VENTILATION REQUIREMENTS IN HOSPITAL OPERATING ROOMS—PART I: CONTROL OF AIRBORNE PARTICLES

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Hospital operating rooms must meet one of the most complex sets of control requirements of any indoor environment if acceptable performance is to be achieved. The overall objective of this research project was to identify and demonstrate control strategies that could reduce energy requirements while not producing deleterious effects on the environmental quality within the operating room.

The objective was achieved through an extensive literature search, through the development of mathematical and biophysical models, and through analysis of data obtained in two existing operating rooms (OR 1 and OR 5) with different system performance characteristics. OR 1 was designed in 1961 to supply 12 air changes per hour (ACH) of 100% outdoor air through high sidewall grilles and low sidewall return registers. OR 5 was designed in 1975 to supply 25 ACH, 20% of which was outdoor air, through ceiling diffusers and mid-height return registers on the wall. The ORs 1 and 5 actually delivered 12 ACH and 17 ACH, respectively, and OR 5 provided a minimum of 17% outdoor air.

No statistically significant differences in settling rates of total particulates in five size ranges were detected between the two operating rooms during occupied conditions that simulated surgery, but a trend toward less settling of viable particles was observed in the recirculated air systems. While the magnitude of the concentration and settling rates measured in operating rooms were less than those predicted in the mathematical model and measured in the biophysical model, the patterns were similar.

A control strategy was identified through mathematical and biophysical models that would result in less settling of the larger particles while reducing the total air exchange rate in the operating rooms from 17 ACH to 12 ACH.

INTRODUCTION

Acceptable performance criteria for hospital environments must include protection and comfort of the patients; medical, nursing, administrative, and ancillary staffs; and visitors. These environmental systems generally result in greater energy demands than those in commercial or other institutional facilities, due to the complexity of the interactive effects that must be controlled. Variables include dry-bulb and mean radiant temperatures, relative humidity, gaseous and particulate concentrations, air velocity, lighting, sound, and space.

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Among the various areas within the hospital, the surgical facility, and more specifically the operating room, require special attention. Within the operating room (OR), the surgical wound must be at least partially exposed. Thus, the health, comfort, and well-being of both the patient and the surgical team must be considered if the patient's recovery rate is to be maximized. Historically, large quantities of outside air have been supplied to accomplish the required contamination control within the OR, and the energy required for heating, humidification, or cooling has been furnished as demanded. Increases in fuel costs and depletion rates of natural resources for the last decade now dictate a review of currently accepted practices.

The overall objective of this research project was to identify and demonstrate control methods that could reduce energy requirements while not producing deleterious effects on the environmental quality within the operating room.

BACKGROUND

The need for air quality control in operating rooms has been recognized for more than 100 years. Lister, whom many consider the father of the present era of aseptic surgery, reported in 1867 that infection rates could be reduced by employing antiseptic techniques (Lister 1867). Yet, as pointed out by Coriell et al. (1968) and Nelson (1975), a report in 1888 stated that two-thirds of the patients hospitalized for abdominal surgery died of infection after their peritoneums were opened. Also, in 1895, 30% of so-called "clean operations" at a New York hospital were reported to have resulted in infections. When antiseptic and aseptic techniques became accepted in the 1930s, postoperative infection rates decreased to below 10% and at times approached 1%.

During the next 30 year period, viable airborne particulates in the operating room, contaminated instruments, and sepsis of the surgical team were identified as sources of infection (McKissock et al. 1941; Lidwell and Blowers 1962). Today, contamination of surgical wounds is generally thought to result from sources summarized in Table 1. This contamination can lead to nosocomial infections, typically defined as: *

> An infection that developed during hospitalization and apparently not present or incubating at the time of admission to the hospital.

The relative importance of these sources of infection is not yet clear, though it is generally agreed that each pathway requires attention. Dixon (1973) stated that "airborne microbial contamination in operating theatres may contribute to the risk of surgical wound infection, but endogenous infection, infection acquired postoperatively, and infection transmitted by contact or common vehicle are of vastly greater importance." On the other hand, Intag et al. (1975) reported "very strong correlations" between bacteria concentrations in the operating room and postoperative infection rates, between room air changes per hour and bacteria concentrations, and between room air changes per hour and postoperative infection rate. Charnley (1973) reported that he was able to reduce postoperative infection associated with hip surgery from 7% in 1960 to 0.5% in 1970, but that he was unable to reduce the level below 1.5% through control of clean air only. To obtain the lower rate of 0.5%, he found it necessary to isolate the surgical team by use of special suits. The residual 0.5% was suspected by Charnley to be due to an endogenous vector.

Data that seem to confirm Charnley's have been reported by Nelson (1975). During total hip replacement arthroplasty, the bacterial contamination level was significantly reduced from an average of 12 colony-forming units (CFU) per liter of air per second ($L \cdot s^{-1}$), to 2.8 $CFU/L \cdot s^{-1}$ when a "laminar flow" clean air system was employed under identical conditions. When the surgical team also wore Charnley-type isolation suits, the bacteria count was further reduced to 0.86 $CFU/L \cdot s^{-1}$ at the wound site. To compare the effect of the isolators alone, tests were conducted in which the isolation suits were used but not the clean air system. The resultant counts were 3.8 $CFU/L \cdot s^{-1}$, which was not a significantly different result than that using the clean air system without the isolators. Nelson also stated that no infections were reported during any of the test conditions reported.

Another study that supported the concept of clean air control was reported by Whitcomb et al. (1971). This study resulted in a reduction of infection rate from 1.4% in a "control" room to 0.79% in a laminar downflow clean room.

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* This definition has been adopted by Mary Greeley Medical Center, Ames, Iowa, the hospital at which field data were obtained.

These studies indicate that both types of exogenous sources, shown in Table 1, must be controlled with equal care if infection is to be minimized.

Airborne infection is generally considered to be caused by two primary sources: (1) aerosolized microorganisms within the operating room and (2) contamination introduced by ventilation or infiltration (Fox 1969; Bourdillon and Colebrook 1946). Traditionally, bacterial counts have been controlled by supplying air to the operating room at rates much in excess of those required for thermal control. Several indices for performance evaluation of these systems have been proposed (Blowers and Crew 1960; Galson and Goddard 1968). Each index provides an "equivalent air change rate" required to maintain an acceptable viable particulate count within the space, but none of the indices account for filtration efficiencies, infiltration and ventilation rates, or concentration values in the outdoor air. Galson and Goddard (1968) compared their recommended air exchange rates to those recommended by Kethley et al. (1963) and found close agreement. These recommended air exchange rates were also shown to be 3.75 times greater than required by the thermal loads.

Performance of sepsis control may also be evaluated by criteria other than equivalent air exchange rate. The American College of Surgeons Committee on the Operating Room Environment (CORE) has offered a definition of microbiologic clean air (Lange 1976), in which an operating room is defined as "an enclosure specifically designed for the performance of open surgical procedures under aseptic precautions." A microbiologic clean area is defined as "a space having a filtered air supply and designed for the performance of biomedical activities where the control of viable microbiologic particles is considered essential." Viable particles are defined as "those independently airborne particles of variable size, containing or transporting microorganisms that produce colonies on culture media."

Three microbiologic classes have been defined by CORE as shown in Table 2. The document (Lange 1976) further states that testing must be done "during normal periods of work activity at a location which will yield the viable particle count of the air as it approaches the location of the actual site of work and/or equipment used in the work. This may be at a surgical incision, at an instrument table, etc." Testing of the operating room for air cleanliness has been defined to include "observation and recording of the temperature, humidity, air changes per hour, and pressure differentials, as defined for the operating room and as consistent with this definition."

It is important to note that the CORE definition does not specify ventilation rates or filter efficiency. Therefore, this definition easily could be included as part of a performance standard that could be developed for operating rooms. In this regard, a study by Marsh and Nelson (1975) indicated that the application of 99.0% filters rather than 99.99% filters in surgical clean rooms resulted in 13% reduction in power consumption with only slightly higher particulate counts at the wound site. However, they reported that the concentration of 0.5 μm diameter particles was significantly higher upstream of the work area when the lower-efficiency filter was used.

In addition to sepsis control, large quantities of outdoor air have been supplied to operating rooms to reduce the concentration of anesthetic gases below the lower explosive limits as specified by the National Fire Prevention Association (NFPA). For instance, the 1944 NFPA regulations defined, as a hazardous location, the entire operating room including an area ten feet outside the operating room doors and a height seven feet above the floor. However, if 20 CFM (10 $L \cdot s^{-1}$) per person were supplied, the hazardous area could be defined as that inside the operating room. Buck (1948) responded that 75% of the hospitals in the U.S. would have to install either ventilation systems or explosion-proof lighting to meet the 1944 NFPA criteria. He argued that a height of five and one-half feet above the floor would be sufficient for explosion protection. Subsequently, this level was approved by the NFPA.

Today, flammable anesthetics are rarely used, but codes retain the requirement for explosion-proof wiring for heights up to five feet above the floor in operating rooms (NFPA 1977). Recirculated air is now allowed, but new regulations have increased the total amount of supply air required, even though the required percentage of outdoor air (OA) has been reduced (HRSA 1984).

It is possible that these increased air exchange rates can lead to thermal discomfort due to drafts (Nevins and Miller 1972), increased risks of infection due to particle impingement in the surgical wound (Blowers et al. 1960), and more rapid diffusion of anesthetic gases that

leak into the operating room (Whitcher et al. 1975). Conversely, lower air exchange rates could minimize drafts, particle impingement, and diffusion. To further reduced gaseous concentrations in recirculated air systems, scavenger devices can also be incorporated into the ventilation system (Whitcher et al. 1975).

The number and variety of HVAC systems that have been developed for the operating theater are too numerous to detail thoroughly. However, many designs gradually became stereotyped as the designers strove to meet the requirements of codes and standards.

Many of the operating theaters now in use have been designed and built since the early 1960s (U.S. DHEW 1970). Thus, a great number of HVAC systems have followed the criteria of the ASHRAE recommendations or the HRA regulations. An older system probably would use 100% outside air at 12 ACH, while a more recent design would use 25 ACH with recirculation of the room air up to a specified maximum. As a result, two main types of systems have become common: 100% outdoor air systems and recirculating air systems.

A system that incorporates recirculation is essentially the same as the 100% outdoor air system, except that it contains a set of dampers that allows a controlled amount of air to recirculate in the system. Also, ceiling diffusers are typically used, since they are capable of handling the higher volumetric flow rates of 25 ACH, without inducing uncomfortable conditions. A fan may be employed to return some of the room air to the system. A portion of this return air is recirculated and a portion is exhausted. The amount of air that is recirculated is governed by the thermodynamic requirements of the system and the limitations as required by the regulations.

Laminar airflow systems are sometimes identified as a type of operating room HVAC system (Whitcomb 1971; Beck 1967). However, laminar airflow actually describes the type of room air distribution system in the space, as opposed to the way the air is treated and transported to the space. Thermodynamically, the laminar airflow system can be treated as a high volumetric flow rate recirculating system.

The use of variable air volume systems in operating rooms, as well as in other zones within hospitals, recently has become acceptable in both new and remodeled systems. The most current HRSA guidelines (1984) allow use of innovations such as variable air volume systems in critical areas if pressurization control and ventilation control are maintained and if the design is approved by the agency funding the construction or remodeling of the hospital.

SYSTEM MODELS

Mathematical models have been developed to identify air quality (i.e., sepsis), energy, and economic factors that can be used in assessing the performance of existing operating rooms. Because some of the analytical results led to departures from conventional sepsis control theory, biophysical models were also constructed to help validate various alternatives that could result in improved sepsis control at reduced energy requirements and annual costs. The development of the energy and economic models used in this project are reported in Part II (Woods et al. 1986).

Air Quality Model

Airborne particulate control within the operating room was modeled as a two-compartment system, as shown in Figure 1. The space of primary concern was identified as the micro-environment and was defined as the space bounded by the patient, the surgical team around the table, and the surgical lamps above the patient. The space within the operating room, which envelopes the micro-environment, was defined as the mini-environment. A buffer zone between the micro- and mini-environments was identified as the sterile zone. This latter zone is shown because it is defined by surgeons as the zone within which items required for surgery must be sterilized. For purposes of this model development, the sterile zone was assumed to be included in the mini-environment.

The two-compartment model of the operating room, Figure 1, is based on the room-coupled system previously developed for laboratory animal facilities (Woods et al. 1975). A schematic of the room-coupled system is shown in Figure 2. The two equations that define these compartments are:

$$V_r \frac{dx_r}{dt} = \dot{V}(x_s - x_r) - \dot{G}_r x_r + (\alpha \dot{V} + \dot{H})(x_c - x_r) + (1 - \phi)\dot{q} \qquad (1)$$

$$V_c \frac{dx_c}{dt} = \alpha\dot{V}(1 - \varepsilon)x_r - (\alpha\dot{V} + \dot{G}_c)x_c + \dot{H}(x_r - x_c) + \phi\dot{q} \qquad (2)$$

where

V_r = volume of mini-enviroment (i.e., the operating room less the micro-environment)

V_c = volume of micro-environment

$\dot{V}$ = room air exchange rate

$\dot{q}$ = heat or mass generation rate

$\dot{H}$ = heat or mass transfer parameter

x_r = variable describing mini-environment condition (i.e., concentration or temperature)

x_c = variable describing micro-environment condition

x_s = variable describing supply air condition

t = time

α = room-coupling coefficient

ε = filtration efficiency

ϕ = fraction of generation rate occurring in the micro-environment

$\dot{G}_r$ = settling rate factor in mini-environment

$\dot{G}_c$ = settling rate factor in micro-environment

If $\dot{q}$ and x_s are considered inputs with step perturbations about steady-state values and all other parameters are considered constant, Equations 1 and 2 simplify to a set of two linear differential equations, which may be solved for $x_r(t)$ and $x_c(t)$. A closed-form solution for these equations was obtained as part of this project and is included as Appendix 12.4 of the final report of this research project (Woods 1983).

The primary differences between this and the previous model (Woods et al. 1975) are the particle setting rate factors $\dot{G}_r$ and $\dot{G}_c$. The settling rate factor was defined by Sutton et al. (1964) as the product of the settling area, A_s, and the settling velocity, $\bar{V}_s$. Since the settling velocity is not a constant, the settling factor, $\dot{G}$, was redefined in terms of the terminal velocity of the particles, $\bar{V}_t$, and a new term, K, which was assumed to be a control factor:

$$G = KA_s\bar{V}_t \qquad (3)$$

where

A_s = settling area

K = settling rate coefficient

$$\bar{V}_t = \frac{\rho_p g D_p^2 C}{18 \mu_g}$$

ρ_p = particle density

g = gravitational acceleration

D_p = particle diameter

C = Cunningham's correction factor

μ_g = fluid viscosity

Thus, it is possible that by minimizing K, the settling of particles into surgical wounds can be minimized. To study the feasibility of this concept, numerical examples were considered. For these examples, the following factors were assumed constant:

$A_c = 3.7\ m^2$

$A_r = 33.5\ m^2$

$\dot{H} = 0.0\ m^3/min$

$\phi = 0.75$

$V_c = 6.8\ m^3$

$V_r = 106\ m^3$

$\bar{V}_t = 1.68 \times 10^{-3}\ m/s$ ($D_p = 7.5\ \mu m$; $\rho_p = 10^6\ g/m^3$)

$x_s = 0.6\ \mu g/m^3$ (in air supply x_s = TLV/100)

The independent factors that were manipulated were α, ε, t, $\dot{V}$, and $\dot{q}$. The dependent factors were x_c, x_r, G_c, and G_r.

Review of the literature indicates that the primary source of particulates in the operating room is the surgical team. By use of Schlierien photography, Lewis and his co-workers (1969; 1971), have identified the thickness of boundary layer at the surface of a standing human subject wearing briefs as varying from approximately 15 mm at a height 0.1 m from the floor to a thickness exceeding 0.1 m at a height of 1.53 m. The boundary layer was found to be laminar at the lower position with a maximum upward velocity of 0.14 m/s occurring at 3.0 mm from the body surface. However, the boundary layer was turbulent at the upper position and maximum velocity of 0.30 m/s was observed 20 mm from the body surface. These researchers also reported that the boundary layer of the nude standing man contained 30% to 400% more microorganisms than the ambient air, and that the concentrations were inversely proportional to a function of the boundary layer velocity. They have reported that clothing reduces development of the boundary layer due to the reduction in temperature difference between skin and clothing. However, they also reported that the boundary is reestablished on the outside of the clothing. From these data, typical generation rates of 7.5 µm mean diameter skin flakes were estimated at 6.0 µg/min, and for a "high-sluffer" the generation rate was estimated at 12 µg/min.

Dynamic responses to "square-wave inputs," which simulate a sudden burst of particles from a sneeze or cough, are shown in Figures 3 and 4. Note that the effects are highly significant in the micro-environment, while little effect is expected in the mini-environment. This predicted response is important, as it indicates that control of the air quality at the point of concern is critical, and that contamination control of the supply air or the air in the mini-environment may not be sufficient to protect against increased generation rates in or near the micro-environment. Furthermore, attempted solutions outside of the micro-environment may be more energy-intensive and less cost-effective (Woods et al. 1986).

Effects of filtering the micro-environmental air supply ($\alpha\dot{V}x_r$) at three room air exchange rates are shown in Figure 5. At six changes per hour a 25% reduction in $\dot{G}_c$ might be expected, if ε were increased from 0.0 to 0.99, while at $\varepsilon = 0$, a 41% reduction in $\dot{G}_c$ might occur when V_r is increased from 6 ACH to 12 ACH. However, this situation is not repeated when ACH of 12 and 24 are considered. In the latter case, only 4% difference occurs in the percent reduction of $\dot{G}_c$ by increasing ε or $\dot{V}$. The time required for each system to reach steady state is shown in Figure 6. Note that less time is required by filtering the micro-environment at 12 ACH than by increasing flow to 24 ACH. In each condition, values of x_r and $\dot{G}_r$ were essentially constant. Therefore, if significant energy savings can be obtained by an air supply rate of 12 ACH as opposed to 24 ACH, then filtering the micro-environment could apparently provide the necessary sepsis control. The implication of these comparisons is two-fold:

1. The 1974 and 1979 HRA requirements of 25 supply air changes per hour may be excessive.

2. The 1969 Hill-Burton Standards requirement of 12 supply ACH may have been sufficient, but the requirement of 5 changes per hour of outside air may not have been necessary for sepsis control.

A method of further reducing the particulate settling rate $\dot{G}_c$ is to increase α, as is shown in Figure 7. This method is commonly described as a "laminar flow technique." (Fox 1969; Whitcomb 1971). Note that the time to reach steady state decreases as α is increased (see Figure 8).

Another method of reducing G_c is to decrease the settling factor, K, as shown in Figure 9. Techniques for decreasing K may be either mechanical, such as the vortex flow devices (Marsh 1968), or natural, such as enhancement of buoyancy forces to counteract gravitational forces on particles by design of selective insulation values for surgical gowns.

Biophysical Model

Using procedures similar to those reported for validation of models for laboratory animal facilities (Woods et al. 1975), a biophysical model was constructed to simulate the characteristics of the two operating rooms being studied at Mary Greeley Medical Center. The simulation room, 12 ft x 12 ft x 7 ft ceiling height, was constructed of wood frame and plywood and was located inside a larger room in building 112-A at the National Animal Disease Center, Ames, Iowa.

Air was supplied to the "operating room" either through a high sidewall grille or through circular ceiling diffusers. The air supply rates were designed for 12 ACH through the sidewall system and 25 ACH through the ceiling diffuser system. Both systems were designed for an air diffusion performance index (ADPI) of $\geq$ 75% (Nevins and Miller 1972). The airflow rates were measured by locating a pitot tube at the discharge edge of a short radius nozzle located in the first horizontal straight duct. Control was achieved by adjustment of manual dampers in each branch.

The air-handling system for the model did not include thermal control capabilities, as the supply and exhaust air streams were mixed with the room air, which was conditioned. The supply air system consisted of a roughing filter, high efficiency particulate air (HEPA) filter, and a supply air fan controlled by a variac. The exhaust system contained two identical return grilles, one of which was sealed when the system was operated at 12 ACH. The exhaust fan speed was controlled by a variac. The exhaust air was filtered through a 35% dust-spot filter before the air was discharged into the large room.

A set of manikins (five males and three females) were constructed for this project. Each manikin was formed from polyurethane foam molded over standard adult manikins obtained from the Textile and Clothing Department. The polyurethane manikin was then wrapped with aluminum foil, after which a heater tape was wrapped outside of the foil and another layer of aluminum foil was applied. After the manikins were calibrated to maintain a uniform temperature of 32°C (i.e., maximum gradient was 4°C as measured by 20 copper-constantan thermocouples), they were draped with surgical gowns as necessary in the protocol.

A particle-generating system was designed to distribute 7.5 µm diameter particles to each of seven manikins at a rate of 12 µg/min. The system consisted of two basic components: (1) a particle-generating loop and (2) a particle-distribution loop. The particle-generating loop consisted of a chamber within which the spinning disc particle generator was placed. Particles, primarily of 5 to 10 µm diameter, were generated from a 0.10% solution of methylene chloride in methanol deposited on a spinning disc aerosol generator. Connected to the chamber was a cyclone that deposited the particles into the particle-distribution loop. Air was returned from the top of the cyclone, mixed with makeup air (to replace that discharge at the manikins), and recirculated to the generating chamber.

The particle-distribution loop consisted of a sheet metal plenum and flexible tubing through which the particles were distributed to the manikins. The small air gap between the top of the plenum and the surfaces of the manikins allowed the particles to be entrained in the developing boundary layer of the heated manikins.

To calibrate the particle distribution profile developed by the biophysical model, a test was conducted in which room air was circulated through high-sidewall grilles at 18.8 ACH, with α estimated at 0.2 (no active means provided for circulation of air in the micro-environment). Results indicated that a significant increase in particles in the range $1 \leq p \leq 10$ µm could be detected when the generator was operated, but no significant differences were detected for particles less than 1 µm or greater than 10 µm.

Particle concentrations in the micro- and mini-environments and the particle settling rates were measured by a light-scattering particle counter.

To evaluate the effects of the room-coupling coefficient, α, and the filter efficiency, ε, a vortex flow device was constructed. This device was designed from the descriptions by Beck (1967) and Marsh (1968). It consisted of an automobile air intake filter, which was housed in

A small frame connected by a flexible hose to a blower located outside the micro-environment but inside the mini-environment. The filter efficiency was rated by the manufacturer at 99.9% for 1 μm particle on a weight basis. The airflow rate delivered by the blower to the filter was controlled at approximately 48 m^3/h (82 cfm) to maintain an upward vertical discharge velocity from the vortex of approximately 0.75 m/s (150 fpm). These conditions were estimated to produce an α value of 0.41 at 12 room ACH and 0.26 at 18.8 room ACH.

METHODOLOGY

To validate the mathematical and biophysical models, measurements were required from actual operating rooms.

Site Description

Two operating rooms were selected for evaluation in Mary Greeley Medical Center, Ames, Iowa. This hospital is a medium-sized facility, which had capacity for 210 beds in 14,400 m^2 (155,000 ft^2) gross floor area in 1977. Construction was first begun on this hospital in 1915, and additions and modifications have occurred periodically since then.

Operating Room #1 (OR 1) is one of four comprising the suite that was installed in the 1961 addition to the hospital. A schematic of the HVAC system serving OR 1 is shown in Figure 10. This system was designed to supply 12 ACH of 100% outdoor air to each room in the suite having a floor area of 333 m^3 (3,580 ft^2) and a ceiling height of 3.3 m (10 1/2 ft). Thus, the total air change for this suite of rooms was designed to be 13,200 m^3/h (7,750 cfm). The air was supplied into each operating room through two high-sidewall grilles and exhausted from the rooms through two low-sidewall return registers. The air was exhausted from the rooms by means of exhaust blowers located on the roof of the building. To reduce the chances of cross-contamination, the exhaust airflow rates from the operating rooms were balanced to maintain the operating rooms at positive pressure with respect to the corridors and scrub area. Although this system was basically in compliance with the 1969 USPHS Standards (1969), the lack of final filters in the system should be noted.

Operating Room #5 (OR 5) is one of three (i.e., # 5, 6 and 7) comprising the suite that was installed in the 1975 addition. Three future ORs were also designed for this suite but had not been commissioned at the time of this study. A schematic of the HVAC system serving OR 5 is shown in Figure 11. This system was designed to supply 25 ACH, 20% of which was outdoor air, for each room in the suite. The total area of this suite is 780 m^3 (8,400 ft^2) including the new and future ORs and associated corridors and scrub area. Also included in this area are the recovery room, linen supply room, office, and central store area. This latter space is planned for conversion to additional operating rooms. The ceiling height in this area is a minimum of 3.3 m (10 1/2 ft). Thus, the total air change for this suite of rooms was designed to be 64,350 m^3/h (37,840 CFM), with 20% (12,870 m^3/h of 7,570 CFM) as a minimum of outdoor air. The air was supplied to each operating room through four four-way ceiling diffusers located in the center of each room quadrant. The air was returned from each OR through a mid-sidewall return air register. Unlike the 1961 HVAC system, no preheating was provided in the 1975 system, as only 20% of the air is introduced to the system in cold outdoor conditions. The mixed air is prefiltered and cooled, if necessary, before being discharged by the blower. Injection-type steam humidifiers, reheat coils, and final filters are located in each zone of the system. The zoning of the humidification control was noted to be a significant improvement in controllability and maintenance compared to the 1961 system. This system was designed for compliance with the 1974 HRA Standards.

Sampling Methods. A special sampling device was designed and built as part of this project so that the thermal and mass air quality in the micro-environment could be more accurately measured. This device was designed to contain the following sampling probes:

- Total particle sampling probe
- Viable particle sampling probe for six-stage cascade sampler
- Viable particle sampling probe for rotating slit sampler
- Thermistor dry-bulb element
- Dew-point temperature element
- Air velocity and direction sampling probe

To reduce the chance of sampling errors, isokinetic sampling was desirable. However, because of the low velocities expected in the OR micro-environment, isokinetic sampling required sampling probes that were unacceptably large. Therefore, anisokinetic techniques were used.

Our literature review revealed that anisokinetic sampling would yield representative results if the air velocity was low (e.g., $\leq$ 0.10 $m \cdot s^{-1}$ or 20 fpm) and particle sizes were small (i.e., $\leq$ 20 µm) (First 1972; Mercer 1973; Davis 1972; Bloomfield 1968). Details of this device are described in the final report (Woods 1983). The sampling device was introduced into the micro-environment by use of an extension arm connected to an instrument cart outside the sterile zone. This method of sampling particles in the micro-environment is shown in Figure 12. The arm was extended into the micro-environment through an area identified as the anesthesia zone. Techniques utilizing this method were coordinated through the medical staff.

Instrumentation used in conjunction with the remote sampling device was mounted on a cart outside the micro-environment but inside the sterile zone, as shown in Figure 12. The dry-bulb temperature was sensed by a thermistor, and the dew-point temperature was sensed by a lithuim-chloride bifilar element. The dry-bulb and dew-point sensors were connected to a dew-point hygrometer. Total particulate concentrations were monitored by a particle size counter. This instrument counted particles in five size ranges: $\geq$0.5-1.0 µm, 1.0-2.0 µm, 3.0-5.0 µm, 5-10.0 µm, and >10 µm. A sampling pump was integral with this instrument, but the discharge of the pump was exhausted outside the operating room, primarily for acoustic reasons. Viable particulate concentrations were sampled by two instruments in addition to settling plates--a six-stage cascade sampler and a rotating slit sampler. The cascade sampler contained the six standard sieve sizes: 0.5-1.0 µm, 1.0-2.0 µm, 2-3.5 µm, 3.5-6 µm, 5-10 µm, and 8-15 µm. The rotational speed of the slit sampler was set at 40 minutes per revolution. The sampling dishes for those instruments were prepared with standard blood and nutrient agars to measure colony-forming units after 48 hours incubation of the agars. The vacuum pump required for the cascade and slit samplers was located outside the operating room, primarily for acoustic reasons. Settling plates, also prepared with standard blood and nutrient agars, were placed at the head, middle, and foot of the operating table and on another table outside the micro-environment to provide additional sampling for the settling of viable particulates.

Procedures

Data acquisition procedures were developed to compare the environmental conditions within the micro- and mini-environments during occupied and unoccupied periods. To achieve this objective at minimum risk to patients, the procedure agreed upon with the surgical staff was that studies in the two operating rooms would be conducted after normal surgery hours but before the rooms were cleaned for the following day. Thus, unoccupied conditions were defined as those after normal surgery had been completed, the surgical lamps and other internal loads had been de-energized, but the room had not been cleaned. During unoccupied testing periods, only the data recorder (i.e., research team member) had access to the room.

To obtain data during periods of occupancy, the OR nursing supervisor orchestrated members of the research team through exercises in the operating rooms that approximated activities of the surgical team. For the purpose of obtaining data within the micro-environment, agreement was reached with the surgical staff and the research team that this methodology should provide sufficient evidence of concentration differences and settling rates to validate conclusions obtained from the mathematical and biophysical models. Moreover, these data could be obtained without increasing the risk of nosocomial infection. The experimental design and conditions monitored in ORs 1 and 5 are shown in Tables 3 and 4.

For data acquisition in the biophysical model, conditions were established to simulate those observed in the operating rooms. Thus, the biophysical model was operated at reference conditions of 12 ACH, distributed to the mini-environment through a high sidewall grille to simulate OR 1, and at 18.8 ACH, distributed through four circular ceiling diffusers to simulate OR 5. For comparison, the complementary conditions of 18.8 ACH through the high-sidewall grille and 12 ACH through the ceiling diffusers were also tested.

To evaluate the effect of micro-environmental filtration, the tests described above were repeated with the vortex flow device mounted on the thoracic area of the "patient" manikin.

The experimental design and conditions that were monitored in the biophysical model are shown in Tables 5 and 6.

RESULTS

The air supply rate in OR 1 was measured as 1360 m^3/h (800 cfm) of 100% outdoor air, which is commonly equated to an air exchange rate of 12.4 ACH (i.e., floor area = 34.2 m^2 and ceiling height of 3.3 m). The measured total air exchange rate in OR 5 was 2300 m^3/h (1350 cfm), and

is commonly considered to be equal to 17 ACH (i.e., floor area = 41.2 m^2 and ceiling height of 3.3 m). The percentage of outdoor air for OR 5 was measured at 17%.

Thermal conditions measured in the mini-environments of ORs 1 and 5 indicate that steady state could be assumed in each test, as the standard deviations for the dry-bulb temperatures were less than 2% of the mean values, except for test 27, which was approximately 3%. The dew-point temperatures for these tests were also stable, as their standard deviations were less than 1°C except for test 31, which was ± 1.6°C. All of the tests had ranges within 18-24°C dry-bulb temperature and 4-16°C dew-point temperature, except three in OR 1 (i.e., tests 2 and 12, which had dew-point temperatures of 1.6 and 0.8°C, respectively, and test 20, which had a dry-bulb temperature of 25.8°C).

Thermal conditions, measured in the mini- and micro-enviroments of the biophysical model, indicate that steady state existed for each test, as the standard deviations of the dry-bulb temperature were all less than 0.6°C and the standard deviations of the dew-point temperatures were less than 0.4°C. However, the dry-bulb temperatures within the mini-environment were all slightly in excess of the thermally acceptable range of 18-24°C. The dew-point temperatures were within the acceptable range of 4-16°C, with the exception of tests 39, 42 and 43, where the dew-point temperatures were low. These temperature deviations resulted, not from providing a method of cooling the supply air to the biophysical model, but rather depending on the air temperature within the laboratory for thermal control. In future tests, provisions should be made to thermally control the mini-environment of the biophysical model. A significant increase of 1.1 ± 0.7°C ($\alpha < 0.1$; $n = 16$) was detected in the dry-bulb temperature between the mini- and micro-environments. This result supports the hypothesis that effects of convection within the micro-environment may act to minimize the settling of particles, if these effects can be properly controlled.

Concentrations of total and viable particles by size distribution from the micro-environments of ORs 1 and 5 are shown in Tables 7 and 8, respectively. These data indicate the classical pattern of decreasing concentrations of total particles with increasing particle size (First 1972; Mercer 1973; Davis 1972; Bloomfield 1968; Davis 1968). However, the concentrations of viable particulates tended to maximize in the range of 2.0-3.5 µm in the micro-environment of OR 5. These patterns seem to be supported by the work of Lewis et al. (1969), and suggest that the primary source of contaminants to be expected in the operating room may be with particulates in the 2-6 µm range that have been generated from within the operating room.

Although no statistically significant settling rates were detected as measured by the difference in concentration when the probes were horizontal and vertical, respectively, some trends may exist. Table 7 shows that positive settling rates may have existed in OR 1 for all but the largest (i.e., >10 µm) particle size ranges in the unoccupied room and for all but the 3.0-5.0 µm range in the occupied room. Conversely, positive settling rates may have existed in OR 5 in only three of six ranges in the unoccupied room, while positive settling rates may have existed in all but the largest (i.e., >10 µm) ranges in the occupied room.

Results of the setting rate analysis for viable particulates are shown in Table 8. Again, no statistically significant settling rates were detected, but positive values were found in both rooms for some ranges in both the unoccupied and occupied conditions. Of particular interest is the fact that the highest settling rate occurred in the 2.0 3.5 µm range for OR 1 when unoccupied and for larger ranges when occupied. However, the setting rates of viable particles in OR 5 are less obvious.

Table 9 indicates the concentrations for all sizes of total and viable particles sampled in the micro-environments of OR 1 and OR 5. These are the sums of the concentrations listed in Tables 7 and 8. Also shown in Table 9 are the viable particulate concentrations as collected in settling plates located at three locations within the micro-environments and at one location in the mini-environments of OR 1 and OR 5. These data suggest that the operating rooms were close to compliance as Class 10,000 clean rooms (ASHRAE 1982). Also, the airborne samples of viable particles, obtained with the cascade sampler, indicate that ORs 1 and 5 performed approximately as Class 5 and Class 1 clean areas, respectively (see Table 2). These data also indicate that no statistically significant settling rates were detected, except possibly for one condition. That condition was as sampled by settling plates in the mini-environment of OR 1 during unoccupied conditions. Although statistically significant data were not obtained, some interesting trends were observed:

-- Positive, but nonsignificant, settling rates were detected by all measures in the unoccupied conditions for ORs 1 and 5, except for total particulates in OR 1.

-- When compared to unoccupied conditions, either negative or smaller positive values of settling rates were detected by all measures in the occupied conditions of ORs 1 and 5, except for total particulates in OR 5.

These results indicate that if standard deviations are reduced with additional tests, the concept may be validated that the presence of the boundary of the micro-environment, imposed by the surgical team, may result in sufficient convection to increase the buoyancy of the particles in the micro-environment during occupied conditions.

Table 10 shows the viable particulate concentrations sampled during four 10-minute periods. No specific trends are obvious from these data to indicate that a transient characteristic was present. Thus, these data seem to reinforce the previous evidence that steady-state conditions existed during these tests. However, as shown in Figure 13, the viable concentrations obtained by the slit sampler were significantly higher than those obtained with the cascade sampler. Thus, if CFU/m^3 is to be a meaningful figure-of-merit for evaluating the microbial cleanliness of operating rooms, a standard method of sampling will be required. For example, the data obtained with the slit sampler indicate that ORs 1 and 5 should be classified as Class 20 and 5, respectively, rather than Class 5 and 1, as indicated by the data obtained by the cascade sampler.

Ratios of viable to total particulates, which were sampled in ORs 1 and 5, are shown in Figure 14 as a function of particle size. This ratio is significant as it increases with particle size ($r > 0.8$ for each test), although the total particulate concentrations decrease with particle size, as indicated in Table 7. No difference in this ratio by particle size was detected due to room effects (i.e., OR 1 and OR 5) or occupancy (occupied or unoccupied). The importance of this ratio is that the large viable particles may be the most likely to cause bacterial infection in the surgical wound. That the concentration of viable particles persists, while the concentration of total particles decreases, may indicate that the larger non-viable concentrations are removed from the micro-environment at a faster rate than they are generated, whereas the larger viable particles may be generated at rates that either equal or exceed the rates of removal.

DISCUSSION

A comparison of total and viable particles sampled in the micro-environment of OR 1 and of total particles sampled in the micro-environment of the biophysical model is shown in Figure 15. For this comparison, only the particles sampled with the plate of the sampling probe in the horizontal position were considered. For the cases where the air was distributed through the high sidewall grille at 12 ACH and at 18.8 ACH, the lower rate is to simulate the air exchange rate in OR 1 and the higher rate is to simulate the total supply rate in OR 5, but in a high sidewall configuration. A similar comparison of total and viable particulates sampled in the micro-environment of OR 5 and of total particles sampled in the micro-environment of the biophysical model is shown in Figure 16. For this comparison, the biophysical model was adjusted to provide 18.8 ACH through four ceiling diffusers. This air exchange rate was approximately 10% higher than that measured in OR 5 but was nearly 25% less than that designed for that room. For this comparison, the particles in both OR 5 and the biophysical model were sampled with the plate of the sampling probe in the horizontal position. Also, for comparison, the particle size distribution in the biophysical model is shown in Figure 16 for the case where the air was distributed through ceiling diffusers at 12 ACH to simulate the air exchange rate in OR 1.

As indicated in Figures 15 and 16, the particle size distributions sampled in the biophysical model exhibited higher concentrations than those sampled in the operating rooms but appeared to be compromises between those obtained in the operating rooms for viable and total particulates. A comparison between the concentrations of viable particles in OR 1 and total particles in the biophysical model, both operated at 12 ACH, indicates that peak concentrations tended to occur in a particle size range of 2-3 μm and that the concentrations of larger particles tended to remain constant for larger particles. When the biophysical model provided supply air at 18.8 ACH through the high sidewall grille, a pattern similar to that at 12 ACH resulted, but the particulate concentrations were lower. Of particular interest is that the concentrations of the particles in the biophysical model exhibited patterns that more closely resembled those for viable particles than total particles in OR 1. This finding may indicate the sensitivity of the micro-environment to the location of the generating sources. A comparison between the concentrations in OR 5 and in the biophysical model, operated at 17 ACH and 18.8 ACH, respectively, indicates that a slight increase in viable particles was detected in the 4-8 μm size range; however, the biophysical model did not verify this. Rather, only a

reduction in the decrease of particulate concentrations was indicated as a function of increasing particle size. As in the case of high sidewall grilles, the concentrations of larger particles in the biophysical model more closely resembled those for viable particles than total particles in OR 5. When the biophysical model provided supply air at 12 ACH through the ceiling diffusers, concentrations were detected to be lower than at 18.8 ACH, and the pattern that resulted was similar to those for high sidewall grilles; note the peak at the 1-2 μm particle size range. These results indicate that the air supplied through ceiling diffusers at 12 ACH may be more effective in controlling the distribution of particles in the micro-environment than at 18 ACH. Conversely, the air supplied through high sidewall grilles at 18 ACH may be more effective in controlling the distribution of particles in the micro-environment than at 12 ACH.

The higher concentrations of smaller particles detected in the biophysical model, compared to total particulate concentrations (i.e., viable and nonviable) in the operating rooms, are probably due to our inability to minimize the number of small particles produced by the spinning-disc particle generator. If the small particles could have been minimized, patterns more closely resembling those for viable particles in the operating rooms may have resulted. This possible relationship between mono-dispersed total particles and viable particles is of interest for future studies.

The measure of colony-forming units per cubic meter of sampled air is highly dependent on the type and size of viable particle (e.g., bacterial, fungal, etc.). This measure is also slow as it depends upon an incubation of approximately 48 hours. Thus, if real-time control is to be achieved, new methods for determining viability are required, or reliance on measures of total particulate concentrations must be continued. The comparisons in Figures 15 and 16 indicate that concentrations of total particles in the micro-environment of OR 1 during occupied conditions are similar to unoccupied conditions for all but the largest size ranges, whereas the concentrations during occupied conditions in OR 5 were consistently higher than during unoccupied conditions. Moreover, the concentrations of viable particles up to 8 μm tended to be less for occupied conditions than for unoccupied conditions. These results are similar to tests previously reported for air-distribution patterns in rooms containing animal cages (Woods et al. 1975). In this case, as well as for the laboratory animal facilities, the location of the air terminal devices is important.

The concentrations of total and viable particles up to 8-10 μm in the micro-environment of OR 1 are similar for occupied and unoccupied conditions; this possibly is due to a combination of effects (Nevins and Miller 1972; Woods et al. 1975):

-- Additional convective currents in the micro-environment may have developed from the heat dissipated by the surgical team and the surgical lamp.

-- "Throw" characteristics of high sidewall grilles at 12 ACH and 18.8 ACH may have transported the supply air over the top of the micro-environment (see Figures 1 and 10), thus minimizing "dumping" of the supply air into the micro-environment.

-- The additional convective currents and the throw characteristics may have had a combined effect of "lifting" and "inducing" the smaller particle (i.e., less than 8-10 μm) out of the micro-environment and into the "secondary" or "tertiary" air stream above the micro-environment (Nevins and Miller 1972; Blowers and Wallace 1960).

The reduction in concentrations as the air exchange rate was increased from 12 ACH to 18.8 ACH in the micro-environment of the biophysical model with the high sidewall grille also supports this argument. The "throw" would increase as the air exchange rate and the ability to induce transport from the micro-environment would be enhanced.

The concentrations of total particles were greater while the concentrations of viable particles tended to be fewer in the micro-environment of OR 5 for occupied compared to unoccupied conditions; this also may be explained by a combination of effects:

-- Additional convective currents in the micro-environment may have developed from the heat dissipated by the surgical team and the surgical lamp.

-- "Throw" characteristics of the ceiling diffusers may have caused a "downdraft" at the center of the room, which is also the center of the micro-environment, thus enhancing "dumping" of the supply air into the micro-environment.

-- The additional convective currents and the throw characteristics may have suppressed the lift of the smaller particles (i.e., less than 8-10 μm) out of the micro-environment.

The reduction in concentrations as the air exchange rate is decreased from 18.8 ACH to 12 ACH in the micro-environment of the biophysical model with ceiling diffusers also supports these reasons. If the "downdraft" due to the throw characteristic were decreased by reducing the airflow, the suppression of the "lift" in the micro-environment may have been reduced, thus increasing the discharge of particles and decreasing the concentrations.

The concentrations of total particles in the micro-environment of OR 5 during occupied conditions exceeded unoccupied conditions, while the reverse occurred in OR 1; this may be explained by the methods of air cleaning (i.e., filtration):

-- A two-stage filtering system for mixed air existed for OR 5, while a single-stage filtering system for outdoor air existed for OR 1 (see Figures 10 and 11).

-- The filtration efficiency for OR 5 was better than for OR 1.

-- The concentrations of total particles for unoccupied conditions were less in the micro-environment of OR 5 than in that of OR 1.

-- The concentrations of total particles for occupied conditions were approximately the same in the micro-environments of OR 5 and OR 1.

The biophysical model could not be used to support or refute these reasons, as the same method of filtration was used for both types of air distribution systems.

Comparisons of concentrations of the 5-10 μm particles within the micro-environments, as measured in the operating rooms and biophysical model and predicted by the mathematical model, are shown in Table 11. Likewise, comparisons of the settling rates of the 5-10 μm particles are shown in table 12. Because of the large standard deviations resulting from these tests, statistical analyses could not be used. However, some trends are apparent from the data. During unoccupied conditions, the concentrations of both total and viable particles in the micro-environments were less in OR 5 than in OR 1. During occupied conditions, the concentrations of both total and viable particles in OR 1 remained essentially unchanged from the unoccupied values. However, in OR 5, an increase in total particulates and a decrease in viable particles apparently occurred when the room was occupied. Moreover, the concentration of total particles in the micro-environment of OR 5 during occupied conditions was similar to those measured in OR 1 during both occupied and unoccupied conditions. It is particularly interesting to note that the concentration of viable particles measured in OR 5 during occupied conditions was the lowest value obtained in both operating rooms, whether occupied or not.

The concentrations of 5-10 μm particles (i.e., methylchloride particles) measured in the biophysical model apparently decreased as the air distribution was changed from that simulating OR 1 to that simulating OR 5. Although the concentrations in the biophysical model were much greater than those measured in the operating rooms, the changes with system type were similar to those obtained in the operating rooms. These differences are similar to those predicted from the mathematical model, as shown in Figure 5, for the unfiltered micro-environment; however, it should be noted that the mathematical model did not account for differences in diffuser locations.

When the micro-environmental filtration system (i.e., vortex flow device) was tested in the biophysical model, decreases in concentrations were observed for both types of room air-distribution systems. Furthermore, the concentrations in the system simulating OR 5 without the vortex flow device were similar to those in the system simulating OR 1 when the vortex flow device was energized.

The large variances in the data, shown in Table 12, precluded statistical analyses, but trends also were apparent for settling rates. In patterns similar to those for concentrations, the settling rates of both total and viable particles in the micro-environments were less in OR 5 than in OR 1 during unoccupied conditions. The negative settling rate of total particles in OR 5 during unoccupied conditions indicates that a slight upward mobility of particles might have occurred. A comparison of data for unoccupied and occupied conditions indicates that patterns for settling rates for both total and viable particles differed from the patterns for concentrations. Whereas in OR 1 the concentrations of total and viable particles remained unchanged and in OR 5 the concentrations of total particles increased while the concentrations

of viable particles decreased, the settling rates in both operating rooms decreased when the rooms were occupied, except for viable particles in OR 1. These results support the hypothesis that natural convective currents within the micro-environment may be sufficient to restrain the particles from settling into the surgical wound and that enhancement of the currents may be one means to improve sepsis control in the operating room.

A comparison of the settling rates, as predicted by the mathematical model for the occupied operating rooms within the vortex flow device and as measured during simulated surgery in the operating rooms, indicates that reasonable agreement was obtained for total particles (i.e., -22% error for OR 1 and 4.5% error for OR 5). The mathematical model overestimated the magnitude of settling rates of viable particles in the operating rooms, but the model did predict that the settling rate would be less in OR 5 than in OR 1. The most obvious reason for this difference is the large generation rate of particles that was assumed in the model. If the value for $\dot{q}$ was less than 12 µg/min, differences in terms of concentrations and settling rates would be smaller. However, the closeness of predicted and measured values of settling rates of total particles also adds support to the hypothesis regarding the effectiveness of natural convection.

The reduction in settling rates due to the vortex flow device as predicted by the mathematical model (Table 12) is also consistent with the reduction in concentration as measured in the biophysical model (Table 11). These data indicate that forced-convection effects within the micro-environment also can be used effectively to improve sepsis control with the operating room.

CONCLUSIONS AND IMPLICATIONS

That airflow patterns may be as important to sepsis control as airflow rates is inferred from data obtained in the biophysical model. As shown in Figures 15 and 16, when the highly filtered air was supplied through the high sidewall grilles at 18.8 ACH rather than 12 ACH, the total particle concentration in the micro-environment decreased. Conversely, when the highly filtered air was supplied at 18.8 ACH rather than 12 ACH through the ceiling diffusers, the total particle concentration in the micro-environment increased. Thus, the larger throw value of the high sidewall grilles at higher flow rates may induce the air from the micro-environment into the mini-environment. Conversely, the larger throw value of the ceiling diffusers at the higher flow rates could cause "dumping" of the air from the mini-environment into the micro-environment and result in a suppression of the upward mobility gained by the particles due to the effects of natural convection.

A major inference to be drawn from these data is that 12 ACH of highly filtered air supplied to the mini-environment through ceiling diffusers may minimize the total particulate concentration in the micro-environment during occupied conditions. This implication also supports the hypothesis that effects of natural convection within the micro-environment may act to lift the contaminants upward and out of the field of surgery.

A second major implication of the data obtained in the existing operating rooms is that a significant relationship exists between the concentrations of viable and total particulates within the micro-environment. As shown in Figure 14, the ratio of viable to total particulate concentrations increases substantially as the particle size increases. The differences in concentrations between viable and total particulates are also shown in Figures 15 and 16. From these data, it may be implied that the smaller viable particles are more readily removed from the micro-environments than are the larger ones; thus, the probability of filtering the smaller viable particles is better. Conversely, the larger viable particles apparently remained airborne in the micro-environments, even though the larger total particles were either removed or settled. One plausible explanation for these differences is that buoyancy force dominated the gravitational force on the smaller particles, thus lifting them out of the micro-environment, whereas the gravitational and buoyancy forces may have been similar on the larger particles, thus suspending them in the micro-environment. Whether the lower overall concentrations of viable particles in OR 5 during occupied conditions (i.e., Class 1 for OR 5 versus Class 5 for OR 1) was due to the room air distribution or to system filtration could not be determined from these results.

A third major finding from the data obtained in the existing operating rooms is that settling rates of particles within the micro-environments probably can be measured. As indicated in the derivation of the mathematical model for this system, the primary objective, or objective function, for sepsis control in the operating room is the suppression of settling of viable particles into the field of surgery. Indirect methods of achieving this objective

function, which have been relied upon in the past, include introduction of large quantities of outdoor or highly filtered recirculated air, laminar flow systems, and other similar methods of control in the mini-environment. Data obtained in this study indicate that the settling rates of viable particles in the micro-environment tend to decrease during occupied as compared to unoccupied conditions, even though the concentrations tend to remain constant or increase. These results indicate that the methods of control within the mini-environment are not as important to sepsis control as methods of control within the micro-environment. For example, the effects of natural convection generated by the body heat of the surgical team and the surgical lamp may contribute significantly to the suppression of particulate settling into the field of surgery and may enhance upward mobility of the particles in the micro-environment.

A fourth inference drawn from these data is that thermal control for the "comfort" of the occupants may affect the sepsis control within the micro-environment. The dry-bulb temperature within the micro-environment was elevated an average of 1.5°C (SD = 0.69, n = 16) above that in the mini-environment of the biophysical model tests. Assuming that the relative humidity was also elevated in the micro-environment, that the activity level of the surgical team was about 2.0 met, and that the thermal insulation of the surgical apparel was about 1.0 clo, thermal sensations of "slightly warm" to "warm" should be expected from the surgical team. Moreover, regulatory sweating of the surgical team should be expected. If skin wettedness enhances skin sloughing, then higher concentrations of particles and higher values of their settling rates in the micro-environment should be detectable at the higher dew-point temperatures.

A fifth implication of these results is that control of the micro-environment can be achieved directly and that reliance only on indirect methods is not necessary or desirable. As indicated in Tables 11 and 12, the vortex flow device was able to reduce the concentrations and settling rates of the particles in the micro-environment. Moreover, this and other types of micro-environmental control devices could also provide spot cooling and spot lighting for the surgical team.

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We are thankful to Dr. Joseph R. Songer at the National Animal Disease Center for the use of his laboratory and for making the special arrangements for our use of the remote laboratory 119 for the biophysical studies during this project; to Ms. Phyllis Crouse, director of nursing, and Dr. Roger L. Westerlund, anesthesiologist, both of Mary Greeley Medical Center, for their support and advice during this project; and to Dr. William C. Beck, president of Donald Guthrie Foundation for Medical Research, Sayre, Pennsylvania, and Mr. R. Claude Marsh, biomedical consultant, Albuquerque, New Mexico, for their advice and consultation.

We are especially thankful to Mr. John D. Worley, director, to the members of the Board of Directors, and to the medical staff at Mary Greeley Medical Center, for their cooperation and encouragement in this research.

TABLE 1

Sources of Nosocomial Infections in Operating Rooms

Source of Infection	Route of Pathway
Endogenous	1. Self contamination by the patient through viscera or improper skin cleansing prior to surgery (3,6,7).
Exogenous	1. Direct contact from unsterile instruments, contaminated surfaces or spread of droplets generated by hospital personnel in close contact with the patient (3,7,8,9).
	2. Airborne droplet nuclei and dust which transmit microbiological agents to the surgical wound (3,7,8,9).

TABLE 2

Air Cleanliness Classes for Microbiologic Clean Areas (17)

	Colony-forming Units Per Unit Air Volume		Minimum Sample Volume	
Class	CFU/ft^3	CFU/m^3	ft^3	m^3
1	1	35	30	0.85
5	5	175	30	0.85
20	20	700	10	0.28

TABLE 3

Experimental Design for Assessment of Thermal and Mass Air Quality in Operating Rooms 1 and 5

Occupancy	Probe Position	OR #1	OR #5
Unoccupied	horizontal	Tests 1-4	Tests 5-8
	vertical	Tests 9-12	Tests 13-16
Occupied	horizontal	Tests 17-20	Tests 21-24
	vertical	Tests 25-28	Tests 29-32

TABLE 4

Data Recorded during Each 40-minute Test Interval in Operating Rooms 1 and 5 during Thermal and Air Quality Assessment

Micro-environment	Mini-environment
1. Total particulates	1. Supply airflow rate
2. Total viable	2. Supply air dry-bulb temperature
3. Total viable	3. Supply air dew-point temperature
4. Dry-bulb temperature	4. Return air dry-bulb temperature
5. Dew-point temperature	5. Return air dew-point temperature
6. Settling viables (settling plates)	6. Electrical load in room
	7. Room occupancy-activity level
	8. Settling viables (settling plates)

TABLE 5

Experimental Design for Assessment of Thermal and Mass Air Quality in the Biophysical Model

Air Change per Hour	Filtered Micro-environment	Type of Air Distribution	
		High-sidewall Grilles	Ceiling Diffusers
12	yes	Tests 34-35	Tests 36-37
	no	Tests 38-39	Tests 40-41
18.8	yes	Tests 42-43	Tests 44-45
	no	Tests 46-47	Tests 49-50

TABLE 6

Data Recorded during Each 10-minute Test Interval in Biophysical Model after Particles Had Been Generated for 45 Minutes

Micro-environment	Mini-environment
1. Total particulates (probe horizontal)	1. Supply air temperature
2. Dry-bulb temperature	2. Dry-bulb temperature
	3. Dew-point temperature

TABLE 7

Average Total Particulate Size Distributions (10^3 particles/m^3) in the Micro-environments of Operating Rooms #1 and #5 during the 40-minute Sampling Periods (M ± SD)

Occupancy	Probe Position	Sampling Size	Sampling Range (μm) 0.5-1.0	1.0-2.0	2.0-3.0	3.0-5.0	5.0-10.0	>10
Operating Room #1								
Unoccupied	Horizontal	3[1]	320 ± 52	148 ± 193	14.7 ± 7.9	2.30 ± 1.85	0.56 ± 0.36	0 ± 0
	Vertical	2[2]	288 ± 26	14.1 ± 7.9	4.94 ± 2.0	1.27 ± 1.21	0 ± 0	0 ± 0
	difference[3]		32 (NS)	134 (NS)	9.8 (NS)	1.0 (NS)	0.56 (NS)	0 (NS)
Occupied	Horizontal	4	266 ± 78	39.6 ± 13.7	16.7 ± 5.7	2.50 ± 1.26	0.68 ± 0.48	0.26 ± 0.28
	Vertical	4	256 ± 44	34.7 ± 4.0	16.3 ± 3.4	5.90 ± 5.33	0.49 ± 0.29	0.07 ± 0.23
	difference[3]		10 (NS)	4.9 (NS)	0.4 (NS)	-3.4 (NS)	0.19 (NS)	0.19 (NS)
Operating Room #5								
Unoccupied	Horizontal	4	80 ± 32	11.4 ± 8.9	3.0 ± 1.3	1.2 ± 1.5	0.04 ± 0.05	0 ± 0
	Vertical	4	105 ± 87	10.0 ± 11.0	2.7 ± 2.5	0.68 ± 0.42	0.18 ± 0.25	0.02 ± 0.04
	difference[3]		-25 (NS)	1.4 (NS)	0.3 (NS)	0.5 (NS)	-0.13 (NS)	-0.02 (NS)
Occupied	Horizontal	4	228 ± 75	25.4 ± 3.1	11.9 ± 2.2	3.8 ± 1.2	0.62 ± 0.30	0.04 ± 0.05
	Vertical	4	208 ± 63	22.6 ± 4.4	10.2 ± 1.2	3.1 ± 1.3	0.53 ± 0.32	0.06 ± 0.08
	difference[3]		20 (NS)	2.8 (NS)	1.7 (NS)	0.7 (NS)	0.09 (NS)	-0.02 (NS)

[1]Test #2 deleted from analysis.

[2]Tests #1 and 12 deleted from analysis.

[3]The difference between Horizontal and Vertical values divided by the 40-minute sampling period and normalized for a 1 - m^2 unit area of surgical wound represent the particle settling rates (particle/min - m^2).

TABLE 8

Average Viable Particulate Size Distributions (CFU/m^3) in the Micro-environments of Operating Rooms #1 and #5 during the 40-minute Sampling Period (M ± SD)

Occupancy	Probe Position	Sampling Size	Sampling Range (μm)					
			<1.0	1.0-2.0	2.0-3.5	3.5-6.0	5.0-10.0	8.0-15.0
Operating Room #1								
Unoccupied	Horizontal	3[1]	0.3 ± 0.3	33 ± 12	91 ± 41	41 ± 14	23 ± 6	15 ± 6
	Vertical	2[2]	1.5 ± 0.7	20 ± 16	59 ± 57	53 ± 3	16 ± 9	14 ± 5
	difference[3]		-1.2 (NS)	13 (NS)	32 (NS)	-12 (NS)	7 (NS)	1 (NS)
Occupied	Horizontal	4	1.75 ± 1.3	24 ± 8	50 ± 22	24 ± 6	24 ± 10	35 ± 19
	Vertical	4	0.75 ± 0.5	32 ± 7	53 ± 28	20 ± 6	13 ± 7	19 ± 10
	difference[3]		1.0 (NS)	-12 (NS)	-3 (NS)	4 (NS)	9 (NS)	16 (NS)
Operating Room #5								
Unoccupied	Horizontal	4	3.5 ± 2.4	4.2 ± 2.9	8.0 ± 4.7	15 ± 5.6	11.0 ± 5.8	1.8 ± 2.9
	Vertical	4	5.5 ± 4.2	4.5 ± 4.5	3.5 ± 1.0	11 ± 3.8	5.2 ± 2.9	1.2 ± 1.9
	difference[1]		-2.0 (NS)	-0.3 (NS)	4.5 (NS)	4.0 (NS)	5.8 (NS)	0.6 (NS)
Occupied	Horizontal	3[4]	17 ± 3.0	5.7 ± 3.8	3.7 ± 0.6	5.7 ± 3.8	6.0 ± 3.6	1.7 ± 1.5
	Vertical	3[5]	11 ± 6.0	4.7 ± 2.9	5.3 ± 3.2	5.0 ± 2.6	5.7 ± 2.9	1.0 ± 1.0
	difference[3]		6.0 (NS)	-4.0 (NS)	-1.6 (NS)	0.7 (NS)	0.3 (NS)	0.7 (NS)

[1]Test #2 deleted from analysis.

[2]Tests #1 and 12 deleted from analysis.

[3]The difference between Horizontal and Vertical values divided by the 40-minute sampling period and normalized for a 1 - m^2 unit area of surgical wound represent the particle settling rates ($CFU/min - m^2$).

[4]Test #24 deleted as samples were destroyed; particles could not be counted.

[5]Test #32 deleted as samples were destroyed; particles could not be counted.

TABLE 9

Average Concentrations of Total and Viable Particulates Collected in Operating Rooms #1 and #5 during the 40-minute Sampling Period (M ± SD)

			Micro-environment						Mini-environment
					Viable Particles				Viable Particles
					Settling Plates (CFU/m^2)				Settling Plates
Occupancy	Probe Position	Sampling Size	Total Particles (10^3 part/m^3)	Andersen Sampler (CFU/m^3)	Head	Middle	Foot	Average[4]	(CFU/m^2)
Operating Room #1									
Unoccupied	Horizontal	3[1]	374 ± 66	204 ± 71	1,075 ± 671	1,667 ± 610	1,398 ± 652	1,380 ± 614	1,290 ± 559
	Vertical	2[2]	307 ± 251	163 ± 84	323 ± 0	888 ± 798	806 ± 456	672 ± 493	241 ± 114
	difference[3]		67 (NS)	41 (NS)	752 (NS)	779 (NS)	592 (NS)	708 (NS)	1,049 ($\alpha \leq 0.05$)
Occupied	Horizontal	4	325 ± 97	159 ± 47	1,935 ± 574	1,814 ± 579	2,097 ± 1,010	1,949 ± 713	1,048 ± 773
	Vertical	4	310 ± 50	132 ± 42	1,411 ± 580	1,854 ± 806	2,016 ± 963	1,761 ± 770	1,693 ± 773
	difference[3]		15 (NS)	27 (NS)	524 (NS)	-40 (NS)	81 (NS)	188 (NS)	-645 (NS)
Operating Room #5									
Unoccupied	Horizontal	4	96 ± 43	43 ± 20	645 ± 348	202 ± 155	685 ± 203	511 ± 321	242 ± 208
	Vertical	4	119 ± 91	31 ± 15	363 ± 155	161 ± 186	242 ± 94	256 ± 161	40 ± 80
	difference[3]		-23 (NS)	12 (NS)	282 (NS)	41 (NS)	443 (NS)	225 (NS)	202 (NS)
Occupied	Horizontal	3[5]	270 ± 79	42 ± 10	1,021 ± 246	1,397 ± 1,303	538 ± 246	986 ± 771	161 ± 161
	Vertical	3[5]	244 ± 68	37 ± 12	806 ± 483	1,614 ± 1,408	806 ± 582	1,076 ± 896	215 ± 186
	difference[3]		26 (NS)	5 (NS)	215 (NS)	-217 (NS)	-286 (NS)	-90 (NS)	-54 (NS)

[1]Test #2 deleted from analysis.

[2]Tests #1 and 12 deleted from analysis.

[3]The difference between Horizontal and Vertical values divided by the 40-minute sampling period and normalized for a 1 - m^2 unit area of surgical wound represent the particle settling rates (particles/min · m^2 or CFU/min · m^2).

[4]Average concentration at head, middle and foot (n = 3).

[5]Tests 24 and 32 were destroyed; viable particle counts could not be read, but total particles were read.

TABLE 10

Average Viable Particulate Concentrations (CFU/m^3) Collected during Four 10-minute Intervals of the Sampling Period in the Micro-environments of Operating Rooms #1 and #5 ($M \pm SD$)

Occupancy	Probe Position	Sample Size	10-min Interval 1	2	3	4	Total
Operating Room #1							
Unoccupied	Horizontal	3[1]	107 ± 60	137 ± 115	99 ± 30	84 ± 11	426 ± 214
	Vertical	4	146 ± 23	81 ± 19	65 ± 30	83 ± 36	375 ± 89
	difference		-39 (NS)	56 (NS)	34 (NS)	1 (NS)	51 (NS)
Occupied	Horizontal	3 or 4[2]	93 ± 57	99 ± 68	97 ± 80	53 ± 24	276 ± 154
	Vertical	4	90 ± 22	75 ± 29	95 ± 11	74 ± 21	334 ± 64
	difference		3 (NS)	24 (NS)	3 (NS)	-21 (NS)	-58 (NS)
Operating Room #5							
Unoccupied	Horizontal	3	27 ± 14	17 ± 2	15 ± 10	23 ± 8	81 ± 30
	Vertical	3	16 ± 4	25 ± 37	15 ± 15	20 ± 4	76 ± 56
	difference[3]		11 (NS)	-8 (NS)	0 (NS)	3 (NS)	5 (NS)
Occupied	Horizontal	3	27 ± 20	13 ± 12	24 ± 7	19 ± 9	83 ± 38
	Vertical	3	19 ± 6	19 ± 5	17 ± 8	32 ± 14	87 ± 23
	difference[3]		8 (NS)	-6 (NS)	7 (NS)	-13 (NS)	-4 (NS)

[1]Test 2 deleted from analysis.

[2]Test 19 deleted from analysis of intervals 1 and 4 and Total.

[3]The difference between Horizontal and Vertical values divided by the 10-minute sampling and normalized for a 1 - m^2 unit area of surgical wound represents the particle settling rates ($CFU/min \cdot m^2$).

TABLE 11

Comparison of 5-10 μm total and Viable Particle Concentrations in Operating Room Micro-environments with Concentrations Estimated by the biophysical model. Measurements Obtained with Plate of Sampling Probe in Horizontal Position.

	OR 1	OR 5
Unoccupied		
Total particles (p/m^3)	560 ± 360[1]	44 ± 50[5]
Viable particles (CFU/m^3)	23 ± 6[2]	11 ± 5.8[6]
Occupied		
Total particles (p/m^3)	680 ± 480[1]	617 ± 298[5]
Viable particles (CFU/m^3)	24 ± 10[2]	6.0 ± 3.6[6]
Biophysical Model (10^3 p/m^3)		
Without vortex	55 ± 35[3]	8 ± 11[7]
With vortex	12.5 ± 9.0[4]	0.5 ± 2[8]

[1]From Table 7, n = 3.

[2]From Table 8, n = 3.

[3]n = 20, Tests 38 and 39.

[4]n = 20, Tests 34 and 35.

[5]From Table 7, n = 4.

[6]From Table 8, n = 4.

[7]n = 10, Test 48.

[8]n = 20, Tests 44 and 45.

TABLE 12

Comparison of Settling Rates of 5-10 μm Particles, Total and Viable, in Operating Room Micro-environments with Settling Rates Estimated by the Mathematical Model

	OR 1	OR 5
Unoccupied		
Total particles (p/min · m^2)[1,2]	14 ± 9	-3.2 ± 6.4
Viable particles (CFU/min · m^2)[1,3]	0.18 ± 0.27	0.14 ± 0.16
Occupied		
Total particles (p/min · m^2)[1,2]	4.75 ± 13.9	2.2 ± 10.9
Viable particles (CFU/min · m^2)[1,3]	0.22 ± 0.30	0.01 ± 0.12
Mathematical Model (p/min · m^2)		
Without vortex	3.7[4,5]	2.3[4,7]
With vortex	2.44[4,6]	1.22[4,8]

[1]Difference between H and V divided by 40-minute sampling period and normalized to 1 m^2 target area.

[2]From Table 7.

[3]From Table 8.

[4]Mass of particles assumed to be 0.66 $\mu g/m^3$.

[5]From Fig. 5, 12 ACH, $\varepsilon = 0$.

[6]From Fig. 5, 12 ACH, $\varepsilon = 0.99$.

[7]From Fig. 5, 24 ACH, $\varepsilon = 0$.

[8]From Fig. 5, 24 ACH, $\varepsilon = 0.99$.

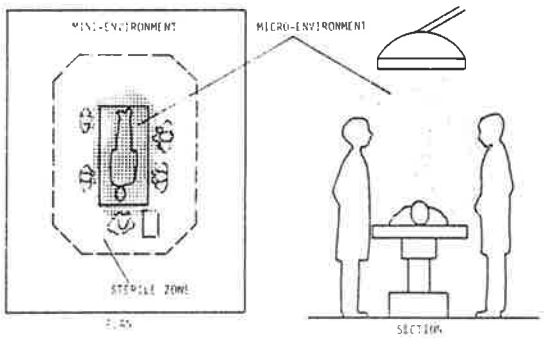

Figure 1. Typical operating room showing graphic definition of micro-environment and location of sampling equipment

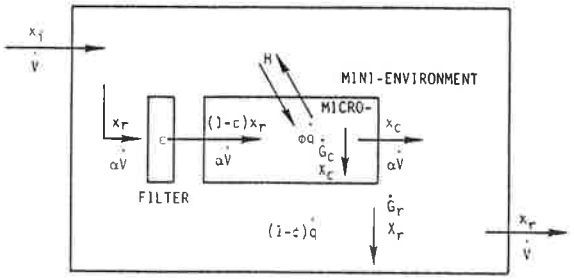

Figure 2. Room-coupled system between micro- and mini-environments

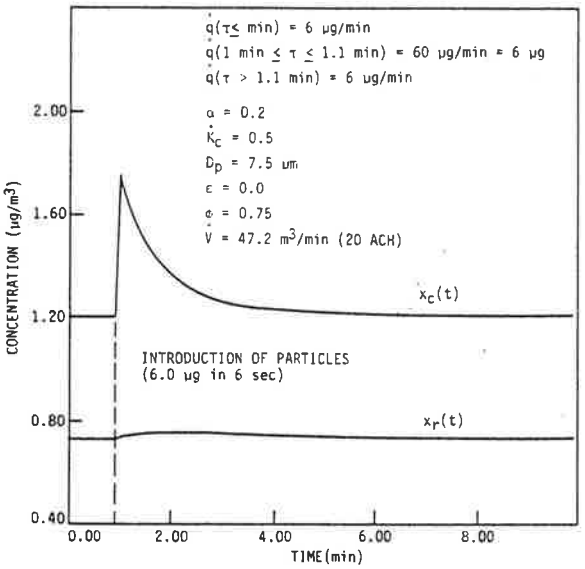

Figure 3. Dynamic responses within micro- and mini-environments in terms of particle concentrations due to "square wave" pulse (i.e., generation rate)

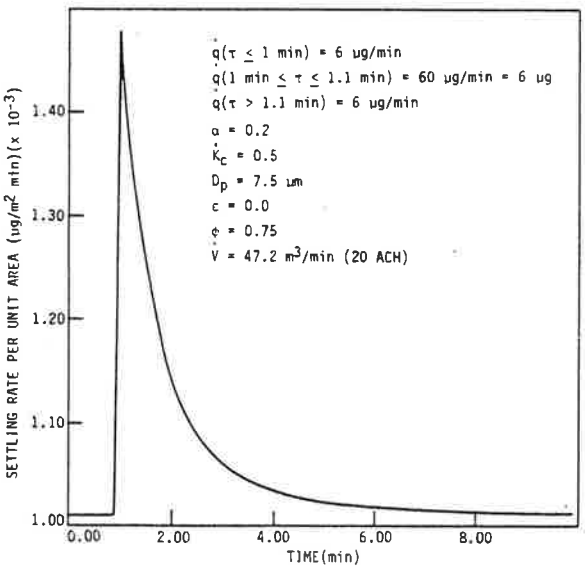

Figure 4. Dynamic responses within micro-environment in terms of particulate settling due to "square wave" pulse (i.e., generation rate)

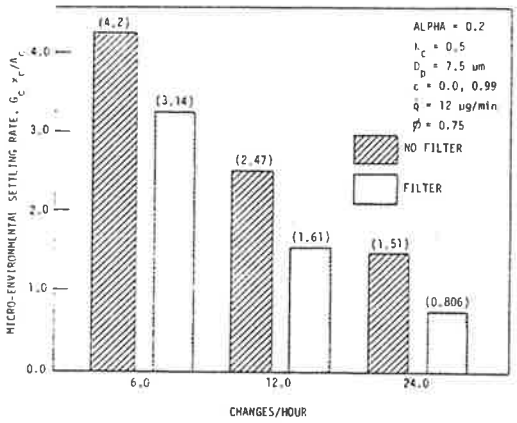

Figure 5. Particulate settling as a function of filtration

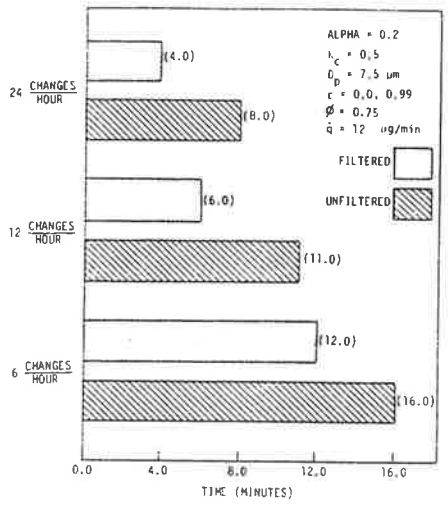

Figure 6. Time to steady steady as a function of filtration

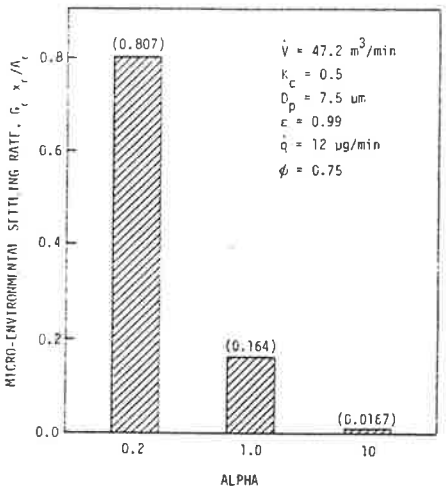

Figure 7. Particulate settling as a function of alpha

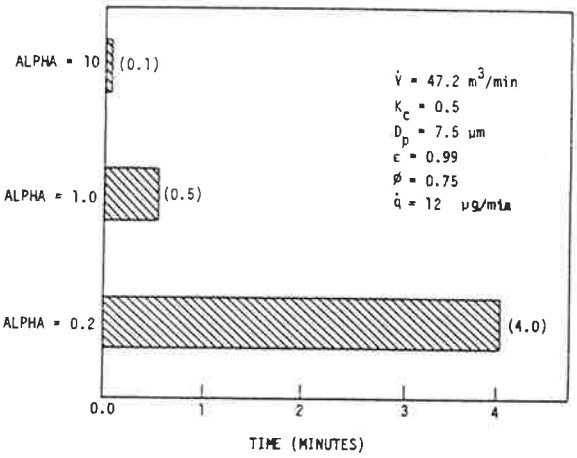

Figure 8. Time to steady state as a function of alpha

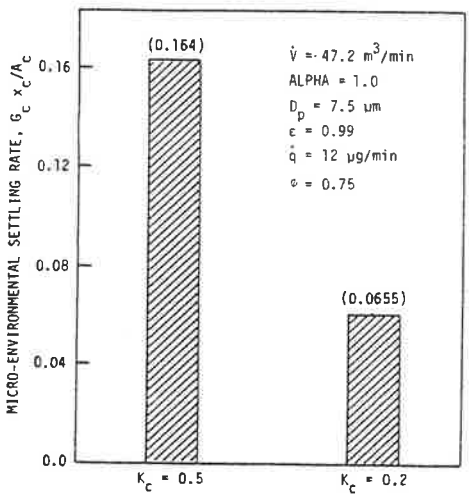

Figure 9. Particulate settling as a function of settling factor

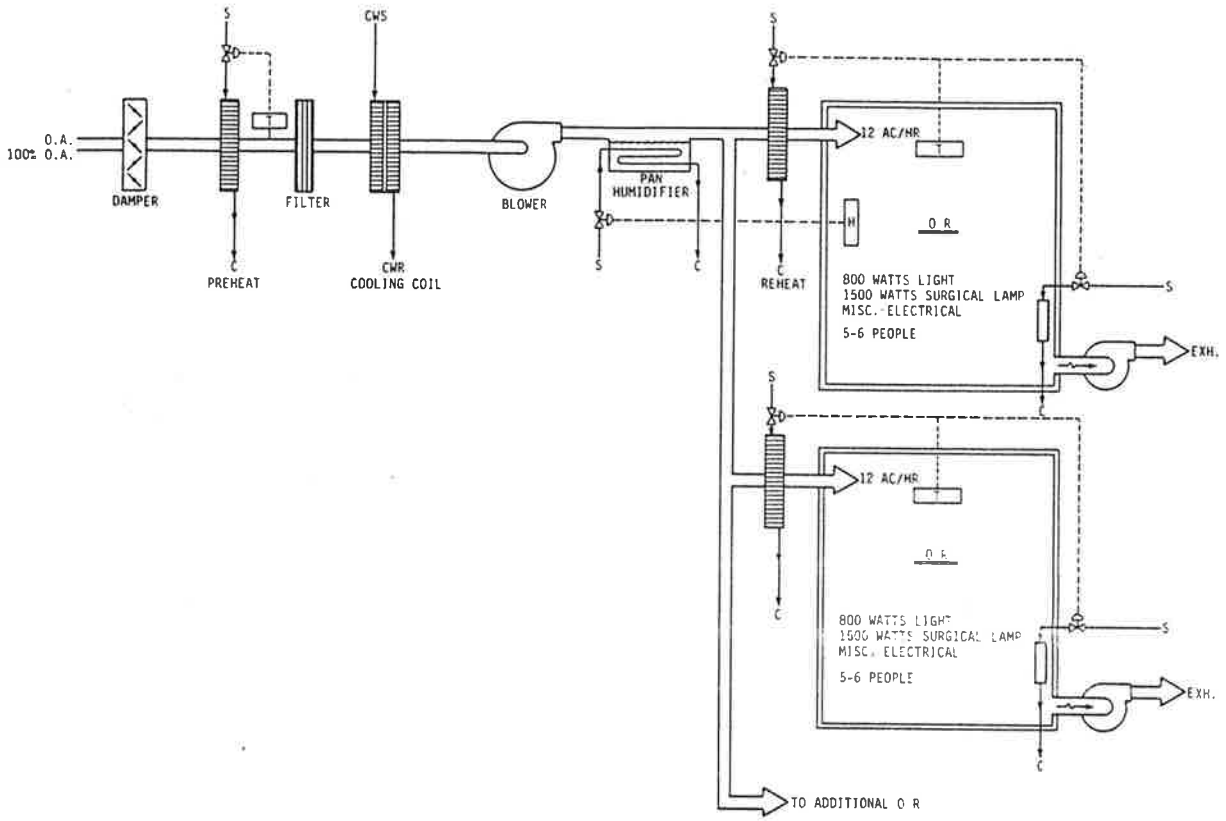

Figure 10. Airflow schematic of 1961 OR facility providing 100% OA at 12 air changes per hour

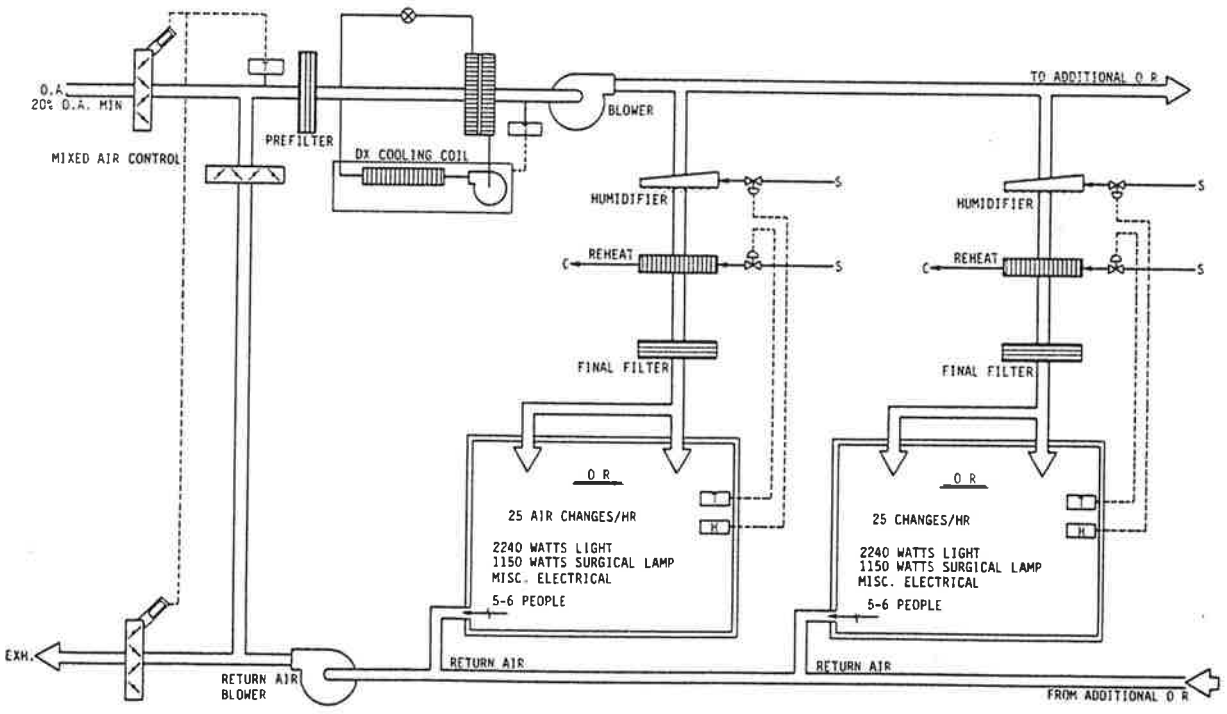

Figure 11. Airflow schematic of 1975 OR facility providing 20% OA at 25 air changes per hour

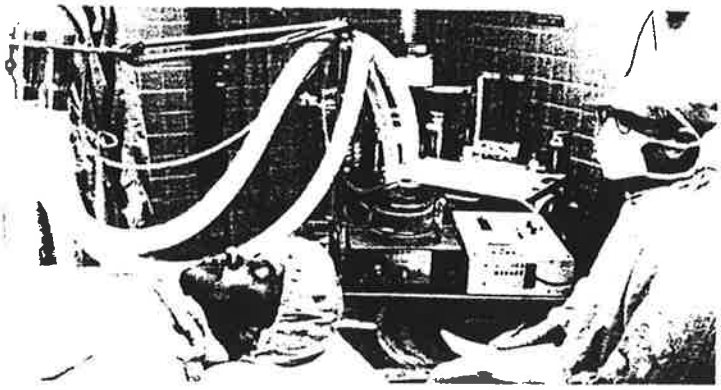

Figure 12. Particulate air-sampling apparatus for measurements within OR #1. The sampling probe is extended into the micro-environment by means of the four-bar mechanism constructed for this project

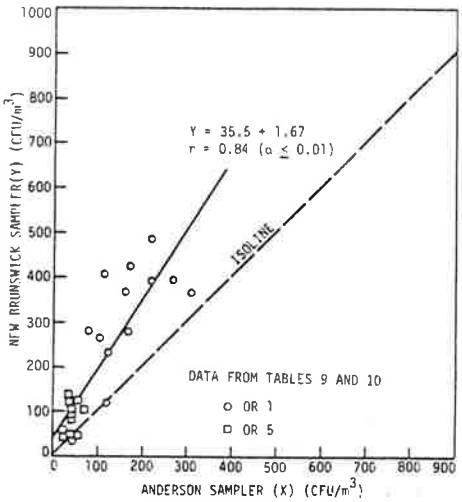

Figure 13. Viable particulate concentrations measured in operating rooms 1 and 5 with two types of samplers

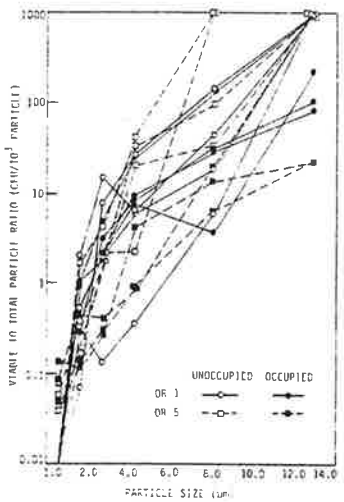

Figure 14. Ratio of viable to total particles (CFU/10^3 particle) sampled in OR 1 and 5 micro-environments with sampling probe horizontal

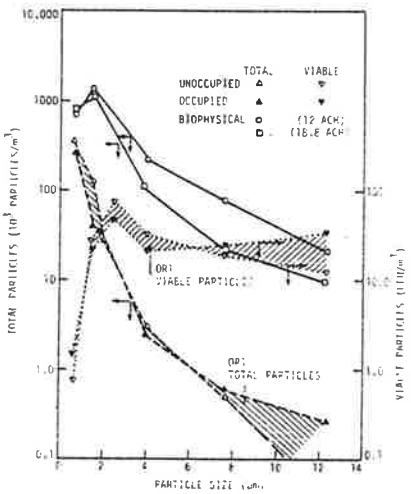

Figure 15. Comparison of mean particle size distributions in systems with high-sidewall grilles at 12 air changes per hour

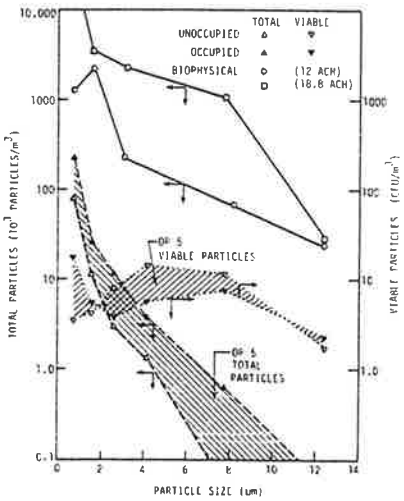

Figure 16. Comparison of mean particle size distributions in systems with ceiling diffusors at 18.8 air changes per hour

Discussion

J.R. LEWIS, John Lewis & Assocs., San Francisco, CA: Did you coin the phrase "thermal plume"?

J.E. WOODS: No. The term "thermal plume" is often used to describe the effect of heated air rising from a bounded source. Other examples include "thermal plumes" from cooling towers and smoke stacks. I'm not sure when I first heard this term used.

LEWIS: Could you elaborate on the characteristics of the thermal plume in the O/R environment?

WOODS: The thermal plume observed in the O/R environment originated within the microenvironment bounded by the surgical table, the surgical staff, and the surgical lamp. The heat sources were metabolic heat dissipated by the surgical team and patient (estimated at approximately 1200 watts) and by the surgical lamps (approximately 1500 watts). If 50% of the metabolic heat were dissipated into the microenvironment, a significant increase in upward airflow due to the convection effect should be expected. The primary characteristic of this upward movement (or at minimum the decrease in downward movement caused by the air diffusers) is that the buoyancy effect of this air tends to suppress the setting of particulation into the field of surgery.

LEWIS: Could you elaborate on the effect of O/R lighting heat upon thermal plume?

WOODS: The effect of heat from the O/R lighting will tend to enhance the development of the thermal plume by two mechanisms: (1) Approximately 20% of the electrical energy will be converted to light, which will be absorbed by the surface in the microenvironment and be emitted back as infrared energy (i.e., heat). This energy could add to the convection effects of the air; (2) The residual 80% of the electrical energy will be dissipated as heat from the fixture above the microenvironment. The resultant convection effects could cause an induction of microenvironmental air, thus enhancing the development of the thermal plume from the microenvironment.

Please note that these comments are only observations, that these effects were not quantified in this research project, and that we recommended further work be pursued in this area.

LEWIS: How do O/R lights and other significant obstructions around the surgical field affect the more desirable air distribution patterns referred to in your paper?

WOODS: If microenvironmental control is employed, as proposed in this paper, little adverse effect should be expected from the surgical lighting. If conventional air distribution control is used, the shape, size, and location of surgical lamps could affect airflow patterns near the surgical field. However, with care, adverse effects can be avoided. If laminar flow configurations are used, the shape, size, and location of surgical lamps and other obstructions may be critical to the desired airflow patterns near the surgical field.