operating rooms and airborne particle concentration but they add: ñThe most realistic information on airflow can be obtained by direct measurement.ò Nevertheless, parallel studies like the one described in part 6 are still rare.

It is important to point out that a CFD-image is a snapshot of reality in a static situation. After all boundary conditions are put into the model and the calculation starts, i.e. virtual particles are released, it is not possible to study the effect of interaction between personôs movements.

6 PERFORMED STUDY WITH SIMULATED OPERATIONS AND PARALLEL CFD CALCULATIONS

6.1 Introduction

The Stockholm County Council decided in December 2014 to start a major investigation study called CHOPIN to help choosing the best room air distribution system to be used in the new surgical ward in a Swedish hospital planned to open 2019. This unit will include 24 top-equipped operating rooms and the room air distribution system is expected to support an average level of 5 CFU/m^3 or less in all those rooms during on-going surgery.

Two different types of operating rooms will be built. The majority of them are being planned as conventional operating rooms (60 m^2) while modern so-called Hybrid or Intervention operating rooms will be larger, around 90 m^2. Hybrid operating rooms will accommodate besides all common surgical equipment, mainly radiology equipment for use under on-going surgery. In this context, the difference is mainly a substantially increased heat and bacterial load in these rooms.

The experimental investigation was performed by a working group led by an anesthesiologist and an HVAC-engineer. A reference group with broad experience, including research competence, was constituted and a few meetings were held during the project time of five months.

My participation in the project was as a member of the reference group and as one of the staff members in all three mockup operations. The results of the investigation were presented by Tell and Cederlund, (2015), in an official report and have also been described by Gandra et al. (2016), see Appendix. It is noted in the report that the conclusions made by the authors, Tell and Cederlund, do not always agree with the opinions of the reference group.

The official report by Tell and Cederlund (2015) is written in Swedish with the translated title "*New Building and Remodeling of Surgery and X-ray Units at Karolinska University Hospital in Huddinge Study on Microbiological Cleanliness and Working Environment for Operating and Intervention Rooms.*"

In the project three different room air distribution systems on the Swedish market were studied:

- Unidirectional airflow, UDF, called LAF in the report
- Mixing Airflow/partly displacement
- A specific Swedish system marketed as Opragon with temperature controlled zones, ñTAFò. See part 2.4.

Some Swedish hospitals with installed unidirectional airflow systems and Opragon systems were contacted in order to obtain their experiences and to share results of performed microbiological measurements. In June 2014, there was no reference operating room with an installed high volume flow of mixing airflow distribution system.

It was decided that the study would primarly focus on microbiological measurements during mock-up operations and that CFD-simulations would be made in parallel with the experimental studies.

According to SIS-TS 39:2015, a level of Ò10 CFU/m^3 is generally accepted as a definition of ultraclean air in operating rooms for infection-prone clean surgery. In order to avoid exceeding that value at any time, it is recommended that a mean value of 5 CFU/m^3 and no single value above 15 CFU/m^3, should be used as a guideline. Therefore, these values were used as acceptable in the study. The microbiological measurements were performed with impaction samplers, all with a d_{50}-value of <2µm; this means that the results are comparable.

Two software tools, namely FloVent and Star-CCM+, were adopted for the CFD simulation. The calculations for the unidirectional flow distribution system and the mixing air system were calculated with the software FloVent. The calculation for the Opragon distribution system was made with FloVent and recalculated with with Star-CCM+, after

a recommendation from one supplier. These two calculated simulations showed similar results.

6.2 Materials and Methods

The three mock-up operations were made in three different rooms with similar microbiological impaction air samplers. For practical reasons it was not possible to make the three experimental studies with exactly the same conditions for all parameters.

The unidirectional airflow distribution system had a 9.35 m^2 air supply inlet with HEPA filters in the ceiling with an average velocity of 0.27 m/s corresponding to 2.5 m^3/s supply air volume flow. Inlet air temperature was 0.5-3°C lower than room air depending on the heat load. The mixing air/partly displacement distribution system had an air volume flow of 2.5 m^3/s, supplied from inlet diffusers in the ceiling. The two-temperature zones distribution system had an air volume flow of 2.5 m^3/s.

The conventional UDF system was tested in an existing operating room at the Linköping University Hospital. The mock-up operation with mixing airflow performed in Kausala, Finland, in Haltonôs factory laboratory constructed as a replica of the operating rooms at New Karolinska Solna (NKS). The mock-up operations with Opragon system were performed at the manufacturerôs test room in Lund. The airflows, outdoor airflow versus recirculated airflow, corresponds to designed values.

During the mock-up operations, the clothing system, the numbers of persons acting, (almost the same individuals) and the pattern of movements (kept to a minimum), were similar in all cases. There were ten staff members acting in the room except during one simulation that had six staff members, which corresponds to common surgery. One or two of ten persons were moving around slowly making observations and measurements of climate parameters, five persons simulated the anesthesiology team and were sometimes talking but stationary.

The heat load was set to 4, 6 and 9 kW respectively and corresponded to the heat load generated by specific surgery and radiology equipment corresponding to hip joint replacement, liver resection and

a procedure using C-arm equipment, respectively. The heat loads were based on preliminary inventory of the heat load in factual surgeries performed at Huddinge University Hospital.

The official report does not give any details about the air samplers used or where they were located, but in an article, Cederlund and Tell (2016), the authors of the official report, reports that three air samplers were located near the supposed wound, on the instrument table and by the corner of the room, nearest the scrub nurse, respectively. The surgery team kept their hands on the table almost totally still during the sampling, which lasted for 10-minute periods.

During the mock-up operations, microbiological sampling of air was performed on 3 locations (on the operating table, on the instrument table and in the periphery of the room). In order to understand the dispersion of contaminants, visualization of air movements was made by smoke. Ambient temperature and air velocity were measured at seven locations.

Other conditions:

Room area used in the CFD calculations: Approximately 60 m^2.

Room area in the mock-up studies were:

- Unidirectional flow room 50 m^2
- Mixing flow room, 75 m^2
- TAF flow room, 75 m^2.

The established anesthesia zone in the room had 4-5 persons standing.

The number of door openings was minimized.

The surgery clothing system (mixed cotton/polyester fabric) was washed between 1 and 3 times.

The source strength in the CFD calculations, was set to 1 CFU/s per person.

The source strength for this system is in the Body-Box estimated to be about 8 CFU/s per person. During on-going orthopedic surgery procedures the source strength at high staff activity is estimated to be

about 4 CFU/s per person and at low staff activity less than 2 CFU/s, see Ullmann (2017).

The heat load in the CFD calculations was set to 4.5 and 6 kW respectively.

During the simulations the heat load was 4, 6, and 9 kW, respectively.

The CFD calculations were made simulating steady-state conditions, i.e. all personal standing upright and not moving.

During the simulated operations low physical activity prevailed in the critical zone other than talking, and in the periphery of the room was very low activity.

Temperature and air velocity were measured in seven places in the room.

The conditions during the parallel studies are summarized in Table 6.1.

Table 6.1 Summary of conditions during the simulated operations and the parallel CFD calculations.

Condition	Simulated operations	CFD calculations
Room Area	UDF 50 m^2 Mixing flow 75m^2 TAF 75m^2	60 m^2
Heat load	4kW, 6kW, and 9kW	4.5kW and 6kW
Activity level	Low activity	Standing still
Source strength	2 CFU/s per person	1 CFU/s per person

6.3 Results

Unidirectional airflow distribution system

The microbiological requirements of a mean value of max 5 CFU/m^3 were met in the CFD-calculations as well as in the mock-up operations. Very low levels of CFU were measured near the surgical wound and at the instrument table.

The smoke study with its visualization of the air movements revealed a stagnation zone within the surgical site during one procedure. That correlated with the CFD calculation, which gave values equal to and less than 5 CFU/m^3 in that area. The smoke study showed also the importance of aerodynamic design of the surgical lamps, which were different in all three simulated operations, see Figures 6.1, 6.2 and 6.3. Conventional lamp design constitutes a substantial flow obstacle to unidirectional vertical airflow in certain positions.

An illustration of the airflow visualization of the experiment with a conventional UDF ceiling is shown in Figure 6.1

There was not any visually detected entrainment of room air from the less clean air in the periphery into the surgical site area. No entrainment of air from below the table into the surgical site area was visually detected, not even with the greater heat load (9 kW) under the operation table in the mock-up study.

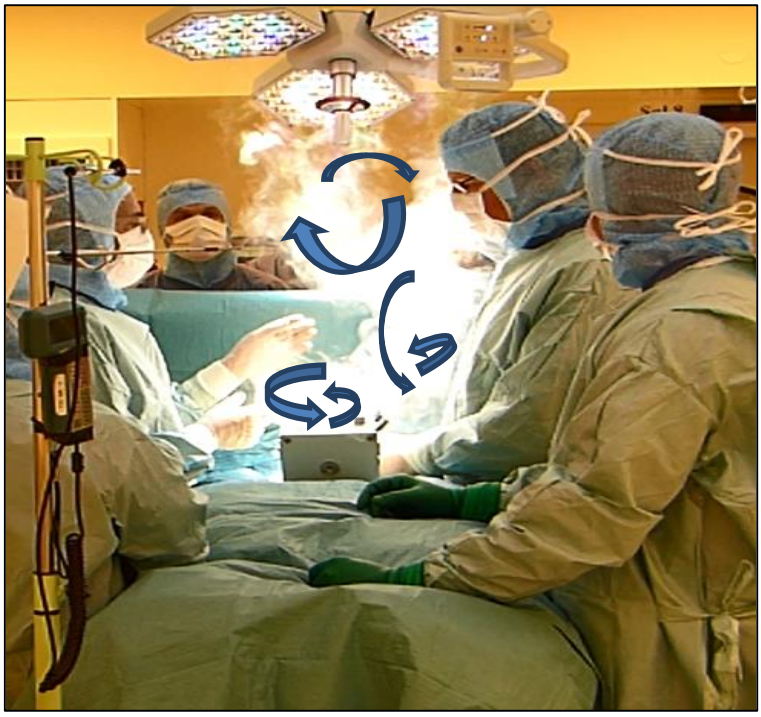


Figure 6.1 Visualization by smoke during simulated operation under a UDF ceiling at Linköping University Hospital, Sweden. The smoke was released under the neck of the operator on the right side. (Photo: Thomas Tell).

Mixing airflow/partly displacement distribution system

The microbiological requirements of a mean value of max 5 CFU/m^3 were met in both the CFD-calculations and in the mock-up study. The CFD calculation showed small areas with higher particle concentration close to the surgeons. The CFD calculation indicated low rates of CFU on the instrument table. Microbial measurements on the instrument table showed a few results at 3 CFU/m^3 and thus verified the CFD calculation.

Visualization of air movements with smoke revealed that the system showed good efficiency diluting contaminants in the surgical site. The smoke dissipated fairly quickly when emitted near the operatorôs neck. The mock-up experiment showed that a horizontal airflow along the operating table prevented the smoke to reach the wound area.

Smoke from below the operating table moved mainly towards the exhaust terminal devices but some part of it moved upward.

An illustration of the airflow visualization of the experiment with mixing airflow is shown in Figure 6.2.

The mixing air distribution system showed the lowest sensitivity to disturbances from surgical lamps, the anesthesia drape, and other obstacles.

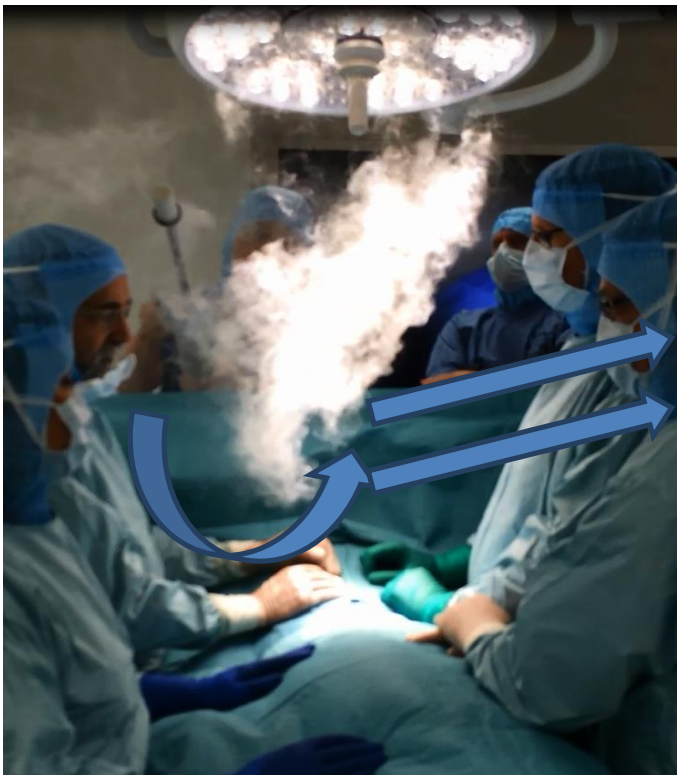


Figure 6.2 Visualization by smoke during the simulated operation in a high flow mixing (partly displacement) room air distribution system, in Halton factory laboratory in Kausala, Finland. The smoke was released under the neck of the operator on the right side. Note the large lamp, compare Figure 4.2 (Photo: Thomas Tell).

The two-zone distribution system, TAF

The microbiological requirements of a mean value of max 5 CFU/m^3 were met in both the CFD-calculations and in the mock-up study. However, during the mock-up study, single values of 5-10 CFU/m^3 were measured on the instrument table.This occured when the heat load was increased to 9kW.

In the smoke study with its visualization of air movements, wakes were observed near the surgeon. The system was sensitive to the distance between the surgeonôs shoulder and the anesthesia drape. The surgeon standing less than 0.1 m from the drape trapped the smoke and caused it to climb up the drape and to descend into the wound area.

No entrainment of air was observed into the surgical site from the less clean room-air in the periphery of the room or from below the operation table. However, the central zone protected by displacing airflow becomes smaller when the heat load increased. The smoke test revealed that air from below the operating table moved upwards over the instrument table.

The airflow visualization of the experiment with the TAF system is shown in Figure 6.3.

During the experiment, the airflow in the center lost its controlled flow pattern and turned to a higher degree of mixing due to a failure in the temperature control system. The problem was rapidly noticed and corrected. It showed that the monitoring of the temperature difference in the room is of importance.

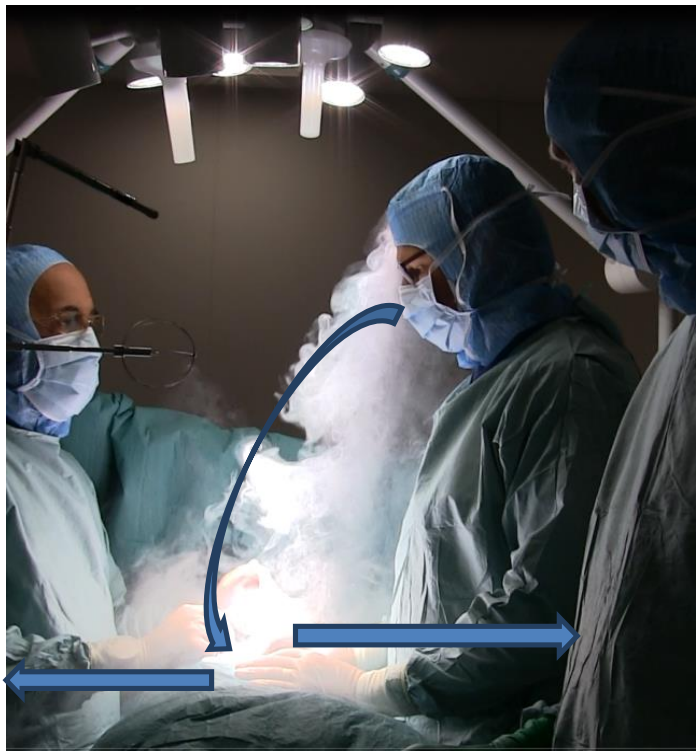


Figure 6.3 *Visualization by smoke during simulated operation in the two-zone distribution system, in the Avidicare test hub in Lund, Sweden. The smoke was released under the neck of the operator on the right side. Note the aerodynamic design of the lamp, compare Figures 6.1 and 6.2 (Photo, Thomas Tell).*

6.4 Discussion

This CHOPIN-study had the specific aim to support the decision-makers for the choice of room air distribution principle for the new operating rooms. Thus, it had a short time schedule, limited resources and was not designed as a scientific study.

One of the found limitations in the study was that the physical activity of the team simulating the surgical procedure was low compared to the activity during regular hip and knee prosthesis operations, which are considered the most demanding in this context. Low body activity means lower emission of bacteria-carrying particles, i.e. a lower source strength thus giving the erroneous idea that common, less protective, ordinary scrub suits of mixed material are as effective bacterial filters as clean air suits.

The source strength of 1 CFU/s per person used in the CFD calculations is not possible to achieve with mixed material other than when the staff in the room stands more or less still. It can therefore be assumed that a more representative level of activity during the mock-up study would have led to higher bacterial load in the room air and maybe shown a difference between the three systems. This shows the importance of that the CFD analysis is based on relevant data.

Room air distribution systems based on UDF and TAF principle with high air supply velocity or, at least, enough velocity to overcome the disturbances from obstacles and heat loads, is well known to be effective in protecting the work area from airborne contaminants in industrial cleanrooms. However, in operating rooms there are requests to lower the supply air velocity for medical reasons to avoid cooling of the patient. It should be noted that there is a conflict between the two demands.

The advantages of using the mixing airflow principle is the flexibility of reaching almost the same level of cleanliness in the whole room and its low sensitivity to disturbances from obstacles and heat loads albeit with slightly lower control of the contamination concentration at the surgical site. Currently this system is the most controversial of the three as it has long been considered that the mixing principle cannot meet the higher cleanliness requirements in infection prone surgery. Advanced operating rooms in Sweden, inaugurated in May 2016 at the

New Karolinska Solna (NKS) in Stockholm, were designed based on the mixing principle. The operating rooms are identical to the mock-up room assessed as the mixing system in this study. In 2016, the first mock-up operations with surgical staff were performed in three operating rooms (60, 90 and 120 m^2) and satisfactory results (<5CFU/m^3) were achieved (from unpublished report). The surgical team of 10, 15 and 30 people respectively, used special clean air suits with source strength of less than 1.0 CFU/s, per person. The clothing system was evaluated in the dispersal chamber at Chalmers University of Technology, see Ljungqvist and Reinmüller (2016).

The two-zone room air distribution system (Opragon) is a relatively new hybrid system designed to maintain two different climate and cleanliness zones and two separate airflow patterns in the same room. Besides that, the system is being supplied by one single manufacturer and it is technically of a more complex design. Presently, the system is used in some operating rooms in Swedish hospitals.

In an analys of the CFD report by Tell and Cederlund (2015), the operating room was divided in four zones with different air cleanliness and temperatures. This kind of division into separate zones did not show any application in the operating rooms for the mock-up studies. It is also important to be aware of the limitations of the CFD calculations, as movements of staff cannot be incorporated.

Due to the limited measuring accuracy at low concentration of airborne CFU (<5 CFU/m^3) with todayôs impaction sampler, conclusions based on differences in results below 5 CFU/m^3 have little real significance.

The goal of this study was, translated from Swedish: ñThe goal was not to reach the depth pursued in academic publications, but instead, at reasonable time and expense, to take a holistic approach to the issue and make a recommendation for a decision on the selection of the ventilation system in a single specified projectò.

Nevertheless, this study is a very comprehensive and therefore unique trial to compare three of todayôs in Sweden most discussed room air distribution systems for ultraclean operating rooms. Some of the flaws depend on insurmountable difficulties as, for example, the possibility

to perform all three experiments in the same room, with the same staff.

6.5 Conclusions of the CHOPIN study

The CHOPIN-study shows that the three evaluated room air distribution systems of clean air to an operating room are able to meet strict requirements for microbiological cleanliness even during the most demanding procedures.

The parallel CFD-simulations have shown to be a useful tool in the evaluation of different room air distribution systems. However, in future CFD simulations the microbial load i.e. the source strength CFU/s per person should be increased until a difference, if any, can be found between compared systems. Higher values than measured seems to be necessary to show the difference between systems.

The three compared room air distribution systems, have specific advantages and disadvantages that from the health care and building management perspective and should be evaluated based on these aspects. To determine which surgical operations require high level of cleanliness is a medical/clinical assessment. It should be noted that in all three studied room air distribution systems, the surgical clothing system plays an important role for the CFU concentration in the room air.

To achieve high microbial air cleanliness during on-going surgery, the HEPA-filtered supply air volume flow should be large enough to dilute the generated contaminations, due to number of people, their activity level and clothing systems, heat loads etc., independently of chosen room air distribution system.

The results of the CHOPIN-study have earlier been described by Tell and Cederlund (2015) and the author of this thesis, see Gandra et al. (2016) in Appendix.

7 UDF SYSTEMS WITH LOW VELOCITY - SOME CALCULATIONS

7.1 Introduction

Operating rooms for patients undergoing surgery susceptible to infections have often unidirectional flow (UDF) supply air systems. In the past 25 years, many UDF supply air systems installed in Europe have low air velocity, i.e. equal to or below 0.3 m/s.

Measurements of airborne viable particles (aerobic CFUs) were performed during ongoing surgery in operating rooms with UDF ceilings at three different hospitals in Sweden, see Gandra et al. (2017) in Appendix. Data from these measurements for three types of UDF units will be discussed in the following, based on Amato (2014), Meda (2014), Erichsen Andersson (2013) and an unpublished report from Linköping Hospital. The measured mean value concentration of bacteria-carrying particles (aerobic CFUs) in the operating rooms with UDF units are compared to theoretical calculated values with the aid of the dilution principle, i.e. total mixing airflow.

Airborne viable particles were collected using a filter sampler (Sartorius MD8®) and a slit-to-agar sampler (Klotz FH6®). The sampling volume per sampling period for the two instruments was 1 m^3. Both samplers were operated according to the manufacturerôs instructions. The two test methods are described as accepted methods in SIS-TS39:2015 (2015). For a more thorough description of the study, see Gandra et al. (2017) in Appendix.

7.2 Operating Rooms with UDF

As mentioned earlier, three types of UDF supply air systems, all with high efficiency particulate air (HEPA)-filtered air, were studied and will here be called Case 1, Case 2 and Case 3. Data from the three cases are shown in Table 7.1.

It should be noted that the areas of the three UDF ceilings are at least 10 m^2. Furthermore, the air velocities are equal to or below 0.3 m/s, which according to Nordenadler (2010), during activity results in disordered airflow pattern above the operating table resembling that of mixing air and can be treated as non-unidirectional airflow. Air movement studies have been performed for Case 2 and Case 3. The studies show that parallel airflow coming from the UDF ceiling into the operating zone is affected by the presence of operating lamps, their arms, and movements of the staff.

Table 7.1. Data from three types of UDF ceilings, Case 1, Case 2 and Case 3.

Case	Airflow UDF (m^3/s)	Additional airflow* (m^3/s)	Total airflow (m^3/s)	UDF velocity Mean value (m/s)	Air filter
Case 1	2.54	-	2.54	0.25	H14
Case 2	3.6	0.7	4.3	0.3	H14
Case 3	2.75	-	2.75	0.27	H14

*Additional airflow is supply air in the room outside the UDF ceiling.

Source strength

With the assumption of no leakage into the operating room and the HEPA-filters having an efficacy close to 100%, the simplest possible expression, which is applied on the dilution principle, describes the source strength, protective efficacy of surgical clothing system (outward particle flow) by Equation (4.10).

The source strength is here described as the mean value of the number of aerobic CFU per second emitted from one person. Data are given as

mean value based on several persons dressed in specific clothing systems. The source strength is a valuable tool to describing the protective efficacy of clothing systems against bacteria-carrying particles; see Ljungqvist et al. (2004, 2014).

Clothing system

The same type of surgical clothing system was used during the measurements of on-going surgery for the three cases. The clothing systems consisting of 50% cotton and 50% polyester was described by Erichsen Andersson (2013). The total number of air samples during surgery was 91. With the presented data from Erichsen Andersson (2013), calculation of source strength can be performed with the aid of Equation (4.10). Such calculations show that the mean value becomes 1.85 CFU/s and the 95% confidence interval (t-distribution) for lower and upper level are estimated to be 1.5 CFU/s and 2.2 CFU/s respectively. These values should be compared to the value of 2.0 CFU/s estimated by Nordenadler (2010).

7.3 Comparison between Theoretical Calculated and Measured CFU-Values

When the air movements are total mixing, the dilution principle is valid. The theoretical mean value concentration of bacteria carrying particles can be calculated if the total air volume flow is determined and the number of people in the room (beside the patient) is known. In this case, the CFU concentration can be calculated with aid of Equation (4.8).

In Table 7.2 the mean value of number of persons present, their source strength and total air volume flow during on-going surgery are given. With these values, the CFU mean value concentrations are calculated for the three cases. In Table 7.2, also the measured mean value CFU concentrations are given.

Table 7.2. Comparison between theoretical calculated and measured CFU mean value concentrations.

Case	Number of persons present (mean value)	Source strength (CFU/s)	Total airflow (m^3/s)	Concentration (mean value), Theoretical* by Equation (4.8) (CFU/ m^3)	Concentration (mean value) Measured (CFU/ m^3)
Case 1	5.0	1.85	2.54	3.6	1-3**
Case 2	6.5	1.85	4.3	2.8	2.0
Case 3	5.6	1.85	2.75	3.8	2.9

* Values are given with one decimal.
** The value 3 CFU/m^3 was measured when the probe pointed slightly upwards.

The result from the three cases show that all mean value concentrations are less than 10 CFU/ m^3 and that measured mean value concentrations of aerobic CFUs during on-going surgery in operating rooms, equipped with UDF supply air systems (UDF ceilings), are in the same range as the mean value concentrations calculated with the expressions of the dilution principle, Equation (4.8), when the air velocity of the UDF is low (Ò0.3 m/s). This might depend on the fact that the airflow pattern above the operating table is affected by the presence of obstacles, such as large operating lamps and monitors, and movements of the staff and their convection flows. This results in a non-unidirectional airflow, which gives disordered airflow pattern, partly resembling that of mixing air which is in agreement with Nordenadler (2010). Figure 7.1 shows an operating room with UDF ceiling and equipment.

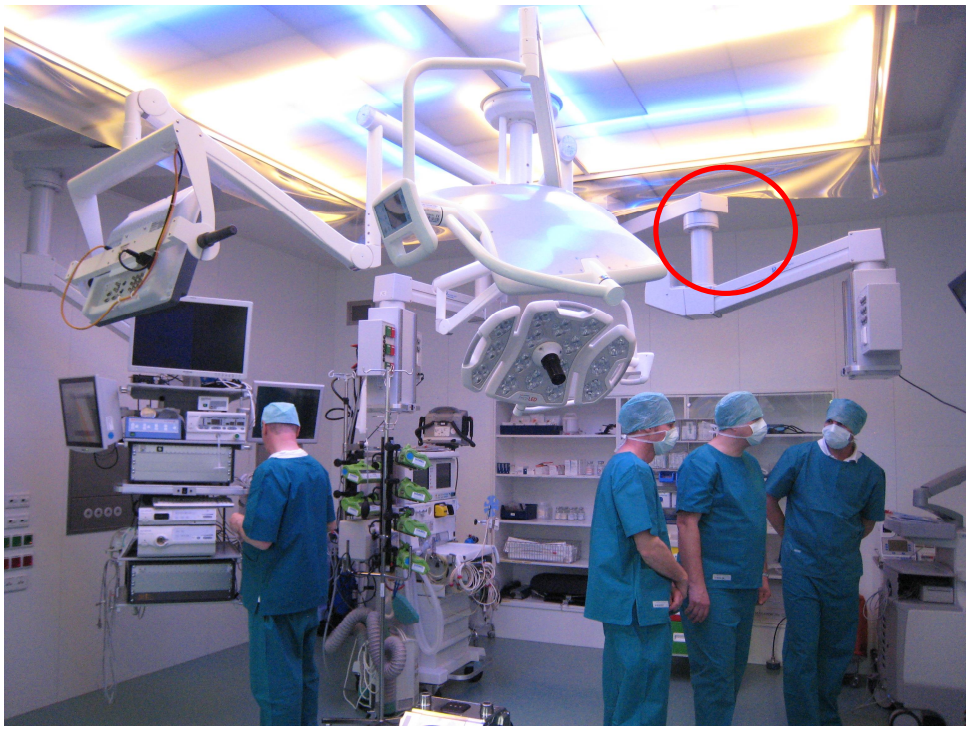


Figure 7.1 Operating room with UDF supply air device on the ceiling with short side walls and different equipment inside the airflow zone. Note the equipment arm disturbing the position of the side wall.

Activity level

In Case 3 measurements of airborne viable particles were performed during on-going surgery at all operations in five identical operating rooms with exactly the same type of UDF ceiling. The grand mean value of measured concentrations and the grand mean value of number of persons present during the 11 operations are described by Gandra et al. (2017) in Appendix and given in Table 7.2.

During the 11 operations, there were different staff activities, here called low staff activity and high staff activity. Tables 7.3 and 7.4, show concentrations of aerobic CFUs and estimated source strengths with the aid of Equation (4.10) during different operations with low staff activity, (Table 7.3) and high staff activity, (Table 7.4). Low staff activity occurred during on-going surgery when the staff was almost standing still and high staff activity occurred during on-going orthopedic surgery.

Table 7.3 Concentration of aerobic CFUs and estimated source strength, Equation (4.10), during different operations with low staff activity during on-going surgery in operating rooms equipped with UDF ceiling with an air volume flow of 2.75 m^3/s.

Operation (number)	Concentration* mean value (CFU/ m^3)	No of persons present* (number)	Source strength* Equation (4.10) (CFU/s)
1	1.0	7.0	0.4
2	1.8	6.4	0.8
3	1.0	5.5	0.5
4	1.4	4.0	1.0
5	2.3	5.0	1.3
6	5.3	6.5	2.2
Mean value	2.1	5.7	1.0

* Values are given with one decimal.

Table 7.4 Concentration of aerobic CFUs and estimated source strength, Equation (4.10), during different operations with high staff activity during on-going surgery in operating rooms equipped with UDF ceiling with an air volume flow of 2.75 m^3/s.

Operation (number)	Concentration* mean value (CFU/ m^3)	No of persons present* (number)	Source strength*, Equation (4.10) (CFU/s)
7	9.3	5.3	4.8
8	6.3	5.0	3.5
9	1.1	6.6	0.5
10	1.0	4.0	0.7
11	1.0	6.5	0.4
Mean value	3.7	5.5	2.0

* Values are given with one decimal.

Tables 7.3 and 7.4 show that the source strength mean value during surgical procedures during low staff activity is half the mean value obtained at high staff activity at orthopedic surgery. This difference between low and high activity is in agreement with data given by Ullmann et al. (2017).

The source strength mean values calculated for the same type of surgical clothing system with data from orthopedic procedures given by Erichsen Andersson (2013) and Nordenadler (2010) are in the same range as the source strength given in Table 7.4 (high staff activity during orthopedic surgery).

7.4 Conclusion

As a first approximation, when calculating necessary air volume flows or predicting CFU concentrations in an operating room, one can assume that the dilution principle is valid in the operating zone during on-going surgery. In such cases, beyond the total air volume flow, the number of people, their activity levels, and the chosen clothing systems should be taken into consideration.

This is in agreement with results presented by Nordenadler (2010) and recommendations by SIS-TS39:2015 (2015).

To sum up, in the described systems, when the air volume flows have the same level during on-going surgery, there are little differences in CFU levels between different room air distribution principles. Other parameters, such as clothing system, number of people and their activity level, play a more important role than the chosen room air distribution principle.

8 DISCUSSION

8.1 General

Before 2010, i.e. before Nordenadler (2010) published his doctoral thesis, most HVAC design engineers had limited knowledge about which type of room air distribution system should be used for the more demanding operating rooms for infection-prone procedures. ñLAF-ceilingsò, i.e., UDF systems, were at that time unofficial standard, as in industrial cleanrooms of ISO Class 5 and cleaner.

Most studies measuring and comparing mixing and displacing air distribution systems at that time, came to the conclusion that displacement airflow, commonly vertical downwards airflow, gave the cleanest air in the critical zone. As shown in several parts of this work, those studies compared mixing low air volume flow systems with unidirectional high air volume flow systems without normalizing the air volume flow conditions or naming the air volume flow conditions.

Many UDF-ceilings work with a supply air velocity lower than the velocity needed to ensure sweeping action. In reality, taking into account the thermals from all equipment and the staff, the airflow pattern during ongoing surgery is unstable and resembles that of mixing air. Even in Charnleyôs full-walled ñgreenhousesò with maximal physical control of the airflow, wakes and other disturbances were not avoided, see Figure 8.1.

Another example of that the airflow patterns do not follow the arrows by the designer of ventilation products can be seen in Figure 8.2.

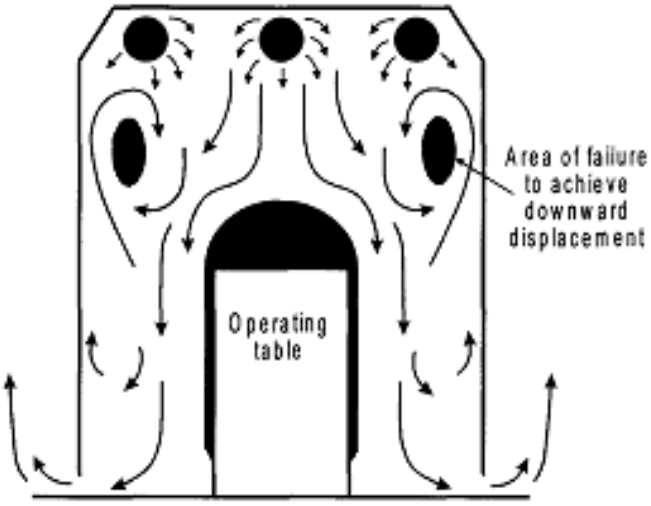


Figure 8.1 Principle of Charnley clean air enclosure ventilation using a room in the room, popular called ñgreenhouse.ò Note the stagnation zones. (Retrieved from Whyte, (2015a) based on Charnley's drawing in Charnley, (1964)).

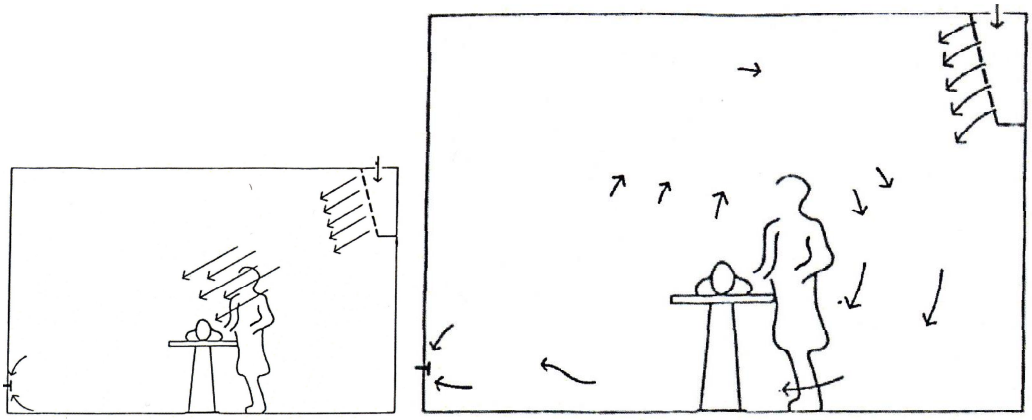


Figure 8.2 Interpretation by Ljungqvist and Öhlund, (1983) of the visualized airflow pattern generated by an inclined screen supply air terminal device in an operating room. Compare Figure 2.2 on the left.

For theoretical reasons different systems on the market can be categorized either as mixing type or displacement type of room air distribution systems. In practical use, they will perform as hybrids. It is noteworthy that supplier of the first mixing airflow system with high air volume flow presents its room air distribution system as a hybrid system, see Hagström et al (2016).

As shown in the Swedish CHOPIN-project, see part 6, it can be expected to achieve levels of aerobic bacteria in the room air as low as Ò5 CFU/m^3 with any of the three room air distribution systems studied.

The number of staff members (including visitors and other occupants in the room beside the patient) should be minimized, the grade of occlusiveness of their clothing systems should be analyzed and the airflow volume available should be known. Based on those aspects the selection of the room air distribution system should be done.

It has earlier been a widespred view that UDF-based air distribution in operating rooms generally performs as expected, independently of the number of staff members and their microbiological emission. Analysis of published studies, show that when disturbances from obstacles, thermals loads and movements are generated, the idealized displacement transport of contaminants (sweeping action of the air) is rarely met. Independently of that, the requirements of air cleanliness are mostly met.

The CHOPIN study showed that the mixing system is less sensitive than UDF and "TAF" systems to obstacles in the ceiling, movements of the surgical team, and practically offers a one-zone concept of the whole room. On the other hand, it is plausible that a UDF system with sweeping action of the air can offer the lowest level of airborne CFU in the critical zone during activity.

The hybrid system, òTAF,ò included in this study is designed out of todayôs need of two temperature zones in the same room and might offer high comfort level for the surgeons and the anesthesiology team. However, from patient safety aspects it seems advisable to have the anesthesiology team using the same basic clothing system as the surgeons in the same room. The need of higher temperature in the periphery of the room might disappear.

Other relevant aspects in system selection, not studied here, are all common aspects in construction projects: Investment cost, logistics, flexibility for future changes in work routines, requirements for energy conservation, etc., which give input to the process of selecting room air distribution system to operating rooms.

A recent CFD study (Chow and Wang, 2012) has assessed the particle concentration caused by inevitable movements of the surgeon´s bending over the wound, forwards and back again. Thus, modeling variation is an important improvement of CFD-calculations but still far from the reality of an ongoing surgery. Consider the situation (below a UDF ceiling with low air velocity) when the surgeon, after working for a while, bends over the wound, straightens his back to rest at the same time the scrub nurse makes an horizontal arm movement to give the surgeon an instrument. The intensive and complicated movement patterns during total hip arthroplasty or equivalent high activity surgery are difficult to simulate with CFD calculations.

CFD-simulations can preferably be used for designing the room air distribution system in new or rebuilt operating rooms, but not as a substitute for microbiological sampling and airflow visualization studies during mock-up or ongoing surgery. The results from those CFD-calculations should be seen as indications of possible air movements and the dispersion of contaminants during none or low staff activity and CFU levels below 10 CFU/m^3 should not be overrated.

8.2 Comparison Criteria

The choice is primarily between diluting mixing and UDF airflow to distribute HEPA-filtered air into an operating room. However, uncontrolled diluting mixing of airflows will inevitably occur occasionally and locally due to heat sources and movements of people and disturbances from equipment.

Because of that, the choice of room air distribution system in a single specific project should be based on the advantages and disadvantages of different specific products. Predominant aspects should be patient safety and working environment, but even other parameters are relevant, like investment and lifetime cost, flexibility and robustness. The calculation of the total supply air volume flow needed, is given, as a first approximation, by the dilution principle, Equation (4.9). This step in the planning process occurs before the choice of air distribution system is made.

UDF vertical downwards airflow has been used for decades in industrial cleanrooms as well as in many operating rooms worldwide. Therefore, advantages and disadvantages of the UDF-systems are well known.

Despite the disturbing effect to the airflow pattern from obstacles and surgical staff movements, there is a solid evidence of effectiveness of such systems to deliver ultra-clean room air. If the main concern is to achieve an almost bacteria-free environment by the sweeping action of the air in a limited zone of the operating room, a UDF-based room air distribution system with inlet air velocities about 0.4 m/s is expected to be acceptable, see e.g., Whyte (2015a, 2015b) and Nordenadler (2010).

It should be noted that Whyte (2015a, 2015b) in his review paper in two parts states that a UDF system, to be able to work effectively, shall have a minimum average velocity of 0.38 m/s for a partial-walled system (0.3 m/s for a full-walled) when velocity readings are taken 2 m above the floor and minimum average velocity 0.2 m/s taken 1 m from the floor.

This is in agreement with Nordenadler (2010), where measurements in operating rooms supplied with UDF-systems with as well as without

ongoing surgeries are described. The results show, when the air velocity is below 0.3 m/s, that the airflow pattern above the operating table occurs in a disordered manner. However, when the air velocity exceeds 0.4 m/s, the airflow pattern more closely resembles unidirectional airflow, and the sweeping action above the operating table seems to be significantly improved.

The disadvantage with UDF-systems becomes evident when the surgical team consists of a high number of people or the zone to be protected is large. The area of the UDF-ceiling shall cover the whole critical zone. An increase of the critical zone would need a larger area of the ceiling and thus restrict the use of ceiling mounted equipment.

The concept of diluting mixing airflow distribution systems with the same air volume flow as UDF-systems (>2 m^3/s) is rather recent in operating rooms. Both theoretical calculations and recent experiences indicate that this concept is an alternative to UDF-technology. One advantage is that they can be expected to meet the microbiological air cleanliness requirement in the whole room, even during infection-prone surgery. Another advantage is that it could be easier to upgrade older operating rooms with mixing air distribution systems, instead of changing to UDF-based systems.

One disadvantage this solution shares with UDF-based systems could be that the whole room will have the same air temperature, i.e., the same temperature as in the surgical site area. Should the anesthesia staff wear a lighter clothing system than the surgeons as is common today, the risk of discomfort could increase for the anesthesia staff. From the patient safety point of view, it is desirable and recommended in the Swedish SIS-TS39:2015 that all occupants in the operating room should use the same clothing system, i.e., with similar source strength. Note that the sterile surgical gown over the clean air suit is only for the surgical team and does not decrease the microbial source strength.

The Swedish system ñTAFò with the brand name Opragon, combines the two air distribution principals and is expected to meet the requirements of microbiological air cleanliness. One disadvantage with Opragon is its unique design of the supply air terminal devices (hemispherical), which cannot be cleaned. It should also be noted that the air movements in the critical zone are disturbed by high thermal

loads (above 6 kW). The dependency of one single supplier of those air systems could be an issue in the future.

One of the advantages of the ñTAFò -design is the thermal comfort for the anesthesia team.

The opinion that systems like ñTAFò and consequently UDF make the source strength of the used clothing systems irrelevant overlook that displacement-based systems can be expected to become occasionally disturbed during surgery. The basic principle of safety ventilation states that contaminants should be controlled near their sources and this concept should be applied independently of the chosen room air distribution system for the operating room.

A large number of new operating rooms are planned to be built in Sweden. An informal inquiry among HVAC technicians within a Swedish national network for hospital building projects, (PTS) showed that the total supply air volume flow in new operating rooms varied from about 2 m^3/s (7200 m^3/h) up to around 3 m^3/s (10800 m^3/h). Thus, it can be assumed that 2.5 m^3/s will become a standard value for the air volume flow for new common ultraclean air operating rooms in Sweden.

If the operating team, during ongoing surgery, all will use a special surgical clothing system (Clean Air Suit) with a source strength of 1.5 CFU/s or less, that allows a relatively high physical activity from all the staff members, theoretically there will be equal or less than 5 CFU/ m^3 in the operating room air with maximum eight people in the operating team.

The choice of a room air distribution system for an operating room could basically include the steps below:

- Determination of the desired microbiological cleanliness level
- Determination of the dimensional number of people
- Determination of the dimensional microbiological source strength based on the preferred clothing system
- Approximate estimation of needed total airflow (m^3/s) with aid of Equation (4.9).

If a unidirectional airflow system in an operating room has air movements with capacity to transport contamination by the sweeping action during ongoing surgery, it is possible to use a lower total airflow than what the formula for the dilution principle (Equation (4.9)) indicates to achieve the required level of air cleanliness in the operating zone. However, it should be noted that the number of people in the operating room, the chosen clothing system, and especially the activity level in the room will play a determining role.

9 CONCLUSIONS

For decades, the displacement air systems based on the UDF concept have been considered superior to dilution mixing air systems for ultra-clean air operating rooms. However, recently it has been shown, see CHOPIN Project, that during activity about the same grade of air cleanliness in the critical zone can be achieved by dilution mixing (non-unidirectional) airflow principles when used total air volume flow is in the same level as used in today's conventional sized UDF systems (low velocity systems <0.3 m/s with airflow ÒÃ m^3/s). For UDF-systems with large filter areas and high airflows (ÓÄ m^3/s) other parameters might also be of importance.

Independently of the preferred system, physical obstacles in the air stream, movements of people, and equipment generate local disturbances can increase the concentration of contaminants. The increased concentration could be a potential source of wound infection. Limitations in assessment methods, both air sampling and CFD-simulations, have not been able to quantify the effect of these disorders. The existence of disturbances has long been known from smoke visualization studies of air movements.

The discussed room air distribution systems have their advantages and disadvantages as it has been shown in this thesis. The reason is that surgical procedures are challenging, complex, and the airflow tends to become unstable in the critical zone (surgical site). Actually, more or less non-unidirectional airflows occur frequently in the critical zone of the operating room, independently of the chosen room air distribution system.

To sum up, the principles of discussed room air distribution systems are shown in Figure 9.1.

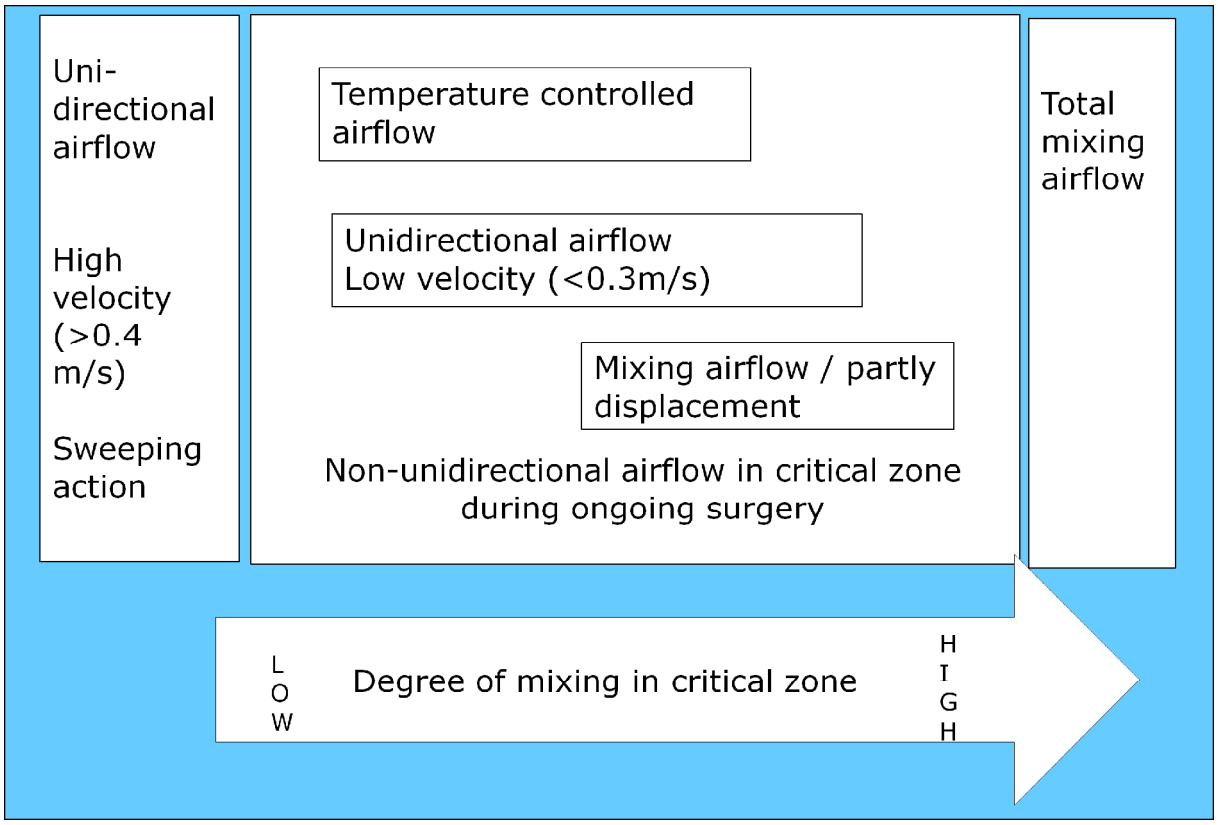


Figure 9.1 Principles of room air distribution systems in ultraclean air operating rooms.

Figure 9.1 is based on a drawing published by Fläkt Review No 71, 1987 and shows the degree of mixing that varies within the three systems; temperature-controlled airflow, unidirectional airflow with low velocities, and mixing airflow/partly displacement. This depends on, e.g., disturbances of obstacles in the airflow, presence of heat sources, and the activity level of the staff.

There are little differences in CFU levels in the critical zone during ongoing surgery among the different room air distribution principles, when the air volume flows are in the same range. Other parameters, such as clothing system, number of people and their activity level have a greater impact.

Future research

- Future research should preferably focus on which systems that are less sensitive for disturbances caused by inevitable surgery movements such as arm and upper body movements, moving the lamps, or moving ceiling-mounted equipment.

- Future research needs also to study UDF-systems with large filter areas used in intervention/hybrid operating rooms, their air movements and dispersion routes.

- Future research may also include collection of data regarding microbial air cleanliness during ongoing surgery. A comparison between results from conventional microbiological methods and results from real-time measurements could establish levels of concerns and increase monitoring quality and thus patient safety.

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APPENDIX

A.1 ï Gandra, P., Ljungqvist, B., Reinmüller, B., Tell, T., Dalaryd, G., (2016), Swedish comparative study of three principally different surgery room ventilation systems by experimental measurements and CFD calculation. ICCCS International Symposium on Contamination Control, Sao Paulo, Brazil, 157-160.

A.2 ï Gandra, P., Ljungqvist, B., Reinmüller, B., (2017), Unidirectional air flow systems with low velocities in operating rooms ï a comparison between measured values of airborne viable particles and theoretical calculated values with the dilution principle. European Journal of Parenteral and Pharmaceutical Sciences, 22(3), 82-86.