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CONTROL OF OPERATING ROOM AIRBORNE BACTERIA

November 8-10, 1974
Washington, D.C.

COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT
COMMITTEE ON PROSTHETIC-ORTHOTIC EDUCATION
ASSEMBLY OF LIFE SCIENCES-NATIONAL RESEARCH COUNCIL

NATIONAL ACADEMY OF SCIENCES
Washington, D.C.

1976

NOTICE

The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the Councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the Committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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F O R E W O R D

The American Academy of Orthopaedic Surgeons (AAOS) established a committee under the chairmanship of Dr. J. Phillip Nelson on November 29, 1972, to study the systems available for providing filtered air to reduce or eliminate bacterial content at the wound site. Establishment of the committee reflected the AAOS' concern about the incidence of deep wound sepsis in clean, refined wounds. AAOS also requested, through the Committee on Prosthetics Research and Development (CPRD) of the National Academy of Sciences, that the role of airborne bacterial contamination in the operating room be reviewed. Approval for CPRD to organize a multidisciplinary meeting to discuss this subject was given by the National Research Council on November 30, 1973.

A steering committee was formed on January 18, 1974; its members were: Dr. George T. Aitken, Mr. Kenneth Credle, Dr. Jo Miller, Dr. J. Phillip Nelson, and Dr. John Ulrich.

The steering committee recognized from the outset that there are many factors in wound sepsis, such as the competency of host resistance, virulence and numbers of organisms, and use of antibiotics. They also recognized that endogenous or direct contagion may be significant causes of sepsis. The committee quickly agreed that the magnitude and complexity of the sepsis issue was too extensive for consideration at a single conference. Therefore, they agreed to a narrower charge--to examine the control of airborne bacteria in the operating room.

Given this more manageable subject area, the committee decided that the meeting would be a workshop with participation by invitation only and limited to 40 persons. The participants would be representatives of general and orthopedic surgery, microbiology, and engineering, and would be chosen to present varied opinions within each discipline.

The Workshop on Control of Operating Room Airborne Bacteria was held at the National Academy of Sciences on November 8-10, 1974. It was attended

by over 50 individuals interested in surgical asepsis, and 31 papers were read. The conferees represented an international cross section of the knowledgeable in this area. Their discussion reflected a frank presentation and documentation of their work, and an objective assessment of the work of others.

This report has been divided into two parts. The first part is an overview, a summary of objectives, conclusions and recommendations for further research. It represents a consensus of the steering committee. The second section is an appendix of individually prepared papers on specific aspects of controlling airborne bacteria in the operating room.

George T. Aitken
Chairman

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PREPARED PAPERS

INTRODUCTION

The prevention of postoperative wound sepsis has long been a topic of prime concern to surgeons. With the recent advent of total-joint replacement and the use of methyl methacrylate, the orthopedic surgeon has become increasingly concerned with prevention of sepsis.

It was the purpose of the steering committee to isolate and explore a controversial and crucial aspect of surgical antisepsis. Charnley (1969) found that the establishment of an operating room environment with markedly reduced airborne bacterial content was associated with a significant reduction in postoperative total-hip arthroplasty infection rates. Whether this favorable result was effected by air filtration alone or whether it was also attributable to improved barrier techniques, more attention to aseptic techniques, or a multiplicity of other improvements in technique has remained unanswered. Clean air in the operating room is frequently discussed and often poorly understood. Its implications for capital investment costs are large and there are several techniques for cleaning air. Because of the potential significance of reduced operating room airborne bacterial content to reduced postoperative sepsis rates, the Committee on Prosthetics Research and Development convened a multidisciplinary workshop to discuss this subject.

In their planning sessions, the Steering Committee on the Control of Operating Room Airborne Bacteria discussed many subjects which might influence postoperative sepsis rates. These included host resistance, pre- and postoperative antibiotic therapy, skin preparation, surgical technique, tissue toilet, instrument sterilization, and quality control of commercially sterilized materials used in the operation. The committee also agreed that endogenous infections and the prophylactic or therapeutic treatment of infection would be recognized, but not examined in these discussions. Finally, it was agreed that the direct contamination of clean wounds was not a matter for this workshop, except as it was a reflection of failures of barrier techniques used to prevent contaminating the air. Convening a conference to discuss the entire totality of the problem seemed impossible, yet the urgency to resolve the "clean air" aspect of the problem was evident. Therefore, it was decided

that this workshop would be particularly devoted to a review of the current knowledge of the origins and pathways by which airborne bacteria contaminate clean wounds.

The committee developed the following objectives to provide a general framework for the workshop:

1. to summarize the current state of knowledge on airborne contamination of clean wounds;

2. to tabulate available techniques for estimating the cleanliness or contamination of the air;

3. to list methods that can lower the contamination of the air;

4. to assess, on the basis of available data, the effectiveness of the techniques for controlling operating room airborne contamination and further investigate the adequacy of systems currently used to decontaminate operating room air; and

5. to publish the workshop proceedings. Such a publication would include recommendations on the effectiveness of sampling and decontamination techniques if the data presented were adequate to support and validate such recommendations. The report also would include recommendations and priorities for future studies on airborne bacteria in operating rooms.

SUMMARY OF WORKSHOP OBJECTIVES AND CONCLUSIONS

I. Current State of Knowledge on Airborne Contamination of Clean Wounds.

A. Summary

People in the operating room are the major source of operating room airborne bacteria. Each person sheds bacteria from skin and mucous membranes at a relatively constant rate which varies from person to person and which increases with increased activity. These bacteria are mainly gram-positive and they are agglomerated on nonliving particles larger than two microns in size. A few individuals shed relatively large numbers of microorganisms into the air and these type-specific bacteria have been associated with postoperative infections of clean wounds.

Contamination of clean surgical wounds by microorganisms of the same type found in the operating room air has been demonstrated on repeated occasions. The relationship of this contamination "to subsequent sepsis" is problematical because of the difficulty in separating contamination of the wound by airborne bacteria from contamination from other sources such as the patient or breaks in sterile techniques.

B. Conclusions

1. Airborne bacteria in the operating room derive from people and not from the external environment.

2. Airborne bacteria in the operating room do contaminate surgical wounds and are a definite source of infection in clean refined wounds, particularly in high-risk patients and in surgery requiring implantation of foreign materials. The degree of their significance in production of postoperative sepsis has not been quantified.

3. A few people, known as "shedders," persistently shed large numbers of bacteria and have been associated with significantly increased postoperative rates of infection.

II. Available Techniques for Estimating Bacterial Contamination of Air.

A. Summary

Although nonliving airborne concentrations of particulate matter may bear some relationship to airborne bacterial concentrations, it is the concentration of airborne microorganisms (as opposed to particles) which is relevant

to the etiology of postoperative sepsis. Therefore, attention will be directed only to techniques which measure the amount of airborne bacterial contamination.

1. Settle Plates - These are sterile agar plates exposed to air for varying periods of time. After incubation, numbers of bacterial colonies are calculated for time exposure and area. Their efficiency depends upon direct settling of bacteria or impingement of bacteria carried in air currents onto the agar surface. Settle plates are relatively inexpensive, easy to use, and seem most applicable to the turbulent, low air exchange systems of most modern operating rooms. However, they are probably not accurate in measuring bacteria in high-volume directional airflow systems because the physical presence of the plate acts as an air foil which shunts air away from the surface of the plate.

2. Surface Sampling - Using a swab, suction probe, or contact plate, surfaces may be sampled for types of resident bacteria. This is a useful method in determining the amount of environmental fallout of bacteria after exposure of sterile surfaces to the air.

3. Active Air Sampling - Many devices have been developed which actively pump air from the operating theater which is then impinged onto a sterile agar plate, or drawn through sterile liquid culture media, or suctioned through a gelatin membrane of limited pore size. Information may be obtained relative to particle size and numbers of viable organisms per unit volume of air. However, the volume of air sampled is usually relatively small and organisms may be lost through desiccation if large volumes are sampled.

B. Conclusions

1. Although many methods for sampling airborne bacterial concentrations were described, no paper compared the merits of the various sampling techniques. Information presented at the workshop would not allow recommendation of a specific technique to monitor future evaluations of airborne bacteria.

III. Methods for Reducing Bacterial Contamination of Air

A. Summary

Methods for reducing the amount of air bacterial contamination in the operating room may be divided into traditional and new categories.

1. Traditional Methods

   a. Air conditioning systems which provide:
      1) air exchange rates of at least 12 per hour;
      2) air introduction near ceiling; air exit near floor;
      3) mechanical filtration of air before entering room;
      4) scheduled filter maintenance;
      5) humidity control at approximately 50 percent;
      6) temperature control at approximately 70 deg. F.

   b. Reduction of personnel in operating room.
   c. Reduction of personnel activity and talking.
   d. Exclusion of personnel with infection.
   e. Requirement for all personnel to wear adequate head cover and nose and mouth mask.

2. Newer Methods

   a. Air conditioning systems
      1) clean rooms: unidirectional, high or low velocity, using High Efficiency Particulate Air (HEPA) filters;
         a) full room or room within a room type;
         b) horizontal or vertical flow types.
      2) local airborne bacteria control
         a) plastic bubble isolator;
         b) local high velocity, HEPA filter type (see text);
         c) ultraviolet light.

B. Conclusions

1. There was general agreement that the traditional methods should be recommended for all operating theaters.

2. A specific recommendation for more generalized application of one or more of the newer systems could not be made at this time because of the experimental nature of the systems and the lack of hard statistical data which establishes unequivocably that any of the newer systems in themselves contribute to reduced postoperative infection rates.

IV. Effectiveness of Techniques for Controlling Operating Room Airborne Contamination

A. Summary

As previously noted, it is established that bacterial contamination of the operating room air and sterile surfaces does occur during surgery. A significant portion of the sterile surface contamination results from airborne fallout of bacteria. Quantification of contamination is relatively consistent for each technique in each individual operating room from day to day and case to case. However, the data derived are much less dependable when the amount of contamination is compared between operating rooms or between institutions because of many variables inherent in sampling. These variables include:

1. different operative procedures;
2. different air handling systems;
3. different barrier gown and drape systems;
4. differences in numbers of personnel, personnel activity, and shedding patterns;
5. different sampling and culturing techniques, such as sampling devices, locations of sampling, length of sampling, and differing culture media.

For these reasons, the data from individual system evaluations can be accepted but comparison of data for differing systems from different investigators is much more difficult.

It should be noted that those papers reporting comparative postoperative sepsis rates of patients operated in a regular operating room versus surgery done in one of the newer systems uniformly showed lower rates for patients done in the newer systems. However, in none of these series was it conclusively demonstrated that the reduced airborne bacterial concentrations were the sole

variable associated with the lowered infection rates. It should be noted that recent papers presented at the meeting of the American Academy of Orthopaedic Surgeons in New Orleans in January 1976, reported zero infection rates without the use of "newer systems."

B. Conclusions

1. A specific order of effectiveness for each system could not be ascertained at this time.

2. The Workshop participants generally agreed on the following observations and recommendations:

   a. Improved control of operating room personnel activity patterns, and impermeable drapes and garments, can significantly reduce operating room airborne bacterial concentrations. These principles apply in both conventional and newer system operating rooms.

   b. Conventional air conditioning systems should be checked frequently for filter efficiency, filter cleanliness, and room pressurization.

   c. Clean rooms of the HEPA filter, laminar air flow, high velocity type reduce airborne bacterial concentrations at least 80 percent when personnel wear conventional garments. Contamination is further reduced when personnel wear improved barrier garments. The use of helmet-aspirator-improved barrier gown systems will reduce the level of airborne bacterial contamination at least 90 percent. The walled, vertical flow system seems to be most efficient.

   d. Personnel aspirator systems cannot be endorsed unequivocally because of their impracticality. However, their effectiveness in reducing shed bacteria is accepted.

   e. Low Velocity (25-35 ft/min) HEPA Directional Airflow Systems are considered effective in reducing operating room airborne bacterial concentrations.

   f. For the clean, refined, high-risk wound, supplemental protection with perioperative antibiotics or air treatment systems is recommended.

g. Ultraviolet light is an acceptable method for reducing operating room airborne bacteria, but sufficient data are not available to justify recommending its widespread application to operating rooms at the present time.

RECOMMENDATIONS FOR FURTHER RESEARCH

1. Research activities should be designed that will focus upon the effects of airborne bacteria and separate those effects from causes of infection by other factors.

2. Methods for airborne and surface bacterial sampling should be catalogued according to their efficiency. Also, a list of commercially available devices for monitoring the cleanliness or contamination of air should be drafted. Their advantages and disadvantages should be described and circulated to appropriate microbiologists and engineers for their comments. Recommendations for techniques to be considered "standard" or "comparable" should be developed.

3. Protocols for collecting airborne and environmental bacterial concentration data should be standardized so that environments may be compared from institution to institution.

4. Ultraviolet light systems should be studied further. Sampling techniques (i.e., sterilization of media by radiation after inoculation and effect of obstructions to radiation or untreated air), long-term exposure of personnel to radiation, and effect of radiation on exposed tissue should also be studied.

5. More data are necessary on airborne bacterial and sterile surface contamination rates for the low velocity, plastic bubble isolator, and local high flow HEPA filtered air systems.

6. Further investigations are recommended on the origins of bacteria that cause wound infections.

7. Reported reductions in infection rates through improved barrier and air-handling techniques (which reduce operating room airborne bacterial concentrations) should be evaluated objectively.

SPECIAL RECOMMENDATION

A special committee of workshop participants was appointed by the chairman to develop a resolution indicating the need for defining "biologic clean air." It was recommended that the intent of the resolution become a continuing effort of the workshop's members. The resolution read:

> "That it is recognized that there is a need for a definition of classes of biologic air cleanliness. Such a definition should also contain a standardized method for determining changes in, or new classes of, cleanliness. Such a definition must include not only the number of viable particles per cubic foot of air in specified areas, but also the methods by which they are counted, and the definition of the other factors which deserve consideration.
>
> Therefore, it is recommended that there come into being a multidisciplinary group, preferably of the attendees of this conference, who are delegated to prepare such definitions and who would write a 'Tentative Statement on the Definition of Biologic Clean Air.' This would give guidance to researchers in the field. Ultimately, this might enable surgeons to specify the air quality they might desire."

REVIEW OF POSTOPERATIVE WOUND INFECTIONS

W. A. Altemeier*

Infection is one of the salient features of human life, and many infections in patients are of surgical significance. An understanding of this aspect of medicine is, therefore, an essential part of clinical surgery and the supporting professional scientific disciplines which help to provide the surgeon with a safe environment within which to operate and work (1-5). The ubiquity of infectious agents in man's environment, their propensity for invading the tissues of the body, their potential for producing significant pathophysiologic effects on the various bodily functions, their remarkable adaptability to circumstance and newer forms of treatment, and the necessity for excluding their presence or controlling their growth sufficiently to permit surgical treatment and effective wound healing, all emphasize the significance of infection in surgical practice (1,3). Moreover, the expanding horizons of surgery have often been dependent upon the development and application of special methods of overcoming the hazards of postoperative infections (1,8). It should be remembered also that every operation is an experiment in applied and practical bacteriology.

History has shown that postoperative and hospital-acquired infections have been problems for as long as there have been hospitals, and attempts to prevent their incidence and spread began hundreds of years ago when separate hospitals were built for patients with communicable diseases. Fever hospitals, smallpox hospitals, tuberculosis sanitoria, and "Pest Houses" were established in an effort to separate infected patients from other patients and the community.

It is generally recognized that the introduction of modern antibiotic therapy has had a revolutionary effect on the treatment of many established infections, but clinical experience and experimental bacteriological studies have shown that its general use for approximately one third of a

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century has failed to decrease the overall incidence of postoperative surgical infections (1,2,3,7,8,10). In addition, the widespread use and misuse of antibiotic therapy has undoubtedly increased the problems concerned with their prevention (3,5,8,9,12,15,17,18). Too often its widespread use prophylactically in surgical patients has contributed to the development of an unwarranted overdependence on its effectiveness, a de-emphasis or discredit of the importance of the established surgical principles, a relaxation of the "surgical conscience," a breakdown of isolation procedures, and the establishment of a reservoir of virulent and antibiotic-resistant bacteria concentrated in the hospital environment (1,4,8).

These trends have been accentuated by the complexities of modern surgical practice with the concentration of large numbers of patients with established infections in hospitals, the extension of prolonged surgical operations and supportive procedures to a rapidly increasing number of high-risk patients, the increase of the number of individuals with severe trauma, and the growing use of drugs which decrease bodily resistance to infection. Thus, it must be kept in mind that the modern general hospital has become a complex community in which the opportunities for infection are numerous and ever present. Current hospital practice has resulted in the concentration of many people admitted with a large variety of infections as well as many others who are unusually susceptible to secondary or hospital-acquired infections. The latter have included patients admitted for treatment of recent trauma, persons debilitated by chronic disease, individuals undergoing surgical operations and a multitude of other technical diagnostic procedures, people requiring steroid therapy, and those under treatment for neoplastic diseases. The extension of surgical treatment to aged and debilitated patients, and the widespread use of complicated diagnostic, therapeutic, and anesthetic procedures also have favored the development of hospital-acquired infections. In addition, the urgency associated with the treatment of many patients with life-threatening disease or extensive injuries, the demands of large numbers of patients in a short period of time, and shortages of skilled nursing and other personnel have tended to produce compromises and administrative trends not necessarily in the best interests of infection control (1-3).

Postoperative Wound Infections

A particularly important effect of general and indiscriminate antibiotic therapy in hospitals has been the progressive development of resistance to penicillin and many of the other antibiotic agents which was acquired by a large variety of important bacteria concentrated in the hospital environment. These virulent microorganisms, both Gram-positive and Gram-negative, have the potential of becoming pathogenic in patients weakened by disease, injury, metabolic conditions, and other debilitating factors as mentioned above (8,10,12,17,18).

There are a number of other important factors which have influenced the incidence of postoperative infections at the present time. In a 2 1/2-year collaborative investigation of 15,613 consecutive operative procedures done in five American university centers, an overall infection rate of 7.4 percent for all types of operations was determined under close, energetic, and continuing surveillance. These centers included the University of Pennsylvania, Hahnemann Medical School, the University of California, Los Angeles, George Washington University, and the University of Cincinnati. This project was carried out under the support of the U.S. Public Health Service and the aegis of the National Research Council (13).

Many national and international conferences have been held in an effort to bring the various aspects of this situation into proper perspective, to disseminate existing knowledge between countries and scientific disciplines, and to stimulate research for the solution of related problems. One of the first and highly significant meetings of this type was the National Conference on Hospital-Acquired Staphylococcal Disease, held on September 15-17, 1958, in Atlanta, Georgia under the joint sponsorship of the United States Public Health Service and the National Research Council. An International Seminar on Hospital Infections was also held by the Council for International Organizations of Medical Sciences in London, September 24-28, 1962. Delegates from 26 countries and the World Health Organization participated in the discussion, representing a considerable body of resource knowledge and research potential. There were 111 delegates in attendance, each being an expert on some aspect of hospital-acquired infection. Another important example was the International

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Conference on Surgical Infections held by the International Society of Surgery in Moscow on August 21-28, 1971 (8).

These and many other conferences have been helpful, but the fact remains that the problems of postoperative wound and hospital-acquired infections persist, and that considerable confusion exists in the minds of surgeons, physicians, hospital administrators, lay hospital boards, bacteriologists, epidemiologists, sanitary engineers, architectural engineers, attorneys, judges and others regarding the significant factors actually responsible for these infections.

In the meantime, the controversy over the relative importance of the aerial spread and contact spread of infection has continued from the last half of the 19th century to the present (10). Following the discovery and introduction of the surgical antisepsis by Lister, Von Bruns and Von Bergmann became convinced that contact was the principal method for spread of infection and by their evidence persuaded Lord Lister to abandon his carbolic acid spray of the operating room aerial environment. The use of ultraviolet light, lithium oxide, electrical precipitation of bacterial-laden dust particles, and various types of laminar flow have each been developed and used in an effort to reduce the incidence of postoperative wound infections.

Moreover, the increasing costs associated with the care of surgical patients with infections, the progressive threat of malpractice claims, and the growing demands of an informed and often "oversold" public have become important related matters of concern.

THE INCIDENCE OF INFECTIONS

Currently there is still considerable confusion about the incidence, nature, and causes of infections in surgical practice. There is also much confusion and great divergence of thought regarding the best methods of preventing and controlling surgical infections. Consequently, there are no accurate figures in the United States to indicate the incidence of the many types of infection acquired by hospitalized surgical patients, but there is evidence that it is much greater than generally suspected.

Postoperative Wound Infections

It is generally recognized, however, that from 40 to 65 percent of the patients in general hospitals are usually surgical, and that approximately 30 percent of hospitalized surgical patients either have established infections at the time of admission or develop some type of infection during their hospital stay.

In 1963 it was estimated that approximately 25,000,000 patients had been admitted to hospitals in the United States and that over 1,000,000 of them developed postoperative or hospital-acquired infections.

More recent figures made available for the year 1967 have been reported by Altemeier as follows (6,8,10):

Table 1. Hospital Infections USA - 1967

Estimated Incidence:

Hospital admissions	31,600,000
Surgical operations performed in the operating room	18,800,000
Estimated number of postoperative wound infections for all types of operations (7.4% of operations)	1,391,200
Estimated number of hospital-acquired infections	2,101,037

These estimates are based upon data obtained from 1,118 hospitals in the United States; this number being approximately one-fourth of the total number of hospitals under surveillance of the Joint Commission on Accreditation of Hospitals and Blue Cross-Blue Shield.

The overall wound infection rate of 7.4 percent used in these estimations was the incidence for all types of operative wounds as determined during a 2 1/2-year collaborative ultraviolet study of 15,613 consecutive operative procedures done in five American university centers under the support of the U.S. Public Health Service and the aegis of the National Research Council. The operative wounds thus studied were composed of clean, clean-contaminated, contaminated, and dirty types. Elective and emergency operations were both included in Table 2 (13).

Table 2.

Type of Operative Wound	No.	Incidence of Infection No.	Percent
Clean	11,690	594	5.1
Clean-contaminated	2,589	280	10.8
Contaminated and dirty	1,262	277	21.9
Not reported	72	6	8.3

In the 11,690 clean elective operations in this series, the average wound infection rate was 5.1 percent, but the average rate for all types of operations was 7.4 percent. It also became apparent that the incidence of infection varied a great deal with the type of operation (Table 3).

Table 3. Incidence of Infection Following Selected Commonly Performed Operative Procedures (Adapted from Ultraviolet Study)

Operative Procedure	Number of times performed	Incidence of infection percent
Herniorrhaphy*	1,312	1.9
Thyroidectomy	406	2.2
Hysterectomy	628	6.1
Cholecystectomy	756	6.9
Partial Colectomy	220	10.0
Subtotal Gastrectomy	288	10.1
Appendectomy	551	11.4
Nephrectomy	127	17.3
Radical Mastectomy	227	18.9

*Including inguinal, femoral, and epigastric; excluding incisional and ventral.

Noteworthy too was the fact that the incidence of postoperative wound infection was increased three to five fold or more whenever one of the major tracts was transected or resected during a planned elective operation, as compared to elective operations without such procedures.

For example, the incidence of infection following hernioplasty was 1.9 percent; whereas it was 6.1 percent for hysterectomy, 6.9 percent for cholecystectomy, 10.0 percent for partial colectomy, and 10.1 percent for subtotal gastrectomy.

It can be seen from the above discussion that hospital-acquired infection is also a problem of considerable monetary magnitude. The average cost per infection has been reported by Swartz at the University of Virginia to vary between $6,000 and $9,000. Using an estimated postoperative wound infection cost of approximately $7,000 per patient, on the basis of 1,400,000 postoperative wound infections (as shown in Table 1), the estimated overall cost to society has been estimated to be $9.8 billion (6,8,11).

Specific programs are matters for physicians to consider and correct. There appears to be some consensus that a broad-based control program centered around isolation procedures, combined with both formal and informal education, would help to decrease the incidence and cost of infection.

Government subsidies would help to defray the cost of infection control and help to insure an optimal output of this public good. Another avenue of possible effective action under consideration is Professional Services Review Organization (PSRO).

A review of postoperative wound infections should include a consideration of their classification on the basis of the source or base of infection. In this regard, there are three generaltypes: community or home-based infections, operating room-based infections, and hospital-based (other than operating room-based) infections.

COMMUNITY OR HOME-BASED INFECTIONS

These are infections which develop spontaneously or otherwise in the home or community, being unrelated to the hospital and the hospital reservoir of microorganisms. As many as 30 or 40 percent of patients admitted to a busy surgical service in a general hospital may have infections of this type.

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Examples are acute appendicitis, acute cholecystitis, acute diverticulitis with perforation and peritonitis, acute perforated peptic ulcer with peritonitis, etc. Infections in this category are generally not caused by antibiotic resistant bacteria, and they do not present at this time new or special problems related to the primary disease.

OPERATING ROOM-BASED INFECTIONS

These are hospital-based infections which consist primarily of operative wound infections developing postoperatively in relation to surgical procedures performed in the operating room. Because of their importance and the problems which they currently present, they are considered separately from other hospital-acquired infections for purposes of special discussion. The sources of these infections are both endogenous and exogenous.

HOSPITAL-BASED INFECTIONS (OTHER THAN OPERATING ROOM)

Infections which occur in patients during their hospitalizations are designated as hospital-acquired or nosocomial infections. They are the result of microbial invasion, most often by antibiotic-resistant and virulent microorganisms of the hospital environment. Invasion may follow diagnostic and various therapeutic procedures such as lower urinary tract catheterization or instrumentation, intravenous therapy (especially continuous), tracheostomy, or arteriography. Infection may also be related to the emergence of virulent bacteria during antibiotic therapy and other medications, the decreased host resistance by immunosuppression, the impairment of other host defenses, the replacement of the normal flora of organisms in the major tracts of the body by virulent or antibiotic-resistant bacteria of the hospital reservoir during prolonged preoperative hospitalization periods, and the progressive extension of surgical practices in the high-risk, aged, or otherwise debilitated patients.

In a review of surgical postoperative infections, their classification by anatomic location and pathologic changes is of interest (Table 4) (11).

Postoperative Wound Infections

Table 4. Classification of Surgical Infections By Anatomic Location and Pathologic Changes

I. Local Wound Infection

- A. Cellulitis
- B. Suppuration or septic liquefaction of tissues
- C. Abscess
- D. Septic necrosis
- E. Local wound, septic thrombophlebitis

II. Regional Extension

- A. Adjacent tissues by direct extension
- B. Lymphangitis and lymphadenitis
- C. Thrombophlebitis
- D. Peritonitis
- E. Central nervous system infection, including meningitis and brain abscess
- F. Mediastinitis
- G. Retroperitoneal cellulitis

III. Organ or Visceral Infection

IV. Systemic Invasion

Based upon clinical and laboratory research on the Surgical Services and the Surgical Research Bacteriology Laboratory of the University of Cincinnati during the past 32 years and a review of pertinent literature, an etiologic classification of surgical infections has been developed (Table 5) (1,11). This emphasizes the large numbers and varieties of bacteria which may produce wound infections.

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Table 5. Etiologic Classification of Surgical Wound Infections

I. Aerobic Bacterial

A. Gram-positive cocci
1. Staphylococcus
2. Streptococcus
3. Pneumococcus

B. Gram-negative cocci
1. Neisseria catarrhalis
2. Neisseria gonorrhoeae

C. Gram-negative bacillary
1. Escherichia coli
2. Aerobacter aerogenes
3. Klebsiella
4. Pseudomonas aeruginosa
5. Proteus
6. Serratia
7. Paracolgon
8. Alcaligenes faecalis
9. Salmonella
10. Haemophilus influenzae

D. Gram-positive bacterial
1. Bacillus anthracis
2. Corynebacterium
3. Diphtheroid
4. Bacillus species
5. Mycobacterium
a. Tuberculosis
b. Balnei

II. Microaerophilic Bacteria

A. Gram-positive cocci
1. Streptococcus
a. Hemolyticus
b. Non-hemolyticus

III. Mixed Infections

A. Aerobic and Anaerobic
B. Gram-positive and Gram-negative
C. Synergistic

Postoperative Wound Infections

IV. Anaerobic Bacterial

A. Gram-positive cocci
1. Peptococcus
2. Peptostreptococcus

B. Gram-positive Bacilli
1. Cl. perfringens
2. Cl. novyi
3. Cl. septicum
4. Cl. histolyticum
5. Cl. tetani

C. Gram-negative bacilli
1. B. fragilis
2. Bacteroides species
3. B. melaninogenicum

V. Non-bacterial Infections

A. Fungal
1. Candidiasis (Candida albicans)
2. Actinomycosis (Actinomyces Israelii)
3. Nocardiosis (Nocardia asteroides)
4. Blastomycosis (Blastomyces dermatitides)
5. Coccidioidomycosis (Coccidoides immitis)
6. Histoplasmosis (Histoplasma capsulatum)
7. Sporotrichosis (Sporotrichum schenckii)
8. Phycomycosis (Mucor sp.)
9. Aspergillosis (Aspergillus niger)

B. Viral
1. Herpesvirus
2. Poxvirus (vaccinia)
3. Varicella (Herpes Zoster virus)
4. Cytomegaloviruses
5. Mumps virus (parotitis and pancreatitis)
6. Polovirus
7. Hepatitus virus (infectious and serum)
8. Rabies virus

Finally, I would like to point out two other important considerations: first, that there is considerable confusion and controversy as to the definition of a surgical postoperative infection and, secondly, the classification of infections based upon the recognition of different degrees of wound contamination (11).

W. A. Altemeier

There are significant differences in the minds of many surgeons as to what actually constitutes a postoperative wound infection and particularly a significant infection. This has emphasized the importance of establishing certain criteria in order to provide objective definitions of surgical infections which would permit consistent evaluation and comparable reports. Laboratory microbial culture studies alone are not completely reliable for a number of reasons which include technical limitations of many hospital laboratories, inadequate wound sampling and testing methods, and the report of secondary microbial invaders or wound contaminants which are incorrectly considered to be of primary etiologic importance. Cultures obtained from studies of purulent discharges not infrequently are negative following culture by the usual standard technics whereas special bacteriologic procedures may reveal the true pathogen. Moreover, it is not unusual for microorganisms to be recovered from wounds that are healing without any evidence of infection. Individual clinical judgment thus comes into play, and this admittedly may often be subjective and biased. When the five-university collaborative study on the evaluation of ultraviolet irradiation was undertaken, these factors were taken under consideration and uniform criteria were established to promote understanding and agreement among surgeons and other observers concerned with the problem of wound infections. During the past ten years, these criteria have become relatively standard and have also been incorporated in a useful classification of operative wounds in relation to their contamination and the increasing risk of infections.

CURRENT DEFINITION OF POSTOPERATIVE WOUND INFECTION

Postoperative wounds are considered to be definitely infected if there is a purulent discharge, even if microorganisms are not cultured from the purulent material. Wounds are considered to be uninfected if they heal *per primam* without discharge. Minute stich abscesses are excluded if the inflammation and discharge are minimal and confined to points of suture penetration or if the incision itself heals *per primam* without drainage.

In the belief that clinical judgment is most important in the diagnosis of wound infections, however, wounds may be judged infected or uninfected by the

responsible surgeon who should be free to diagnose infection that doesn't meet the above criteria, but not allowed to judge a wound "uninfected" that does meet the above criteria for infection.

OPERATIVE WOUND CLASSIFICIATION CONTAMINATION-INFECTION RISK

A wound classification developed on the basis of a clinical estimation of bacterial density, contamination, and risk of subsequent infection is contained in the following outline which has now become widely accepted as a standard classification of operative wounds (Table 6).

Table 6. Classification of Operative Wounds in Relation to Contamination and Increasing Risk of Infection

I. Clean

- A. Non-traumatic
- B. No inflammation encountered
- C. No break in technic
- D. Respiratory, alimentary, genitourinary tracts not entered

II. Clean-Contaminated

- A. Gastrointestinal or respiratory tracts entered without significant spillage
- B. Gastrointestinal and repiratory tracts not entered
  1. Transection of appendix or cholecystic duct is considered clean-contaminated in the absence of acute inflammation
  2. Entrance into genitourinary or biliary tracts is clean-contaminated in absence of infected urine or bile
- C. Minor break in technic

III. Contaminated

A. Major break in technic
B. Acute bacterial inflammation encountered, without pus
C. Gross spillage from gastrointestinal tract
D. Traumatic wound, fresh, from relatively clean source
E. Entrance of genitourinary or biliary tracts in presence of infected urine or bile

IV. Dirty

A. Pus encountered
B. Perforated viscus encountered
C. Old or traumatic wound, or from dirty source

A clean wound is considered to be a non-traumatic, uninfected operative wound in which neither the respiratory, alimentary, or genitourinary tracts or the oro-pharyngeal cavities are entered. Clean wounds are elective, primarily closed, and undrained wounds.

Clean-contaminated wounds are operative wounds in which the respiratory, alimentary, or genitourinary tract is entered without unusual contamination, or wounds which are mechanically drained.

Contaminated wounds include open, fresh traumatic wounds, operations with a major break in sterile technic (e.g., open cardiac massage), and incisions encountering acute, non-purulent inflammation.

Dirty wounds include old tramatic wounds and those involving abscesses or perforated viscera. The very definition of this classification suggests that the organisms causing postoperative infection are present in the operative field before operation.

SUMMARY

A review of the subject of postoperative wound infection leads to the conclusion that this type of surgical sepsis is a complex phenomenon in clinical practice whose dimensions are real, continuing, significant, and changing. The general use of antibiotics during the past one-third of a century has had many

revolutionary effects on the treatment of established infections, but infections nevertheless continue to be serious problems of world-wide scope.

It has been disappointing to note that antibiotic therapy has not decreased the overall incidence of postoperative infections. The estimated cost of postoperative wound infections in the United States during 1967 was approximately $9.8 billion. This does not include community or home-based and nosocomial infections other than wound infections. While we have been successfully preventing some types of infection, others have replaced them.

There are differences of opinion in the minds of many surgeons, microbiologists, and others as to what a postoperative wound infection is. Needed are criteria to provide objective definitions and the mechanism of consistent evaluation and comparable reporting. A classification of operative wounds in relation to the degree of contamination and increasing risk of infection has been recommended for these purposes.

The controversy over the relative importance of aerial microbial contamination in the incidence of postoperative infection has continued since the last part of the nineteenth century to the present. Experimental evidence and clinical experience have emphasized the greater importance of contamination from endogenous and exogenous sources through contact. It is generally agreed, however, that there have been proven examples of infection from aerial contamination in hospital practice, but that additional research is needed to further define its importance and to develop appropriate methods of control.

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OPERATING ROOM ENVIRONMENT AND DEEP WOUND SEPSIS FOLLOWING JOINT REPLACEMENT AT UCLA

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INTRODUCTION

Deep infection following total-joint replacement usually requires removal of the prosthetic components; therefore, studies concerning the prevention and control of wound sepsis in total-joint replacement procedures have high priority at UCLA. The main modes of surgical infection, direct, airborne, and endogenous, were considered with relevance to existing preventive measures and controls. Use of prophylactic antibiotics was found to provide coverage at surgery and during the immediate postoperative period. Whether the so-called "clean air laminar flow" room can be used safely for total-hip joint replacement (THR) procedures without the use of antibiotics was also considered.

This author participated in one of the earliest total-hip replacement (THR) studies (8), in which 98 percent of these procedures were performed without the use of prophylactic antibiotics in conventional operating rooms and without high velocity directed horizontal filtered airflow systems (HVDHFAFS). The deep sepsis rate from this series is now 12 percent in the first 100 procedures with a four- to six-year follow-up. Subsequently, studies by investigators such as Stinchfield (7), Coventry (5), and Wilson (8) indicate that low infection rates were achieved using prophylactic antibiotics without "clean air laminar flow."

MATERIALS AND METHODS

Control of sepsis at UCLA includes: 1) preoperative evaluation to exclude all direct sources of infection; preparation of the operative site; 2) the use of antistaphylococcal prophylactic antibiotics; 3) evaluation of methods of reducing or eliminating airborne bacteria at surgery; 4) stringent control of urological procedures and control of other potential sources of bacteremias and septicemias; and 5) early diagnosis and treatment of subcutaneous infection to prevent the involvement of deep space (2).

PATIENT MANAGEMENT AND SURGICAL FACILITIES

Since October 1970, all patients who received total-joint replacements at UCLA have had standard preoperative preparation and postoperative evaluation

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and care. Special efforts to avoid intraoperative contamination have included the wearing of double gloves, use of impermeable disposable drapes, gowns, and headwear which completely covered all hair. Stringent limitation of operating room traffic was attempted.

Clinical and microbiological evaluation of 274 THR procedures was performed to determine whether there was a correlation between postoperative infections and airborne organisms present at surgery (6). After 167 of these procedures had been performed in the modern (1953) "conventional" operating room which has 10 to 12 air changes per hour, we attempted to reduce airborne contamination further by installing an HVDHFAFS. This system, installed in an operating enclosure 3.05 m by 3.65 m by 2.74 m has an air velocity of 26.5 m per minute with 400 air changes per hour. Initially, the ancillary use of aspirator systems was also planned; however, because of the inconvenience and difficulty in communication during surgery caused by this equipment and the overall good results using the HVDHFAFS with prophylactic antibiotics, this additional change has not been made.

Within this series of 274 THRs, a study was made of 16 total-hip replacements which included detailed bacteriological sampling and speciation of operating room air obtained during surgery and microorganisms cultured from patient wounds. Bacteriological studies for operating theater air were performed during eight procedures performed in a HVDHFAFS room.

All patients received systemic prophylactic antibiotics and anticoagulants. One and a half grams of methycillin was given intramuscularly every six hours for three doses preoperatively, followed by one gram intravenously during surgery. At surgery, each patient received 750 to 1,000 ml of antibiotic irrigation solution consisting of 10 g of neomycin, 100 mg of polymyxin B and 100,000 units of bacitracin diluted to one liter of 0.90 percent sterile saline.

After surgery, each patient received one gram of this agent intravenously every six hours until the intravenous infusion was discontinued; one half gram of cloxacillin was given every six hours by mouth thereafter until the sixth postoperative day.

Patients who were allergic to penicillin received 600 mg of lincomycin or clindamycin phosphate intramuscularly every eight hours for three doses before surgery, 600 mg intravenously during surgery, and 600 mg intravenously every eight hours until the intravenous infusion was discontinued. Then, 300 mg of clindamycin hydrochloride or 500 mg of lincomycin were given every six hours orally until the sixth postoperative day. Warfarin was given the night of surgery and subsequent daily dosages were adjusted to maintain the prothrombin time at approximately 40 to 60 percent of control values.

RESULTS

Analyses of all 274 THR procedures in this series were made in conjunction with microbiological studies of air sampled at the wound site in both rooms. Bacterial counts revealed a constant five- to eight-fold decrease in the directed flow room (1). However, during these studies, the microorganisms cultured from patients with deep sepsis were usually gram negative and from the patient's genitourinary tract.

Deep sepsis occurred in nine patients (two percent), all of whom had been considered high-risk patients for special complications. Seven patients had previous surgery, three of these had previous hip sepsis. Gram-negative bacteria were cultured from the wounds of eight. One patient with negative cultures had histological evidence of acute inflammation at the time of debridement three months postoperatively. Two patients had systemic arthritis and associated steroid therapy. Three had problems of obesity and one had minimal subcutaneous tissue. During surgery, four patients had excessive blood loss and two received bilateral replacements.

To date, a total of 430 THR procedures with a follow-up range of six months to four years have been performed at UCLA. Since completion of the 274 THR series, stringent methods of reducing urinary tract infections have been instituted, and no sepsis has occurred in the 156 THR procedures subsequent to the initial series. We have tried to avoid catherization; but when this is necessary, patients receive gram-negative suppressives (Gantrisin, Furadantin,

or Hyprex), and adequate antibiotic treatment when the catheter is removed. The importance and rationale of prevention has been summarized in previous articles (2,3).

Initially, there were slightly higher deep sepsis rates in total-knee joint replacements. All of these procedures were performed in the HVDHFAFS room. In the first 100 procedures, the deep sepsis rate was four percent. In the next series of 125 patients followed for six or more months, the infection rate declined to one percent. Factors that seem to correlate with poor wound healing include the superficial nature of the joint and possibly the close positioning of the surgeon's skin to the operative wound site. This was evidenced by the presence of staphylococcus epidermidis in two deep infections. The decline in THR sepsis reflects the increased care in ensuring wound healing during the postoperative period.

The question remains unanswered as to whether surgery can safely be performed in "clean air laminar flow" rooms with or without isolation systems, without the use of prophylactic antibiotics to provide coverage at surgery and during the immediate postoperative period. If antibiotics prevent replication of infectious organisms which directly contaminate the wound intraoperatively, then we must consider whether the use of HVDHFAFS is needed. However, the airborne bacteria should be periodically cultured and speciated to determine whether gram-negative organisms are present. We also need to determine whether the prophylactic antistaphylococcal antibiotics increase wound susceptibility to infection from gram-negative organisms.

The high-risk patient may require the methods of "clean air", plus isolation systems, plus prophylactic antibiotics to prevent infection. Certainly, if "clean air" systems are to be used, they should be used properly, e.g., the operating table should be placed close to the filtered air inlet and oriented in a way to maximize unobstructed passage of air through the region of the surgical site (4).

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LOCAL AIRFLOW PROTECTION OF SURGICAL WOUNDS TO PREVENT AIRBORNE CONTAMINATION

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M. Bakels

It is well established that wounds can be contaminated by airborne bacteria. That these airborne bacteria are a significant cause of postoperative wound infection, however, has not been proven. If one reviews the available literature on wound infection, one must reasonably consider that the air is one of many possible modes of surgical contamination.

Charnley's infection rate in total-hip replacement surgery has decreased dramatically in recent years (2). He attributes this to his clean room facility. One cannot help but feel that the same effect may have come as a result of his increased experience with the procedure and, in part, to his elaborate preoperative preparation of the patient. Series of cases presently being gathered in the United States (4) already show that a super-clean ordinary operating room in which the surgeons follow a rigid aseptic technique, and in which modifications to present air filtration systems are made, can result in an infection rate for total-hip replacement as satisfactory as Charnley's (13). These are relatively early studies, and with the well known delayed onset of infection in total-hip replacement surgery, the figures may not stand the test of time. If one approaches the problems of surgical wound contamination with these thoughts in mind, and realizes that the air is only one mode of bacterial transport, then a rational program to eliminate these factors can be considered.

Bacteria range in size from 0.3μ to over 10μ. Bacteria in air will usually not appear singly, but rather in droplets, in dried droplet nuclei, attached to dust, or on epithelial cells. The particles which carry these microorganisms are usually 8μ to 14μ in diameter (9,10,11). It has been appreciated for some time that the highest concentrations of bacteria in an operating room are found within the circle of the surgical team, directly over the wound (3,8). It is ironic that such is the case, but its cause can be readily understood when one considers that the wound is "where the action is." This is where the surgeon's breath forms a droplet aerosol, and his face and neck shed bacteria-laden particles of skin and sweat.

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To become infected, a wound must not only have a low resistance, but the virulence and dose of bacteria must be substantial. In the presence of foreign material, the infective dose of bacteria is substantially less than in its absence (3,5). It is in these wounds that small quantities of airborne bacteria previously considered insignificant may play a major role in the onset of a subsequent infection.

It is generally agreed that the operating room personnel and patient are the largest source of bacteria (6,11). It is therefore only reasonable that attempts be made to isolate these reservoirs from the surgical environment despite the type of air filtration system used.

Unidirectional airflow systems for removing bacteria from the air in operating rooms are generally quite expensive, hot, and frequently noisy. To eliminate the heat generated by the electric motors and compression of air behind filter banks, major modifications to existing air conditioning systems may be required. Major changes in electrical wiring and in the construction of the operating suite itself may also be required. Horizontal laminar-flow wall systems have the disadvantage that they create laminar flow for only a distance of approximately three feet from the filter bank (8). From this point the air becomes turbulent, and this effect is accentuated by the presence of any obstruction in the airflow, i.e., instrument tables, the operating table, and the surgical team. Because of this turbulence, it is conceivable that eddy currents set up about the operative site could actually bring air from the surgeon's head and neck into contact with the wound.

Because of the aforementioned problems concerning turbulence, cost, heat, and noise generation in existing clean air systems, a new method was developed. It was felt that placing a source of unidirectional flow bacteria-free air quite close to the wound could eliminate much of the undesirable turbulence at the operative site. By making the air filtration units small, it was hoped that heat, noise generation, and cost could be kept to a minimum. In early 1971, after much trial and error, such a system was devised. It was not until a year later that Dr. Beck's (1) work on a similar system was

brought to our attention. A prospective controlled study was designed to evaluate its effect on the number of bacteria and particles at the wound and over the instrument tables during surgery, and on the particulate content of the operating room outside the direct flow of air. All studies were conducted in a small community hospital on clean orthopaedic and general surgical cases.

A filter system was devised which projects essentially sterile air at a desired tangential angle across the surgical wound. The air is first passed through a prefilter which removes large particles of lint and dust, then it is forced through a high efficiency particulate air (HEPA) filter which removes 99.9 percent of all particles 0.3μ and larger. The exhausted air obtains its identity and flows in smooth, streamline, or laminar-flow profiles having a Reynolds number less than 2,000. This air is then passed through an exit nozzle which was made removable for sterilization so that it could be moved into close proximity to the surgical wound. The entire unit was mounted on an adjustable base, so that the height and the potential flow core angle could be changed at will (Fig. 1).

The maximum design capacity of the unit was 2,000 cubic feet per minute; however, the blower speed was variable so that flow rates could be adjusted. In an average operating theater, the air theoretically could be filtered in one minute. Actually, part of the air would be in a recirculating sequence, and the probability would be that in a 2,000-cubic foot operating room, 50 percent would have passed through the system in one minute, and 90 percent would have been exchanged in approximately 10 minutes.

AIRFLOW STUDIES

Several studies of air jets exhausting into quiescent air were made to achieve a laminar air profile having a constant velocity region as wide as possible from a small source.

If air is exhausted through a filter at uneven pressures, the high pressure zones will tend to mix with low pressure areas. Thus, the streamline having the higher pressure will shear the weaker stream, become unstable, and eventually break up to form vortices. These vortices will transport mass inertia, temperature, and any other characteristics slowly across the stream.

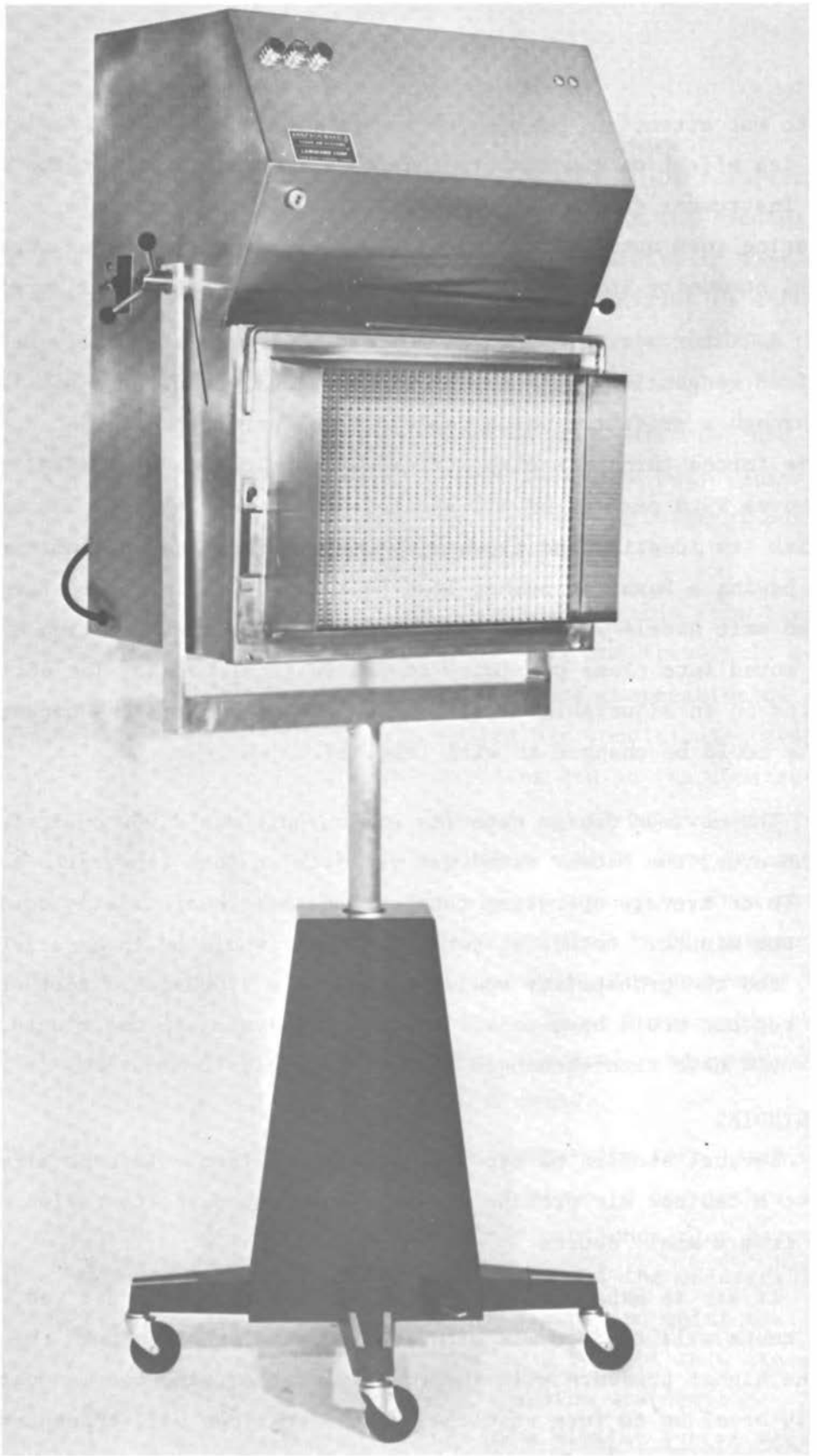

Fig. 1. Filter unit on an adjustable base.

Local Airflow Protection

Due to the importance of equalizing the pressure over the HEPA filter face, a series of vanes was developed and mounted at the blower exit orifice. The extreme turbulence created by these vanes resulted in a remarkably equal diffusion of pressure behind the HEPA filter.

Airflow measurements were made with a hot wire anemometer for low velocity flows and for determining the turbulent regions. A Kiel probe in conjunction with a six-degree inclined micromanometer was used to plot the core flow region. To further extend the laminar airflow region, a low angle nozzle was designed so that the filter exit flow would be compressed and thus maintain its identity for a longer time when exhausted into ambient environment.

Entrainment of room air into the clean zone was discouraged by placing sterile drape sheets at a tangential angle along the sides of the exit nozzle. The operating team along the table is usually in quite close contact with these drapes so that a partial side wall along the sterile flow is created.

Warren (12), Kranz (7) and others have shown that air streams will remain linear in a constant velocity coneshaped pattern when released from an orifice for a distance equal to approximately three times the orifice diameter.

That this distance was extended by the incorporated modifications to the air source is shown in Figure 2, which illustrates the actual measured air patterns. The central triangle of the diagram should be considered a three-dimensional cone.

The apex of this constant velocity region where the flow is laminar extends to six feet eight inches from the filter face, after which the velocity drops and gradually becomes zero. As can be seen in Figure 2, the flow becomes less laminar outside the central core. The outer funnel-shaped area is the edge of the flow profile in which maximum mixing with ambient air takes place. It delineates the most peripheral area in which the filtered air has any effect, and where zero velocity was measured with the hot wire anemometer.

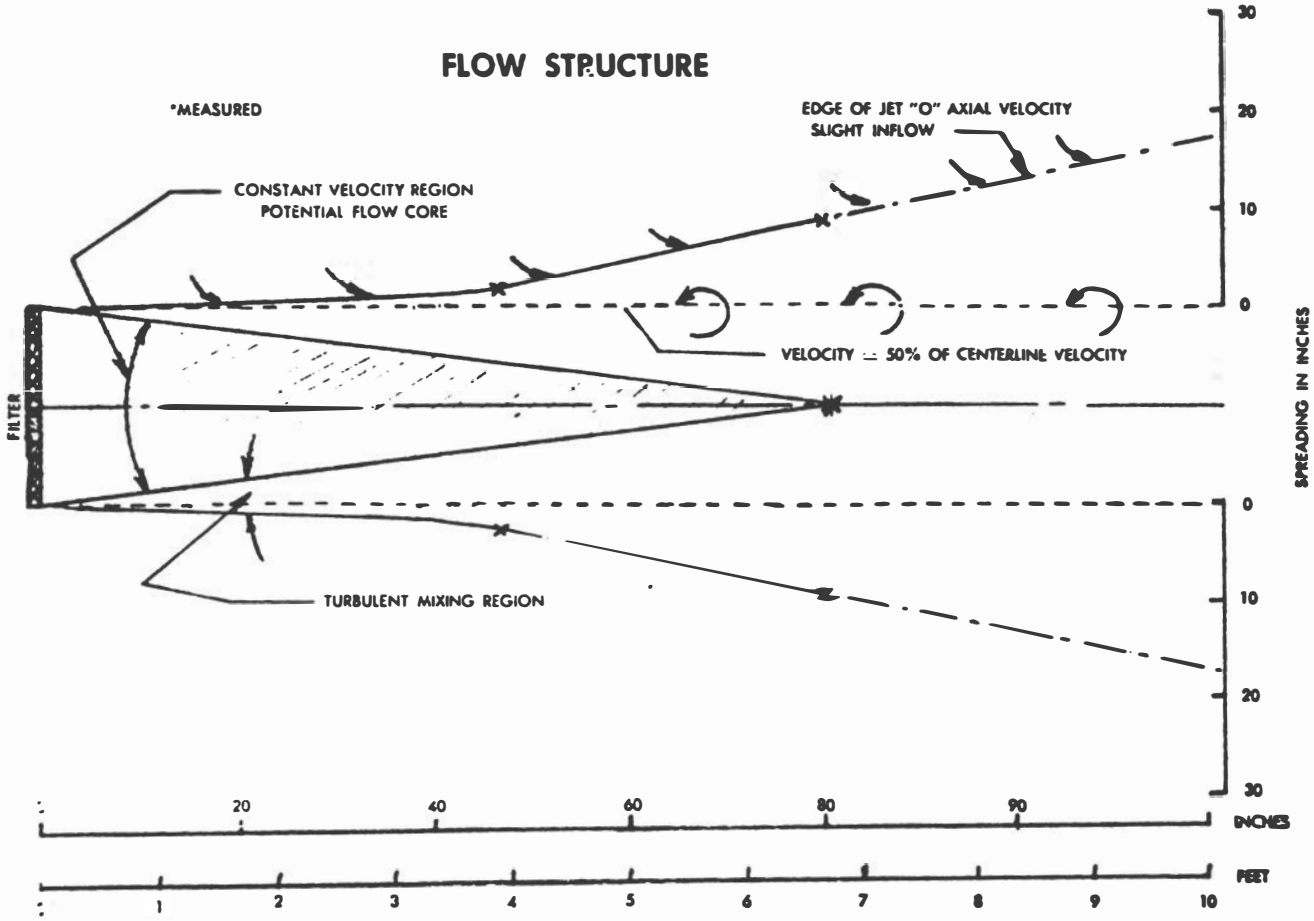

Fig. 2. Measured air patterns.

Local Airflow Protection

PARTICLE COUNTS

Particle counts were obtained using a Coulter 550 Airborne Particle Counter which tabulates the number of 0.5μ particles per cubic foot of aspirated air. A hose was run from the counter to the area in which air was to be sampled. During surgery, a sterile plastic tube was clamped into the surgical incision so that its orifice aspirated air directly from the wound. It has been our experience that when studies of airborne particles are made in an operating room, they are seldom taken directly from the wound but rather from an adjacent area which would not produce data representative of the actual wound. Control samples were taken with the air unit turned off but with the tube left in its original position. Intermittently, during each surgical case, air samples were taken over the instrument tables. Particle counts were also taken with and without the surgical team's hands and arms in the airflow.

Figure 3 compares the number of 0.5μ particles counted per cubic foot of air at the wound during surgery within the airflow, and particles counted with the unit turned off. The air unit was always kept within 42 inches of the wound and closer, if possible. The average of 61.3 particles per cubic foot with air unit turned on is considerably less than the 19,541 particles per cubic foot found in the same area with the system off.

It was initially felt that the turbulence generated by the surgeon's hands and arms in the airflow would adversely affect particle counts. There is no question that turbulence is generated in this fashion, but we were surprised to find that the particulate content rose only if the surgeon's hands were placed directly upwind and in line with the sampling probe. If the hands were placed even an inch or so above the sampling orifice, no increase in the particle count was recorded. It is hypothesized that the central core of laminar flow air is quite uniform and that transfer of particulate matter from one lamina to another occurs only with some difficulty in this region. Particle counts made over the back instrument tables averaged 1,500 - 2,500 0.5μ particles or larger per cubic foot with the unit on, as compared to 15,000 with the unit off.

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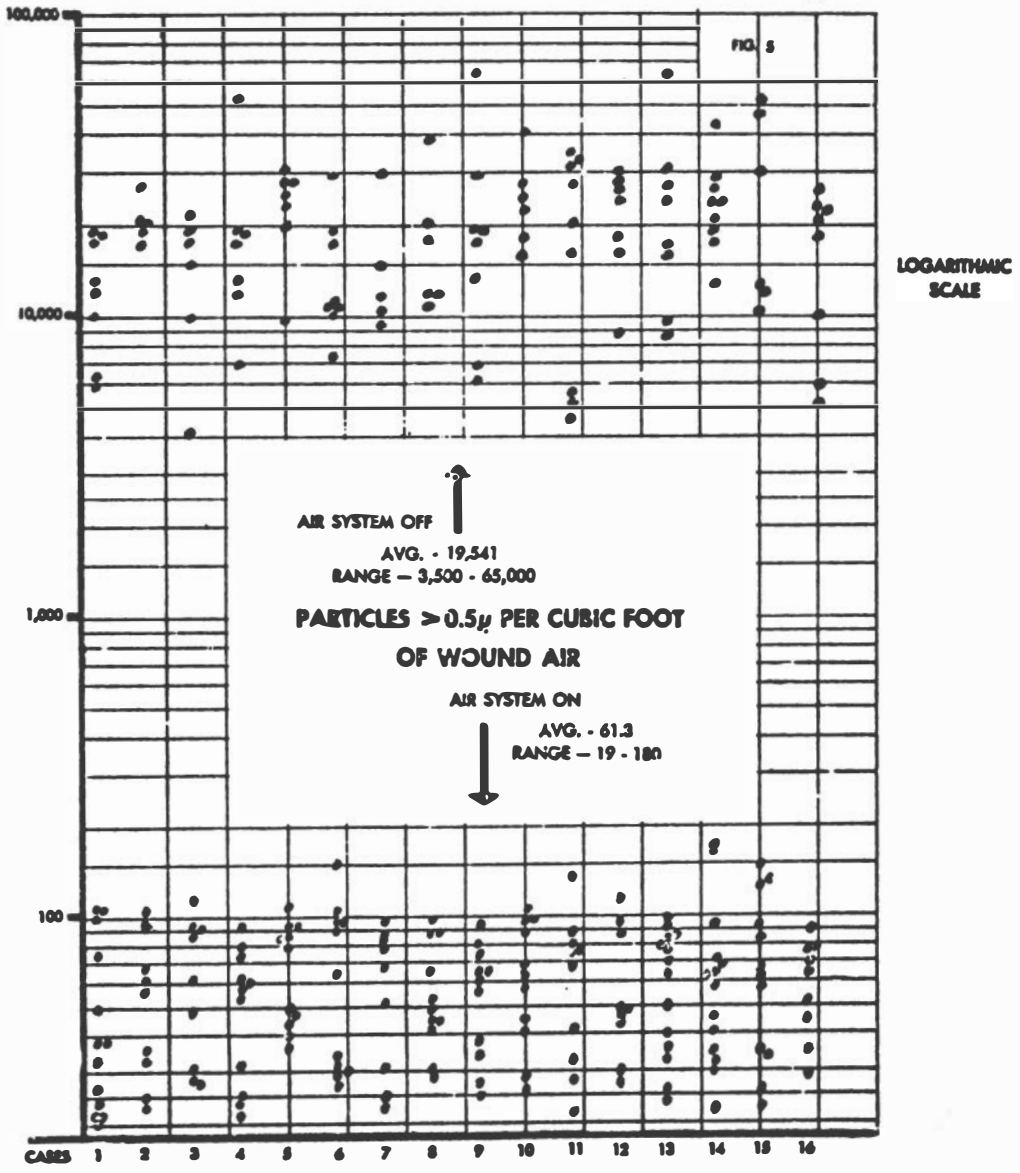

Fig. 3. Comparison of particles counted during surgery with airflow unit on vs. airflow unit off.

Local Airflow Protection

BACTERIOLOGIC SAMPLING

Viable airborne particles were counted by clamping two sterile plastic hoses with their orifices directly at the wound edge. The hoses were kept as short as possible to minimize entrapment of bacteria along their inner walls, and were connected to either a standard millipore air sampler or a slit sampler.

The millipore sampler is, essentially, a sterile chamber containing 30 cc brain-heart infusion broth. Air is projected into the broth, thus trapping most particulate matter. This culture media is then passed through a millipore filter where bacteria are deposited on its surface. A pad beneath the filter is kept saturated with a nutrient media to promote bacterial growth. This system, although theoretically quite efficient, has many disadvantages. It is fragile, difficult to set up, samples only one cubic foot of air, and if the slightest error is made when the broth is drawn through the filter, the filter is left too dry and very little growth will result. At the present time all counts are taken with a New Brunswick STA-101 slit sampler which monitors two cubic feet per minute.

The experimental samples were taken with the air unit on, and the control samples aspirated from the same region with the filter turned off. In ten clean orthopaedic cases an average of .83 viable particles per cubic foot were found with the unit on, as compared to 12.5 with it off. Figure 4 shows similar data except the samples were collected by a slit sampler (New Brunswick STA-101). In this series, a comparison was made to a horizontal air wall system installed in the same operating room.

The types of bacteria isolated on blood agar are shown as approximate percentages in Figure 5. These compare favorably with studies performed by Nelson (8).

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VIABLE PARTICLES PER CUBIC FOOT

34 Clean Orthopedic Cases
Slit Sampler

	Wound Average	Range	Instrument Table Average	Range
No Air Flow	1.8	0.7 - 5.0	0.9	0.6 - 2.0
Local Air Flow	.1	0 - 0.6	0.2	.02 - 1.7
Horizontal Wall	.2	0 - 4	.1	0 - .8

Fig. 4. Viable particles per cubic foot.

83% - Non Hemolytic Staph
11% - Diptheroids
5% - Bacillus Subtilis
1% - Hemolytic Staph, Pseudomonas

Fig. 5. Types of bacteria.

Local Airflow Protection

DISCUSSION

The present report describes the effectiveness of locally directed clean air for the protection of surgical wounds from airborne contamination.

The core area of true laminar flow across the wound was found to form a very effective barrier to prevent particles dropped into it from reaching the wound. Particulate matter generated by the surgical team and entrained in this flow could, however, be carried away and deposited on the open instrument tables. This does not seem to be a significant factor however, as the counts over these tables were satisfactorily low. To minimize this posibility, we are now using aspirator suits for all personnel in the operating room. The surgeon's expelled breath is exhausted via a small vacuum system into the air unit's HEPA filter where it is isolated from the ambient environment. It may be that these additional steps are unnecessary, as the total room counts are quite low. On the other hand, it may eventually be proven that isolating the surgical team and the patient from the operating room atmosphere will result in such low air bacterial counts that no special air filtration system may be required.

SUMMARY

A portable air filtration unit for use in hospital operating rooms has been described. Prospective studies of its effectiveness in controlling airborne particles and bacteria were presented, and compared to a horizontal wall system. It is concluded that both systems significantly decrease the number of airborne bacteria.

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THE DEFINING OF BIOLOGIC CLEAN AIR AND ITS CLINICAL SIGNIFICANCE

William C. Beck*

Every surgeon wants to work in an operating room surrounded by biologically clean air. The Committee on Operating Room Environment of the American College of Surgeons published a position paper in 1972 in which it mentioned clean air emerging from a final bacterial filter. It is generally believed by this committee that the 1972 statement is still valid.

There is presently no definition of biologic clean air. If one wants to make any specification in either the design, the function, or the effects of the use of either conventional ventilation or special air systems in operating rooms, one is forced to employ the definitions of Federal Standard 209B (2). This standard makes reference only to the particulate control parameters and not to desirable microbial control conditions. It states that airborne microorganisms are a part of the particulate count of the different air cleanliness classes.

An attempt was made in the NASA standard for the microbially controlled environment to adapt the clean air of industry by engrafting "bioclean" concepts upon the particulate ones.

In surgery, we have no information at all that nonviable particulates have any adverse effects upon the healing processes, at least in the numbers found in our operating rooms (although Warren Cole has suggested that airborne powders from rubber gloves might supply rafts for carrying microorganisms) (1). Therefore, many of the constraints imposed by either 209B or NHB 5340.2 (4) do not apply to surgical environments.

There still remains a need for a definition of biologic clean air. It is not difficult to create such a standard if one uses the guidelines on which the particulate standards were based: the recognition of degrees of cleanliness or, to stay with existing terminology, Biologic Cleanliness Classes.

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CREATING A DEFINITION

Some conference, such as the one in which we are presently participating, could create a committee which would set up three or four levels of air cleanliness. Federal Standard 209B does this (Table 1). Our committee could do it in an identical manner (Table 2).

There would also be needed a variety of other definitions which would enable the designer to specify, the manufacturer to provide, and the experimenter to evaluate the effect of clean air systems, both conventional and special. These can parallel 209B. It must be remembered that the minimum requirements of construction and equipment for hospital and medical facilities of the Health Resources Administration (HEW-74-4000 (3), which are guides to all engineers and architects, define filter efficiencies, air changes, pressure relationships, etc., for all hospital areas. These are the conventional systems which also should be put to test for level of biologic cleanliness.

Certain decisions will be necessary. The first, of course, would be to accept viable particles rather than bacterial counts. The second would be to accept the use of a specified volumetric air sampling system with certain minimum feet per minute so that statistically valid figures were obtained.

SIGNIFICANCE

From an economic standpoint, it might prove very useful to have a standard of biologic cleanliness and not have to rely upon 209B. Ulrich, Cribbs, and Michaelson (5) have shown that High Efficiency Particulate Air (HEPA) filtration is not necessary in removing viable particulates. Other studies have shown that completely acceptable results are obtainable using 99.0 percent efficient filtration rather than the previously ubiquitous HEPA filter. Possibly even lesser filtration would be even more efficient thus permitting lesser blowers, lowered noise, and diminished cost. Such effect can only be sought if we can define the clean air for surgical environments.

The clinical significance of such a definition will permit us to evaluate whether or not special air systems are worth the added expense, and

might extend the studies of the type which have been reported at the conference with a baseline of a common definition. This will reduce one of the variables in the study of surgical nosocomial infection.

Table 1. Air Cleanliness Classes

Maximum number of particles per cu ft (per liter)* 0.5 micron & larger	Class English System (Metric System)*	Maximum number of particles per cu ft (per liter)* 5.0 micron & larger
100 (3.5)*	100 (3.5)*	
10,000 (350)*	10,000 (350)*	65 (2.3)*
100,000 (3500)*	100,000 (3500)*	700 (25)*

*Metric system

Table 2. Air Cleanliness Classes

Maximum number of bacterial particles per cu ft	Maximum number of bacterial particles per cu meter	Maximum number of particles in total sample test of ( ) feet
1 *	35	(30) 30
5 **	175	(30) 150
20 ***	700	(10) 200

*Class 1 Microbiologic Cleanliness: viable microbiologic airborne particle counts not to exceed one particle per cubic foot of air, with a minimum sample of 30 cubic feet of air.

**Class 5 Microbiologic Cleanliness: viable microbiologic airborne particles to average more than one and up to five per cubic foot of air with a minimum sample of 30 cubic feet of air.

***Class 20 Microbiologic Cleanliness: viable microbiologic airborne particles to average more than five, and not to exceed 20 per cubic foot with a minimum sample of 10 cubic feet of air.

These classifications are based upon viable microbiologic particle counts (colony forming units). Counts are to be taken during periods of normal 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 the work and/or equipment used in the work. This may be at a surgical incision, at an instrument table, etc. The site must be described for each sampling including surface, height from floor, relation to walls, etc. Reliability is achieved by multiple repetitive sampling.

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ULTRACLEAN OPERATING THEATRES VERSUS CONVENTIONAL THEATRES-- A CONTROLLED CLINICAL TRIAL

George Bentley and Andrew B. Simmonds*

INTRODUCTION

From early times it was appreciated that contact contamination could be reduced by improved hygiene (Semelweiss 1861). Later Lister improved wound sepsis by antiseptic surgery. The role of airborne bacteria in the aetiology of sepsis was first introduced in relation to burns (Bourdillon and Colebrook 1946). The use of Plenum ventilation gradually replaced exhaust ventilation in the 1950s (Girdlestone et al., 1951) and different types were evaluated by Blowers and Crew (1960). The logical extension of this work was the introduction of clean air downward linear flow enclosures (Charnley 1964). During the 1960s, the American aerospace industry introduced industrial laminar flow clean rooms with High Efficiency Particulate Air (HEPA) filters, and these were later introduced into medical practice (Lidwell and Towers 1969, Whyte and Shaw 1973). Both developments result in substantial reduction in airborne bacteria (Charnley 1972, Lidwell and Towers 1969, Scott 1971) and the relative merits are largely logistic. Improved surgical wound sepsis rates have been claimed by Charnley (1969, 1972) by operating on patients in ultra-clean air, although similar low sepsis rates have been reported by others using systemically administered prophylactic antibiotics in a conventional operating room (Coventry et al., 1974). The need for a controlled clinical trial of these ultra-clean air systems is clear, and so far has not been performed. This paper describes the early results of a trial in which air contamination, wound contamination, and wound infection were compared in two vertical laminar flow enclosures and a conventional operating room.

METHOD

After six month's practice with body exhaust systems a controlled clinical trial was set up. A physical assessment of the airflow patterns

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within the enclosures and a conventional operating room was made using the Hiamine bubble technique (Carpenter and Moulsley, 1972). All patients having total-joint replacement surgery were randomly allocated to either conventional theatre or enclosure independently for each of five orthopaedic services. Pre-operative urinary, nasal, and perineal bacteriology was performed. During the operation three settle plates were placed as follows: one immediately behind the operator, one on the opposite side of the operating table, and the third at the foot of the table. Volumetric assessment was made by slit sampler studies (700 litres/min; 20 ft^3/min for three two-minute periods on a limited number from both environments using a sterile wide-bore polythene extension tube aspiring air from the immediate vicinity of the wound.

Quantitative wound bacteriology was performed by a washout procedure (after Blowers 1973). One hundred fifty millilitres of 25 percent Ringer saline solution were washed into the blood-free wound at the close of surgery. (Fig. 1).

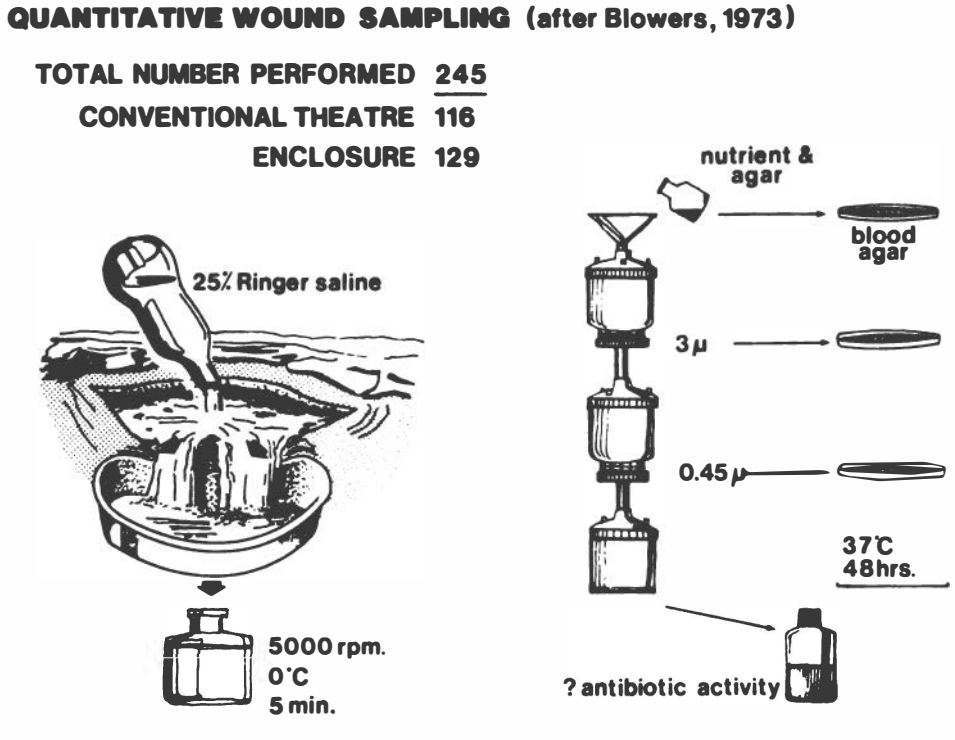

Fig. 1. Method of wound washout and quantitative sampling (after Blowers, 1973).

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The fluid was collected in a sterile pot, cooled, centrifuged, and the supernatant filtered through a double millipore chamber (3 μ and 0.45μ). Each filter was washed through with Ringer saline and the filters placed on blood agar plates. The deposit was made into a pour plate after mixing into 20 mls. of liquid nutrient agar. The filtrate was assessed for antibacterial activity as the patients routinely received systemic cloxacillin prophylaxis with the premedication one hour before induction of general anaesthesia.

Postoperatively, wounds were individually examined and discharges were assessed bacteriologically. Routine and independent follow-up has been performed on all patients.

RESULTS

The Patients

Three hundred and sixty six total-joint replacements were performed over the 10-month period studied, 225 in the enclosures and 141 in the conventional operating room (Table 1).

Table 1. Total-Joint Replacements Performed

ENCLOSURE	CONVENTIONAL	TOTAL
225	141	366

Ultra-Clean Operating Theatres

Staphylococcus aureus was grown from the nares in 27 patients (19.8 percent) and from the perineum in nine patients (7.5 percent). The midstream specimens of urine contained coliforms in 18 patients (14.5 percent).

Airflow Patterns

The assessment of the airflow patterns was a rewarding exercise and revealed satisfactory linear flow rates of 100 ft/min in the central part of the enclosure with slower flow rates of 30 to 90 ft/min at the sides (Fig. 2).

Fig. 2. Photograph of air bubble pattern in Charnley-type enclosure demonstrated by Hiamine technique of Carpenter and Mousley (1972).

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The pattern of airflow in the conventional operating theatre was from inlets on the upper wall at one end, across the theatre diagonally to exhaust vents immediately above floor level at the other end. The conventional operating room was found to have more turbulent flow than had been previously thought with variable flow rates [30 to 90 ft/min in the operating area but with considerable mixing and recycling (Fig. 3)].

Fig. 3. Air bubble pattern in conventional theatre at operation site showing satisfactory horizontal flow.

Ultra-Clean Operating Theatres

Bacterial Colony Counts

Settle plate studies revealed a 10-fold difference between the airborne bacteria in the two environments (Table 2).

Table 2. Airborne Bacterial Sedimentation

	Mean col./sq.ft./hour	Standard Deviation
ENCLOSURE 1	14.87	11.94
ENCLOSURE 2	16.28	12.07
CONVENTIONAL THEATRE	166.72	65.94

These remained fairly constant throughout the study. Volumetric sampling by slit sampler was more difficult but the results showed a similar 15-fold difference between the two environments. There was, however, an approximate 20 percent tube loss resulting in lower recovery rates than would have occurred were it possible to sample air without this exentsion tube. The results are shown in Table 3.

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Table 3.

VOLUMETRIC SAMPLING AIRBORNE BACTERIA

slit samples - 3 samples of 1400 litres (50 cu.ft.)
total air volume sampled – 4,200 litres (150 cu.ft.)
tube loss ≏ 20 %

	ENCLOSURE	CONVENTIONAL THEATRE
SLIT SAMPLES	0.38 c/cf	5.3 c/cf
BACTERIAL SEDIMENTATION	av. 10 col./sq.ft./hour	av. 150 col./sq.ft./hour

Wound Contamination

Results of quantitative wound samples are shown in Figure 4. The majority of patients from both environments had minimal contamination but small numbers from both environments had more than 30 organisms recovered. These small number of "significant" washouts are tabulated in Tables 4 and 5. It can be seen that there is a large number of high wound washouts from the conventional theatre [17 out of 117 (15 percent)] than the enclosures with 9 out of 130 (7 percent). Applying the X^2 test the result is 3.78 (X^2 = 3.84 indicating significance at five percent level) so these results are of borderline significance.

Fig. 4.

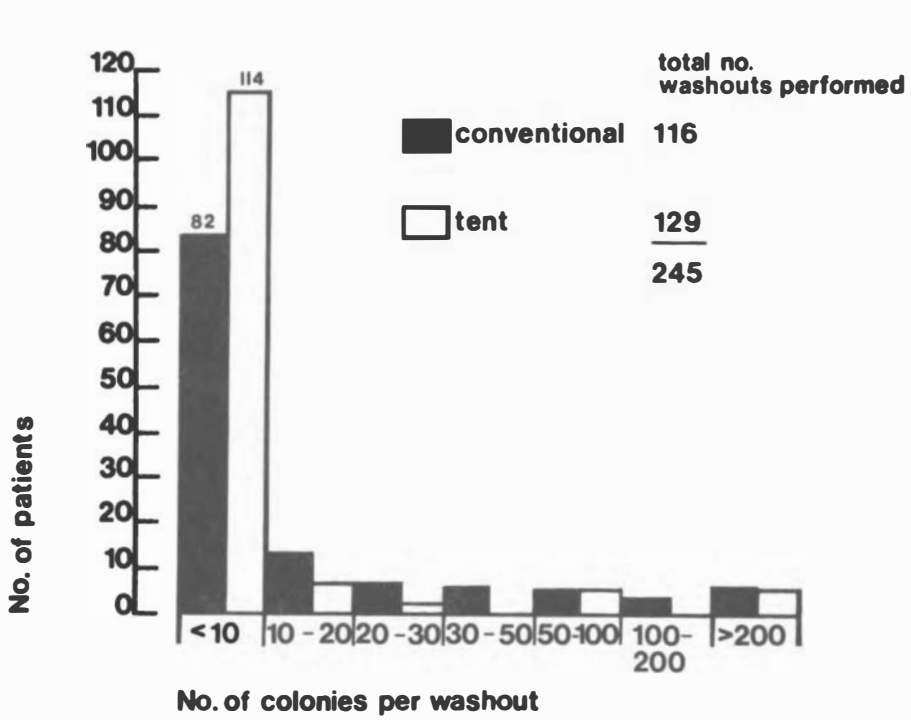

Table 4.

QUANTITATIVE WOUND SAMPLING

no. of organisms grown :	< 30	30-100	> 100
CONVENTIONAL THEATRE	100	9	8
ENCLOSURE	121	4	5

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Table 5.

QUANTITATIVE WOUND CONTAMINATION

no. of colonies :	<30	>30	total
CONVENTIONAL THEATRE	100	17	117
ENCLOSURE	121	9	130
Total	221	26	247

$X^2 = 3.78$ (X^2 significant at 5% - 3.84)
i.e. BORDERLINE SIGNIFICANCE

If these results are analysed from a lower level of washout the results become significant. For example, results comparing the two theatres taking washouts over 20 organisms show that the conventional theatre has a higher statistical number ($p = 0.0001$, $X^2 = 7.94$). However, we decided to use the former level, since Lowbury and colleagues were able to recover up to 28 organisms regularly in wounds which were not infected using a different method in hip fractures (Lilly et al., 1970). The organisms recovered from washouts were all skin commensal, and were roughly indentified by their colonial appearance.

The influence of systemic antibiotics on the growth of organisms is interesting. Antibacterial activity was noted in 29.8 percent of the washouts and there was an overall reduction in numbers of organisms recovered from these. However, there were four notable exceptions in which large numbers of organisms grew out in the presence of antibacterial activity in the filtrate (Table 6).

Table 6. Presence of Antiobiotic Activity in Washouts

organisms :	< 30	30 - 100	> 100	total
PRESENT	62 (31.7%)	2	2	66
ABSENT	133 (68.3%)	11	11	155

Percentage with antibiotic in washout 29.8%

CLINICAL FOLLOW-UP

The clinical follow-up is, as yet, too short to provide clinical correlation with crude sepsis figures. Only three patients have developed probable or certain sepsis, two from the conventional threatre, and one from the enclosure. Two of the patients had "significant" washouts of more than 30 colonies (one from the conventional theatre and one from the enclosure). At the same time there were eight wounds in the enclosure and 16 wounds in the conventional theatre with more than 30 organisms, but no infection at 6-12 months.

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DISCUSSION

It is likely that sepsis in joint replacement surgery arises through wound contamination at the time of surgery. The source of contamination remains uncertain, and modern ultra-clean operating environments can predictably reduce airborne bacteria. Whether this can eliminate or reduce contamination from contact sources is doubtful.

In the vertical laminar flow enclosure, the prevention of contact contamination depends on the efficiency of the body exhaust systems.

Quantitative wound sampling in our study has demonstrated a trend toward less wound contamination in vertical laminar flow enclosures using body exhaust systems, compared with standard operating dress in a conventional theatre. There remains, however, a small unpredictable group of cases in which heavy wound contamination occurs, the source of which is uncertain.

SUMMARY

1. Three hundred and sixty six total-joint replacements were randomly allocated to one of two clean air enclosures or a conventional operating room.
2. Physical evaluation of the airflow patterns by the Hiamine bubble technique was instructive and simple.
3. A 10-fold difference in airborne bacteria was noted with the higher levels in the conventional room.
4. Quantitative wound sampling has revealed a higher rate of wound contamination in conventional rooms than in the laminar flow enclosures, the significance of which is unknown.
5. Three wound infections have occurred: two in the conventional theatre and one in the enclosures. Two of these had "significant" wound contamination at the time of surgery but 24 wounds had a "significant" contamination with no infection.
6. The relative importance of impermeable theatre clothing in the different operating environments is not yet evaluated.

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LOW VELOCITY UNIDIRECTIONAL ULTRAFILTERED AIR SYSTEMS

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Laminar airflow ventilation is widely accepted as being the most efficient method for removing particles and microorganisms from air. The two principles involved, ultrafiltration through High Efficiency Particulate Air (HEPA) filters and rapid piston-like displacement of air assures almost complete freedom from viable airborne microorganisms. HEPA filters were first developed by the Army Chemical Corps for use in respirators and sampling devices (17) and long experience has confirmed that when properly installed they are durable and efficient for removal of airborne bacteria and viruses. The value of the laminar flow principle described by Whitfield (45) has been confirmed in many studies, even though true laminar flow is never achieved in practice. The term should be replaced by a more appropriate descriptor. "Laminar flow" has come to mean ventilation velocity of 100 ft/min throughout an enclosure as recommended by Whitfield and reinforced by issuance of US Air Force Technical Order No. 00-25-203 (40) and by Federal Standard No. 209A (13). This defines laminar airflow as "airflow in which the entire body of air within a confined area moves with uniform velocity along parallel flow lines." Many installations have employed lower flow rates successfully, and it is the purpose of this report to review the use of lower flow rates in ultrafiltered unidirectional air systems for control of airborne contamination.

FILTER EFFICIENCY VS AIR VELOCITY

Harsted *et al*. (19) have shown that the efficiency of modern ultra-high-efficiency filter papers for retention of T1 bacteriophage aerosols is greatest when air passes through at low velocity, and penetration increases progressively as the velocity increases. Data in Table 1 extracted from the Harsted report (19) show that this is true for filter paper from each of three different manufacturers. The column in Table 1, labeled Filter Face Velocity in Feet/Minute is the speed at which air passes through the filter paper, and the second column is a 20-fold multiple of the first column listing the approximate flow rate across the face of a commercial filter where the filter paper surface area is increased 20-fold by means of accordian folds to conserve space. The performance of the filter paper for neutralized phage particles observed by Harsted is close to the

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theoretical values derived by Whitby (43). Both theoretical calculations and direct measurements with a small viable particle indicate that it is not necessary to operate HEPA filters at a flow rate of 100 ft/min and, in fact, they are more efficient at low flow rates.

Table 1. Effect of Velocity on Penetration of Neutralized Submicron Phage Aerosols Through Ultra-High-Efficiency Filter Papers*

Filter Face Velocity Ft./Min.	Approximate Flow Rate Ft./Min.	Geometric Mean % Penetration Manuf. #1	Manuf. #2	Manuf. #3
1.1	22	0.00027	0.000021	0.000002
3.7	75	0.0091	0.0014	0.000083
17.	340	0.099	0.043	0.0027
68.	1400	0.34	0.19	0.017

TYPE OF VENTILATION

Early studies by Bourdillon and associates (8,9) showed the prevalence of airborne bacteria and a high incidence of surgical wound infection in surgical theaters ventilated by exhaust fans where dirty air was drawn into the room from the halls. Progressive improvement was obtained by the addition of positive pressure ventilation, filtration through cloth filters, plenum ventilation, and exclusion of ward blankets and clothing. Many others added refinements to these observations (1,4,24,33,39) and by 1968 the British Medical Research Council considered plenum ventilation of operating suites an established practice like disinfection of the skin of patients (31).

Laminar flow ventilation (45), more appropriately called unidirectional flow, is the successor to plenum ventilation and involves continuous introduction of filtered air at a uniform velocity across the whole ceiling or wall of a room, and its containment by four walls until it is exhausted through the floor or opposite wall. The two major advantages of such ventilation are 1) all areas of the enclosure are ventilated by air free from microorganisms, and 2) any microorganisms aerosolized within the enclosure from personnel or equipment are removed in seconds. Other described advantages (36) include: 3) scant opportunity for airborne particles to settle onto a wound or clean surface since they tend to move with the moving airstream; 4) reduced housekeeping and maintenance because less dust settles on exposed surfaces; 5) improved control of humidity and temperature

*Extracted from Harsted et al Table 5, 1967 (Reference 5).

through recirculation of already conditioned air; 6) freedom of movement of personnel within the conditioned space in downflow rooms; and 7) elimination of air locks, air showers, and extra garmenting in electronic assembly rooms.

Some disadvantages of high velocity unidirectional ventilation systems are: cost of installation; increased volume of air moved, which requires larger motors, fans, and ducts; increased heat generation; higher noise level; increased space for ceiling or wall and floor plenums. In spite of their efficienty in removing particles and microorganisms, these disadvantages, plus the lack of proof of cost effectiveness in reduction of infections, have prevented widespread adoption of unidirectional filtered air systems in operating theaters. There have been many attempts to minimize the disadvantages by modifying some portion of the basic design without loss of effectiveness. One of the most promising modifications is to reduce the velocity of the unidirectional airflow because this modulates every one of the disadvantages listed above.

VELOCITY

One of the early publications by Whitfield (46) listed results of dust sampling at different flow rates in vented hoods. There were an average of 213 particles/ft^3 with a flow rate of 100 ft/min (600 air changes per hour) whereas a flow rate of 50 ft/min (300 air changes per hour) showed 450 particles/ft^3, an insignificant difference of 0.02 percent considering the sampling rate of dust samples (0.1 ft^3/min), the relative lack of sensitivity of samples in 1963, and the control of values of 10,000 particles/ft^3.

In another report Whitfield (47) states that "Downflow rooms fulfill class 100 standards (less than 100 particles >0.5μ in diameter) for the entire room, and crossflow rooms will maintain class 10,000 standards. Downflow rooms show good control at 60-100 ft/min air velocity, and for best control, crossflow rooms should operate from 100 to 130 ft/min." These data indicate that lower velocities are more effective in vertical flow installations than in horizontal flow installations.

In each of three recent controlled studies in operating rooms by Scott *et al.* in 1971 (38), Whyte *et al.* in 1973 (48), and Wardle in 1973 (42), the numbers of bacteria per ft^3/air pointed to vertical flow as the optimal

airflow configuration for application in the operating room. The well controlled studies by Whyte et al. (48) showed that little improvement in airborne bacterial counts was obtained with air velocities over 60 ft/min (.3 m/sec).

In a simulated nursing unit in a horizontal flow industrial clean room, Lidwell and Towers (24) found little movement of particles against the direction of airflow or lateral movement of particles if the linear velocity of air did not fall below 35 ft/min. We observed similar results in a vertical flow room with lower velocities of 25 ft/min using test suspensions of latex particles, T3 bacteriophage and Serratia marcescens.

A low-velocity system was developed by Horneff (14) to reduce the disadvantages of high-velocity laminar flow. It utilized remotely located HEPA filters with the filtered air ducted to a perforated ceiling and vertical velocity of 15 ft/min, and gave good protection from bacterial contamination as measured by settling plates and sieve sampler. Modifications of this system with flow rates of 19 to 25 ft/min have been used to prevent airborne contamination of cell cultures during transfer (29), spread of airborne infection in laboratory animals (3), and removal of viable airborne bacteria from an operating room during surgical procedures (15). Pelosi (34) compared particulate counts in a downflow clean room with flexible side walls and a plenum ceiling operated at velocities of 20, 50, and 80 ft/min. He observed no significant difference at the three velocities and therefore recommended velocities of 20 ft/min.

Patients with reduced resistance to infection have been studied in laminar flow nursing units with horizontal flow rates at 35 ft/min (24), 90 ft/min (6,7), and at 90 and 60 ft/min (35,37). In the latter study, mean bacterial counts/ft^3 of air before, during, and after bedmaking at air velocities of 90 and 60 ft/min were not significantly different, varying between 0.04 and 0.06/ft^3. The mean was 170 times less than in a conventional isolation room and 370 times less than in a conventional hospital room. Laminar flow units have been devised with various air velocities for isolation of a single bed (10,23,26), and high-velocity flow air jets (2,49) directed

at the operative site have been tested in surgical theaters. The air jets entrain dirty air, do not protect instrument tables and other equipment outside the air jet, nor do they isolate observers and other supportive personnel in the room. An unrestrained filtered air jet draws contaminated air around its entire periphery which results in a mixture of clean and contaminated air. To counteract this, partial walls have been placed around the jet source by some investigators to contain the jet stream until it is almost delivered to the site to be protected. However, this also leads to contamination by creep of dirty air up the inner side of the partial retaining walls as observed by Whyte (4). We have also observed this phenomenon in early studies with an over-bed unit equipped with a ceiling plenum and flexible walls that reached to the surface of the bed. With vertical flow rates of $\pm$ 25 ft/min and the bed in place, bacterial counts remained essentially zero within the enclosure while the room air was heavily contaminated. When the bed was removed smoke tests showed that room air crept up the inside of the flexible walls and contaminated the whole enclosure.

The basic principles of unidirectional airflow are as illustrated in Figure 1: a) entrainment quickly contaminates an unprotected jet stream; b) partial walls around a jet stream lead to contamination by aspiration of dirty air up the inner side of the partial walls; and unidirectional flow can be maintained only by c) complete containment of air by four walls until exhausted at the opposite wall or floor or until exhausted around the periphery at the floor through a restricted opening that increases the speed of the escaping air to prevent penetration of contaminated air. Figure 2 shows application of these principles in a temporary installation with flexible side walls which is similar to the first OR built at the Lovelace Clinic. Figure 3 shows the same principles applied to a permanent hard-wall room that provides more usable space.

Lewis L. Coriell

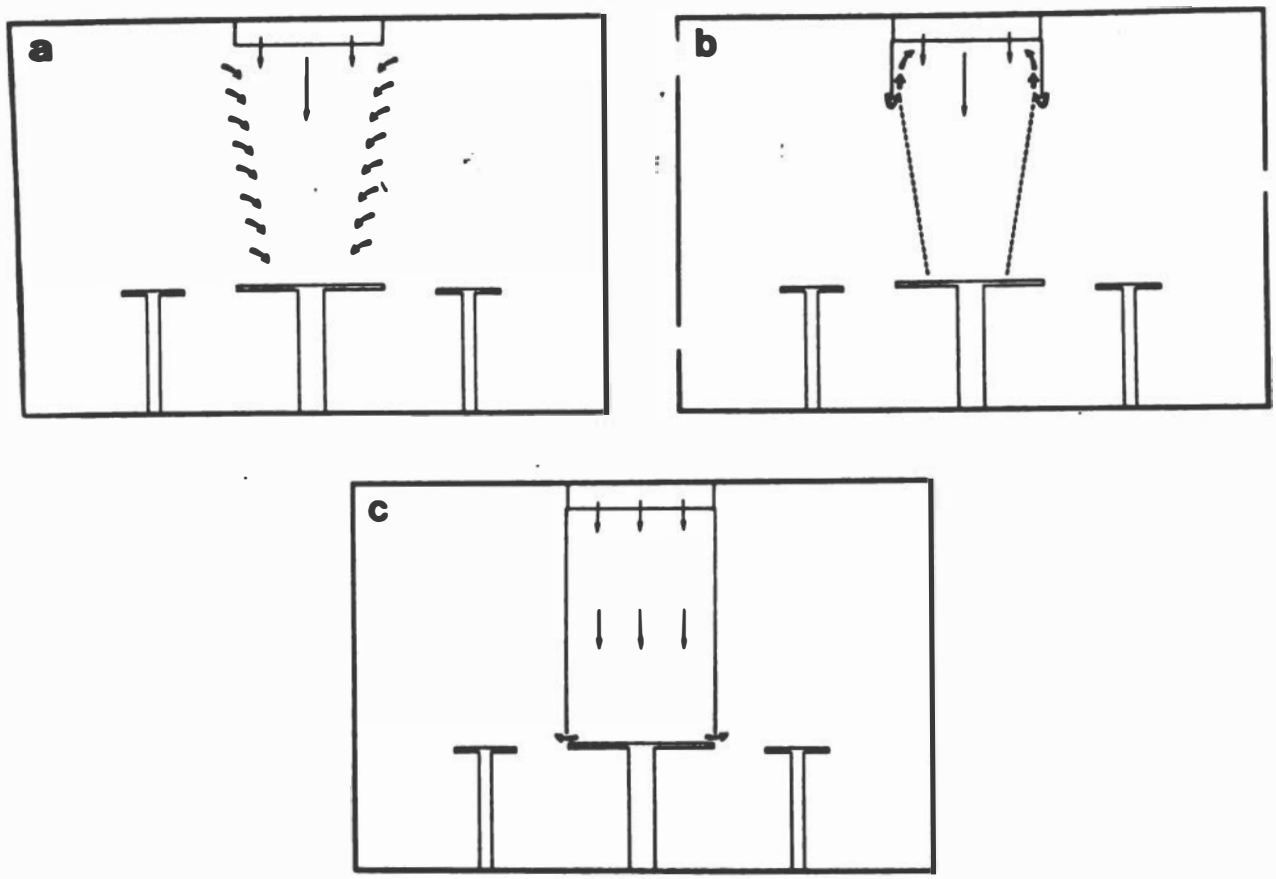

Fig. 1. Basic principle of unidirectional airflow; a) entrainment of dirty air by an unprotected jet of clean air; b) contamination by entrainment and aspiration in a jet with partial walls but no floor; and c) complete containment of the clear air jet by four walls and a restricted escape opening at two sides.

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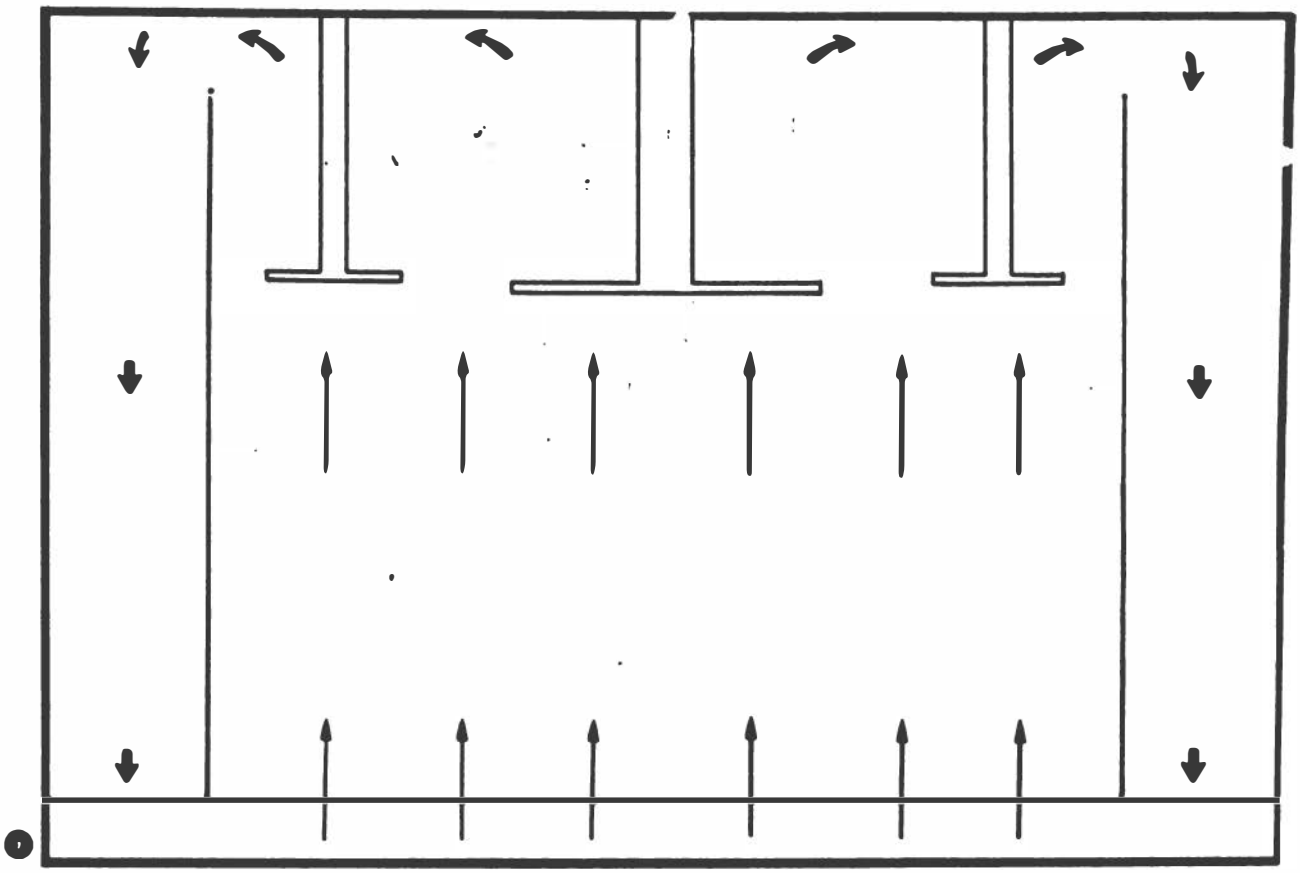

Fig. 2. A flexible side-wall temporary downflow clean room that includes all the basic principles for delivering clean air to all critical areas of the room.

Lewis L. Coriell

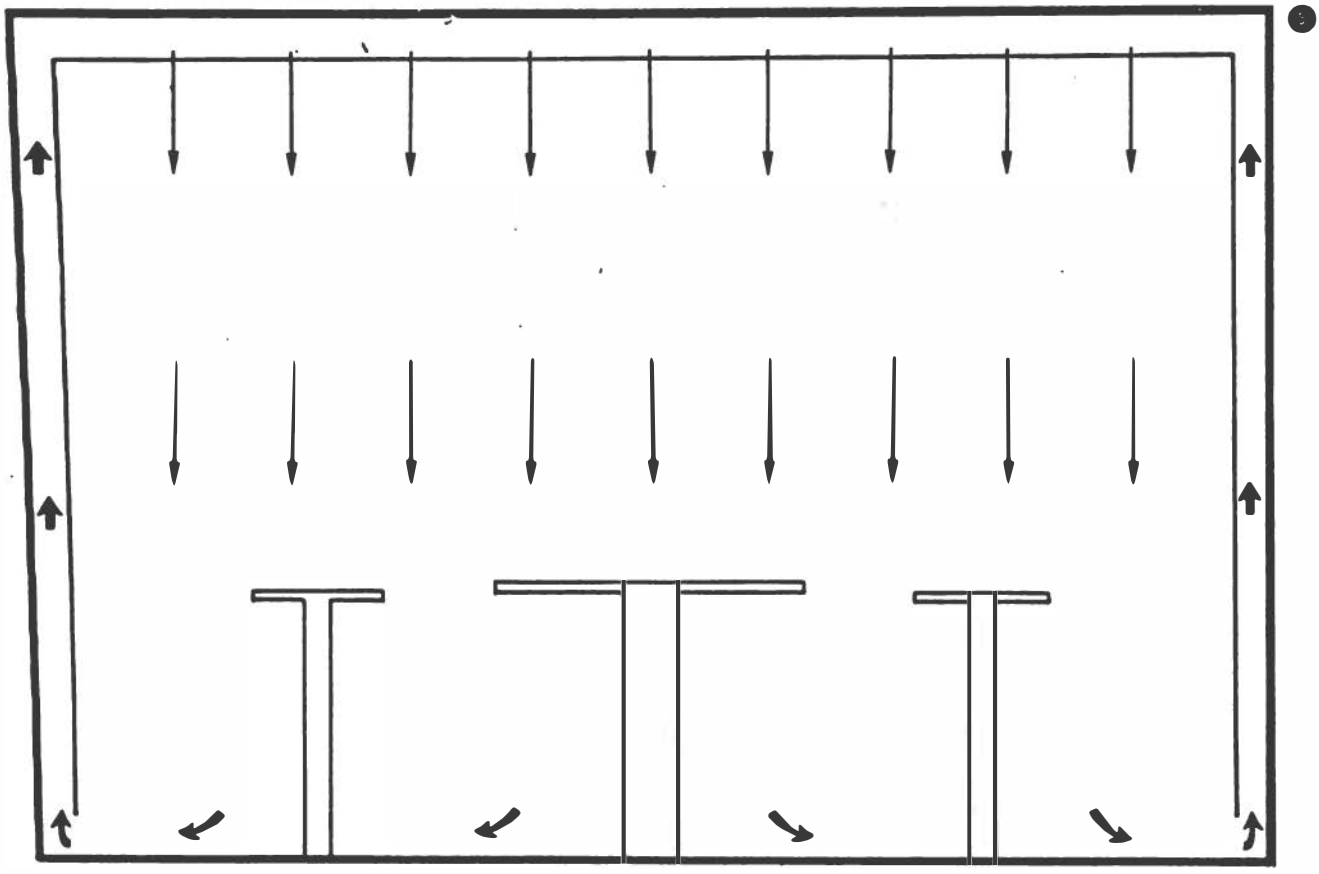

Fig. 3. A permanent hard-wall installation that protects all critical areas of the room, including more space for personnel, observers and equipment.

Low Velocity Unidirectional Ultrafiltered Air Systems

INFECTION CONTROL

Proof of efficiency of unidirectional ultrafiltered air in prevention of airborne infection in the operating room is still open to debate and is not the subject of this report. However, in testing the efficacy of low flow rates we have gone to controlled studies of airborne spread of infection in laboratory animals. McGarrity *et al*. (27,28,29) have shown effective control of airborne spread of infection of laboratory mice in cages placed six inches apart by vertical velocities of 35 ft/min. Rodent studies were performed using cross infection with *Serratia sp*., *Proteus sp*. and polyoma and Reo-3 viruses. Based in part on these studies more than 50 commercial organizations have installed low velocity (15-25 ft/min) vertical unidirectional ultrafiltered air systems to protect experimental and stock animals from airborne infection (22). We cannot escape the conclusion that the air in animal rooms so equipped is cleaner than the air in the conventional operating room.

DATA FROM THE OPERATING ROOM

In 1971 Scott *et al*. (38) observed after comparative studies in three operating rooms and three industrial clean rooms-- "operating rooms with their elaborate rituals are not as clean as some electronic workshops which admit and disgorge several shifts of workers each 24 hours" (Table 2). Whitcomb (44) was unable to draw firm conclusions about the beneficial effects of laminar airflow in the operating room because infection rates in his hospital were very low without the use of laminar flow ventilation. This situation occurs in other hospitals when aseptic procedures and Halsted's principles are faithfully followed (16). Morris and Burke (32) noted the common error of determining infection rates over too short a time period. They urged long-term studies, especially where infection rates are low to exclude the possibility that random variations based on chance alone could be responsible for an apparent alteration of infection rate. Lidwell (25), using multiple regression analysis in a study of postoperative wound infections in 12 hospitals, showed that differences in infection rates could be explained almost entirely by differences in types of patients and operative procedures. The infection rate of clean wounds in the average conventional operating room is in the range of three to five percent (3,5,18,20,21,41).

Table 2. Comparison of Operating Rooms and Industrial Clean Rooms*

Test Area (and Fed. St. 209 Class.)	Ventilation System	Air Changes Per Hour	Particles >0.5μ diameter		Bacteria	
			Mean	Range	Mean	Range
O.R. #1 (unclassifiable)	turbulent	10	776,000	370,000 1,269,000		
O.R. #2 (unclassifiable)	turbulent	?	3,980,000	3,300,000 4,350,000	24.3	10-42
O.R. #3 (unclassifiable)	turbulent	?	350,000	95,000 1,120,000	3.4	0-9.4
Ind. Clean Room A (class 10,000)	turbulent	20	3,600	2,900 3,900	1.4	0.6-2.2
Ind. Clean Room B (class 10,000)	horizontal laminar flow	120	900	250 3,100	0	0
Ind. Clean Room C (class 100)	vertical laminar flow	600	30	0-170	0	0

*Extracted from Scott, Sanderson, and Guthrie (Reference 38)

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On the other hand Charnley ([11,12]) makes an excellent case for reduction of postoperative infection after total-hip replacement by control of the airborne route of infection. He stresses that evaluation for the statistical significance of any new procedure in total-hip replacement requires at least 800 cases and a postoperative observation period of two years. Under the protection of clean air in the operating room he records the decline of both early and late infections including blood-borne infections, and attributes most of the decline to elimination of the airborne route of infection at the time of surgery. A summary of Charnley's data is shown in Table 3 to illustrate the steps by which he arrived at recommendations for a flow rate of 300 air changes per hour, entire ceiling distribution of filtered air to eliminate turbulence in the entire operating room, and air filters for removal of particles of 1-2 microns in size.

Table 3. Ventilation for Control of Infection in Total Hip Replacement[1]

Period	c.p.h.*	a.c.h.**	Ventilation	Filter	Infection %
Jan. 1959-Nov. 1961	80-90	0	exhaust		7.0
Nov. 1961-Jun. 1962	25	10	pos. press.	precipiton	3.7
Jan. 1962-Mar. 1966			plenum	+***	2.2 peripheral turbulance
Jun. 1966-Sep. 1967	0.0	300	unidirectional	+***	1.3
1968-1970	0.0	300	unidirectional	+***	.7 apron, wound closure

* c.p.h. - colonies per settling plate per hour
** a.c.h. - air changes per hour
*** filter efficiency 1-2 micron

COSTS

In a metered 6 x 10 ft downflow room with variable flow rates and 90 percent recirculation of air, we observed that power consumption and cost of operation increased in proportion to the ventilation rate. Costs doubled for each 40 feet of increased velocity as shown in Figure 4.

[1] Extracted from Charnley et al (Reference 11,12)

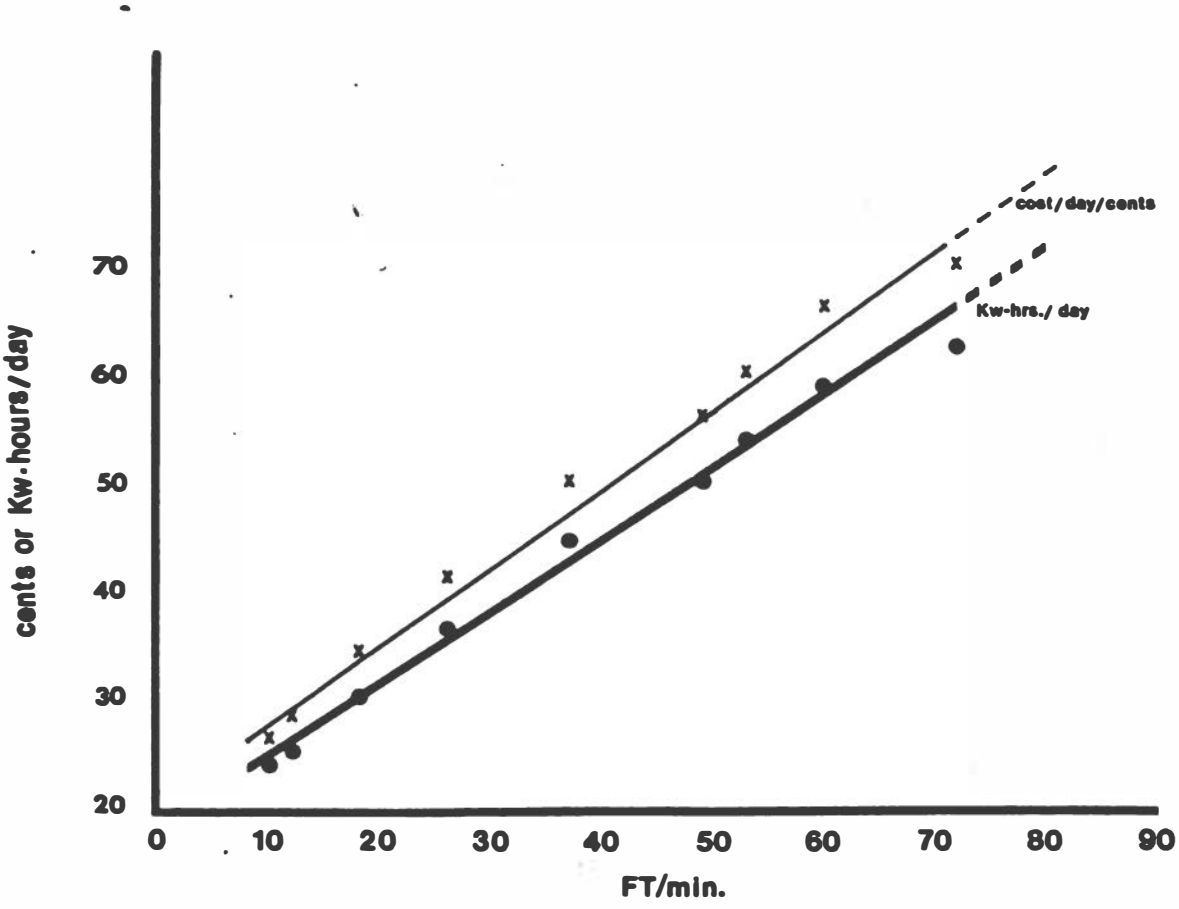

Fig. 4. Costs per day in Kw-hrs, and in cents to operate a unidirectional downflow room when operated at different airflow rates.

The effect of velocity of air movement on temperature buildup and noise levels is shown in Figure 5. The noise level increased 0.4 decibels on the A scale for each foot per minute of increased air velocity, or 20 dB-A for an increase of 50 ft/min. The temperature elevation was more rapid at low air velocities but over the range from 20 to 70 ft/min it averaged 0.2 deg C for each ft/min of increased air velocity, or 10 deg C for an increase of 50 ft/min.

Cost of original installation for a low velocity (15-25 ft/min) vertical unidirectional soft-wall room is currently $\$75/ft^2$ of room area, and free-standing, hard-wall installations are about $\$100/ft^2$ (22). Recent quotations on high velocity installations are at least double the above figure.

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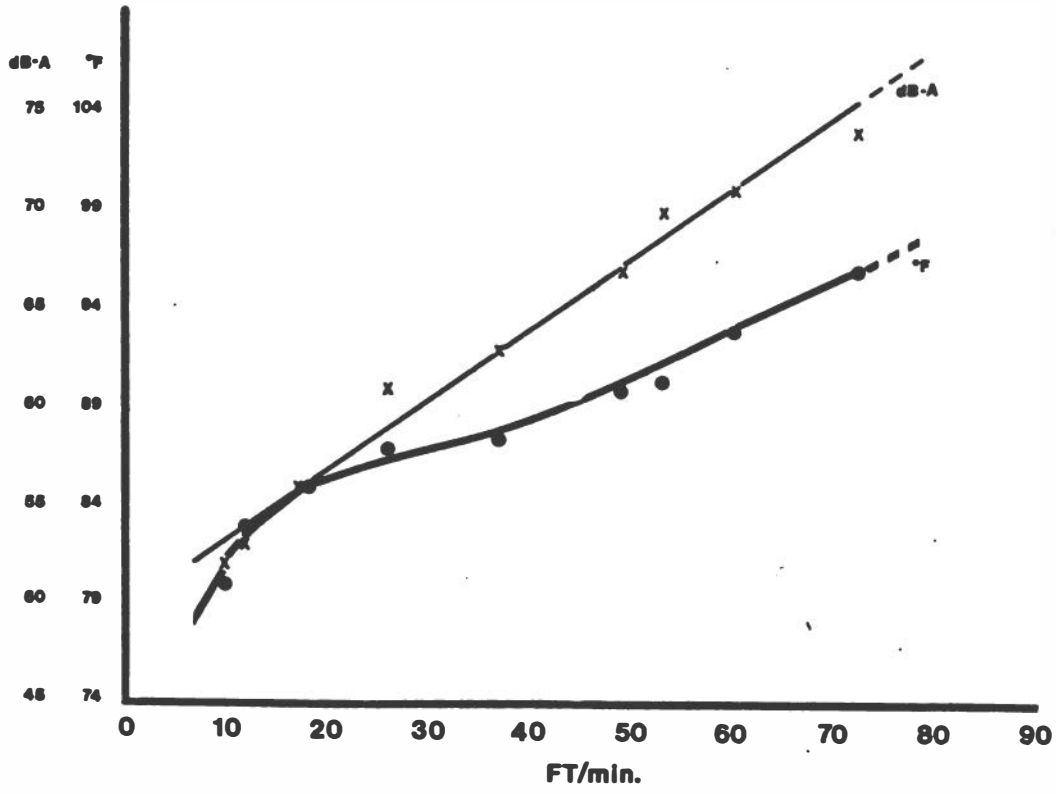

Fig. 5. Decibels of noise on the A scale, and ambient room temperature without refrigeration in a unidirectional downflow room when operated at different airflow rates.

Discussion

The purpose of this review is to examine the merits of high velocity vs low velocity unidirectional airflow room ventilation in control of airborne particulates and microorganisms, not to justify the use of laminar flow ventilation in operating rooms. The impetus for this reexamination of the merits of low velocity airflow springs from a desire to obtain optimal cost effectiveness. Decisions made in the early days of laminar flow research in medical environments utilized flow rates of 100 feet per minute, and have through repetition and regulations, assumed more stature than they deserve.

For example, a review of the literature shows the HEPA filter media are more efficient at lower flow rates and progressively less efficient at

higher flow rates. It also shows that achievement of unidirectional ventilation with the filtered air is essential to achieve maximal freedom from airborne particles. The mechanisms for achieving this are now well understood. The basic principles are: 1) entry of the filtered air across the whole ceiling at uniform pressure to prevent recycling through areas of lower pressure; 2) containment of the air stream by walls until; 3) its escape at floor level through lateral openings sized to increase the escape velocity. When all these conditions are observed the performances at flow rates of 35 ft/min are not significantly different from those observed at 100 ft/min. Our own experimental studies on containment of particles, bacteria, and viruses in experimental rooms and operating rooms, and in prevention of airborne spread of infection in animal rooms, lead us to conclude that vertical flow rates of 25 to 35 ft/min and 150 to 200 air changes per hour will provide most of the benefits, and minimize the disadvantages that can be expected to accrue from application of HEPA-filtered unidirectional airflow room ventilation.

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THE ORTHOPEDIST'S SPECIAL INTEREST IN SURGICAL INFECTION

Mark B. Coventry*

A scant five and one-half years ago the first joint implant fixed with methyl methacrylate was authorized in America by the Food and Drug Administration. After a year's trial period as an investigational new drug, it was released, the "bomb burst," and hundreds of thousands of hip, knee, finger joint, elbow, shoulder, and ankle implants have since been inserted.

What has this to do with our symposium? While surgical infection is a fear which surgeons (and patients, too, if they are intelligent and informed) have constantly lived with in the past, the catastrophy to a patient's well-being produced by an infected major joint implant now rests solidly on the shoulders of virtually every practicing orthopedist.

Why are we in orthopedics so specially interested and involved? Certainly a surgical infection in other fields can be, at times, even more devastating. Is it the seriousness of the infection--or the sheer quantity of potential problems--or the obviousness of a crippled patient which has absorbed the interest of the orthopedist? It is all of these, plus the nagging conscience of an honest surgeon that somehow he is responsible for this complication. The abdominal surgeon, the thoracic surgeon, the urologist--all work constantly in contaminated areas, and the potential for infection is always there. True, the neurosurgeon is usually operating in a sterile field, as is the cardiovascular surgeon. But the orthopedist almost uniquely violates a microbially sterile field when he makes his incision to replace a joint. Thus it is hard to "blame" the patient for a poor result--a rationalization that we are all guilty of at times. So we look to other sources of infecting organisms besides the patient--the surgical team, the surgical instruments, the air of the surgery. And this is what we will be discussing at this workshop.

Again, so why does the orthopedist have such a special interest in this field besides his peculiar feeling of having no one to blame but himself? His surgical infection rates are not higher than in other surgical specialities; indeed, they may be lower. At Mayo Clinic in 1973, orthopedic surgical infections totaled

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1.33 percent, both deep and superficial, including trauma as well as elective surgery. But the devastating effects of sepsis in any one patient, and the actual numbers of infections occurring are now coupled with the relative newness of the challenge to determine the cause of the infection, and the means to alter these causes. Careful focus on the problem shows that "accepted rates" such as I have quoted simply aren't good enough today. Means must be found to lower these rates.

John Charnley of Wrightington deserves credit for generating impetus in this direction. But all of us have taken up the challenge and have by many and diverse means sought to decrease the rate of infection. Research in immunology and stress response is ongoing. Practical measures have included skin preparation studies regarding the effectiveness of different lotions; methods and materials in draping the patient using specially woven cloth or paper impervious to microparticles; improvements in gowning the surgeon and masking his exposed skin, including such methods as exhaust systems; antibiotics, administered both generally and locally, for prophylaxis; and, very importantly, wound-handling techniques which avoid tissue trauma and pocketing. But above all is the study of the air which contacts the operative wound. This is the subject of intense examination.

In our own institution it was the orthopedist who said, "I am now involved, and I am going to do something about the problem." He has been aggressively pursuing the problem (some of his colleagues think too aggressively). Studies of particle collection in the operating rooms began. An entire review of the engineering of the operating theater was undertaken to determine airflow, volume patterns, filtration, etc. Better reporting and classification of surgical infections was insisted upon. Changes were made in operating room procedure, including traffic control, draping and gowning. Other surgical teams in the hospital were often openly resistent. But slowly they have tended to follow. Other surgeons are becoming aware. All surgeons are now virtually forced to culture the drainage from their postoperative wounds in spite of the frequent comment: "Why culture? This is just drainage - stitch reaction. Drainage

doesn't mean infection." We orthopedists have now been joined by other involved surgeons, and we must continue to obtain every bit of important information and evaluate it.

This quest for information that can be applied to the safety of our patients continues. Perhaps we will know relatively soon whether our filter systems are proper, whether high volume air exchange is important, and the details as to its direction and its mode of administration. If we find these answers, the orthopedists of this country can take much of the credit. But, candidly, we must admit we were forced to take action by the magnitude of total-joint replacement, and the dire consequences of an infected implant to the patient, the surgeon, and society.

I cannot close without paying tribute to at least three of the great men who gave us the knowledge and methods which we continue to refine: first of all to Anton van Leeuwenhoek, without whose microscope organisms could not be seen; then to Louis Pasteur, without whose methods organisms could not be grown; and perhaps most of all, to Lord Joseph Lister, who applied the knowledge gained up to his time in the surgery of the operating theater.

IMPROVED OPERATING ROOM BARRIER MATERIALS

Peter Dineen*

INTRODUCTION

Over the past several years there has been a widespread utilization of disposable operating room materials which include gowns. These materials have two purported advantages. The first is that they reduce bacterial contamination of the environment, and the second is that they are more economical. While the latter consideration is open to debate, there does seem little doubt that the various barrier materials do reduce the number of organisms in the atmosphere.

Naturally there has been a great deal of consideration as to whether the degree of microbial contamination is important. It is often stated that patients have been operated upon for a good many decades with reasonably good results by simply using sterile reusable cloth and muslin drapes and gowns. There has not been any pandemic of infections, and the question is reasonably raised as to why something new should be added at the present time. The answer lies in the type of patient upon whom surgery is being performed in the modern era. In recent years the number of individuals who are immunosuppressed, or who are having open cardiac or vascular surgery, or joint and/or organ replacement has significantly increased. Also, the patients upon whom we are operating are older and more debilitated in many instances. These are individuals who in years gone by were considered too risky. Therefore, the host is at a significantly higher risk than in the past. The possibility of contamination and serious disease caused by bacteria which previously were considered nonpathogenic is high.

The materials that have been studied by the Surgical Bacteriology Research Laboratory at this Center include cloth which was used for drapes and gowns, and nonwoven fibers (paper) materials. In the study of masks, both cloth and various fiber materials were studied. Examination of these drape and gown materials microscopically shows that the cloth is not closely woven and the interstices allow the passage of bacteria whereas the nonwoven material has no such interstices to allow bacteria through. This is particularly evident when water is placed on either of these two groups of materials. The cloth allows water or

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any liquid to pass through quite rapidly, whereas the nonwoven materials are water resistant for varying periods of time up to a couple of hours.

MATERIALS AND METHODS

Two identical operating rooms were selected. These rooms were used for general surgical procedures. The same type of operation was done in both rooms and the personnel were essentially unchanged during the period of the study. In each room during sampling time there was an anesthesiologist, a surgical team of three individuals, a scrub nurse, a circulating nurse, and a technician.

Simultaneous air sampling of these two operating rooms was conducted for one-hour periods during morning and afternoon surgical procedures. For two weeks, cloth drapes and gowns (muslin or cotton) were used exclusively in Room 1, and single use, disposable nonwoven drapes and gowns were used exclusively in Room 2. For the next two-week period the materials were reversed. Single use, disposable drapes and gowns were used exclusively in Room 1; cloth material in Room 2. This two-week reversal was continued for the two-month duration of the study.

Air sampling was done with a Reynier air sampler with a rotating Petri dish, sampling at the rate of one cfm. This air sampler is constructed in such a way that the time of impingement of the organisms on the plate can be fixed with great accuracy. When the colonies grow out after incubation the plate represents the face of a one-hour clock. For example, the 15-minute point in time of sampling can be separated from the second 15-minute period and so forth. Bacteria which were isolated were randomly sampled and subcultured for diagnostic identification.

RESULTS

The number of organisms isolated from the environment were significantly lower when disposable, single-use nonwoven materials were used. As can be seen, there is some degree of variation in the amount of bacteria in the air, particularly related to activity. The middle periods seem to have the lower counts when there is less movement and traffic in the rooms. The majority of the cases in this study were abdominal procedures, many of which were finished by the end of the hour sampling time. A 90-percent reduction in airborne organisms was provided by these disposable drapes and gowns compared to cloth. Average air

sampling counts for the study were 23.5 for cloth and 2.2 for single-use disposables. In a similar series of studies the data were collected again over a period of 59 days. On different days the assignment of disposable and nondisposable drapes was randomly assigned to the two rooms.

	No. Days
Lower Counts with Disposable Drapes.....	53
Lower Counts with Nondisposable Drapes.....	4
Equal Counts.....	2
Total.....	59

The average number of organisms isolated from the environment in the last study:

Disposable Drapes.....Daily Average...15.05 Organisms
Nondisposable Drapes..Daily Average....36.59 Organisms

A third study measured the passage of bacteria through drapes during the operation. A steady increase with time was noted with muslin drapes, while in those operations with paper and disposable drapes the bacterial count remained constantly low for the length of study time.

DISCUSSION

From these studies it is evident that the use of nonwoven material significantly reduces the bacterial contamination of the environment. In these studies reported here only disposable paper drapes were studied. However, there are similar nonwoven materials on the market which are reported to be equally efficient.

Recent meetings of the Sub-Committee on Aseptic Barriers of the Committee on Operating Room Environment of the American College of Surgeons has endorsed the use of nonwoven materials.

It has been the experience at this Center that the reduction of the number of organisms in the environment has been consistently maintained by the use of nonwoven drapes and gowns. Systematic monitoring has continued during this time. It is still too early to have statistical significance on the reduction of wound infections by this means. Because of the number of variables and individuals involved, it may never be possible to have a definitive answer to this question.

Peter Dineen

MASKS

An ongoing study of surgical masks in this laboratory has shown, as have many other investigators, that there are wide diversions in mask filtration efficiency. It is obviously desirable to have the most efficient mask which is also comfortable and functional.

MATERIALS AND METHODS

In brief, using a known inoculum aerosolized into a cloud chamber, and passed through an air sampler, it is possible to calculate the efficiency of any particular mask.

RESULTS

As can be seen from Table 1, there is a significant difference in the efficiency of the various masks. Mask A is a 16-ply cloth mask. The remainder of the masks are all various currently available disposable masks.

Table 1. Filtration Efficiency of New Masks

Mask	No. of Experiments	Percent Efficiency	Range
A	20	50.2	1-81
B	10	93.0	87-97
C	20	91.1	76-98
D	10	91.6	86-97
E	20	94.0	82-99
F	12	86.3	76-94
G	6	82.7	77-92
H	10	36.8	20-59
I	20	86.4	72-98
J	6	8.8	2-13
K	20	97.1	89-99

DISCUSSION

As can be seen from this study, the number of organisms in the environment will vary greatly depending on the type of mask utilized. Under the circumstances of present day technology, it seems unconscionable to use masks with a filtration efficiency of less than 93 to 94 percent.

THE CASE FOR CLEAN AIR

John A. Feagin, Jr.*

In June of 1972 upon completion of a six-month Registrarship with Professor John Charnley, I had the privilege of discussing clean air with him under "relaxing" circumstances. Scientifically most of the data has now been published, but one phrase stuck with me far longer than the scientific proof. Charnley said, "Once one has enjoyed surgery under clean air conditions, aesthetics alone would bar him from ever practicing his craft in a conventional room." This has proved true and although it may be emotional, perhaps aesthetics is as rational an approach as statistics at this time. Nevertheless, being an institutional practioner my clean air room required "justification." "Justification" in 1971-1972 was not easy; my institution required scientific proof and reason and historical perspective were suspect. We here, though, have been invited for decisions involving social responsibility. This is a thought process above mere "justification." For that reason, I would like to discuss operating room environment from four perspectives: the Historical perspective, the Charnley perspective, the Letterman Army perspective, and the Responsible perspective.

THE HISTORICAL PERSPECTIVE

The historical perspective entwines the lives of two great men, Lord Lister and Pasteur, whose careers fortunately overlapped. One said, "Chance favors the prepared minds." The other was a prepared surgeon.

The dramatic development of aseptic surgery occurred simultaneously with the rise of bacteriology. The role of Pasteur in this drama is unquestioned. Lister said that sepsis was the principal obstacle to any great advance in surgery.

Lister discussed his problems in 1865 with Dr. Thomas Anderson, Professor of Chemistry, who called his attention to the work of Louis Pasteur. Pasteur in his well-known experiment demonstrated that an infusion will putrify when boiled in a flask which is left open. However, if the neck of the flask is drawn out to a fine point, the solution will remain pure because the air will drop its dust and germs at the opening of the neck. Here Lister found the

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solution to his problem. It was not the air, but the germs in the air that produced suppuration.

Volkman became Lister's most devoted disciple saying, "England may be proud that it was one of her sons whose name is bound up with the greatest advance of surgery."

Lister died a Peer of the Realm honored by the world.

It is my conviction that Pasteur and Lister lit the lamp and that Charnley's data are more sophisticated evidence that where surgical infection is concerned, airborne contamination must be considered.

Lister and Pasteur marked the way. Now we will consider the Charnley perspective.

THE CHARNLEY PERSPECTIVE

All of us know John Charnley by name. Most people know him by reputation, and I am here to assure you that he ranks with the Listers and Pasteurs. Charnley's data are additional sophisticated evidence that where surgical infection is concerned airborne contamination must be considered. His surgical unit, published statistics, and trained students bear witness to the efficacy of his beliefs. I do not want to belabor published statistics, but in a unit that is performing 2,000 hips per year and is wholly responsible for its own complications, each complication is critical to the unit. Otherwise, the Centre would be overburdened with the care of its complications. To those of you who have visited Wrightington the Charnley perspective speaks for itself.

THE LETTERMAN PERSPECTIVE

Letterman is one of five Army Medical Centers. It is relatively new having been constructed in 1969. It has seven operating rooms that accommodate almost every specialty. To justify a clean air room for our implant surgery, we began to monitor airborne contamination in search of the "proof" to justify a clean air enclosure. We embarked on as extensive an airborne monitoring program as we could support. How did it differ from previous studies?

The Case for Clean Air

1. We compared our orthopaedic cases in clean air and in a conventional room by sampling with the Matson-Garvin Slit Sampler and the Climet Particle Counter.

2. We monitored all seven operating rooms and were able to construct a profile by specialty of the various operating rooms. What does this prove? No more than any other study except that we now know the conditions to which we subject our patients. This is not only a matter of academic interest but of responsibility. To those of you who have monitored your surgical suite, I have no new data. To those who have not, I share with you our results in the hope that you too will insist on a monitoring program. The results of an airborne monitoring system may well lead you from aesthetics to absolute conviction.

Unoccupied, our relatively modern operating suites have a generally low order of contamination. These values represent the average of a number of monitorings and as you may note our operating rooms are generally assigned by specialty (Fig. 1).

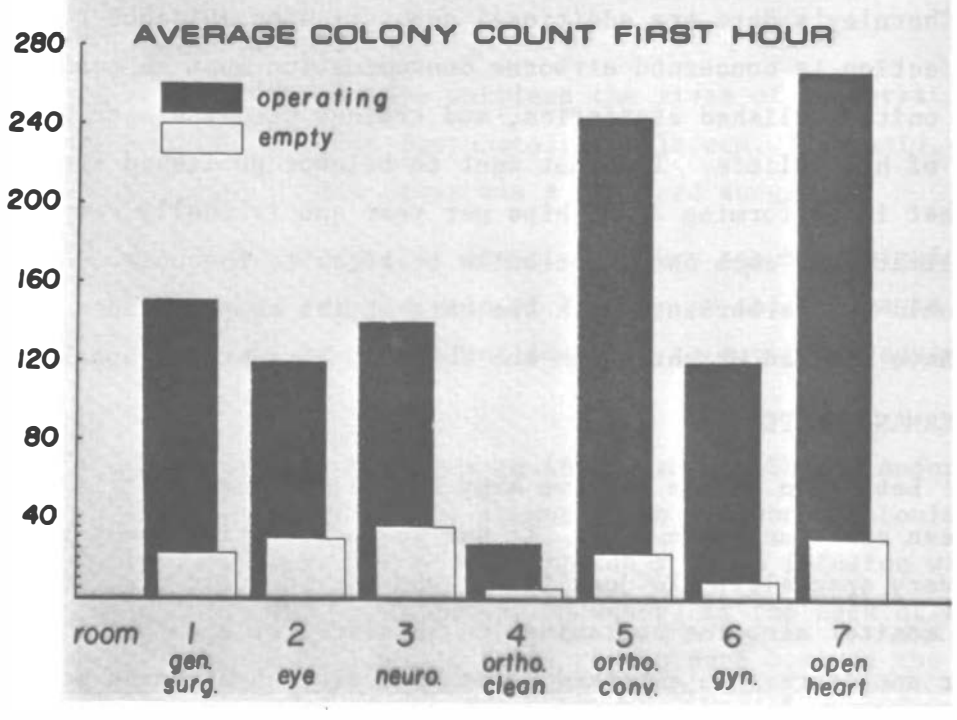

Fig. 1

John A. Feagin, Jr.

The darker bar represents the average colony count during a number of monitorings through a variety of surgical cases. It is the quantum jump that I think is significant. The conventional operating room is unable to handle the pollutants of the operating team. Many people deny the value of the particle counter, but particles are the transport mechanism for airborne bacteria and after settling in the wound are a synergistic link toward clinical infection. They serve as adjuncts. Therefore, I feel the particle count is an important variable although it is in no way a parallel function of the colony count (Fig. 2).

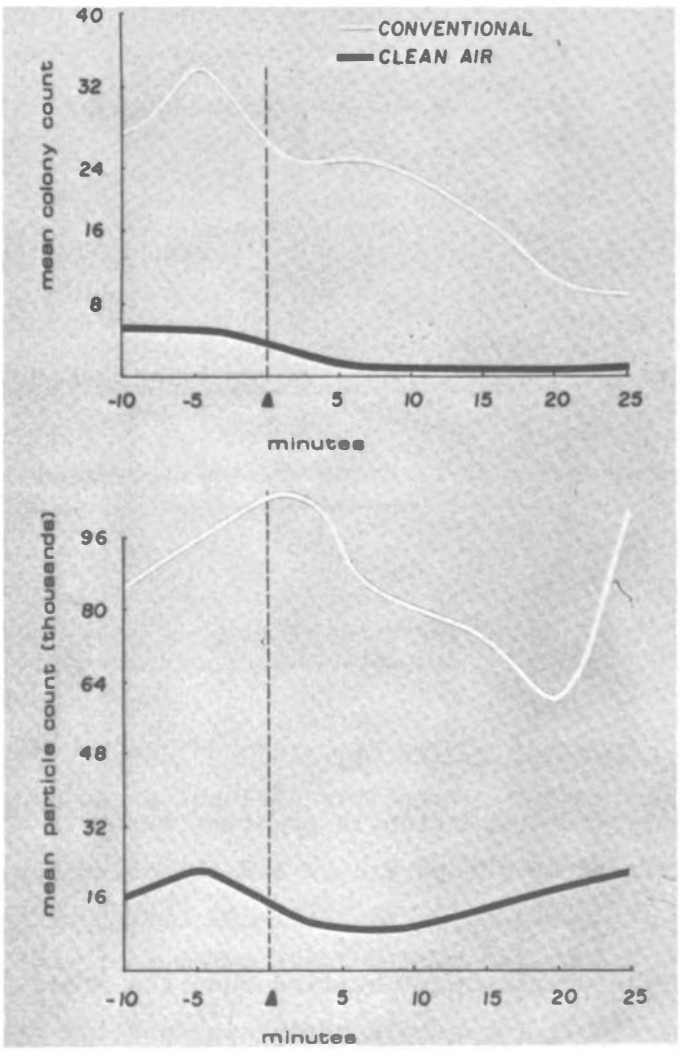

Fig. 2

The Case for Clean Air

Another feature of our study was comparable cases performed under similar circumstances. To emphasize this we selected monisectomy (Fig. 3).

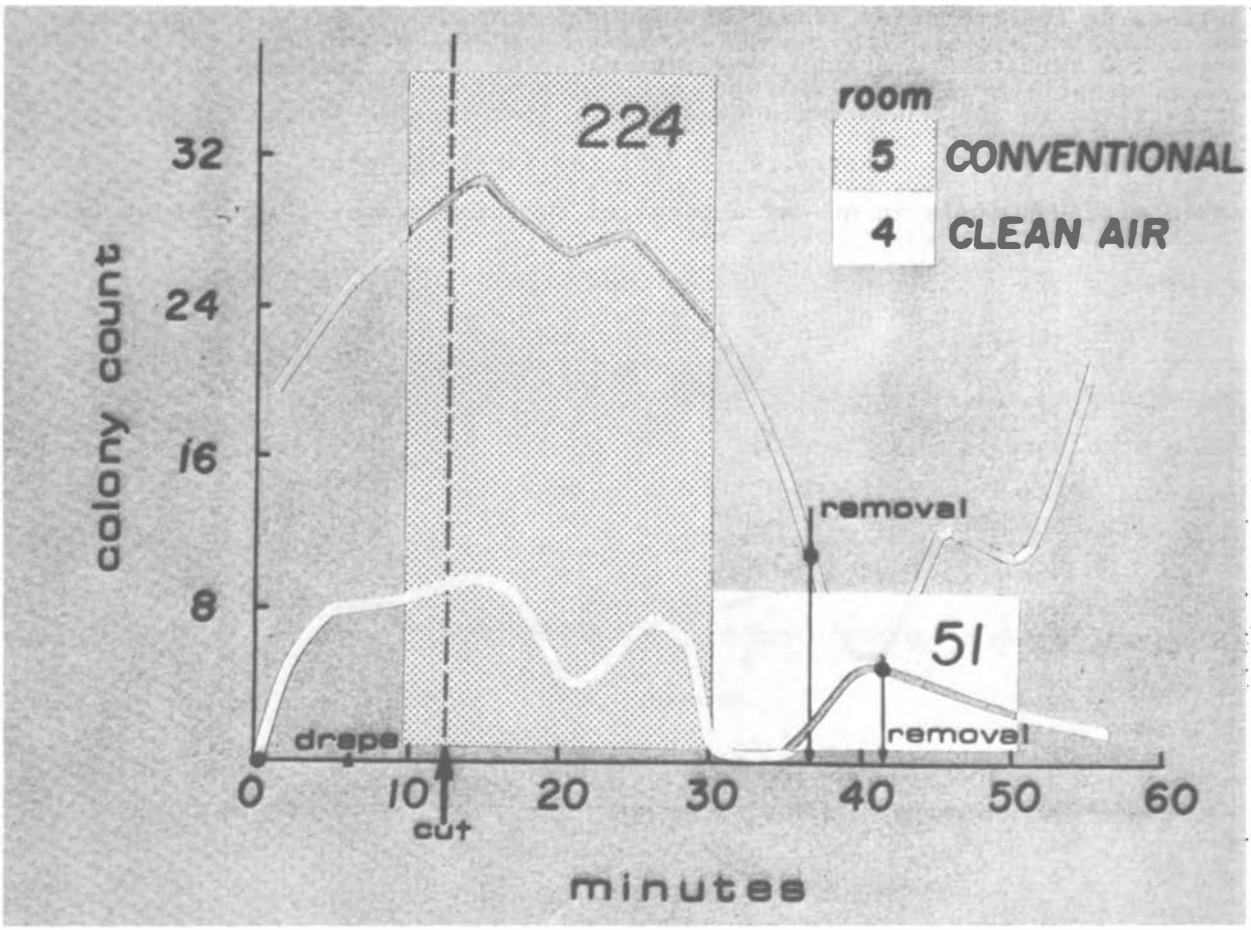

Fig. 3

Predictably, contamination is greatest early in the case when draping and traffic have stirred up the particles and the coincident lint serves as an airborne vehicle.

Our particle counter has verified that the areas of residual particles in the room are the floor, the people coming in, and the drapes. Vacuuming and washing between cases seems only to stir up a host of contaminates.

The most shocking aspect of room discipline is the role of our circulator. While we intently putter away, they attend the business of their own

concern and the average number of door openings is greater than fifty per hour and is relatively constant from room to room, hour to hour, surgery to surgery, case to case; verifying they must have a routine of their own independent of the surgical team and quite inconsiderate.

In summary, two years of monitoring at Letterman emphasize the contamination caused by the surgical team and draping. Equipment poorly handles these contaminates.

THE RESPONSIBLE PERSPECTIVE

John Charnley has not been able to scientifically prove the value of clean air to the American College of Surgeons. I doubt that any of us can provide more convincing statistics. It is unreasonable and futile to demand a plethora of statistics. Therefore, let us look to our own responsibilities to the best of our abilities based on the documentation that is at hand.

Just what are our responsibilities?

1. To acknowledge airborne contamination. Historical perspective requires that we acknowledge airborne contamination. "Those who ignore the lessons of history are doomed to repeat them."

2. To define the risk of implant surgery and to acknowledge that we have created a new surgical milieu with new requirements. Therefore, let us not stumble on implant surgery, but use this as a rationale to a higher technological plateau.

3. To reappraise the statement of the American College of Surgeons. In December 1971 this was a laudable statement. We owe the College a reappraisal in 1974.

4. To take a stand regarding new operating room constructions. I personally cannot imagine a new operating room designed for implant surgery without including body exhaust, ultraviolet, and clean air as part of the standard equipment. This is not overkill; it is reasonable insurance.

5. To strive for a mental and physical goal of zero operating room contamination. Let us set our goal at no contamination and explain deviations

from there, rather than accepting a seven percent infection rate as the starting point.

To summarize, we have considered the operating room environment from the historical perspective, the Charnley contribution, from our own in-house monitoring, and as a social responsibility. It is my hope that this workshop will accept these challenges and take a strong stand for improved operating room environment.

AIRBORNE BACTERIAL CONTAMINATION IN THE CONVENTIONAL OPERATING ROOM

Robert H. Fitzgerald, Jr.*

Airborne bacteria in a variety of conventional operating rooms have been implicated in postoperative wound sepsis (1,3,4,5). The variation in the design of the operating rooms studied and the wide range of data have clouded the significance of airborne bacterial contamination. The divergence of design and capability of "modern" operating rooms in which orthopaedic surgery is performed at the Mayo Clinic stressed the need for additional information on the bacterial environment in the conventional operating room.

The bacterial environment of four operating rooms located in the two hospitals used by orthopaedic surgeons of this clinic was evaluated. The level of airborne bacterial contamination was determined with standard techniques employing the Andersen and Casella samplers located within a few feet of the operating table. All four operating rooms were sampled on 8 to 16 separate occasions during total-hip arthroplasty--a procedure in which there has been strict adherence to a protocol. The rooms chosen for evaluation varied in air-handling capabilities and design. In two of the rooms, with 12 to 14 exchanges of room air per hour, air passed through a roughing and an electronic precipitating filter (high intermediate efficiency filtration) prior to entering the operating room. All air was freshly filtered without an admixture of recirculated air. Both were located in an operating suite with less than ideal traffic control. The two remaining operating rooms with 28 to 32 exchanges of room air per hour were located in an isolated operating suite with strict traffic control. The air delivered to these rooms passed through roughing and bag filters (high intermediate efficiency filtration) and was recirculated to a variable degree, depending on atmospheric conditions. All four rooms studied had a positive pressure relationship with the adjacent corridors, work rooms, and scrub rooms.

The mean level of airborne bacterial flora was 0.31 viable particles per cubic foot of air in all four rooms when they were not in use. During surgical procedures, the mean levels of contamination were lower in the room with

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high rates of room air exchange per hour (Table 1). However, even rooms with high rates of room air exchange were noted to have elevated levels of airborne bacteria. Recirculation of air did not appear to influence the level of contamination.

Table 1. Airborne Bacterial Contamination of Operating Room

Room air exchange/hour	Mean viable particles/cu ft of air		
	With room empty	With room in use	Range
12-14	0.36	6.5	2.9-9.1
	0.4	7.0	4.0-9.9
28-32	0.3	5.7	3.2-9.5
	0.2	5.3	2.9-8.8

The air-sampling data obtained using the Andersen sampler on three occasions demonstrated that the majority of the microorganisms were isolated on the first two stages (Table 2).

Table 2. Level of Airborne Bacterial Contamination Using Andersen Sampler

Stage and particle size (μm) collected	Colony-forming units/stage, Andersen sampler		
1 (9.2-larger)	1.18	1.58	1.82
2 (5.5-9.2)	0.67	0.82	1.24
3 (3.3-5.5)	0.38	0.37	0.85
4 (2.0-3.3)	0.79	0.59	0.87
5 (1.0-2.0)	0.01	0.10	0.89
6 (0 -1.0)	0.02	0.09	0.04
Average viable particle/cu ft of air per minute during procedure	3.05	3.56	3.57

Thus, the majority of the microbial particles were 5 μm and larger. Since the air-filtration system removes 97.5 percent of particles of this magnitude, the microorganisms recovered must have been shed by personnel in the room.

High levels of airborne bacterial contamination were noted with increased numbers of personnel working in the operating room (Fig. 1). This relationship was more readily apparent in operating rooms with lower rates of room room air exchange per hour. Restriction of the number of personnel in the operating room to only those required for care of patients, even in teaching institutions, is necessary.

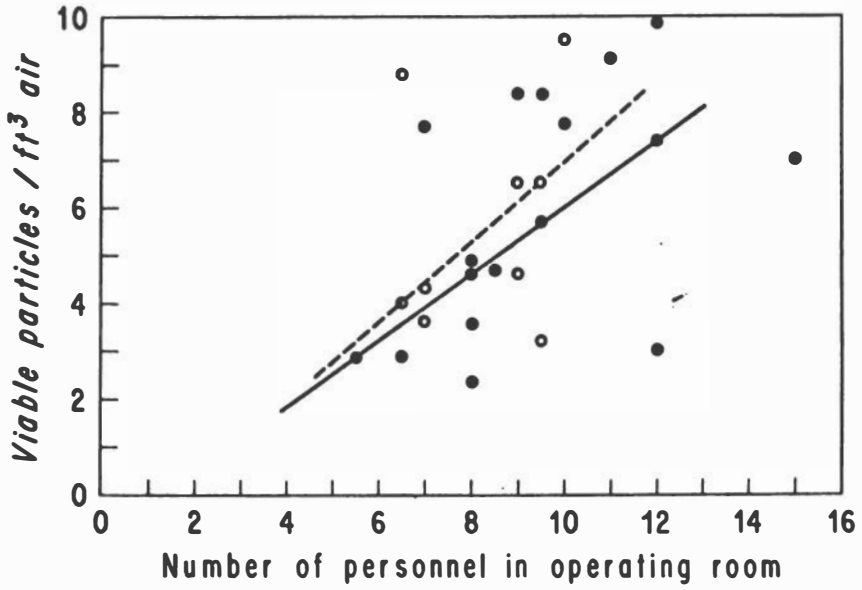

Fig. 1. Relationship of airborne bacterial contamination to increased numbers of personnel working in operating room. (Room air exchanges per hour: open circles, 12 to 14/hour; closed circles, 28 to 32/hour.)

Chronologic recording of the level of airborne bacterial contamination during total-hip arthroplasty demonstrated a rather consistent pattern (Fig. 2). Elevated levels of bacterial contamination were noted during those periods when physical activity was prominent, with lower levels in the intervals between these periods. Thus, elevated levels of contamination existed with the arrival of the patient in the operating room and with the increased activity of the anesthesia team.

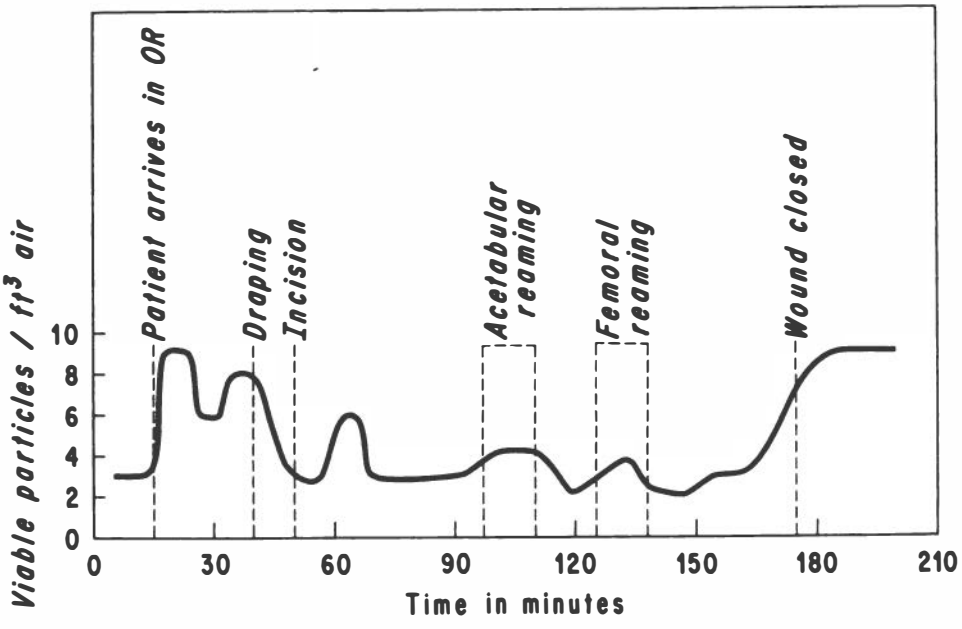

Fig. 2. Chronologic recording of airborne bacterial contamination during 25 total-hip arthroplasties.

The level fell to 4 to 7 viable particles per cubic foot of air per minute at the time the incision was made. Similar increases were noted when the trochanter was osteotomized, the acetabulum was widened and deepened, the femoral canal was prepared, and the trochanter was reattached. The level of airborne bacteria at each of these intervals was higher in rooms with lower rates of room air exchange per hour (Figs. 3 and 4). The mean level of airborne bacterial contamination during the entire procedure was higher (6.2 versus 5.4 viable particles per cubic foot of air per minute) in rooms with low rates of room air exchange per hour.

The level of bacterial contamination noted on settling plates on back tables supports the case method of preparation of instruments (Table 3). The difference between rooms of high and low rates of room air exchange per hour was obvious.

Contamination in the Operating Room

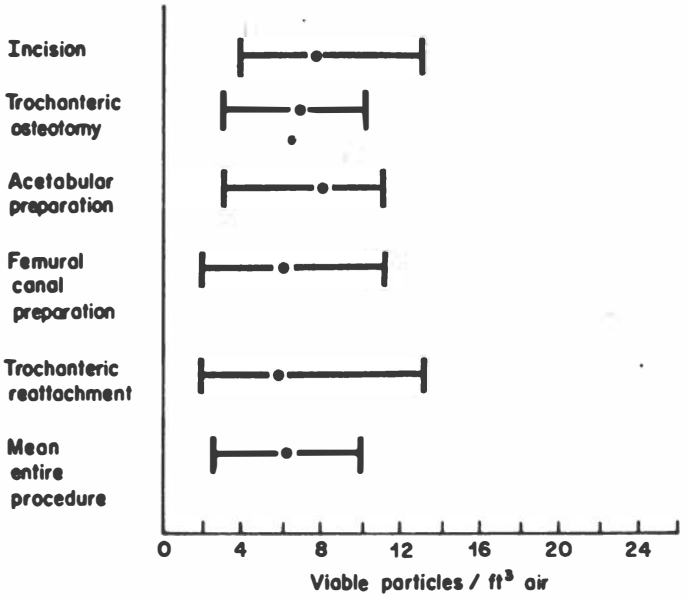

Fig. 3. Chronologic recording of mean and range of airborne bacterial contamination during 13 total-hip arthroplasties in operating room with 12 to 14 room air exchanges per hour.

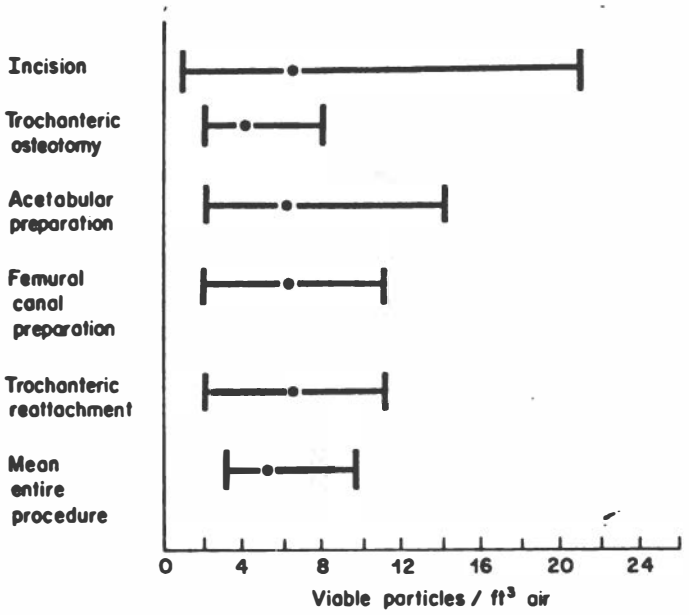

Fig. 4. Chronologic recording of mean and range of airborne bacterial contamination during 12 total-hip arthroplasties in operating room with 28 to 32 room air exchanges per hour.

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Table 3. Bacterial Contamination on Back Table

Room air exchange/hour	Mean no. of colony-forming units/sq ft per hour	No. of observation periods
12-14	121	31
28-32	48	8

The level of contamination of the instrument table observed on settling plates was elevated in both types of operating rooms (Table 4). Higher levels of contamination on settling plates placed near the orifice of the wound were noted in rooms with low rates of room air exchange (Table 4). The level of contamination at the orifice of the wound appeared to be related to the difficulty of the procedure. High microbial contamination was consistently noted when failed endoprosthetic or cup arthroplasties were converted to total-hip arthroplasties. Such procedures require greater activity with associated bacterial shedding by the surgical team. The use of an impermeable hood and large mask to cover the entire face except for the area about the eyes by the entire surgical team resulted in a significant decrease of the direct bacterial shedding by the scrub nurse onto the instruments and by the surgeon and his assistants about the orifice of the wound (Table 5).

The high levels of airborne bacterial contamination found in the cast rooms and corridors of the operating suite necessitate positive pressure within the operating room (Tables 6 and 7). Periodic checks of the pressure relationships and smoke studies to examine their flow patterns are necessary to ensure maintenance of these parameters.

Table 4. Bacterial Contamination of Instrument Table and Orifice of Wound

Room air exchange/hour	Instrument Table		Orifice of Wound	
	No. of observation periods	Mean no. of colony-forming units/sq ft per hour	No. of observation periods	Mean no. of colony-forming units/sq ft per hour
12-14	13	60	16	109
28-32	7	43	7	18

Table 5. The Effect of Hoods on Bacterial Contamination of Instrument Table and Orifice of Wound

Hoods	Instrument Table		Orifice of Wound	
	No. of observation periods	Mean no. of colony-forming units/sq ft per hour	No. of observation periods	Mean no. of colony-forming units/sq ft per hour
Without	11	65	10	134
With	9	41	13	43

Robert H. Fitzgerald, Jr.

Table 6. Airborne Bacterial Flora in Corridor

Activity level	Viable particles/cu ft of air
Mild	16.3
Moderate	20.3
Maximum	24.9

Table 7. Airborne Bacterial Flora in Cast Room

Room air exchange/hour	Viable particles/cu ft of air	
	Cast removal	Room empty
12-14	9.8	6.0
28-32	11.8	6.0

Previously published studies of total-hip arthroplasty with wound cultures at this institution have shown contamination of the operating wound in up to 33 percent of the procedures (2). Differentiation of endogenous contamination from exposed skin surfaces and airborne seeding of the operating wound is not entirely possible. When serial cultures of the operative wound were carefully performed in aerobic and anaerobic fashion during 157 total-hip arthroplasties, rooms with high and low room air exchange were noted to have roughly the same rates of bacterial colonization of the operating wound (Table 8).

However, anaerobic organisms were isolated in almost 50 percent of the wounds with positive cultures (Table 9). These anaerobic organisms probably are not airborne contaminants but most likely represent endogenous contaminants from exposed edges of skin. Bacterial colonization in an additional 28 percent of the wounds by Staphylococcus epidermidis could represent either endogenous or exogenous contamination. Differentiation is not possible at the time of this writing.

Contamination in the Operating Room

Table 8. Positive Wound Cultures* in 157 Total-Hip Arthroplasties

Room air exchange/hour	No. of procedures	Positive cultures	
		Number	Percent
12-14	42	17	40
28-32	115	39	34

*Tissue culture.

Table 9. Organisms Recovered From 57 Positive Wound Cultures*†

Propionibacterium acnes	24
Staphylococcus epidermidis	16
Streptococcus, viridans group	11
Corynebacterium	6
Staphylococcus aureus	2
Peptococcus	2
Neisseria	2
Bacillus	2
Eubacterium quintum	1
Lactobacillus	1

*More than one organism recovered from some positive cultures.

†Tissue cultures.

Robert H. Fitzgerald, Jr.

Bacterial colonization of the operative wound has been associated with an increased incidence of deep wound sepsis; however, the organisms recovered at the time of sepsis may differ from those recovered during surgical procedures (2).

Although higher levels of airborne bacterial contamination and operative wound cultures were noted in rooms of low room air exchange, there was no statistical difference in the rate of deep sepsis after total-hip arthroplasty (Table 10).

Table 10. Deep Sepsis After Total-Hip Arthroplasty
(March 1969 Through February 1972)

	Room air exchanges/hour	
	12-14	28-32
No. of procedures	1,853	1,360
No. of patients with deep sepsis	25	10
% Patients with deep sepsis	1.3	0.7

CONCLUSIONS

The personnel working in the operating room and the patient are the sources of airborne bacterial contamination within the operating room. The level of airborne bacterial contamination in the conventional, modern operating room is variable, depending on the air handling capabilities in the particular operating room. In general, rooms with low rates of room air exchange per hour have higher levels of airborne bacterial contamination. The level of airborne bacterial contamination in operating rooms with high rates of room air exchange per hour can be elevated if traffic control is not enforced and if increased numbers of personnel are in the operating room during surgical procedures. To maintain a low

level of airborne bacterial contamination during an operating procedure in rooms with low rates of room air exchange, strict adherence to traffic control and limitation of the number of personnel in the operating room are necessary. A direct relationship between airborne bacterial contamination and wound colonization has not been established. However, bacterial colonization of the operative wound is associated with an increased incidence of deep sepsis after total-hip arthroplasty.

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ULTRAVIOLET LIGHT IN THE ORTHOPAEDIC OPERATING ROOMS AT DUKE UNIVERSITY-- 37 YEARS' EXPERIENCE, 1937-74

J. Leonard Goldner*
Robert W. Gaines*
Mary Higgins*

The operating room environment at Duke Hospital in 1930 was patterned after standard operating rooms throughout the United States. During the winter months, the incidence of operating room infections caused by hemolytic Staphylococcus aureus was approximately ten percent. Deryl Hart attempted many changes in order to decrease the incidence of infection (13). Hart published an article in 1938 giving the efforts that had been made to reduce the number of bacteria in the operating room air (14). The procedures attempted were:

1. Rigid isolation with no visitors and a minimum number of personnel in the operating room during any procedure.

2. Large heavy masks covered the nose and mouth, both during and between operations.

3. All carriers of Staphylococcus aureus in the nose and throat were excluded. Serious operative procedures were postponed when contamination of the air was found to be high.

4. Meticulous cleanliness was maintained by frequent washing and painting, and by eliminating or decreasing air currents from other parts of the hospital.

5. Large amounts of air were taken from outside the building, where there were few, if any, pathogenic bacteria, filtered and washed and the air conditioning system then used to dilute the air in the operating rooms.

6. Various types of helmets and suction devices were used in an effort to decrease the number of pathogenic bacteria.

In spite of these precautions, contamination of the air with pathogenic bacteria rose as the number of carriers during and following epidemics of infection of the respiratory tract occurred (17).

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Not until ultraviolet (UV) light was introduced to the operating rooms at Duke did the incidence of infection decrease to a level that was acceptable to the surgeons working at Duke in the late 1930s and acceptable when compared with statistics quoted throughout the country at that time.

THE INITIAL EXPERIENCE WITH ULTRAVIOLET LIGHT AT DUKE

Ultraviolet light eliminates pathogenic bacteria, just as does sunshine. Air particles carrying bacteria could be sterilized by ultraviolet light (13). Experiments demonstrated that Petri dishes of blood agar, when sprayed with hemolytic Staphylococcus aureus and exposed at the operative site, would be sterilized within one to three minutes; and at this point, the number of bacteria dropping out of the air could be reduced by 95 percent to 100 percent.

The intensity of the radiation will not give the patient an appreciable skin erythema during an exposure of 90 minutes; and the surgeon wearing minimal protection of a paper hood, plastic or plain glasses, a standard green eyeshade and ordinary gown may work for hours in this environment without the eyes or the skin being affected.

In 1937, Hart demonstrated that contamination of operating room air was universal. Fifty surgeons in 25 states were asked to make cultures in their operating rooms in order to determine the extent and degree of air contamination. Reports received from 32 surgeons covering 37 operating rooms in 33 hospitals located in 17 states showed Staphylococcus albus on all plates, and over 50 percent of the plates showed Staphylococcus aureus.

Hart emphasized during the same period that exclusive of bactericidal irradiation, air conditioning is the most important single means of reducing bacterial count of the air in the occupied operating room (22).

Organisms given off in an operating room by the occupants are predominantly gram-positive cocci and gram-negative bacilli, and these are removed rapidly by clean circulating air from an efficient ventilating system (19).

Ultraviolet Light at Duke

All things being equal, the number of pathogenic bacteria in the air of a room increases directly with the number of occupants and the duration of occupancy. Conversely, the bacterial count drops directly in proportion to the length of time the room is unoccupied and closed.

The air in an operating room that contains ordinary air conditioning and no special environmental antibacterial devices, and which has been closed between 15 to 20 hours, is almost free of bacteria. A room with many occupants, however, has a much higher bacterial count than an adjoining room with a few occupants.

Hart and his co-workers found that four occupants suffering from colds in an operating room resulted in Petri dishes of blood agar exposed for one hour to show an average of 13.8 colonies of streptococci per Petri dish (17,18,19).

The total number of colonies of bacteria sedimenting from the air gives some idea of the degree of contamination of the air, but is less significant than the number of pathogenic organisms present. In this respect, the air conditioning, by removing most of the nonpathogenic organisms from the incoming air and only diluting the concentrations of the pathogens in the room, gives more apparent than actual improvement in operating room conditions. In recent years, however, the nonpathogens of former times, in other words, Staphylococcus epidermidis, and certain gram-negative cocci and bacilli, are now considered pathogens because of metallic and plastic implants that are being used as substitutes for all or part of an organ system. Hip joints, knee joints, metacarpal and phalangeal joints, and heart valves include such foreign materials as high density polyethylene, methyl methacrylate, metallic alloys, silicone, and densely woven Dacron, all of which provide mechanical crevices and cracks and prevent the components of the natural immune system and antibiotics from getting to the bacteria.

Airborne bacteria thus become an even more serious problem since both pathogens and nonpathogens may affect the mechanical stability and the durability of an implant. The combination of ultraviolet light and a superior air conditioning system in 1974 has maintained an infection rate for the Orthopaedic

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Service at Duke of less that 0.5 percent. When the ultraviolet lights were introduced initially, the air conditioning system was difficult to maintain, the filters were not as efficient, and the air changes per hour per room were less frequent than during the past ten years.

In spite of the inconsistent airflow and the difficulty in controlling room temperature and the contamination that resulted when individuals with respiratory infections were in the operating room, once ultraviolet lights were introduced to the operating rooms at Duke (1934), the high infection incidence decreased to a level that was acceptable (14). The percentage of infections has continued to remain at the same low level from that time to the present. The Orthopaedic Service at Duke has utilized ultraviolet light since 1937 for all major surgical cases. The record of wound infection in refined, clean wounds (first operation in a particular region on a particular patient) has been maintained at a very low level. The incidence of orthopaedic wound infections since 1940, reviewed on an annual basis, has been less than 0.5 percent for all operative cases done. This percentage has not changed even though the staff has increased from 1 full-time to 7 full-time orthopaedic surgeons, from 4 orthopaedic residents to 35 different residents (not all at the parent hospital simultaneously), and from 100 orthopaedic operations per year average to approximately 3,000 orthopaedic procedures each year.

CURRENT STUDIES OF OPERATING ROOM ENVIRONMENT AT DUKE

Many questions, especially those concerning the relative benefit of ultraviolet radiation versus newer techniques, such as unidirectional airflow in reducing surgical infections, cannot be answered unequivocally. However, one cannot refute the hypothesis that horizontal or vertical unidirectional flow with High Efficiency Particulate Air (HEPA) filters in the system provides the "cleanest" possible air with reference to particles. The point of maximum patient protection by air cleanliness has neither been determined nor set in perspective with contact contamination and endogenous sources of bacteria (8). While the sterilization of exposed surfaces, the germicidal effect on exposed skin, and the continuous radiation of wet areas on drapes and the surgeons'

clothing are benefits of ultraviolet light, the information presented relates to the incidence of operating room infections for the Orthopaedic Service at Duke and the data relative to contamination in the air, both recently and during the past 35 years (10).

Total-hip arthroplasty, other heart and joint implants. and organ transplantation have introduced variables into the criteria for operating room cleanliness and stimulated review of techniques, operating room air, and incidence of operating room infection. In many hospitals, and in individual operating rooms supervised by particular services, conditions that had been satisfactory for prior major surgery have proven unsatisfactory for these procedures. The relative value of "sterility of the air" must be defined. We believe that clean air decreases the incidence of operating room infection; however, we continue to ask ourselves such questions as:

1. How important is the reduction of atmospheric bacteria from one to three colony-forming units per cubic foot of air to essentially sterile air?

2. What is the relative importance of contact contamination which may involve thousands of bacteria?

3. How important are endogenous bacteria which can never be completely eliminated from the patient's skin or certain foci within the body?

4. How important is the waning immunologic competency of the patient population undergoing the procedure (11)?

Furthermore, how many bacteria per gram of tissue must be in a particular kind of wound in certain patients in order to cause a clinically evident wound infection? And, how important is the presence of a prosthesis in living tissue, when considering the effect of small numbers of nonpathogenic bacteria inoculated in an area where a prosthesis is present, in causing a clinical infection? These questions under consideration and the data presented by many investigators should provide the answers soon, if not at the present time. Ultraviolet light will provide clean air and kill the bacteria on exposed surfaces.

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DUKE OPERATING ROOM AIR CONDITIONING SYSTEM

At Duke, the air conditioning system is superior and efficient and even without ultraviolet light, the air is relatively clean, the air exchange averages 35 times per hour, and the particle count is relatively low. Under ordinary circumstances, i.e., limited traffic, minimal turbulence, and a refined, clean case without endogenous elements, the incidence of infection on any service is low. A safety factor should exist to protect the patient against a pathologic shedder, a respiratory infection in one of the operating room personnel, or air contamination from some other source. Ultraviolet light will do this in addition to the protection provided by the air conditioning system.

In the Duke operating rooms, modifications of the air conditioning systems or additions of new rooms with new systems have been carried out since 1957. In 1969 when total-hip arthroplasty was initiated at Duke, the procedures were done under System #4 (Operating Room Suites 16, 17, 18, and 19).

The air handling unit is located in the attic of the Davison Building. The fresh air intake and exhaust are in the roof above the air handling unit. Incoming air passes through the fan, medium efficiency filter, a preheat coil, a heat wheel, high efficiency filter, an air washer, and a cooling coil. Next the air enters the individual ducts leading to the operating rooms where it is reheated and humidified before entering the rooms. The exhaust duct has a high efficiency filter just before the heat wheel. The heat wheel is designed to transfer heat from the exhaust air into the supply air for economy. This is the only point of contact between the exhaust air and the supply air, and this is the reason a high efficiency filter is in the exhaust duct. There is no recirculation of air. These rooms are equipped with ultraviolet lights. Many of the first 200 total hips done at Duke were done in this suite. This information is given only to emphasize the importance of investigators knowing as much as possible about the basic airflow design of the room, the number of changes per hour, the pressure readings, the humidity, the temperature, and other details related to flow of particulate matter.

Ultraviolet Light at Duke

System #2 at Duke, serving Operating Rooms 3 through 10, consists of an air handling unit located on the 5th floor of the 1957 addition. The fresh air intake and exhaust are in the east wall of the mechanical room of the observation suite. The fresh air passes through medium efficiency filters, high efficiency filters, preheat coil, an air washer, cooling coils, a reheat coil, and then the fan. After leaving the fan, the air enters individual ducts leading to Rooms 3 through 10 and passes through a final reheat coil. There are no provisions for the air to be recirculated.

System #1 serves Operating Rooms 1 and 2, and includes an air handling unit located on the roof of the 1957 addition which is the location of the fresh air intake and exhaust. The fresh air passes through medium efficiency prefilters, preheating coils, an air washer, and cooling coils. It then enters the fan, passes through high efficiency filters, is reheated, humidified, passes through volume control dampers, and then enters the operating room. This system normally uses 100 percent fresh air, but it is designed so that the air can be recirculated.

System #3 serves Operating Rooms A, B, C, and D, and includes an air handling unit located in the hospital attic over the supply rooms for the operating suite. The fresh air passes through medium efficiency filters, high effeciency filters, preheating coils, an air washer, and cooling coils. The air then enters the fan, passes through a reheat coil and a humidifier, then enters the operating rooms. There is no provision for recirculation of air in this system.

The high efficiency filters used are Farr Model HP-200 which remove 95 percent of particles in the five micron range. Continental Models 9C24, 9C12M, and 9C24M, remove 95 percent of particles in the one micron range, or 92 percent in the 0.3 micron range.

The medium efficiency filters are Farr Model RP-2A, removing 36.5 percent of particles in the five micron range, and Continental Models CF-445, CF-248, and CF-448, removing 45 percent of particles in the 1.8 micron range. The particle efficiency ratings are based on the NBS tests using atmospheric dust.

There are 36 air changes per hour in Operating Room 3, and 34 air changes per hour in Operating Room 4.

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TOTAL-HIP ARTHROPLASTY AT DUKE

Total-hip arthroplasty utilizing methyl mathacrylate was initiated on the Duke Orthopaedic Service in 1969. This operative procedure was carried out in Great Britain, France, Canada, Australia, and New Zealand in large numbers prior to that time. Initially, the infection rate in certain centers was high (7 percent to 14 percent) (5). With alterations in operating room environment, these centers decreased their infection rate to an acceptable level. At Duke, we initiated the procedure following the same draping and prepping techniques as we had done for other hips, and followed essentially the same program as had been followed for any major orthopaedic procedure. The air conditioning system was as before, and the ultraviolet lights were used consistently. During the time that the first 100 total hips were being done (about one year), other modifications in techniques were added to avoid "taking unnecessary chances." These included:

- the use of protective booties on the shoes;
- use of a throw-away hood to decrease shedding from hair and neck;
- occasional use of wrap-around disposable paper gowns;
- limitation of traffic; and
- initiation of a clean corridor which eliminated all unnecessary traffic.

The open "all-day-long" back table technique which had been used for over 20 years was discontinued even though prior bacteriologic studies had shown the UV lights to be effective in maintaining sterility.

To the present time, there have been eight infections evidenced by wound suppuration in about 700 total-hip patients. These problems occurred during the first 300 hip operations. No major infections occurred in the subsequent 400 hip procedures. These operations have been done by both senior staff and resident staff, and the operating room techniques and the environment have not been altered except in the way that has been mentioned. The use of prophylactic antibiotics was not consistent, and this aspect of the procedure will be discussed later.

Ultraviolet Light at Duke

Hips that have been operated upon previously are aspirated and the material cultured prior to operation; swab culture, as well as tissue for culture, is taken at the time of the procedure although the latter has usually occurred after the initial dose of antibiotic has been given. The patients are screened for endogenous sources of bacteria such as urine, respiratory tract, teeth, and historically at least for such conditions as chronic gallbladder disease, ulcerative colitis, or thrombophlebitis. If the history or findings are positive the operative procedure is delayed.

Certain members of the orthopaedic staff have had no operative infections in doing total-hip replacements; whereas, other members who may have been involved in a greater number of procedures, or procedures of a more difficult nature, may have had a higher incidence of infection. Many factors must be considered in assessing the average figure. The overall incidence of sepsis in all total-hip arthroplasties utilizing methyl methacrylate on the Duke Orthopaedic Service and including all patients, whether they have been operated upon previously or not, has been 1.1 percent. These infections occurred during the time that the first 300 patients were operated upon. There have been no infections during the last 400 total-hip operations. This emphasizes the importance of determining statistics on a large number of patients that may include change of seasons as well as change in personnel. We emphasize again that the patients included in these statistics are no longer those which Hart defined as refined, clean cases, but now include patients who have had prior operative procedures including endoprostheses.

PROPHYLACTIC ANTIBIOTICS ON THE DUKE ORTHOPAEDIC SERVICE

The necessity or the value of prophylactic antibiotics for orthopaedic patients at Duke has not yet been ascertained completely. The infection rate for all major orthopaedic operations during the past 30 years has been 0.5 percent or less, reviewed on an annual basis. This excludes the period of time when the total-hip study was initiated. Antibiotics had been used haphazardly by members of the Duke staff. In certain instances they were started preoperatively. A double-blind control study was initiated in 1969. In this study were included patients chosen at random, all of whom had a major orthopaedic operation such as spine fusion, joint replacement, but excluding all hand cases,

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most foot operations, and most knee operations. Over 200 of the patients included in the double-blind study were patients undergoing a total-hip arthroplasty. All of the patients were operated upon under ultraviolet light. There was no significant difference in the infection rate in those patients receiving antibiotics compared with those who did not; all were operated upon under UV light. We can see that in view of the prior low infection rate which we believe related to use of UV light, the number of patients involved in a double-blind antibiotic study from which significant convincing figures would evolve may be over 1,000.)

Our current practice is to use a prophylactic antibiotic regime in all patients receiving an implant in view of the possibility of undetected endogenous sources of bacterial contamination. The first dose is given the night before operation, continued during the procedure, and discontinued 48 hours postoperatively. The side effects have been minimal although some have been recognized occasionally. The alteration of natural occurring bacteria and the alteration of bacterial flora within the hospital and within the individual patient have been noted. Further, the resistance of certain gram-negative and gram-positive bacteria related to the widespread use of antibiotics cannot be ignored. Gastrointestinal alterations, delayed sensitivities, and yeast and fungal infections are all potential dangers of antibiotics.

ANALYSIS OF TOTAL-HIP INFECTIONS SINCE 1969

There have been eight deep wound infections in a total of approximately 700 patients who have had total-hip arthroplasty. Three of these infections occurred in previously unoperated hips and would be in the category of refined, clean cases. In one instance, a Clostridium perfringens organism was isolated without evidence of gas gangrene. This developed in the subcutaneous tissues approximately three weeks after the operative procedure. The methacrylate cement cultured at the time of the initial operation was also positive for this organism. Eventually the prosthesis had to be removed. A second patient developed a deep infection eight months after total-hip replacement even though the immediate postoperative course and the subsequent months showed no unusual signs or symptoms. This patient had a urinary tract infection at the time she re-entered the hospital with hip pain, and Escherichia coli was cultured from both the urine and from the hip aspiration. The prosthesis was removed. A

third patient developed pain about the greater trochanter several months after total-hip replacement which was accompanied and followed by a benign course. The pain was thought to be due to trochanteric wire and was removed by a surgeon where the patient was visiting. The wound had been closed at the time the wire was removed, but when he returned to Duke several weeks later, drainage had occurred and Staphylococcus aureus was cultured. Case #1 was definitely an operating room infection but probably not airborne. Case #2 is in the category of endogenous infection, and Case #3 was probably not an operating room infection at the time of the initial total-hip arthroplasty.

The five other patients being considered with deep wound infections had all undergone operative procedures prior to the total-hip replacement. One patient developed a wound hematoma two weeks after the operation while on Coumadin. A gram-negative organism was cultured from the hematoma; the wound was opened, evacuated and dressed daily for about three weeks. The wound subsequently healed, and four and a half years later the prosthesis is in place without evidence of loosening and the patient has no pain. This was considered as a secondary infection and not primarily one that occurred in the operating room. A second patient with a painful endoprosthesis of the femur developed wound drainage about two weeks after total-hip replacement was done. Preoperative aspiration had not been productive, but a positive wound culture was obtained from tissue material at the time that the total replacement was done (unknown until 48 hours after total-hip replacement). In spite of long term antibiotic, the prosthesis loosened and had to be removed. This patient infection was considered as one which was present when the total-hip replacement was done, and was not considered as one that originated from the operating room environment at the time of the procedure. A third patient in this group of five had a primary diagnosis of lupus erythematosus and required steroids for control of vasculitis. She developed a gram-negative septicemia and a draining wound, and the prosthesis had to be removed. The origin of the gram-negative organism was not determined. Two other patients in this group developed wound drainage after total-hip replacement. Both had positive bacterial cultures from these wounds, although cultures taken at the time of the total-hip operation were reported as negative. We do not have an absolute opinion as to the origin of these two infections.

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If one is willing to accept the thesis that airborne contamination is an important source of wound infection in refined, clean cases or in apparently clean areas that have been operated upon before, there were no proven infections that were airborne in origin in this group of hip patients operated upon at Duke Hospital. The air conditioning system as described, the regulation of the ultraviolet lights as will be described, and the precautions already mentioned were in effect during this five-year period.

AIR SAMPLING IN RADIATED AND NON-RADIATED ROOMS AT DUKE--VOLUMETRIC AIR SAMPLING

In March of 1972 another study was initiated on atmospheric conditions in the Duke operating rooms, and this time the volumetric Raynier Air Sampler was used. The collecting unit was placed first above five feet from the operating table where the room traffic and activity were tabulated as the plate was inoculated and the effect of these variables could be documented. Later, a plastic tube to collect air was anchored within six centimeters of the wound for collection of air. The colony-forming groups per cubic foot per minute (CFG/ft^3/min) and per cubic foot per five minutes (CFG/ft^3/5 min) were gathered and plotted on a graph on several occasions -- none of which initially were hip arthroplasty. The colony-forming groups varied from zero to three CFG/ft^3/min, averaging one to two in the relatively quiet, unoccupied room. As the number of individuals in the room increased, the level of air contamination increased. Opening and closing doors did not in itself cause a significant alteration if the individuals left the room. However, if the doors were opened and more individuals entered the room such as a nurse, anesthesiologist, surgical attendant, physician, or observer, the CFG increased rapidly (Table 4-A through 4-C).

Details concerning the culture plates within the sampler have been reviewed. All culture material is prepared as needed and refrigerated until used. Refrigeration keeps the surface area moist, and prolongs the "shelf life" of the media. The efficiency of collection is dependent upon the distance of the slit to the media plate. This is adjustable each time the plate is inserted into the sampler. The efficiency is approximately 95 percent. The advantage of this sampling procedure is that the particles are impacted on the plate, and only a small portion of the plate is exposed to the airflow as the plate rotates every thirty minutes. Therefore, drying out the media

and the collected particles is minimized. Once the operative procedure is completed, the plates are taken immediately to the Microbiology Laboratory and incubated.

The question always arises as to the effect of ultraviolet light on the culture media in order to ascertain the possibility of the media being affected in such a way that the organisms would be less likely to grow than on the usual media. The media used in settle plates during operative procedures is Trypticase Soy Agar and not Blood Agar. Our observations have been that the culture media, once exposed to ultraviolet light, was not discolored or affected.

Additional review of the area outside the main operating rooms at Duke showed that the traffic in the hallways was not strictly controlled. Individuals passing from one part of the hopsital to another did have access to the hallways, street clothing was permitted in these corridors and referring or supervising members of the staff could walk in the hallways outside of the main operating room without changing shoes or clothes. This is the pattern that had been allowed for many years and presumably because of the ultraviolet lights in the operating room, the infection rate had not been affected adversely. The initial volumetric sampling in the total hip rooms was done during the time the free flow of traffic was allowed, and in spite of this, the level of airborne organisms within the rooms was well below the suggested minimal standard. The fluctuation in bacterial counts when individuals entered the rooms, and the elevation of counts during cases when air currents were increased and between cases when motion and talking increased was evident. The orthopaedic infection rate has been maintained at the low level mentioned despite relative freedom of traffic throughout the entire operating suite since 1935.

With the advent of total-hip arthroplasty and other joint implants in orthopaedics and in keeping with the effort to standardize the operating room environment, a restricted traffic policy and specified requirements of dress for those within the operating room area have been established. Entrance and exit from the orthopaedic operating rooms have been reduced somewhat, but control is not stringent. Members of the nursing service, surgical attendants,

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anesthesiology personnel, orthopaedic residents, and others, continue to enter and leave the operating room on numerous occasions. In spite of this, the air sampling study shows satisfactory control of the bacterial content in the air because of the air conditioning system, and that the number of pathogens reaches a low level if the ultraviolet lights are used. Data concerning comparative studies of air sampling in orthopaedic rooms both with and without ultraviolet lights are presented in a preliminary form in this paper without precise conclusions being drawn at this time (24).

RECONFIRMATION OF THE EFFECTIVENESS OF ULTRAVIOLET LIGHT ON BACTERIA IN THE OPERATING ROOM

The purpose of the study was to demonstrate the time-death relationship of a known number of Staphylococcus aureus coagulase (+) to ultraviolet light irradiation at the operative site in two orthopaedic operating rooms at Duke University Medical Center. These are the two rooms in which total-hip arthroplasties are done and in which volumetric air sampling is being done with ultraviolet lights either on or off. The placement and arrangement of the ultraviolet lights in the two rooms was different, and this study allowed comparison of the placement in a low ceiling room with placement in a high ceiling room.

An appropriate Staphylococcus aureus coagulase (+) dilution was made as follows: a lyophilized disk of Staphylococcus aureus coagulase (+) (Standard Disk; Difco) was aseptically placed in Trypticase Soy Broth and incubated at 37° C for 24 hours. After 24 hours of incubation, serial dilutions of the original broth culture were made and spread onto a Blood Agar Petri dish (15 mm x 150 mm). The surface of the Blood Agar plates was allowed to dry at room temperature and then incubated at 37° C for 48 hours. After incubation, the dilution (10^6) that produced approximately 200 CFG on the Petri dish was chosen. Preparation of a Staphylococcus aureus coagulase (+) 10^6 dilution was prepared and one milliliter of the 10^6 dilution was spread onto 16 Blood Agar Petri dishes (15 mm x 150 mm). The surface of the Blood Agar plates was allowed to dry

at room temperature. The Petri dishes were taken to Operating Rooms 3 and 4 and placed at what approximated the operative site. In Operating Rooms 3 and 4, there was a control plate (no exposure to UV irradiation), and the remaining Petri dishes were exposed to ultraviolet irradiation for 5, 10, 15, 20, 30, 60, and 120 minutes respectively. Petri dishes were then incubated at 37° C for 48 hours and remaining colony-forming groups were counted and recorded. The original number of colony-forming groups in the broth culture is the number of the control plate. Table 1 shows the percentage of reduction of bacteria with the ultraviolet light on during a recorded time interval.

Table 1. UV Light--Percent Reduction in Bacteria

	Room 4		Room 3	
	# Colonies	% Reduct./Time	# Colonies	% Reduct./Time
Control	170	0	130	0
5 min	29	83%	45	65%
10 min	15	91%	6	95%
15 min	8	95%	5	96%
20 min	0	100%	0	100%
30 min	0	100%	0	100%
1 hr	0	100%	0	100%
2 hr	0	100%	0	100%

The time-death relationship of a known number of Staphylococcus aureus coagulase (+) to ultraviolet light was measured in two orthopaedic operating rooms at Duke. The plates with a known Staphylococcus aureus dilution spread on Blood Agar Petri dishes were exposed to ultraviolet light at a point that approximated the operative site.

In Room 4, which was equipped with eight ceiling lights and twelve wall lights, there were 170 colonies X 10^6 as a control. The control plate was not exposed to UV light and at the end of two hours, there was no reduction in the number of colony-forming groups. In the plates exposed to UV light at five minutes, the number of colonies had decreased to 29 (83 percent reduction in the number of colonies). At ten minutes after UV light exposure, the number of

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colonies was reduced to 15 (91 percent reduction), and at 15 minutes, the reduction was to eight colonies (95 percent reduction). By 20 minutes after exposure to UV light, there were no colonies noted, nor were there any at 30 minutes, one hour, or two hours. The UV light reading in that room was 17 MW/cm^2/sec.

Operating Room 3 has no overhead lights but there are 12 sidelights. The intensity in this room is usually 12 MW/cm^2/sec, whereas the readings in Room 4 are usually 17 MW/cm^2/sec.

In Operating Room 3 the ultraviolet lights are on the sidewalls and shining indirectly as ceiling lights. (The ceiling is not of sufficient height to allow lights to be mounted on the ceiling.) The number of colonies on the initial plate was 130 x 10^6. In five minutes, the reduction was to 45 colonies (65 percent). After ten minutes of exposure to UV light, the reduction was to six colonies (95 percent). After 15 minutes there were five colonies remaining (96 percent). After 30 minutes of exposure, there were no colonies noted, nor were there any after one hour, or two hours. These observations confirm the efficacy of ultraviolet light even though the intensity of the reading is not as high as that which is usually recommended and even though a high ceiling room was not available. The variation in the amount of time necessary to kill all the colonies is related to the intensity. The original studies of Hart show that within three minutes the bacterial colonies were absent if the intensity is maintained at 25-30 MW/cm^2/sec.

PRELIMINARY ANALYSIS OF DATA FROM VOLUMETRIC AIR SAMPLING DURING TOTAL-HIP ARTHROPLASTY WITH ULTRAVIOLET LIGHTS ON AND OFF

A random study is currently in progress. The particular operation to be done with ultraviolet lights on or off is determined by the surgeon. A high-risk patient, i.e., a renal transplant patient with avascular necrosis having total-hip replacement or a patient with rheumatoid arthritis who is on continuous steroid intake, should get prophylactic antibiotics based on current antibiotic-controlled studies. As of this time, 35 total-hip arthroplasties have been monitored with the Raynier sampler. Nineteen of these have been in Operating Room 3 and 16 in Room 4. The lights have been off five times in Room 3 (5 of 19) and six times in Room 4 (6 of 16). There have been no clinical

infections in any of these patients. Please note that the study was not done primarily to determine the rate of infection but rather to determine the CFG of bacteria near the wound during the operative procedure. The pattern of the operative procedure has been the same in each instance. However, the operative steps have been divided into 1) incision and exposure, 2) removal of femoral head, 3) preparing and reaming of the acetabulum, 4) mixing cement and placement of the acetabular component, 5) preparation of femoral shaft and trial reduction, 6) mixing and placement of cement and final reduction, and 7) wound closure.

Until the total number of cases with lights on and off are monitored, the comparison of the data will not be completed. The Chi Square Test will be done and other comparisons will be made.

Meanwhile, certain observations based on the data accumulated are emphasized:

1. Thirty-six patients in Rooms 3 and 4 have had total-hip arthroplasty. Personnel has varied from case to case, but the operating rooms have been the same and the operation has been of the same kind, although the natural and expected variations have occurred. The length of the procedure has varied from 56 minutes to four hours depending on the problems encountered.

2. The number of colony-forming groups collected on the Agar plates has increased with the number of people in the room, the amount of movement and motion around the incision, and by the number of persons entering the room. The air conditioning system itself, with 35 air changes per hour, was sufficient to maintain a low number of colony-forming groups measured as CFG/ft^3/min, if there was minimal activity in the room.

3. Table 2 shows the percent of isolates recovered for all total-hip procedures (Room 3, 19 operations; Room 4, 16 operations, UV lights off 11 operations, UV lights on 24 operations). The number of organisms recovered with the lights off is almost as great as the numbers recovered with the lights on even though only half as many operations were done with the lights off.

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Table 2. Percent of Isolates Recovered for all Total-Hip Procedures

Total # Organisms	All Op. 7049	Rm. 3 2854	Rm. 4 4195	UV On 3876	UV Off 3173
Fungi, yeast mold	8.25	5.83	9.86	9.67	6.52
Bacillus species	24.81	37.49	16.18	11.35	41.25
Micrococcus species	33.46	22.84	40.69	40.94	24.33
Diptheroids	19.53	22.10	17.78	22.72	15.63
S. epidermidis	13.33	11.66	14.46	14.88	11.44
Mima polymorpha	0.18	0.00	0.31	0.28	0.06
Klebsiella species	0.01	0.00	0.02	0.03	0.00
S. aureus Coag. (+)	0.39	0.00	0.67	0.10	0.75

No Staphylococcus aureus organism was recovered from Room 4. The difference tween UV lights on and UV lights off is six times greater with the lights off.

Review of the figures of all 35 cases shows that the number of colony-forming groups of all kinds shows a pattern of considerably higher numbers in individual instances with the lights off, as compared with the general pattern of lower numbers of colony-forming groups with the lights on.

These figures reflect 11 operations with the ultraviolet lights off; 24 operations with the ultraviolet lights on. Note that the number of organisms recovered in the rooms with the UV lights off is approaching that with the UV lights on yet over twice as many operations were done with the lights on as with the lights off.

In the entire 35 patients monitored, there were three instances in which Staphylococcus aureus coagulase (+) organisms were recovered by means of volumetric sampling. All occurred in Room 3, where the intensity readings are adequate but where the tests shown in Table #1 indicate that within the first five minutes of exposure of staphylococci on the agar plate, the reduction was 65 percent of the colonies, as compared with 83 percent in Room 4. This may have some bearing on the recovery of this organism in Room 3 only.

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Case #1 in Room 3, with the UV lights off during total-hip arthroplasty, had a total number of 190 CFG recovered of which 19 were Staphylococcus aureus coagulase (+). Twelve of 19 CFG were recovered during preparation and insertion of the glue in the acetabulum, and seven were recovered during exposure prior to removal of the femoral head. Wound cultures for closure showed no growth, and a settle plate on the back table showed four CFG of diphtheroids and five CFG of Staphylococcus epidermidis. The patient was on the operating table a total of 56 minutes and the average bacterial count was 0.16 CFG/ft^3/min (four settle plates, not volumetric sampling).

Case #2, with ultraviolet lights off, showed five of 722 CFG recovered to be Staphylococcus aureus coagulase (+). Comparatively speaking, this was the highest total count of any of the 35 patients monitored. One Staphylococcus aureus of five was recovered during step 4, which was preparation and insertion of the methacrylate in the acetabulum, and four Staphylococcus aureus colony-forming groups of five were recovered during the wound closure. Wound culture after irrigation and before closure showed no growth. The settle plate on the back table showed 12 CFG diphtheroids, 14 CFG micrococcus sp., three CFG Staphylococcus aureus coagulase (+). Total time on the operating table for the patient was 95 minutes, and the average CFG was 0.30 CFG/ft^3/min (four settle plates, not volumetric sampling).

Case #3 in Room 3, with the UV lights on, showed Staphylococcus aureus coagulase (+), and the total number of organisms recovered was four of 80. Three Staphylococcus aureus coagulase (+) of four were recovered during step 4 (preparation and insertion of the methacrylate in the acetabulum) and one of four Staphylococcus aureus CFG during step 6 (final reduction). Wound culture after irrigation and before closure was negative and the settle plate showed no growth. Certain trends are implied as the data from these three patients were reviewed.

As in the determination of variations in volumetric air sampling in other operating rooms in this same suite, sampling was done throughout the entire procedure for a single bypass coronary artery graft. The total number of organisms recovered was 1,020. The specific details concerning organisms and percentages of the total are noted in Table 2. The total time of the operative

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procedure was two hours and 49 minutes. The total number of door openings allowing entrance of an individual into the room was approximately 64. The patient was on the pump for about one hour and considerably more individuals were in the room than are present during a total-hip arthroplasty.

TECHNICAL DETAILS CONCERNING ULTRAVIOLET LIGHT

The ultraviolet light tubes are cool, 30 inches (75 cm) long and contain Argon, Neon and Mercury. Over 80 percent of the output of such tubes is at 2,537 angstrom units. Equipping an operating room with ultraviolet lights requires consideration of the following items (Appendix A):

1. ultraviolet light fixtures (brackets for lights);
2. sterile lamps for fixtures (30 W);
3. variac control switch with two per room, since the top lights and the side lights are controlled separately;
4. ultraviolet light monitors which should be available for daily use by nursing personnel;
5. wiring and installation;
6. portable ultraviolet lights for room or floor sterilization after dirty case;
7. plastic glasses with side covers;
8. hoods for total head, neck and face cover;
9. green plastic visors;
10. modification of eye cover in the form of protective goggles that take the place of plastic glasses and the green eyeshades;
11. Figure 1 shows the placement of side lights and overhead lights. A high ceiling in the operating room provides more efficient use of the lights without excessive exposure of the surgeon's head. If the ceiling is low, then the light source must be the sidelights and indirect ceiling lights or sidelights only. When sidelights only are used, it is mandatory that glasses with side protectors be used by everyone in the room, and that the patient's skin be covered with anti-burn cream, or with plastic or cloth covering.

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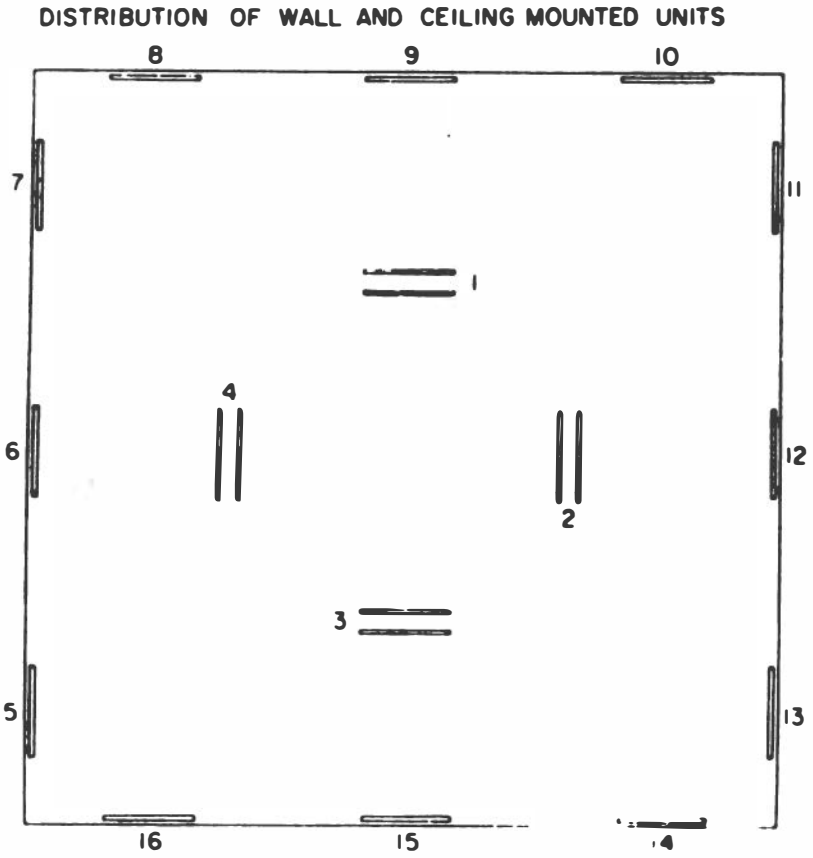

Fig. 1. Distribution of wall- and ceiling-mounted ultraviolet bulbs. The lights mounted on the walls are covered by brackets that prevent direct observation of the bulb by the eyes of the personnel in the room. The overhead lights should have a direct access to the wound and not be blocked by intervening objects. Intensity of the overhead light is inversely proportional to the square of the distance. This arrangement is utilized by all rooms with a high overhead ceiling. If the ceiling is only 10-12 feet, then the sidelights alone are used.

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The ultraviolet light offers the following advantages:

1. high output in the bactericidal range of the spectrum and low output in the erythemic range;
2. negligible production of ozone, which is rarely detectable by odor even with as many as 16 tubes in the operating room;
3. negligible production of heat;
4. low cost of the irradiation unit, which is made of high transmission glass instead of quartz and averages about $1,500 per room, including equipment and installation;
5. low operating cost.

The estimated life of the tube is between 4,000 and 5,000 hours, and from 10-16 tubes can be operated with as little current as is required to light a 150 W electric bulb.

An average-size operating room at Duke is equipped with four overhead brackets with two bulbs in each bracket, and eight sidelights with two on each wall, or a total of 16 bulbs in each room. This has been the usual number of lights used for the past 35 years without harm to personnel.

Intensity of irradiation varies approximately inversely as the square of the distance from the source of radiation and may be compensated by variations in the output of the unit. Room temperature and humidity affect the output. Figure 2 (28) shows that the effectiveness of ultraviolet light drops percipitously as the humidity reaches 60 percent. A humidity gauge should be available in each operating room, and when the humidity approaches 55 percent, the engineer should be asked to reduce it. A desirable level is from 40-50 percent. This increases the efficiency of the air conditioning, and also assures full strength of the ultraviolet light. The dangers thought to be associated with the low humidity are overcome now by the types of inhalation anesthetics being utilized.

The intensity of the ultraviolet light in the Duke operating rooms is sufficient to kill bacteria on the floor, and on objects at levels close to the floor. The intensity is gauged to be safe for exposure of the surgeon who may be standing anywhere from five to seven feet from the floor.

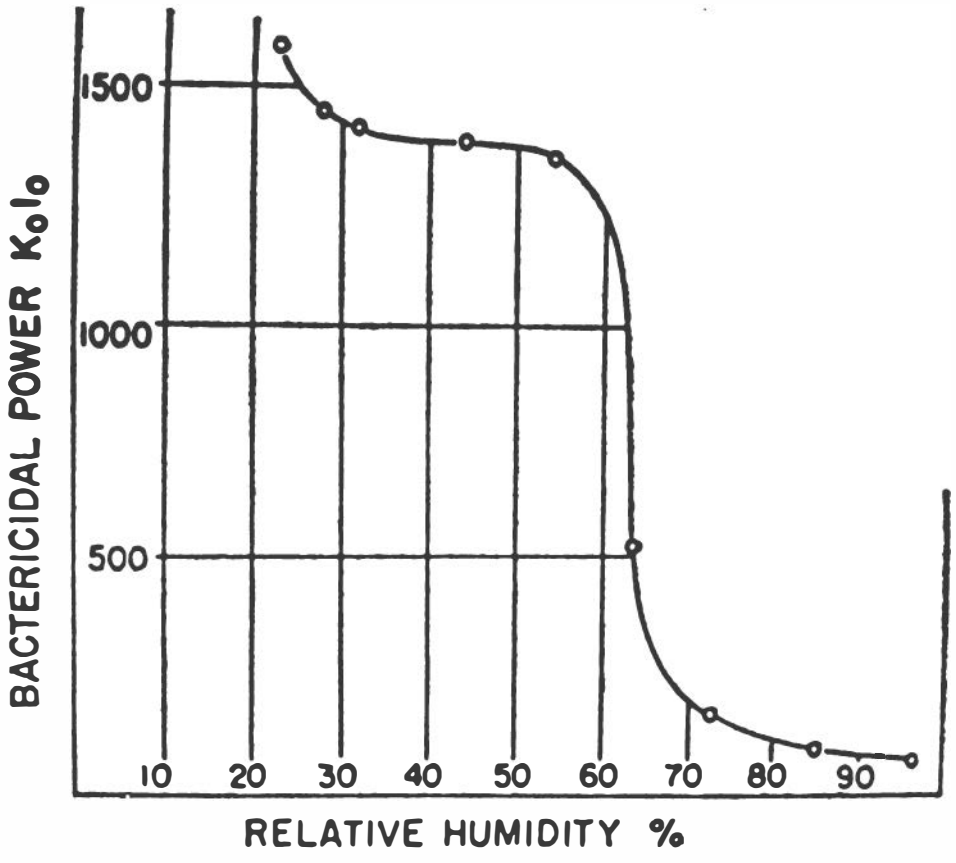

Fig. 2. Graph (from material by Lowell et al.) concerning the effect of relative humidity on bacterial power of ultraviolet light. Note that at 60 percent relative humidity there is a precipitous drop in the efficiency of the intensity of UV light.

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Fungi and bacteria will be killed within three minutes at the five foot distance. Aspergillus, a non-pathogen which grows in the sunshine and produces a large pigment, was the most resistant. It survived an exposure of 20 minutes to one hour.

The recent studies in the Duke operating rooms, demonstrated by Table 1, show that within 15 minutes the Staphylococcus aureus coagulase (+) is eradicated from the exposed areas in the operating room.

Cold air blowing on the ultraviolet bulbs will also diminish the effectiveness of the ultraviolet ray. Daily recordings of room temperature, humidity, and intensity of the ultraviolet lights are desirable. The rheostat that controls the intensity should be available to select operating room personnel, who should be instructed in monitoring the intensity of the ultraviolet light in each room daily.

The use of ultraviolet light in operating rooms at night, when there is no traffic and no activity, is helpful, but after 20-30 minutes, there are probably no viable bacteria in the room. Furthermore, with no convection currents and with no individuals in the room, the likelihood of further contamination is minimal.

The use of ultraviolet light between operating cases is not essential, although from a conditioned reflex standpoint it may be desirable. Occasionally, the lights are turned off while the room is being cleaned, and they are not turned on at the proper time for the next case. If the ultraviolet lights are off between operations and personnel are in the operating room without masks, the environment becomes contaminated. Talking, air currents, the moving of linens and other objects, all increase the bacterial count. However, once the lights are turned on and 15 minutes have elapsed, the bactericidal effect on the exposed organisms in the room and on open surfaces is sufficient to maintain the bacterial contamination at a very low to zero level.

The policy in the orthopaedic operating rooms at Duke is to keep the ultraviolet lights on continuously. The constant flow of traffic from the hallway to the operating room the conversations among personnel within the operating

room, and the frequent visits by the anesthesiologists and the operating room nurses, all provide airborne bacteria that should be eliminated. With the UV lights on and the air conditioning functioning, the environment is sanitized (Fig. 3).

In a room with unidirectional airflow a lax period between cases may not produce a high bacterial count, because rapid turnover of air continues constantly. However, with the room air changing 36 times per hour, as it does in the Duke operating rooms, the air is cleansed reasonably well after several minutes have elapsed. Bacteria that do arise from the areas of shedding, or from the respiratory tract of personnel in the room, or from other sources, may settle out on instruments, prostheses, sponges, drapes, or into the wound, and the flow of air and frequent changes may be inadequate to eliminate bacteria from these locations. Ultraviolet light will affect settled surface bacteria, just as has been demonstrated on the settle plates. Furthermore, antibiotics irrigated into the wound constantly during an operative procedure may be somewhat effective in decreasing the number of live bacteria. Systemic antibiotics may also affect bacteria that survive, provided that the proper antibiotic has been used, that the concentration is high enough, and that it is administered at the proper time. Ultraviolet light, however, is bactericidal on airborne particles. It does affect bacteria within the wound that are exposed to the UV rays, and it will kill the bacteria that appear suddenly from personnel entering the room, or from those in the room who might be shedding.

Also, the pathologic shedder or carrier is really the target of all our efforts, whether this be done with air conditioning and high efficiency filters, unidirectional airflow, antibiotics, or ultraviolet light. Gryska and O'Dea (12) emphasized that even with prophylactic antibiotics, the streptococci carried in an anesthesiologist's rectum may cause a severe epidemic. The solution to that epidemic showed that the organism was recovered from the anesthesiologist, from the settle plate within the room, and from the wound, indicating that the bacteria was primarily airborne.

The points that have been mentioned emphasize the importance of correctly positioning ultraviolet light in the operating room so that it is able to reach critical areas. The overhead UV lights should not be obstructed

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by solid ceiling fixtures that interfere with passage of the rays to the wound, to the instrument tables and to the personnel in the room (Fig. 4).

Bacteria occurring in the air settle on instruments, sponges, prostheses, and other articles used during the operative procedure. Such objects require more than unidirectional airflow for decontamination (Figs. 5-A through 5-D).

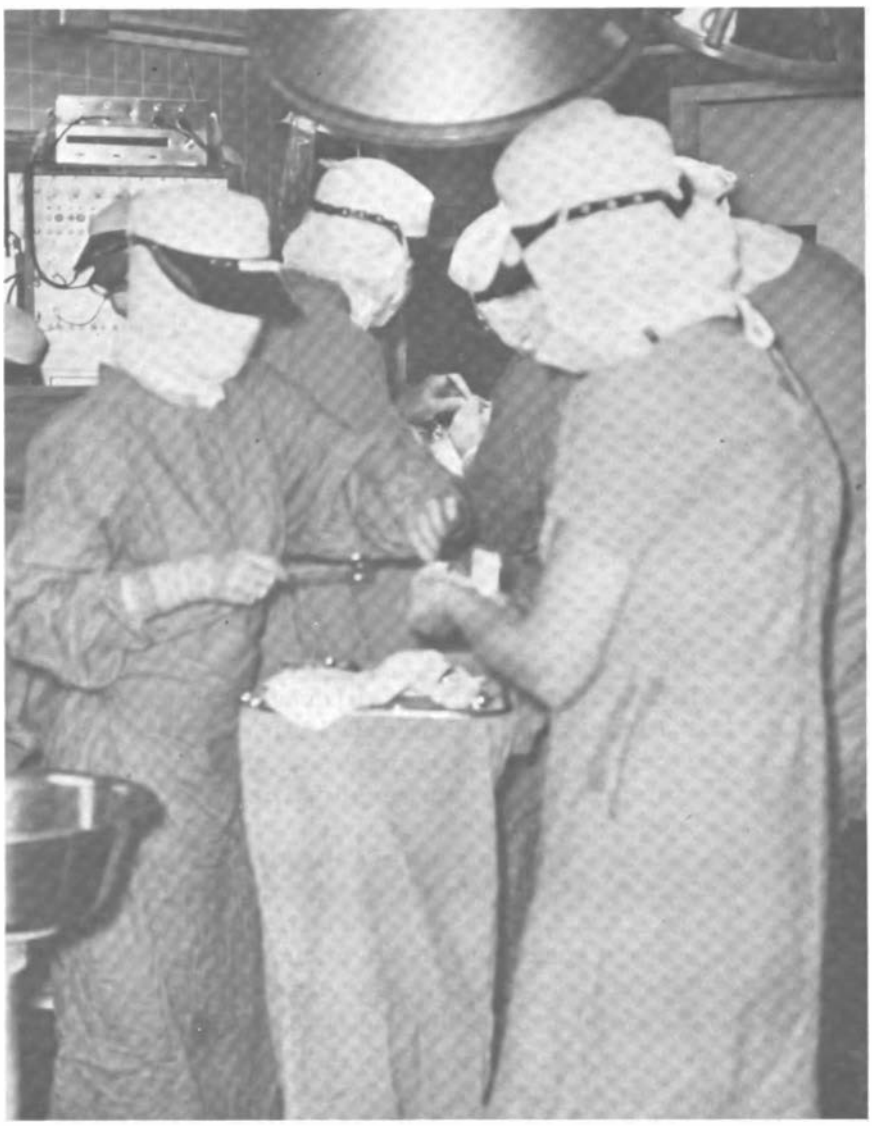

Fig. 3. Photograph taken during an operative case with UV lights on and with personnel wearing usual head and body coverage. With the intensity of 17 MW/cm^2/sec, the circulating nurse will not receive erythema of the arms. At an intensity of 25 MW/cm^2/sec, the arms will become erythematous after an exposure for an hour.

Ultraviolet Light at Duke

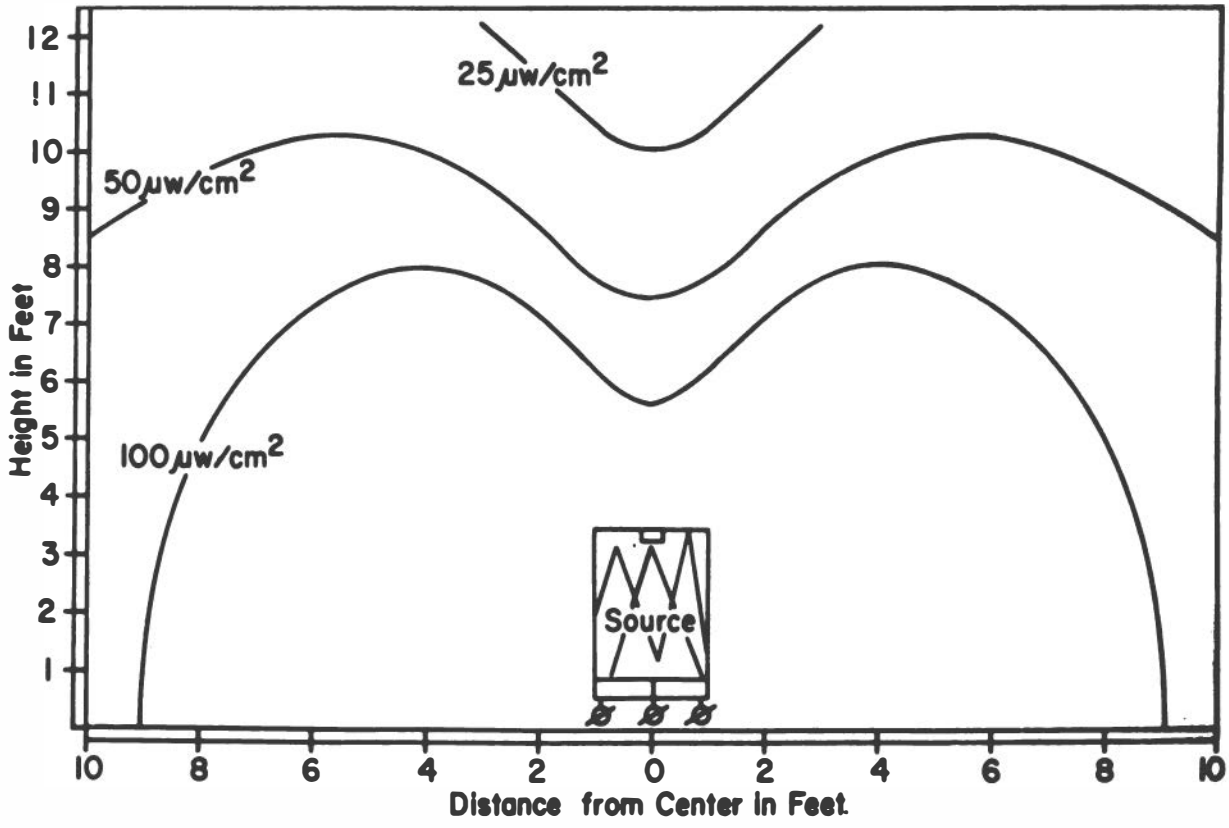

Fig. 4. Vertical intensity pattern of ultraviolet ray output (2537 AU); diagram of the intensity of bactericidal ultraviolet light measured around the central vertical axis of the Duke-Hart UV light irradiator. These intensities were measured with a calibrated UV photometer. Units are in microwatts of ultraviolet light per square centimeter of area at the distances indicated. 25 MW/cm^2 is adequate for very swift bacterial kill. This represents a floor source used for sterilizing rooms that have been contaminated by known infection or for sterilizing rooms that have been occupied by patients who are known to carry pathogenic bacteria. The same principle is applied to the operating room flooded by overhead ultraviolet light or sidewall sources.

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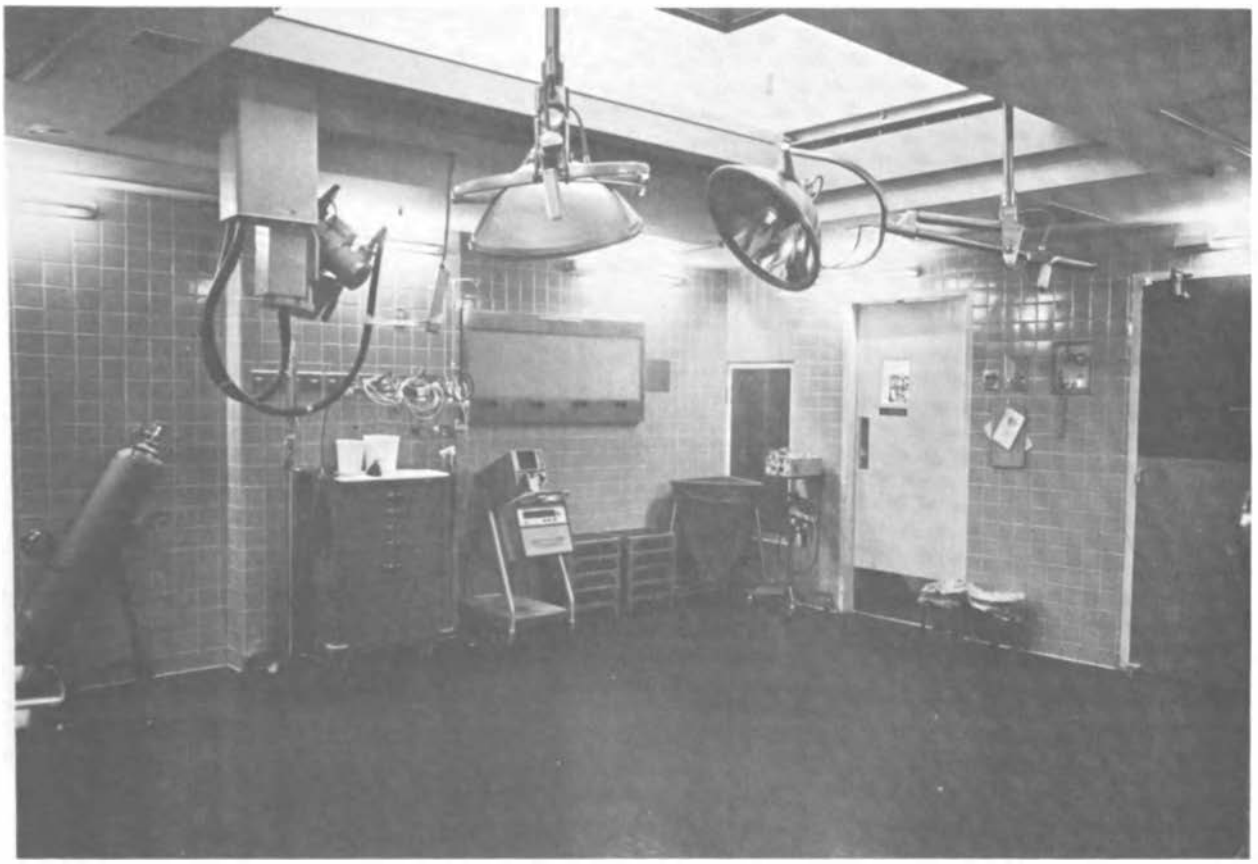

Fig. 5-A. Orthopaedic Operating Room 4 with the conventional lights off and the ultraviolet lights on. Note the UV light mounted above eye level with a protective shield. There are three lights on each wall of the room and eight lights in the overhead well. Intensity of the UV light is inversely proportional to the square of the distance. Thus, the lights at the top of the well provide adequate intensity for bactericidal effect at the level of the open surface of the operating table. The operating room adjustable, movable lights must be placed in such a way that they do not obstruct the UV light rays from the overhead well. In spite of these obstacles, however, the intensity in the room is adequate.

Ultraviolet Light at Duke

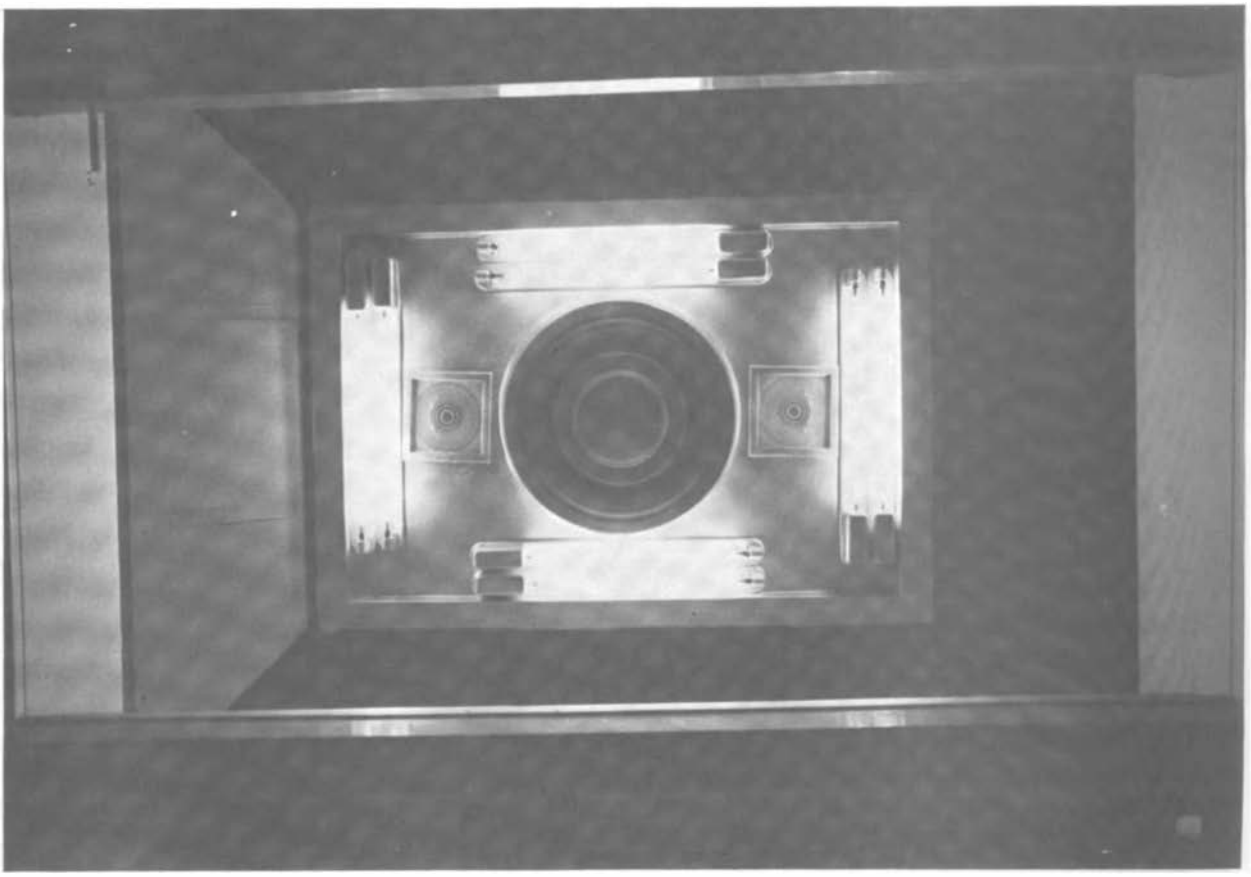

Fig. 5-B. Photograph taken from the top of the operating table showing the central disc which provides the flow of incoming air in a vertical direction. The eight ultraviolet lights, unshielded, shine directly into the room. Minor obstructions occur from the overhead spotlights which are not visible in this picture. The presence of the well enhances the intensity in that the lights can be placed far enough away from the operating table to avoid excessive exposure of the personnel standing next to the operating table. If a well is not present, then indirect lights or sidelights only are used.

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Fig. 5-C. Orthopaedic Operating Room 3 where an overhead well was not present. In order to avoid excessive intensity from overhead lights, the ceiling pans were added and the UV lights are installed within the pans. The lights are directed to the ceiling which is covered with aluminum paint and the reflected light then enters the room. Note that there are three sidelights on each sidewall. A total of 20 lights are in the room. In this situation, the overhead operating light does not obstruct the major diffusion of indirect UV light.

Ultraviolet Light at Duke

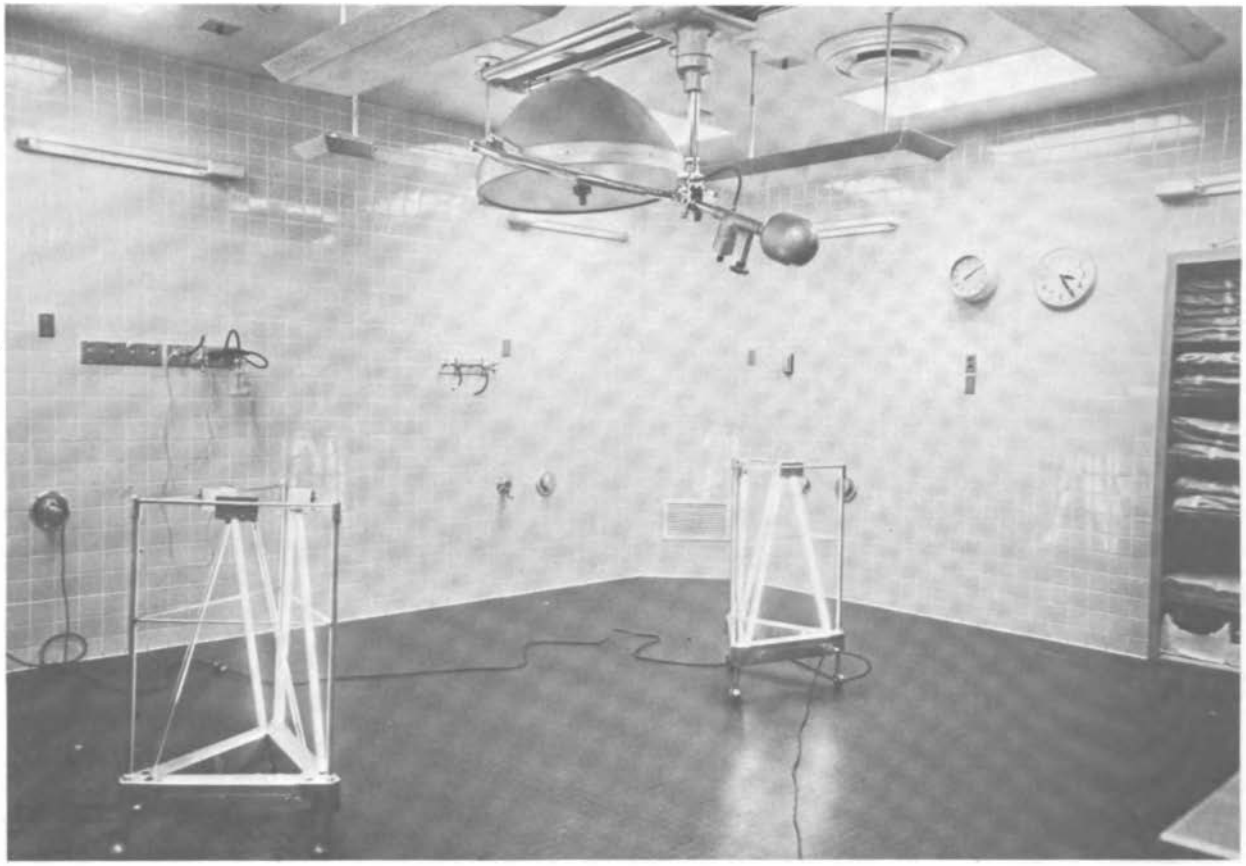

Fig. 5-D. The same room with ultraviolet lights turned off and conventional lights turned on. Note the air inflow disc in the ceiling above the wall clock. The upright Duke-Hart UV lights are used to decontaminate the floor, the sidewalls, the air and the entire room after a known contaminated wound is treated. The intensity of the upright lights is about 100 MW/cm^2/min at a distance of about nine feet. At a distance of 20 feet, these lights are still effective in killing bacteria in the air and on exposed surfaces.

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COOPERATIVE STUDY OF ULTRAVIOLET LIGHT IN OPERATING ROOMS, SPONSORED BY THE COMMITTEE ON TRAUMA OF THE NATIONAL RESEARCH COUNCIL - 1959

The study outlined by the National Research Council (NRC) was to be a controlled one where several centers in the country were selected, and ultraviolet lights were placed in selected operating rooms. Functioning lights were used in one room in the hospital and sham lights were used in another.

The problems related to testing the intensity of ultraviolet light were present at that time and were not monitored closely in each location. Just how well the intensity readings were maintained and how constant the humidity and temperature factors were maintained is not known. Certainly, as much difficulty in determining intensity was encountered then as now. Monitoring is relatively simple and should be the responsibility of supervisors who understand the purpose of the lights and the way they function. The bulbs should be clean, intensity should be logged, and the temperature and humidity should be recorded.

In spite of the variations in ceiling height in certain operating rooms at Duke, the intensity of the ultraviolet lights is still adequate to carry out the assigned task.

Because Duke has 23 years of experience with ultraviolet irradiation, and since we were convinced of its value for clean operations, we did not participate in the NRC study because half of the patients undergoing clean operations at Duke would have been operated upon without lights, and we felt that we had proven to ourselves that the risk of infection was greater for that group. In those hospitals around the country selected for the study that had depended on air conditioning and other means of preventing operating room infection, sham lights or regular lights did not affect their usual and customary routine.

Duke, however, did have an opportunity to present a parallel study without random selection but with good control at the Veterans Administration (VA) Hospital associated with Duke University in Durham, North Carolina. This hospital was not equipped with ultraviolet lights when originally built, but the house staff, the senior staff and the techniques employed in general were the same as those used at Duke where the lights were in action.

Ultraviolet Light at Duke

The Veterans Administration Hospital operating rooms did not have ultraviolet lights from 1958 through 1962. The infection rate for refined clean wounds was 1.7 percent, whereas the overall rate at Duke was 0.34 percent for 23,000 refined clean operations (a difference of five times). Emphasis should be placed on the following fact:

Operating rooms that had reasonably good environments, air conditioning with good airflow, and personnel who practiced careful surgical techniques, were associated with a relatively low infection rate. (Under three percent has usually been defined as a reasonable infection rate throughout the country.) The three-percent infection rate in refined clean cases, however, was considered to be excessively high when compared with the VA Hospital infection rate when lights were not used. Furthermore, there was no assurance from day to day that bacteria introduced into the operating room by a carrier or shedder might not be responsible for an epidemic of infection. The VA Hospital infection rate for drained clean wounds was three times higher than the Duke rate; and the rate for contaminated wounds was two times as high as those treated at Duke with ultraviolet irradiation in the room. Therefore, the latter two categories are eliminated from comparison and only refined clean operations should be considered. At the present time, with the wound hemovac being used on practically all large operative cases, another factor has been added that makes refined clean cases more difficult to define because of this special kind of drainage. The chance of infection occurring is greater because of the hemovac tube which leaves a persistent opening in the skin for a few days, but the likelihood of infection diminishes because of decrease in the size of the hematoma.

A retrospective study at Duke from 1941 to 1945 showed an unexplained infection rate of 0.34 percent in refined clean cases. Prior studies by Hart and his associates had shown that comparative groups of patients operated upon with and without ultraviolet light in the room showed noticeable differences in the percentage of positive cultures obtained from postoperative drainage of the wounds. When ultraviolet light was not used, the occurrence of a positive culture from the wound drainage was eight times more prevalent than when

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ultraviolet light had been used. Also, the amount of postoperative temperature elevation, and the duration of the elevation, was significantly less in those patients operated upon under ultraviolet light than those who were not.

The NRC cooperative study included all three categories of wounds that have already been defined: 1) defined clean cases; 2) drained clean wounds; 3) contaminated wounds. If these three categories are not separated clearly and statistics determined on the basis of individual groups, then the overall statistics will not be valid, and the conclusion will be weighted less in favor of ultraviolet light. UV light will not decontaminate a contaminated wound.

NATIONAL RESEARCH COUNCIL STUDY ANALYSIS

In the NRC study, certain conditions, such as patient population, bacterial carrier states, operative techniques or other unknowns, contributed to the wide variations, all of which cannot be determined. Suggestions were made that sources of bacteria other than through the airborne route were responsible for many infections, and ultraviolet irradiation cannot be expected to have demonstrable benefits for these.

Each hospital that participated in the NRC study showed a reduction in the contamination rate when comparing non-ultraviolet and ultraviolet light environment. Examples of some of the reductions are: 3.0 percent to 1.2 percent; 4.8 to 2.7 percent; 7.0 to 4.8 percent; 11.7 to 8.6 percent and 8.8 to 6.1 percent. These included refined and other clean, combined operations.

The hospitals with the lowest infection rate initially prior to the study showed the greatest improvement with ultraviolet light which would indicate that airborne infection is still the most important cause of operating infection in refined, clean wounds. Also, in certain hospitals where the infection rate was low without ultraviolet light, the number of patients included in the overall study must be extremely high to see a noticeable variation in the final statistics. A change from one percent to 0.5 percent would require a minimum of 200 patients. In order to avoid trends and special problems involved, the statistics should probably be based on 1,000 patients, all of whom have had the same kind of operation (total hip, spinal fusion), were operated on in the

same room, and were managed by the same personnel. Studies should have an adequate and complete follow-up by a trained individual assigned to the project who has free access to all data at all times.

The NCR study and the Duke study agreed on the following:

1. The air in occupied operating rooms without ultraviolet irradiation is contaminated with bacteria of varying degrees of pathogenicity, particularly staphylococci, which precipitate continuously on all exposed surfaces.

2. Direct ultraviolet irradiation has a highly efficient bactericidal effect which kills almost all types of organisms and will markedly reduce any airborne bacterial contamination in the operating room. (Ultraviolet light kills all bacteria, fungi, including Anthrax.)

3. With suitable protection, direct ultraviolet irradiation is safe for operating room personnel and patients.

4. With direct ultraviolet irradiation in the operating room of suitable intensity, there is significant reduction in the number of postoperative wound infections following refined clean operations.

The article (31) written in August, 1964, concerning the NRC study consisted of 192 pages. The only part of the detailed study that has been read by most surgeons is the summary. It presented in three sentences the NRC cooperative study conclusions regarding the value of ultraviolet irradiation. These are contrary to some results given in the body of the report, and are worded in such a way as to disparage the value and discourage the use of ultraviolet irradiation. Hart and his colleagues indicated that they believe the concluding summary deserved further comment "The only category of wounds that benefits significantly from the use of ultraviolet irradiation was the refined clean group in which the average postoperative infection rate was reduced from 3.8 percent to 2.9 percent" (23). An average drop of only 0.9 percent in the infection rate may not impress the casual reader, but it represents an average improvement of 24 percent for the five hospitals with the range of improvement as high as 44 percent obtained by one of the cooperating hospitals. Another way of interpreting this would mean that there was one less infection for every 100 patients operated upon. This is a significant reduction in the infection

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and morbidity rate, and a great economic saving (23). The NRC cooperative study found this decrease in infections following refined clean operations to be statistically significant. The body of the report states: "On the basis of the observed infection rate in irradiated refined clean wounds, it may be concluded that about 30 of the patients would not have had wound infections if ultraviolet irradiation had been used for all of these refined clean cases" (31).

EFFICACY OF ULTRAVIOLET LIGHT IN THE OPERATING ROOM

If the reader is willing to accept a fair interpretation of the NRC study as it referred to refined, clean cases, then the use of ultraviolet light in the operating room is the simplest, most economic, least involved method of obtaining a relatively clean environment. Hart stated:

> "The distribution in radion energy of the ultraviolet irradiation employed in the operating rooms of Duke Hospital is such that it kills virtually all exposed bacteria that ordinarily precipitate onto the sterile field or instruments from whatever source, be it exhaled breath or floating lint. The viable bacteria count in the air of these irradiated rooms at almost any point at the level of the operating table and above, averages per year less than one colony per cubic foot of air as compared to a yield of 30 to 50 colonies per cubic foot in the same occupied rooms without irradiation" (22).

Dr. Hart's quotation refers to studies done prior to installation of new air conditioning units that resulted in change of air an average of 36 times per hour. High efficiency filters were also added. The most recent volumetric samplings with and without the ultraviolet lights revealed that the number of colonies per cubic foot without irradiation and with the modifications in airflow and air conditioning are considerably less than those that were present in the non-radiated rooms when the studies were done many years ago. The results of the volumetric air sampling with and without ultraviolet irradiation during total-hip arthroplasties will be completed by June of 1975. At that time the exact figures as they relate to the many variables mentioned will be available.

OTHER REASONS FOR WOUND INFECTION

As we reviewed the present data concerning wound infection and the efforts directed toward reducing air contamination as well as endogenous sources of infection, we concluded that there may be an irreducible minimum. Hart stated:

> "The elimination of the air as a vector for pathogenic organisms and the provision of more continuously sterile operating environmental surfaces through direct bactericidal irradiation does not prove, by any means, that all unexplained infections after clean operations originate from these sources of contamination. Because of inability to prove the exact source and mode of infection after clean operations, the arguments by surgeons for and against the various possible sources and causes will obviously continue for some time to come. Some will feel that most postoperative infections in clean wounds originate from viable organisms left on or washed up from the pores of the patient's skin; others will be sure that they mainly follow breaks in sterile technic such as punctured rubber gloves, or that they are endogenous from some other infected site within the patient. Certainly, all of these sources and others could be mentioned and they undoubtedly do contribute many infections. However, based on our results from 30 years' experience operating under direct ultraviolet irradiation, we feel that
>
> 1. most unexplained postoperative infections, which occur after clean operations, have their origin in the operating room while the wound is open;
>
> 2. some of the principal sources of the offending bacteria are the mouths, throats, and noses of the operating room occupants; and
>
> 3. the organisms from these sources, along with those on lint and other floating particles, reach the sterile field, the

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instruments and the wound by way of continuous sedimentation through the air. Our studies indicate that ultraviolet irradiation will effectively eliminate this air route or spread of infected organisms, and prevent their continuous sedimentary build-up on all exposed surfaces during operations of any duration" (23).

Altemeier, in a discussion of the use of UV light in the operating room, mentioned the study done at the institution in which he works and pointed out that the rooms with the UV lights on had an infection rate of 1.1 percent and those with the lights off, an infection rate of 0.3 percent with an average of 0.7 percent (2). This indeed is a low percentage and reemphasizes the fact that careful, atraumatic surgical technic, limited traffic, and other factors can be effective in diminishing the infection rate (2). However, the guarantee for any particular patient, or at any particular time, does not exist unless some other element is constantly functioning.

Altemeier found that aspirated saline, which had puddled in the wound, contained bacteria that were endogenous to the patient. His efforts have been on masks, gloves, skin preparation, tissue handling and other technics rather than alteration of the bacteria in the air. Furthermore, Altemeier's allusion was to all kinds of operative procedures -- clean and contaminated -- while the emphasis at Duke in gathering statistics has been on evaluation of ultraviolet irradiation on refined clean wounds. Ultraviolet light cannot clean a wound that is deeply contaminated. Dunphy (6) has emphasized that with parallel experimental wounds, one being contaminated by bacteria but tissues being handled carefully, and the other being uncontaminated and scrupulously clean but traumatized, the latter showed a greater tendency to infection than did the former. Altemeier emphasized the importance of tissue necrosis and tissue trauma as it relates to the occurrence of wound infection (2). Thus, any particular incidence of infection must be analyzed with consideration of 1) endogenous bacteria from the patient's foci, 2) the operative procedure to be done, 3) the number of operations that have been done in this same anatomic

location in the same patient, 4) that patient's resistance, 5) medications being received by the patient that might affect resistance, 6) the amount of time taken to do the operation, 7) the amount of trauma involved in doing the operation, and 8) the use of prophylactic or actual antibiotics and their effect on particular organisms (proof of effectiveness against all infections is still not available). Various kinds of clean air, i.e., vertical and horizontal laminal airflow, have definitely been shown to reduce the infection rate in situations where the basic percentage of infection was extremely high, and the quoted rate in laminal airflow (5) is now at 2.0 to 0.5 percent or less. The latter figures, of more recent origin, compare favorably with the extremely low infection rate in the Duke orthopaedic operating rooms under an ultraviolet light environment during the past 37 years.

Tables 3-A through 3-C demonstrate the air quality study data in Orthopaedic Operating Room 4 during total-hip arthroplasty with the lights off. They demonstrate the efficacy of the air conditioning system in this particular operating room suite and show the colony-forming groups collected during various stages of the procedure. The stages are described within the content of the paper. Table A demonstrates the type of colony-forming groups recovered at the particular time and stage of the operation. The two columns on the right give the results of the Agar plate cultures in colony-forming groups per cubic foot per minute (CFG/ft^3/min) and the same numbers for magnification purposes in colony-forming groups per five cubic feet per five minutes (CFG/5 ft^3/5 min). The latter can be used for better visualization of a graph, but the actual numbers on the right are significant. Table B shows the number of times the doors were opened and closed. This is more important if there is an indication as to when an individual enters or leaves the room. Table C is a graph showing the number of colony-forming groups as it relates to stage of operation.

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Table 3-A. Type of CFG Recovered at the Particular Time and Stage of the Operation

OR ROOM# 4
DATE 2-08-74
UV LIGHTS Off
TYPE PROC. Total Hip - Left

PLATE #	OPER. STEP.	TIME	RESULTS	#CFG/5FT^3 /5 MIN.	#CFG/FT^3 /MIN.
1	1	8:19-8:24	1CFG Fungus; 5CFG Bacillus sp.:	6	1.2
		8:24-8:29	1CFG Fungus; 2CFG Bacillus sp.: 1CFG S. epid. 3CFG Diphtheroids	7	1.4
	2	8:29-8:34	2CFG Bacillus sp.: 3CFG Diphtheroids	5	1.0
		8:34-8:39	1CFG Bacillus sp.: 1CFG S. epid.	2	0.4
	3	8:39-8:44	4CFG Bacillus sp.; 1CFG S. epid.;	5	1.0
		8:44-8:49	4CFG Bacillus sp.: 2CFG S. epid.:	6	1.2
2		8:50-8:55	4CFG Bacillus sp.: 5CFG S. epid.: 2CFG Diphtheroids	11	2.2
	4	8:55-9:00	4CFG Bacillus sp.: 1CFG S. epid.;	5	1.0
		9:00-9:05	2CFG Bacillus sp.; 1CFG S. epid.:	3	0.6
		9:05-9:10	2CFG Bacillus sp.: 1CFG S. epid. 3CFG Diphtheroids	6	1.2
	5	9:10-9:15	2CFG Bacillus sp.: 1CFG Candida sp.: 2CFG S. epid.: 2CFG Diphtheroids	7	1.4
		9:15-9:20	5CFG Bacillus sp.: 4CFG S. epid.:	9	1.8
3	6	9:21-9:26	1CFG Fungus	1	0.2
		9:26-9:31	1CFG Bacillus sp.:	1	0.2
	7	9:31-9:36	4CFG Fungus: 3CFG Bacillus sp.: 1CFG S. epid.	8	1.6
		9:36-9:41	1CFG Fungus: 1CFG Diphtheroid-	2	0.4
		9:41-9:46	1CFG Bacillus sp.: 1CFG S.epid.; 1CFG 1CFG Micrococcus sp.;	3	0.6
		9:46-9:51	1CFG Bacillus sp.;	1	0.2
4		9:52-9:57	1CFG Bacillus sp.; 4CFG Diphtheroids	5	1.0
		9:57-10:02	2CFG Diphtheroids: 3CFG S. epid.:	5	1.0
		10:02-10:07	3CFG Bacillus sp.:	3	0.6
		10:07-10:12	3CFG Bacillus sp.:	3	0.6
		10:12-10:15	1CFG Bacillus sp.; 1CFG S. epid.:	2/3Min.	0.7
TOTAL 113				106	0.9

Ultraviolet Light at Duke

Table 3-A. Continued

OR ROOM # 4
DATE 2-08-74
UV LIGHTS Off
TYPE PROC. Total Hip -Left

PLATE#	OPER. STEP	TIME	RESULTS	#CFG/30FT^3 /30MIN	#CFG/FT^3 / MIN
1	1-3	8:19-8:49	2CFG Fungus: 18CFG Bacillus sp. 5CFG S. epid. 6CFG Diphtheroids	31	1.0
2	3-5	8:50-9:20	1 CFG Candida sp.: 19CFG Bacillus sp.: 14CFG S. epid.: 7CFG Diphtheroids	41	1.4
3	5-7	9:21-9:51	6CFG Fungus: 6CFG Bacillus sp.: 2CFG S. epid. 1CFG Micrococcus sp.: 1CFG Diphtheroids	16	0.5
4	7	9:52-10:15	8CFG Bacillus sp.; 4CFG S. epid. 6CFG Diphtheroids	18/23Min.	0.8
TOTAL		113		106	0.9

Table 3-B. Number of Times the Doors were Opened and Closed

NUMBER OF TIMES DOORS OPENED OR CLOSED

OR DOOR	SCRUB ROOM DOOR	INDUCTION ROOM DOOR
24	22	15

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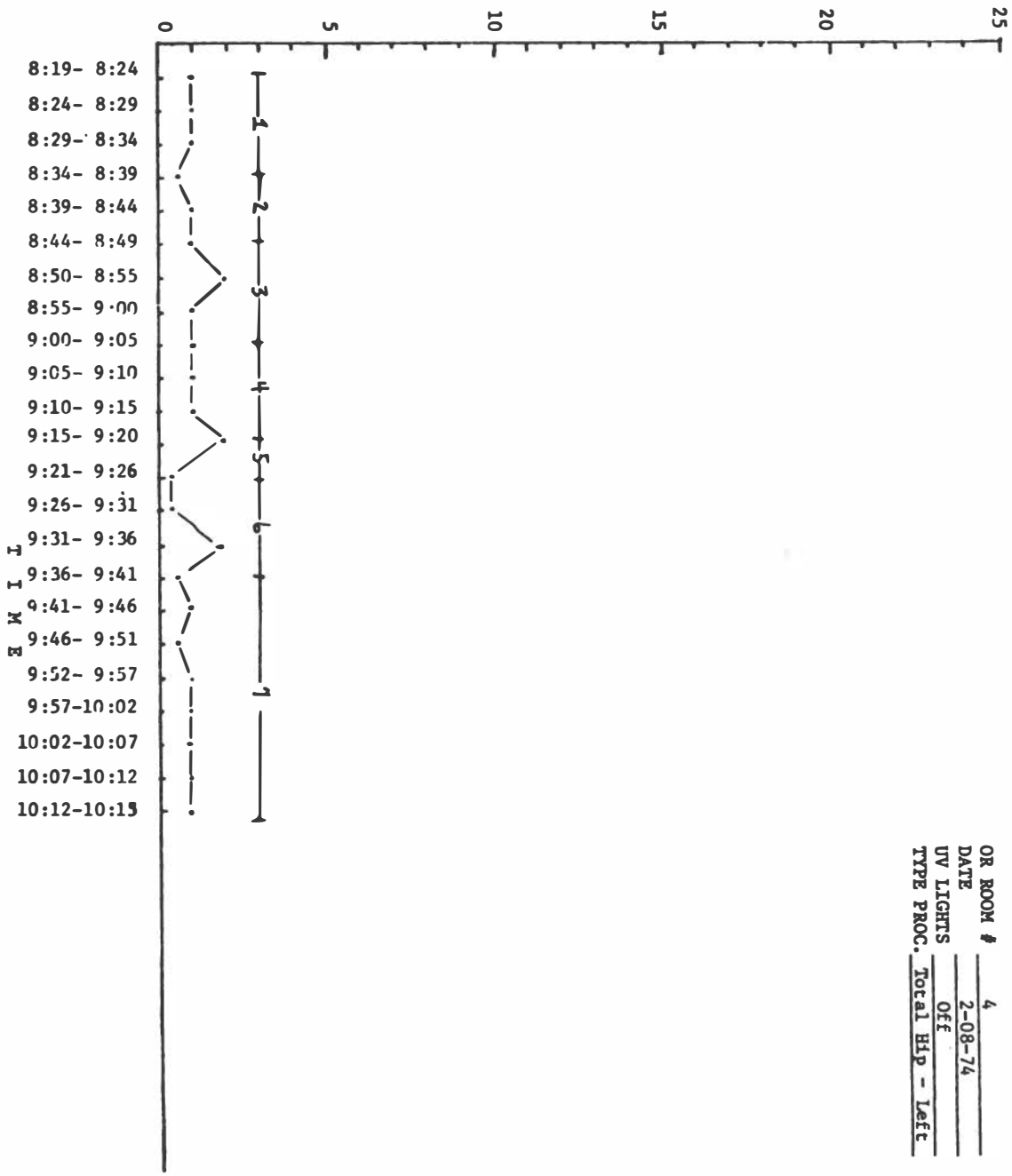
Table 3-C. Graph Showing the Number of CFG as it Relates to Stages of Operation



Ultraviolet Light at Duke

SUMMARY

In order to provide clean air and sanitized objects in the operating rooms at Duke University, Hart installed ultraviolet lights approximately 40 years ago. This method of diminishing the concentration of airborne bacteria has allowed the Orthopaedic Service at Duke to report an infection rate on refined clean cases of less than one percent per year during a 37-year period. Ultraviolet irradiation of a specified intensity is effective in killing pathogenic bacteria and fungi within 15 minutes of exposure. Various methods of doing air sampling and bacteria fall-out concentrations have been utilized in order to determine the environmental conditions in the Duke operating rooms. These studies show that ultraviolet irradiation will sanitize the air and objects in the operating room. If the patients and the personnel in the operating room are protected by appropriate skin covering and glasses, there is no harmful effect from the ultraviolet light. The tissues exposed in various kinds of wounds are not affected adversely. Airborne bacteria are the most important causes of wound infection, but other conditions such as self-contamination from urinary tract or abscessed teeth, contamination of the operating site from adjacent areas such as the perineum, contamination of hematoma from adjacent skin caused by wound drainage or by openings in the skin, or involvement of the hematoma by bacteremia, all can account for wound infection. Also, insufficient air turnover, and inadequate air circulation due to dirty air filters lead to excess sweating of individuals in the room. These conditions are not eliminated by ultraviolet light, nor by any other type of external air flow. The authors reviewed the National Research Council Study and point out that the evidence indicated that whenever ultraviolet light was used, the incidence of infection when refined clean cases were involved was diminished. Experience with total-hip operations is parallel to experience with all other refined clean orthopaedic cases with respect to the incidence of infection. Statistics quoted by those using laminal airflow compare favorably with those from ultraviolet environment.

Ultraviolet Light at Duke

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APPENDIX A

J. Leonard Goldner
Robert W. Gaines
Mary Higgins

EQUIPMENT NECESSARY FOR INSTALLING ULTRAVIOLET LIGHTS IN OPERATING ROOMS AND FOR PROTECTING PERSONNEL WORKING IN THOSE OPERATING ROOMS FROM THE ULTRAVIOLET LIGHT

Ultraviolet fixtures (brackets for lights) Model PF511 - Atlantic Ultraviolet Light Co., purchased through Biddle Purchasing, 10 Riverside Plaza, Chicago, Ill., 60606 (estimated cost $30 each).

Strato-Ray Co,. 6500 Walker Street, Minneapolis, Minn., 55426: Manufacturers of Strato-Ray Air Sanitizer. Distributors of Westinghouse Sterilamp Germicidal Ultraviolet Tubes. You may write to this company for information concerning UV light equipment installation.

Variac Control Switches - Two for each operating room (one for the top lights and one for the side lights - controlled separately). This regulator switch establishes the intensity of the lights. Order from General Radio Co., West Concord, Mass., Box 872, Boston, Mass., 02103. Request a W-5 Variac, catalog #3030-5110 (estimated cost $25 each).

In addition to this Variac, a control switch (custom enclosure) is necessary for each specific room design.

Monitoring equipment - commercial meter - purchased from Ultraviolet Products, San Gabriel, Calif., 91778, Model #J-225, (estimated cost $125).

More efficient monitor and one that can be used by the nurses in the operating room is Germicidal Photometer (IL 254) from International Lights, Newburyport, Mass., 01950, (estimated cost $600).

Sterile lamps for the fixtures manufactured by Westinghouse, catalog #WL 782-L30, #5B-30, obtained from Millpower Inc., Box 299, Charlotte, N.C., (estimated cost $15 each).

Portable ultraviolet lights are used at Duke for additional decontamination of the operating room following contaminated cases; they are manufactured by Ward Laboratories, 727 Markham Avenue, Durham, N.C., estimated cost of $800 each. Also, a different size lamp fixture, one inch shorter than the lamps for the wall units, must be obtained from Millpower Co.

Additional miscellaneous information concerns the protective head coverings and glasses for protection of individuals working under the ultraviolet lights. The hoods can be purchased from several different manufacturers including Spartan Health Care in Spartanburg, S.C., 29301, #HOD409, 50 per box, 48 boxes per case at $37 per case or American Hospital Supply (check with your local dealers) convertors #4381 (also American Hospital #47325-012), 100 per case at $16.50 per case, 3700 Atmore St., Charlotte, N.C., 28205.

Ultraviolet Light at Duke

The protective glasses are purchased from Watchemaket Optical Co., Inc., Providence 3, R.I., Catalogue #CSSF-412 Tuck-A-Way Glasses, 1 per box at $3.25 each. The green visors are purchased from Krisloid Plastics, Inc., Corner Eddy & Porter Streets, Providence, R.I., 02905, #LBX Shades, green, 12 per box at $55 per gross.

TWO CONSIDERATIONS IN THE APPLICATION OF LAMINAR CLEAN AIR

Edward O. Goodrich, Jr.*

In considering possible surgical applications of ultra-refined air systems, I would like to emphasize two frequently overlooked points. These considerations arose during early attempts to apply "laminar clean" air techniques to the general surgical environment.

We were given a four-foot by four-foot vertically adjustable cross flow High Efficiency Particulate Air (HEPA) filter unit capable of projecting clean air uniformly from the filter face at a linear rate of 100 feet per minute or one mile per hour (1600 cfm)(Fig. 1). When running in an empty room, a standing pyramid of clean air (as measured by near zero counts on all channels of a Royco model 200B particle counter from 0.3μ to 10μ, sampling 300 cc of air per minute) projected outward from the lip of the unit to a distance of approximately four feet at the apex. This clean zone was surrounded by a standing outward radiating zone of turbulent mixed clean and ordinary room air. The standing mixed zone contained much cleaner air than the surrounding room. However, when the unit had been operating in the room for an hour or more, the entire room became cleaner because the room volume was only 2800 cubic feet with 12 changes per hour, so that a volume of air equal to the total room volume was being completely cleared of measurable particles every two and three-eighths minutes, and by dilution and turbulent mixing alone, a five-fold decrease from 10,000 to 2,000 particles was observed in the ambient room air.

Measuring particle counts at the wound when it was possible to position and drape the patient so that the wound could be approached from the side, and the part to be operated upon could be placed well within the clean pyramid, such as for a hand or foot procedure, it was possible to operate without registering any particles. However, in the ordinary laparotomy configuration, with the unit at the foot of the table blowing towards the head, counts averaging 500/300 cc were obtained (Fig. 2).

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*Santa Fe, New Mexico. (Chairman, Subcommittee on Air Environment, Committee on Operating Room environment, American College of Surgeons).

Edward O. Goodrich, Jr.

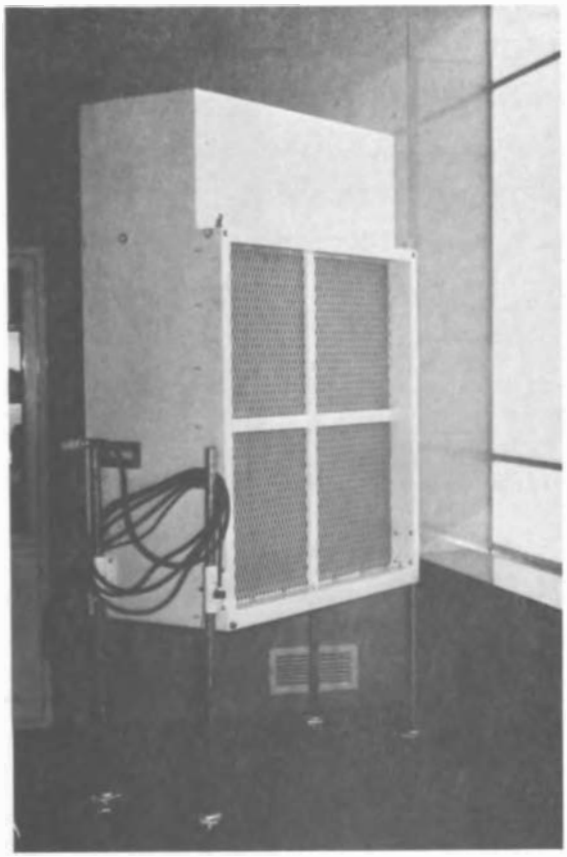

Fig. 1. · HEPA filter unit.

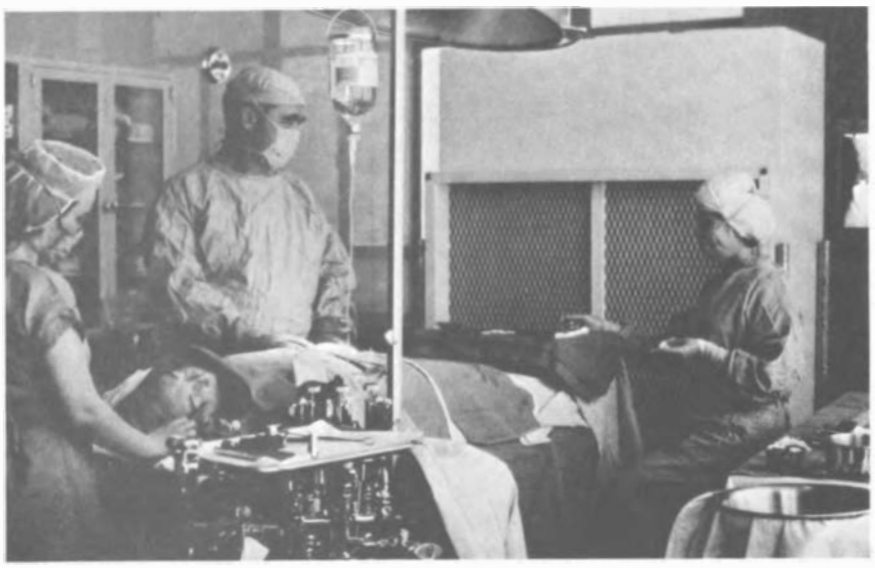

Fig. 2. Configuration of HEPA filter unit at foot of table, blowing towards the head.

Two Considerations in the Application of Laminar Clean Air

In attempting to contain and direct the clean air towards the abdomen, first bottom, then side drapes were added (Fig. 3). This lowered the counts to the 100/300 cc range, but we were still unable to transfer filter face conditions to the sensitive area, and we could not understand why. Only after extensive smoke testing, did we realize that the channeled column of air, which was otherwise maintaining piston characteristics, gradually lifted upward from the bottom sheet as it proceeded away from the filter face, causing room air to be aspirated in a reverse flow from the head of the table, for a distance of three feet in a layer approximately one inch thick right over the bottom drape and the wound.

To control this aspiration, we added a plastic cover to the side drapes (Fig. 4) and then were able to obtain counts in the 0 - 10/300 cc range just upstream from the wound (Fig. 5). Downstream counts were less reliable, since we would occasionally and inadvertently misplace a gauze sponge, or a starch-bearing gloved hand, adjacent to or over the sampling tube. When not so distorted, the downwind counts were usually in the 10 or less range. In all these configurations, the nurse and the instrument stand were positioned

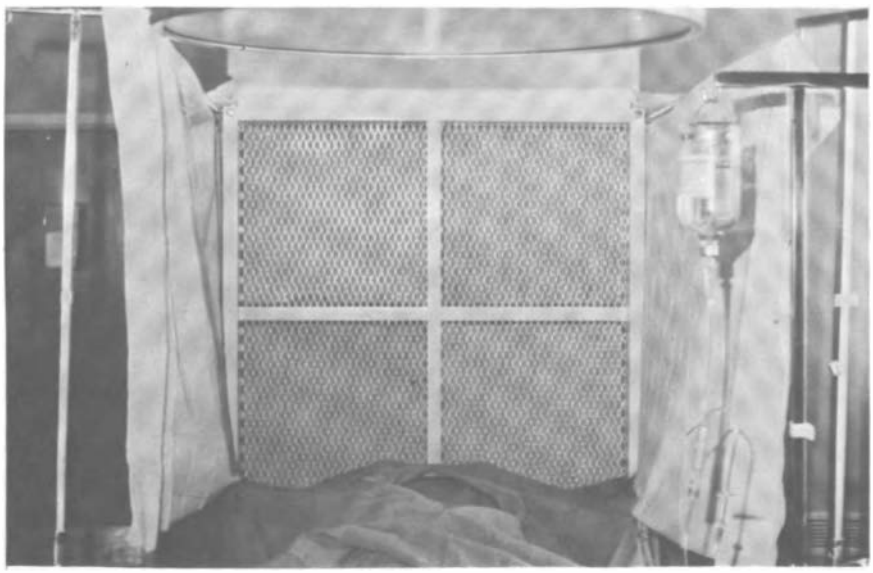

Fig. 3. Unit with bottom and side drapes added.

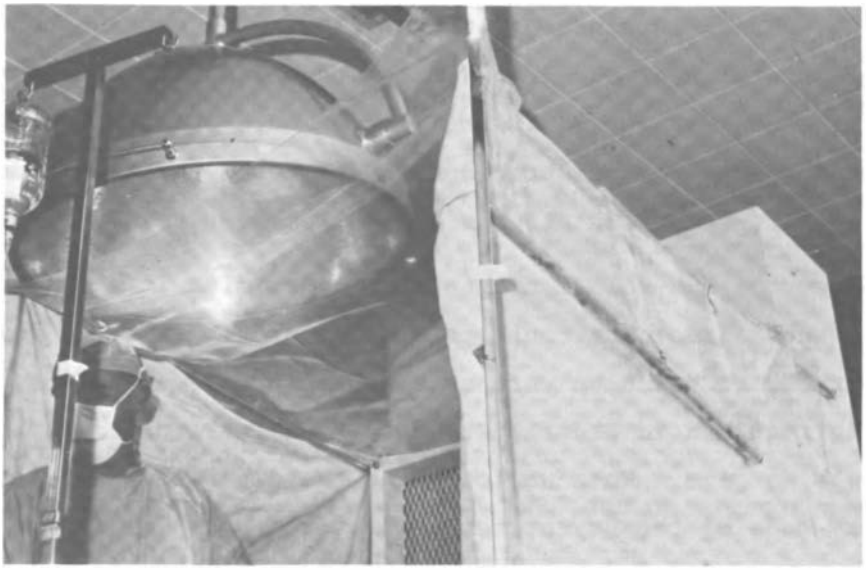

Fig. 4. Unit with plastic cover added to side drapes.

Fig. 5. Obtaining count upstream from wound.

downwind from the wound, and the stand was draped to create the least possible resistance to, and disturbance of, the airflow. Air passage above and below the horizontal portion of the draped Mayo stand was also demonstrated by smoke tests. Using these draping modifications, we were able routinely to perform two- and three-hour abdominal procedures with total particle counts below 10 per 300 cc of air, measuring all particles from 0.3μ to 10μ in diameter.

Since the natural distribution of particles is heavily weighted toward the lowest sizes, one could reasonably expect that the fewer-than-ten particles per 300 cc which we were able to measure (starting at 0.3μ instead of 0.5μ as is required in Federal Standard 209B) were primarily particles of less than 0.5μ in size. When we looked at the sizes of particles using the discretionary mode of the Royco, few were over 1.0μ. Yet it has been well established that bacteria-laden particles are usually over 4.0μ in diameter. Therefore, although one could reasonably state, as has been done several times at this workshop, that viable particle counts are not related to total particle counts, on the other hand, one must be prepared to accept very low total particle counts, especially when measuring at 0.3μ and up rather than at 0.5μ and up, as excellent inferential evidence that this air is sterile, since there exists work which tends to indicate that an average relationship between total particles 0.5μ to 10μ to viable particles is 1000 to 1.

Further, without testing with smoke any ultra-refined room or unit in its full working configuration with machines, people, lights, and drapes, the prediction of the flow of its air currents is nearly impossible. It is only by visualizing the currents that the vagaries of their distribution will be appreciated.

STANDARD TECHNIQUES TO REDUCE OPERATING ROOM BACTERIA

Howard P. Hogshead*

This paper is devoted to a discussion of those techniques which can be used in the average operating room to reduce bacterial contamination. This implies the use of conventional air handling systems and conventional apparel. Time does not permit a review of the history of aseptic surgery; only a few topics can be discussed in this paper. Based upon some recent research studies some suggestions for control of bacteriological hazards in the average operating room will be offered.

Several studies of the total operating room environment have been reported recently. Such studies must be carried out on a grand scale. A mass of data is collected concerning the particles and the bacteria in the air in several locations around the room, the surgical wound, the surgical team and the surgical equipment. Inherent weaknesses of these studies are the vast number of variables. These variables are difficult to control, since they include changing members of the surgical/anesthesia/nursing team, changing surgical patients, breaks in surgical technique, and variance of surgical procedure. Any attempts to relate bacteriological studies to the terminal event--a clinical wound infection--are fraught with further difficulties. At the current low rate of infection, the study of a vast number of cases is required to yield a statistically significant difference between two differing surgical techniques. Because of the difficulties involved in such studies of the total operating room environment, an alternative method of study was selected.

METHOD

In order to eliminate variables and to study individual factors in a controlled environment, a small, sealed "clean-air" room was constructed (Fig. 1). Construction of this unit and subsequent studies described herein were the results of the efforts of several people, including Dr. Charles L. Rogers, M.D., Joseph Morris, M.D., and Jeorge Franco, Ph.D. This unit permitted the study of personnel, operating room dress, and operating room activity.

*Director of Rehabilitation, Cathedral Health and Rehabilitation Center, Jacksonville, Florida.

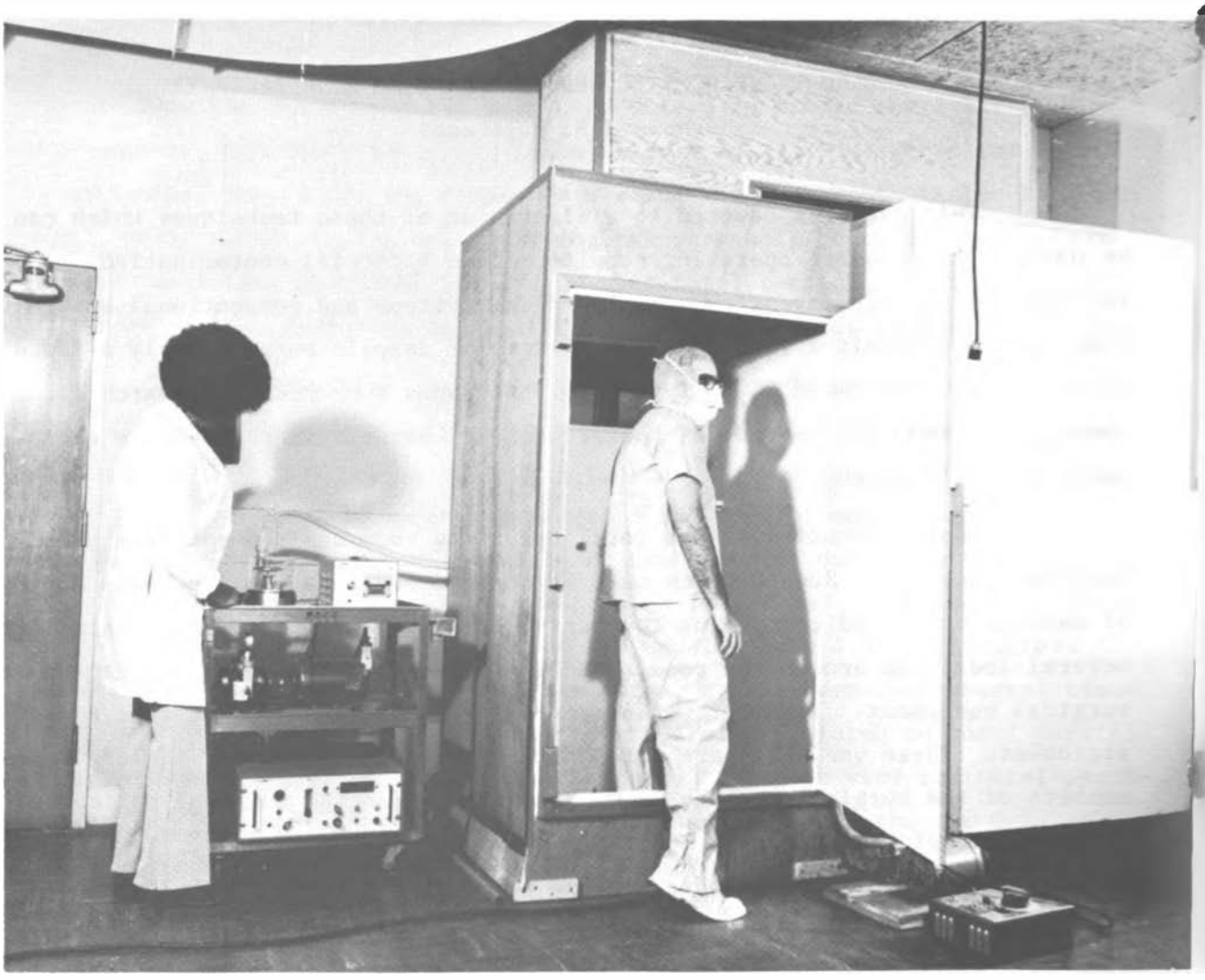

Fig. 1. The "telephone booth" used to study 18 individuals, three types of apparel, and three types of activity. The fans and HEPA filters are at right. High velocity, sterile air is directed through the duct and down into the chamber to flush extraneous particles and bacteria prior to the ten-minute sampling period. Waist-level ports lead to the slit sampler and particle counter at left.

Ports in the walls of the "telephone booth" allowed for sampling of the air surrounding the individual being studied.* Through one port, the air was drawn through a 7/8 in. Tygon tubing 5 ft. in length. A slit sampler capable of plating out airborne bacteria was used to determine the colony-forming units present in two cubic feet of air aspirated from the booth during a ten-minute sampling period. A clockwork mechanism turned the sheep's blood agar culture

*A grant from the Florida Orthopaedic Society was of assistance in funding the "telephone booth."

plate. The culture plates were read at 48 and 72 hours. A second port in the booth led off to a Climet photoelectric particle counter capable of counting particles larger than 0.5 micra in diameter. The counts were printed on a digital printout tape for each minute of testing.

The procedure used for the study required cleaning the walls of the booth and flushing the air with high velocity, High Efficiency Particulate Air (HEPA) filtered air. The experimental subject was then placed in the booth. The sterile air flush continued for an additional two minutes. The airflow was turned off and the subject was evaluated for the first sampling while standing quietly. The booth was then flushed with HEPA filtered air for two minutes and the subject was evaluated for a second ten-minute period while coughing and talking. The air in the booth was again flushed for a two-minute period. During a third ten-minute sampling period, the subject was required to walk in place.

Each individual was first studied for three ten-minute sampling periods while wearing an ordinary surgeon's scrub suit without cap or mask. Hands and arms were not covered. During the second series of three ten-minute sampling periods, the experimental subject was dressed in a surgeon's gown with paper hood, paper mask, shoe covers, and surgical gloves. The surgeon's gown was a conventional loose-weave linen fabric. During a third series of three ten-minute sampling periods, an aspiration suit was worn by the subject. In addition to removing air from around the individual's head, neck and face, the hood provided complete coverage of the head, neck, face, shoulders and upper torso. The fabric of this aspiration suit was a loose-weave linen similar to the common surgical gown. Surgical gloves and shoe covers were worn with the aspiration suit. One group of four individuals tested an aspiration suit of similar design but made of tightly woven fabric (Bar Bac).

In this fashion three activities and three types of apparel were studied.

RESULTS

The fourteen members of the Orthopaedic Surgical Department of the University of Florida were studied for their bacterial- and particle-shedding

characteristics. Additionally, four female operating room technicians from another hospital were evaluated. Sampling periods lasted at least two hours. The temperature ranged from 70 to 80°F and the humidity averaged 70 percent.

The particle counts yielded no correlation with the bacteriological counts. At best, the particle counts indicated the amount of linen within the booth during the sampling. These data are omitted from the report.

Data obtained from the slit sampler agar culture plates on the 18 experimental subjects are shown in (Fig. 2).

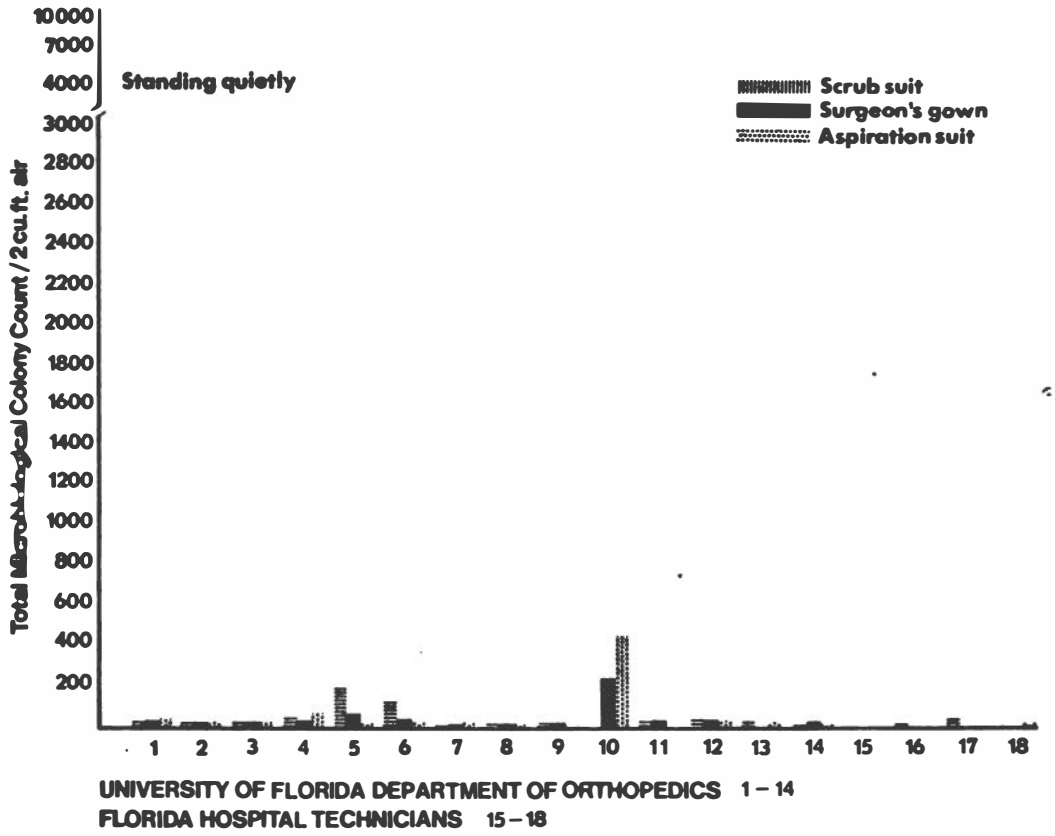

Fig. 2. Standing quietly while dressed in scrub suit, surgeon's gown, and aspiration suit. Individuals retain the same number throughout the graphs. Watch Number 5 and Number 10.

While standing quietly, most subjects lofted only a few viable particles into the air during the ten-minute period. Only small differences were evident between the sampling periods when the individual was dressed in a scrub suit, a

surgeon's gown or an aspiration suit. It is noteworthy that individuals Number 5 and Number 10 shed bacteria at rates in excess of their colleagues. (The number designation in the graphs remains unchanged throughout these figures.) With a few exceptions the scrub suit colony count is highest, the surgeon's gown colony count is lower, and the aspiration suit bacterial colony count is the lowest of the three.

Talking and coughing (Fig. 3) produced a slight increase in colony counts for all individuals. Again individuals Number 5 and Number 10 are noted to shed a greater number of bacteria than their colleagues.

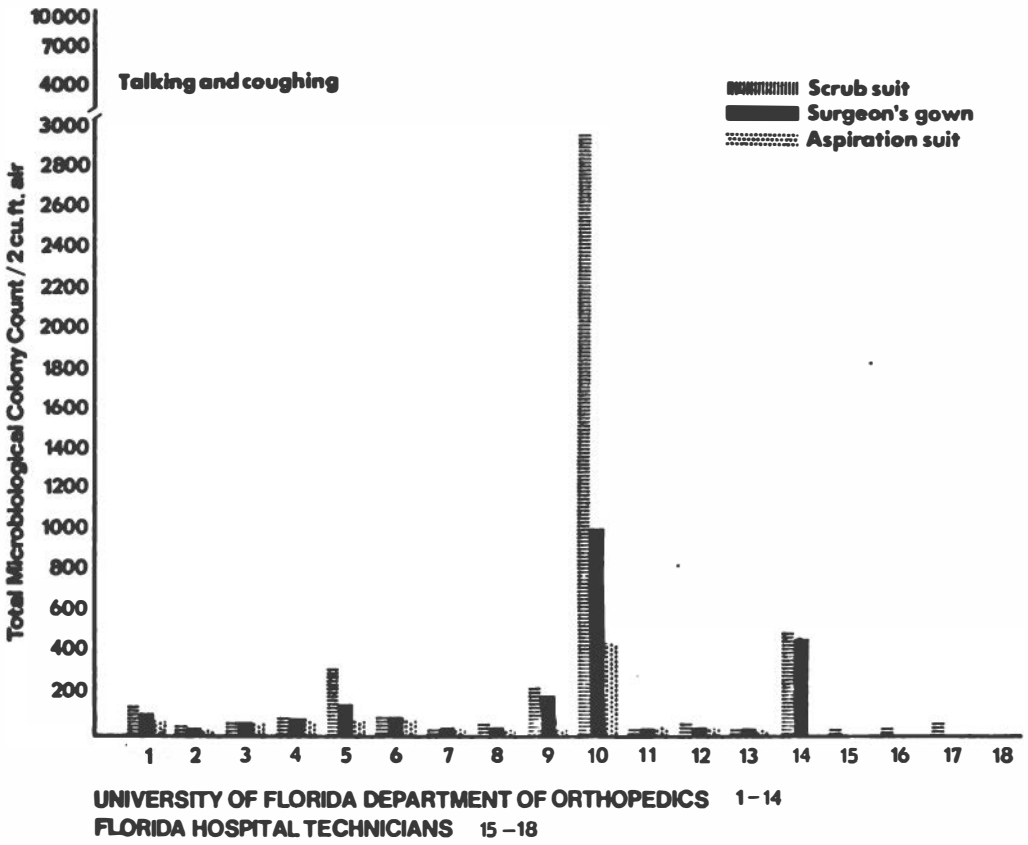

Fig. 3. Talking and coughing while wearing three different types of apparel.

Walking in place (Fig. 4) resulted in dramatic increases in the number of bacteria scattered into the air. Again individuals Number 5 and Number 10 are noted to be extremely productive of active colony-forming units. In both cases a coagulase-positive Staphylococcus aureus accounted for the majority of these organisms.

Howard P. Hogshead

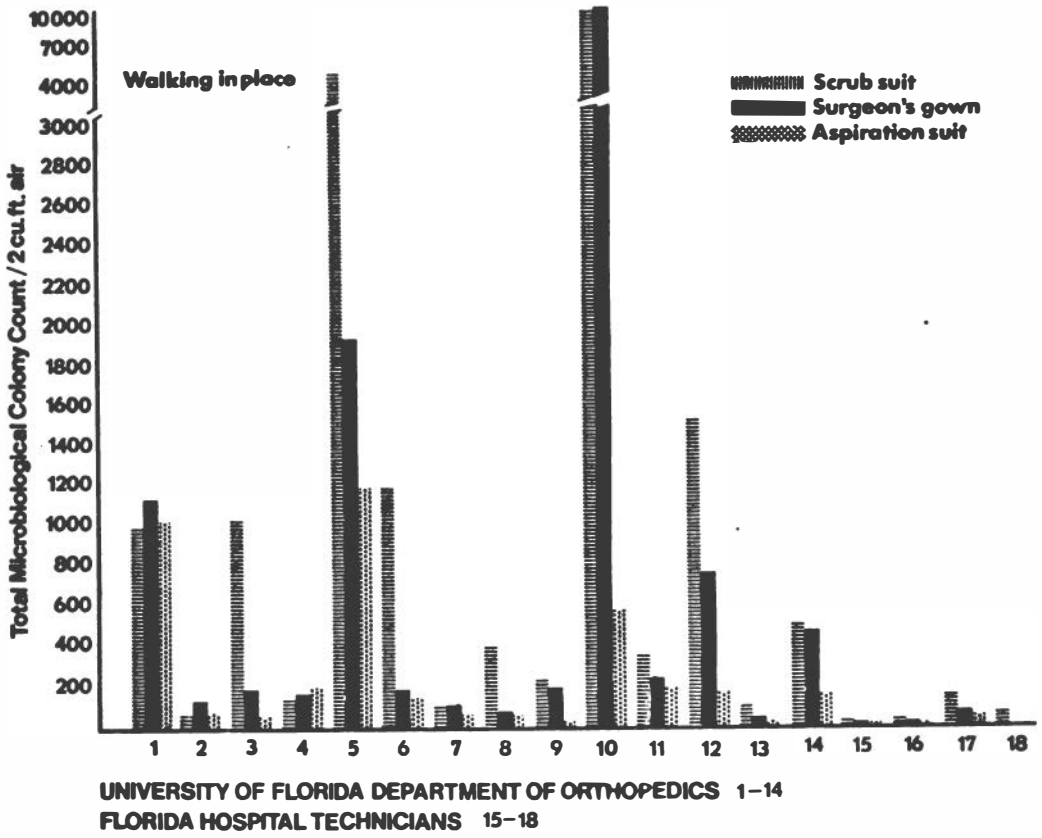

Fig. 4. Walking in place while wearing three different types of apparel. The vertical scale has been broken to accommodate the data. Number 5 and Number 10 are Staphylococcus aureus shedders.

To provide further comparisons of the three types of activity, the same 18 individuals are shown in (Fig. 5) while all were attired in the surgeon's gown. The effect of activity in lofting bacteria into the air can be readily appreciated.

The data are massed as shown in (Fig. 6). Comparisons were made between the square of the means for the 14 male orthopaedic surgeons in three styles of dress and in three activities. The four Florida Hospital technicians' data are treated separately but relating to the same factors (Fig. 7). There is no statistical difference between the average of the means for either group when standing quietly compared to talking. There is no significant difference between the University of Florida surgeons and the Florida Hospital technicians while

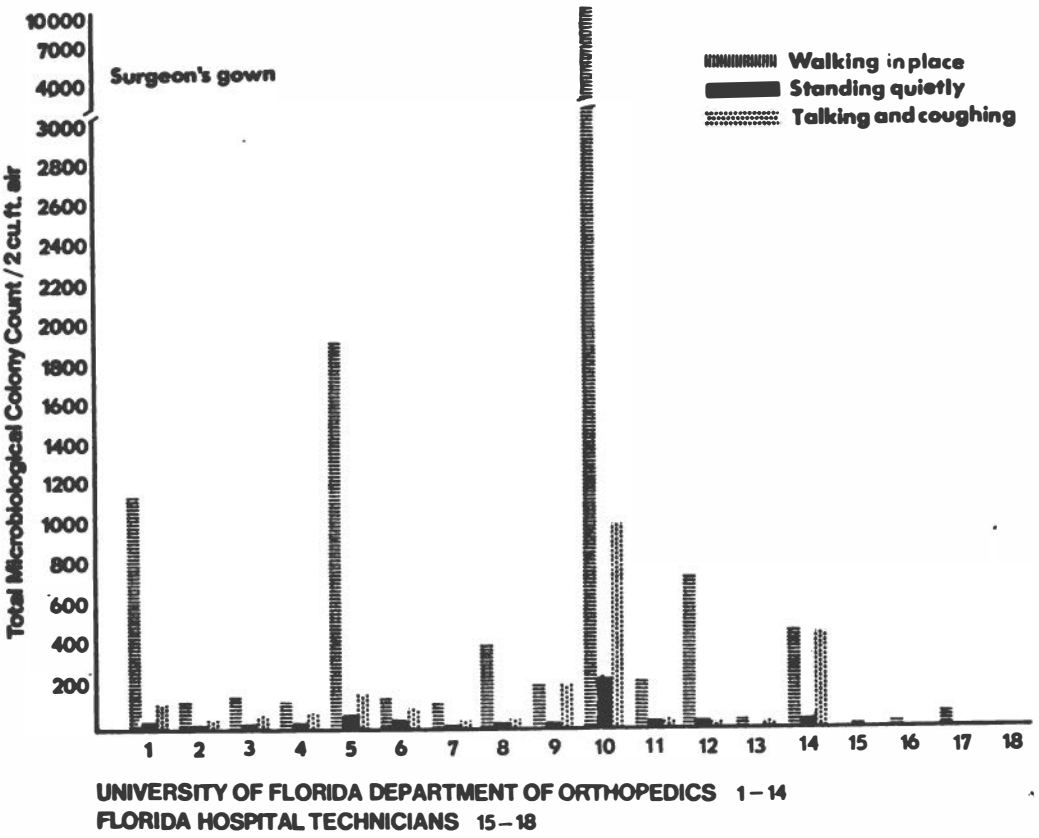

Fig. 5. Three different types of activity while wearing the same garment--a surgeon's gown. The remarkable effect of body movement on lofting airborne bacteria is evident. The great difference between the orthopaedic surgeons and the surgical technicians is not fully explained.

standing quietly or while talking. A statistically significant difference at the 0.05 level of significance exists between the first two types of activity and walking in place. There is a statistically significant difference between the aspiration suit worn by the University of Florida surgeons and the suit worn by the Florida Hospital technicians. Unfortunately, the effectiveness of the two suits was not contrasted on the same individuals.

Total Colony Count
University of Florida Surgeons
(Means ± Standard Error of Mean)

	Standing Quietly	Coughing & Talking	Walking in Place
Scrub Suit	$\bar{X} = 13 \pm 9$	$\bar{X} = 30 \pm 10$	$\bar{X} = 496 \pm 46$
Surgeon's Gown	$\bar{X} = 10 \pm 3$	$\bar{X} = 15 \pm 5$	$\bar{X} = 286 \pm 56$
Aspiration Suit	$\bar{X} = 8 \pm 3$	$\bar{X} = 9 \pm 3$	$\bar{X} = 155 \pm 78$

Fig. 6. Comparisons of colony counts for fourteen male University of Florida Surgeons during three types of standard activities while wearing three types of apparel. Differences between standing quietly and talking and coughing are not significant. Differences between either of those activities and walking in place are significant at p=0.05 level. Colony count decreases as more skin is covered, but this is more evident when activity is greatest. Values in a simple scrub suit are lower when standing quietly than those for the aspiration suit when walking.

Total Colony Count
Florida Hospital Technicians
(Means ± Standard Error of Mean)

	Standing Quietly	Coughing & Talking	Walking in Place
Scrub Suit	$\bar{X} = 2 \pm 2$	$\bar{X} = 5 \pm 4$	$\bar{X} = 40 \pm 7$
Surgeon's Gown	$\bar{X} = 0 \pm 0$	$\bar{X} = 1 \pm 0.8$	$\bar{X} = 12 \pm 5$
Aspiration Suit	$\bar{X} = 1 \pm 0.7$	$\bar{X} = 0 \pm 0$	$\bar{X} = 1 \pm 0.5$

Fig. 7. Comparisons of colony counts for four female Florida Hospital Operating Room technicians during three types of standard activity while wearing three different types of apparel. Differences between standing quietly and talking and coughing are not statistically significant. Differences between either of these activities and walking in place are highly significant. Colony counts decrease as more skin is covered. A tightly woven fabric was used in the aspiration suit used by these individuals. It appears to be highly effective and probably better than the loosely woven garment used by the men. Strict comparisons are not possible, however, because of different shedding characteristics.

DISCUSSION

The differences in shed bacteria of the four female operating room technicians is noticeable in contrast to the larger, more vigorous male surgeons. Reasons for these differences are not clear at the present time. It is observed that the girls were small and marched in place very gently. None were nasopharyngeal carriers of Staphylococcus aureus. It would appear that the more impervious fabric of the aspiration suit worn by these individuals is more effective than the loosely woven aspiration suit worn by the men in this study. Since these four women generated fewer bacteria than the men, a valid comparison of the effectiveness of the suit is unfortunately not possible.

The result of activity is more important than the mode of dress. Indeed, if all individuals were to stand quietly aspiration suits would be unnecessary.

The presence of a vastly increased rate of shedding bacteria of individuals Number 5 and Number 10 marks them as "shedders". In both cases the predominant organism shed was the pathogenic Staphylococcus aureus. Individual Number 10 was noted after completion of this study to have been a long-term sufferer from atopic eczema. Both Number 5 and Number 10 were nasal pharyngeal carriers of Staphylococcus aureus. Number 10 was able to reduce his shedding with the use of a steroid skin cream.

Additional studies of the phenomenon of shedding were carried out on several suspect individuals in order to develop a simple method for the detection of the presence of a shedder. In a quiet office, blood agar settle plates were placed at 6, 12, and 18 inches in front of and to the side of the individual's exposed face and neck. Control values in this setting were zero or one colony per ten-minute sampling period. The shedders produced between four and eight Staphylococcal colonies per plate per ten-minute sampling period. Six or eight pathogenic colonies per plate in a ten-minute period may indicate a surgical risk.

Using this method, an individual with a nasal furuncle was also found to shed Staphylococci in greatly increased numbers. The bacterial counts from this particular individual returned to two or three colonies per plate per ten-minute sampling after the furuncle was resolved. This lesion should prompt further study and probably should curb participation in surgery having a high risk of infection.

Howard P. Hogshead

CONCLUSIONS

Applying these studies to the average operating room situation, the following suggestions are offered:

1. The degree of physical activity in the operating room is the most important single factor affecting the number of bacteria shed into the air. Movement must be minimized.

2. Talking and coughing cause only a slight increase in airborne bacteria in comparison to quiet standing.

3. The number of airborne bacteria is decreased proportionately to the degree to which the skin and hair is covered by garments.

4. In a limited number, the use of an aspiration suit made of tightly woven fabric appears to be superior to a similar aspiration suit of a loosely woven fabric.

5. Particle counting is irrelevant to the bacterial count in these studies. The particle count is mainly a reflection of the amount and type of linen worn as well as the physical activity. Particle counters are not helpful in operating room monitoring.

6. A simple method for detection of shedders is described. Guidelines for the rational management of shedders have not been developed. However, the shedder is undeniably a threat to the surgical wound.

7. It is suspected that many shedders will be found to have skin diseases or other skin lesions which cause or which magnify their shedding characteristics. Individuals with such conditions should be examined and special precautions taken to protect the surgical wound.

8. Screening of the operating and anesthesia teams may be of particular importance in surgical procedures having a substantial risk of wound infections.

OPERATING ROOM AIR AS A SOURCE OF WOUND CONTAMINATION AND INFECTION

Ruth B. Kundsin*

The number of airborne microorganisms in the operating room during a procedure is the equilibrium reached between the addition of microorganisms and their removal. Organisms shed by occupants, together with those lofted by activity, are the means by which they are added; their removal is accomplished by ventilation or its sanitary equivalent, ultraviolet irradiation.

The three essential parameters for evaluating the microbial aerodynamics in the operating room are volumetric air samples, fallout plates, and cultures of microbial accumulation. Volumetric air samples and fallout plates indicate miroorganisms in transit. From these, viable particle size and settling velocity can be calculated. Microorganisms on horizontal surfaces represent the accumulated fallout of large viable particles. Techniques for the detection of microorganisms in these states of suspension differ.

The standards that our laboratory has set up and has found useful in evaluating the operating room environment are shown in Table 1. During a procedure a consistent rise in all counts of viable particles occurs. Counts are lower than standards at the start but usually increase and surpass these standards at the conclusion of the procedure. During a one-hour procedure involving replacement of a pacemaker, volumetric air counts rose from two to nine per cubic foot. Fallout of organisms increased from two to six per square foot per minute. Surface impression plates taken before and after the procedure showed increases in six of nine surfaces sampled.

Table 1. Operating Room Standards for Viable Particles

Volumetric Air Samples	5 vp/ft^3
Settling Plates	5 vp/ft^2/min
Horizontal Surfaces	<25 vp/Rodac Plate

The logical question at this point is how much of a hazard does this present to the patient? Assuming the operating room intake is within our

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hygienic limits and all surfaces have been wiped with an effective germicide, definite predictions can be made.

The original work from our laboratory on airborne infection during surgery was done in collaboration with Dr. Carl W. Walter (4). It was based on a study of 250 surgical procedures of all types. Nasopharyngeal and skin cultures were taken preoperatively and postoperatively of all patients. Cultures of the microbiology of the operating room were done. Cultures of the wound were taken on opening and closing. The team furnished masks and gloves for culture following each procedure. Postoperative follow-up of patients was done by a nurse member of the team. This comprehensive microbiology made it possible to ascertain the source of infecting organisms.

Staphylococcus aureus was recovered on settling plates on the instrument table in 48 percent of procedures, on settling plates on the floor in 58 percent of procedures, and in air samples (15 cubic feet) in 36 percent of procedures. In 69 percent of procedures, S. aureus was recovered from some environmental culture (Table 2). One technician in the periphery of the operating room was found to be a disseminating carrier and his S. aureus had a distinctive phage pattern. This made tracing of his S. aureus possible during the procedures when he was present.

Table 2. Staphylococcus Aureus Recovered From Environment in 250 Surgical Procedures

OR Sites Cultured	Procedures*
Instrument table - settling places	48%
Floor - settling plates	58%
Air samples (15 cubic feet)	36%

*In 69% of procedures, S. aureus was recovered

His particular strain was found on settling plates in 33 percent of procedures, on the floor in 25 percent of procedures, and in air samples (15 cubic feet) in 11 percent of procedures. In 49 percent of procedures, his S. aureus was recovered from the environment (Table 3).

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In the 250 procedures studied, 20 postoperative wound infections were found (Table 4). Sixteen of the 250 (6.0 percent) were endogenous and four of the 250 (2 percent) were exogenous. Staphylococcus aureus from the wound could be traced to three individuals in the operating room in the exogenous wound infections. Two infections were traced to two surgeon members of the team. Two of the infections were traced to the disseminating carrier in the periphery of the room whose S. aureus was recovered in the environment (Table 3). This is an infections rate of one percent for the 169 procedures during which he was present.

Table 3. Staphylococcus Aureus Carrier (52/52A/79/42D/7/53/54/70/73/80/81/82/47C) Present in 169 Procedures

Identical S. aureus found:	
OR SITES CULTURED	PROCEDURES*
Instrument table - settling plates	33%
Floor - settling plates	25%
Air sample (15 cubic feet)	11%

*In 49% of procedures, S. aureus of carrier recovered from the environment.

Table 4. Postoperative Wound Infections

250 Cases		
6.4%	(16/250)	Endogenous
1.6%	(4/250)	Exogenous
8.0%	(20/250)	Total

A more recent experience with an anesthesiologist in our hospital indicated an incidence of four (7.3 percent) infections in the 55 procedures which he attended. In another hospital, where we were consultants, an incidence of 13 infections in 183 procedures (7.1 percent) were found to be due to a specific T-type beta-hemolytic group A streptococcus from an anesthesiologist with

a perianal lesion from which the same streptotoccus was isolated (1). A summary of these three carriers and their rate of infectivity is shown in Table 5.

Based on these observations, the hazard to each patient can be mathematically predicted depending on the number of disseminating carriers in the operating room.

Table 5. The Disseminating Carrier in the Operating Room

ORGANISM	CARRIER	NUMBER OF PROCEDURES	NUMBER OF DOCUMENTED POST-OP INFECTIONS
S. aureus[1]	Technician	169	2 (1.2%)
S. aureus[2]	Anesthesiologist	55	4 (7.3%)
β-Hemolytic Streptococcus Group A[3]	Anesthesiologist	183	13 (7.1%)

[1] 52/52A/79/42D/7/70/73/80/82/47C
[2] 29/52/83A/81/80/47C/82 and 81/80/47C/82
[3] T Type 12

If the probability of not becoming infected for each disseminating carrier is known, the probability that any patient will be infected is equal to

$$p(I) = 1 - q(c_1) \cdot q(c_2) \ldots q(c_n)$$

Where:

$p(I)$ = probability that a patient will be infected.
$p(c_i)$ = probability that the i^{th} carrier is an infector.
$q(c_i)$ = probability that the i^{th} carrier is not an infector.
$q(c_i) = 1 - p(c_i)$.
$i = 1, 2, \ldots n$.

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Assuming all three carriers described in Table 5 were in an operating room together during a procedure, the probability of the patient's being infected, p (I), can be calculated as follows:

$$p\ (I) = 1 - (.93 \times .93 \times .99)$$

$$p\ (I) = .144 \quad \text{or} \quad 14.4\%$$

The airborne component of postoperative wound infections is not a fixed rate but varies from hospital to hospital, from operating room to operating room, and from surgical team to surgical team. The rate is directly proportioned to the number of disseminating carriers in the operating room. The disseminating carrier can be anywhere in the room. He does not necessarily have to be a member of the surgical team. He can be a casual visitor near the operative site, a transient technician in the periphery of the room, but each disseminating carrier in the room contributes to the cumulative risk incurred by the patient.

The emphasis on air supply to the surgical suite is important but not the critical factor. When the air supply plays an etiologic role, exogenous microorganisms are involved. The critical factor in our experience is the commensal flora of the people who are present. They can be scrubbed, masked, capped, gowned, and appropriately shod, but the disseminating carrier will still have the capability to project his microorganisms into space.

Definition of the problem simultaneously suggests the solution. Since the source of airborne postoperative wound infection is the disseminating carrier whether recognized or unrecognized, a technique which can intercept this microbial dissemination must be devised. Only those techniques should be considered which can reliably and reproducibly accomplish this with minimum discomfort to personnel.

One solution which has had support in the past is ultraviolet irradiation (2).

Ultraviolet lamps have been installed in four operating rooms at the Peter Bent Brigham Hospital for irradiation during surgery. With 25-30 $\mu w/cm^2/sec$

at the level of the operating table, a significant reduction in airborne microorganisms on surfaces, fallout plates and volumetric air samples can be demonstrated. Clinical evaluation of results of orthopedic surgery to date with such irradiation are encouraging (3).

Because the airborne component of postoperative wound infections varies with each hospital and is usually a small proportion of total infections, proof of successful control of airborne infections will of necessity involve a large number of patients before statistical significance can be attained. However, objective scientific evaluation of the problem can enable those interested to make a good educated guess as to the methods which will lead to successful eradication of aerially transmitted microorganisms.

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WHAT IS THE HARD EVIDENCE ON THE ROLE OF AIRBORNE BACTERIA IN WOUND INFECTION?

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The term "hard data" is employed by scientists as jargon for data which are irrefutable in the light of present-day knowledge. Hard proof is certain proof. It implies documentation which is convincing, and describes valid observations from which conclusions can be drawn beyond reasonable doubt.

All observations and data require interpretation. The validity of a conclusion is dependent upon the soundness of logic and absence of prejudice at each stage of the three-part deductive process: the premise, the method, and the conclusion. Even when all three are sound, the interpretive logic may be faulty. The same data based on factual material may have no meaning to one observer but significant meaning to another. Or, it may be interpreted according to an individual observer's special interests, experiential and educational background, and a host of other factors that set one individual apart from another. The clear zone around a penicillin mold growth had been observed by many people, but it took the deductive processes of Alexander Fleming's mind to read practical significance into this observation.

In 1882, when Robert Koch cultivated the tubercle bacillus, he presented his results to the Berlin Physiological Society in a paper which included "Koch's postulates." Koch knew that it was insufficient to assume that simple cause-and-effect observations were enough to implicate a given microorganism as cause of a given disease. His fourth postulate states that the organism recovered from the diseased part must be the same as the one introduced to cause it.

With this much background, let us look at the evidence at hand on the role of airborne bacteria in wound infection.

I think everyone will agree with certain facts which have emerged from repetitive observations and hard data. These are: 1) bacteria may be airborne; 2) highspeed, clean directional or moderately turbulent airflows are capable of diminishing the number of airborne bacterial particles in a confined space.

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An apriori deduction from these factual observations -- that because microorganisms may be carried by airborne particles, and because microorganisms may cause wound infection, and because the particles may be diminished in number significantly by high-speed air movement -- that post hoc ergo propter hoc high-speed air blowing should diminish the incidence of wound infection. However, application of elementary logic tells us that this conclusion may be a non sequitur, and not a legitimate conclusion at all. It could be a non sequitur 1) if hard data show that high-speed clean-air movement does not prevent wound infection; 2) if airborne bacteria do not match those recovered from an infected wound, or 3) if infection can be prevented by means other than high-speed clean-air movement, such as, for example, containment of dispersal of airborne bioparticles, exclusion of carriers, correction of engineering defects in a low-speed, turbulent air system, use of antibiotics, special surgical and hygienic technics, and so on.

It would serve little useful purpose at this point to correct an almost hopelessly bogged-down misuse of terminology, but in the interests of the search for hard facts, it should at least be mentioned here that the term "laminar flow" is constantly misused. Directional airflow, as it is employed in operating rooms is at best less turbulent than nondirectional flow. But because of the inevitability of obstacles and movement in the operative space, the flow is certainly not laminar. Misusage of the term extends to the tendency to refer to all ceiling-vent systems as laminar.

Two reports, one by Walter, Kundsin and Brubaker (3) and the other by Gage and associates (4), provide us with data which trace the infection of tissue directly to pathogens circulated into the operating room air.

In the case of the Walter-Kundsin report, a carrier-disseminator (shedder) entered the periphery of an operating room. The air distributors were located on the same wall as the exhaust registers. Thus, all incoming air had to sweep the room before being exhausted on the same side as it entered. The shedder was dressed and shod in the conventional way, but wore a cap, not a hood, and no gloves or shoe covers. The bacteria shed by this person matched specifically by phage type those found in the wounds of a series of patients.

What is the Hard Evidence

We do not know whether the bacteria were deposited directly into the wound from the air, or came to rest on instruments, sponges, or gloves before being deposited into the wound, but the source and the final destination of the bacteria are irrefutable.

In the case of the Gage report, a contaminant was brought into the operating room by a faulty air handling system which delivered undiluted Aspergillus spores directly into the room from a poorly-drained moss-covered roof covered with pigeon excreta. A virtually pure culture of Aspergillus was isolated from the pigeon droppings, from the air ducts, from the air handling machinery, and from the thrombi which adhered to the implanted intracardiac valves of five patients. Interestingly, the skin wounds of these patients and those of other patients operated upon in the same operating room (cholecystectomies, herniorrhapies, etc.) had the same low infection rate as that of patients operated upon in other operating rooms of the same suite. This rate was well below published infection rates in the ultraviolet study published in 1964 (5). Reasons for this phenomenon can only be speculated upon. but one speculation is that the strong suction employed in the area of the open heart was concentrated into the cardiac chambers, acting much like a slit-sampling device in concentrating the airborne bacteria in one place. Other speculations include the possibility that different tissues and anatomical locations have different levels of susceptibitlity to any given pathogen; that the infectious agent was carried into the wound by gloves, instruments, or sponges, while the sides of the wound were protected by pads or towels; or that the foreign body itself (the valve) may have become contaminated before insertion.

The Walter-Kundsin report and the Gage report are examples of hard data gathering, one demonstrating the effects of an incompletely covered shedder and the other, the effects of an erroneously installed and defective air handling system, both definitely supporting the premise that airborne bacteria are responsible for wound or other tissue infection. However, reference to these observations is misapplied by authors who use them correctly to support the thesis that wound infections can be caused by airborne bacteria, but at the same time report cases in which the airborne bacteria do not match (if, indeed, they were cultured) those found in the infected wound. Such reports, in

addition to using hard data to support a questionable conclusion are, of course, guilty of not fulfilling Koch's fourth postulate.

Reports such as that of Amstutz (6) trace wound infections in hip-replacement operations to the urinary tract, and not to airborne bacteria, either in a conventional operating room where four deep infections occurred, or in a directional airflow room where one deep and six superficial infections occurred. Gram-negative rods are rarely, if ever, transmitted by air. Also, the bacteriology of infected hip-replacement wounds is far from uniform.

Reports in which claim is made that the wound bacteria match those of the air, cover a wide spectrum of bacteria, but usually focus upon either Staph. epidermidis or Staph. aureus, both of which are capable of being airborne. The conclusion, therefore, is reached that the infection reached the wound from the air, either directly or indirectly by way of an instrument, sponge, glove, or some other fomite. But, as we have seen, such a conclusion may be a non sequitur. Although it is clear that bacteria can be airborne, their arrival at the wound site via this route must remain conjectural without measurement of cultures from other sources (e.g., the surgical team's hands). When bacterial counts over a wound or instrument table are at virtual zero and the patient develops a Staph. epidermidis or Staph. aureus infection, it is less likely that the microbe got to the wound via the air than it is that it got there by direct implantation, either via a tear in the surgeon's glove or from the patient's own skin. Hard proof would require cultures of objects other than the air, such as instruments, gloves, sponges, surgical team's hands, and so on.

We lack certain basic pieces of information or hard data which appear to be necessary before specific recommendations can be made responsibly. With respect to the air, Lidwell (7) has asked, "How clean should operating-room air be for surgery?" Paraphrased in the present context, "How clean should operating-room air be to provide 'clean-enough' air for clean-refined surgery?"

We have no definite answer based upon hard data for a number of reasons. 1) We have not yet defined clean-enough air. Or, as Beck has put it,

we need standards for biologically clean air, since federal standards for industrial clean rooms are all we have, and these are certainly not relevant to operating rooms. 2) We have no standard protocol for investigators to follow in describing the conventional operating rooms which they invariably use for comparison with directional-airflow rooms. 3) We have no standards for the tests used in monitoring the bioparticles in high-flow rooms. As a result, investigators are measuring different parameters by different methods and attempting to compare such findings. 4) There is little unanimity of opinion on the specifications of the filter necessary to provide clean air into an operating room at reasonable cost. 5) We have had little reliable information, until recently, about comparative permeability of various woven and nonwoven materials depended upon to serve as barrier materials during operations.

The new information about barrier materials (11) indicates, contrary to promotional claims, that not all nonwoven materials used in the manufacture of surgical gowns and drapes are truly barrier materials under conditions of operating room use. Moreover, not all woven materials are permeable to moist contamination. Strike-through of contamination may be important as a means of disseminating bioparticles into the air with drying, or as a means of delivering the wearer's bacteria to the outside for direct contact implantation into the surgical wound or onto fomites. Therefore, it is of some importance to know which materials can be depended upon as barriers under specific circumstances.

Employing a test designed to simulate operating conditions of stress such as stretch, and changes in permeability to Serratia marcescens were measured against time. Under conditions of the test, waterproofed Pima tight-woven cotton cloth was found to be impermeable to moist bacteria through up to 75 washing and sterilizing cycles. On the other hand, untreated Pima cloth and ordinary cotton of the kind used in surgical gowns permitted bacterial penetration almost immediately, as did the stockinette cufflets. Among the nonwoven disposable gown and drape materials, only spread tow plastic film composite remained impermeable through all tests, while scrim-reinforced tissue, scrim-reinforced embossed tissue, spunbonded polyethylene

nonwoven fabric, and spunlace nonwoven fabric were considered satisfactory, up to a point, but became somewhat permeable within a half hour. Other nonwoven materials allowed wet bacterial strike-through within five minutes. Choice of barrier materials for purposes of containment of the surgical team, is, therefore of more than academic interest, and certainly may affect results of environment studies in the operating room. Barrier effects of materials cannot necessarily be depended upon as a constant (Tables 1 and 2).

Table 1. Unopposed Weight-Support Test (2 kg Weight)
Bacterial Penetration = +

Wovens

Material	5 min	15 min	30 min
Tight weave Pima, Quarpel treated	0 0 0 0 0	0 0 0 0 0	0 0 0 0 0
Tight weave Pima, Quarpel treated, 55 cyclings	0 0	0 0	0 0
Tight weave Pima, Quarpel treated, 75 cyclings	0 0	0 0	0 +
Tight weave Pima, Quarpel treated, 100 cyclings	0 0	0 +	+ +
Tight weave Pima, untreated	+	+	+
Linen, new	+	+	+
Linen, cycled twice	+	+	+

(From Laufman, H., W. W. Eudy, A. M. Vandernoot, D. Liu, and C. A. Harris, Strike-through of moist contamination by woven and nonwoven surgical materials. To be published).

Table 2. Unopposed Weight-Support Test (2 kg Weight)
Bacterial Penetration = +

Nonwovens

Material	5 min.	15 min.	30 min.
Spread tow plastic film composite	0	0	0
	0	0	0
	0	0	0
	0	0	0
	0	0	0
	0	0	0
Wet-laid nonwoven fabric laminated to polyethylene film	0	0	0
	0	0	0
	0	0	0
	0	0	0
	0	0	0
Scrim-reinforced tissue	0	0	0
	0	+	+
	0	0	0
	0	0	0
	0	0	+
Scrim-reinforced embossed tissue	0	0	0
	0	0	0
	0	+	+
	0	+	+
	0	0	0
Spunbonded polyethylene fabric	0	0	0
	0	0	0
	0	0	0
	0	0	+
	0	+	+
Spunlace nonwoven fabric	0	0	0
	0	+	+
	0	0	0
	0	0	+
	0	0	0
Wet-laid nonwoven fabric	0	+	+
	0	0	0
	+	+	+
	0	+	+
	0	0	+
	0	0	+
Fiber reinforced tissue	+	+	+
	+	+	+
	+	+	+
	+	+	+
	0	0	+
	+	+	+

(From Laufman, H., W. W. Eudy, A. M. Vandernoot, D. Liu, and C. A. Harris, Strike-through of moist contamination by woven and nonwoven surgical materials. To be published).

Harold Laufman

Charnley and Eftekhar (10) have shown that waterproofed tight-weave coverall uniforms, used with helmets, did reduce particulate shedding significantly even in a directional air chamber. The use of vacuum suction of air from under such coverall uniforms adds materially to the comfort of the wearer by enhancing evaporation, and also prevents perspiration from soaking areas of the uniform and possibly striking through to the sterile surface.

Bernard and associates (14) recently showed that one-piece shoe-cover pants similar in design to fisherman's waders made of tightly woven cotton worn by the surgical team together with hoods, masks, and gloves effectively packaged the surgical team and produced an airborne bioparticle count of 0 to 2.6 at the wound site in a fully occupied conventionally ventilated room. These levels are equivalent to those found in high-flow directional air units.

It has not been settled at what periods overkill sets in through superimposition of one effective controlling system upon another. The same question must be raised relative to the use of prophylactic and intraoperative antibiotics in conjunction with barrier containment of the surgical team, high-flow directional air systems, ultraviolet light, or other control systems. It is assumed that all common aseptic precautions are universally taken in all operations by members of the surgical team including adequate body hygiene, adequate hand scrubbing, and full hood to cover all hair. Special precautions include wearing two pairs of gloves, strict traffic control, controlled ambient conditions such as temperature and humidity, and wearing of special garb. All these factors, as well as others related to the physical environment must be known in order to arrive at a meaningful conclusion from which valid deductions pertinent to prevention and treatment of wound infections can be made.

Finally, I wish to stand up -- not in defense of a stand, but in rebuttal -- to those who would proceed to advise on how to reduce the incidence of wound infection in clean-refined operations without hard evidence on which to base their advice. We skeptics are not against clean air, nor are we against lowering the incidence of wound infection. We submit that we cannot know the degree to which various possible influences participate in the causation of

wound infections until we have more hard data. Until we do, we can only expect to prevent these catastrophic complications either by imprecise, unquantified shotgun methods, or by missing the target altogether through not being able to identify it.

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EVALUATION OF METHODS FOR THE CONTROL OF SURGICAL SEPSIS

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Infection of the wound and the development of sepsis following a surgical operation necessarily involves these conditions:

1. The presence of a source of viable microorganisms somewhere within the circle of possible contact.
2. Dispersal of these microorganisms from their point of origin.
3. Transfer of a sufficient number of microorganisms to a sensitive site.
4. Proliferation of the organisms within the wound.

Prevention or reduction in the risk of sepsis can be achieved by measures which interfere with any one of the above steps. For example, some sources may be eliminated by the exclusion or treatment of carriers among the staff, or by more effective decontamination of the patient. Dispersal can be reduced by improvements in protective clothing or by skin treatments. Transfer to the patient by the airborne route can be minimized by the use of more effective ventilation systems. Reducing the risk of contact transfer involves, among other things, the protection of instruments, swabs, and dressings from contamination before or while they are used. Plastic isolators interpose a barrier to the deposition of bacteria from the environment to the wound. Some form of ultraviolet irradiation may kill organisms which have reached the tissue surface. Multiplication within the wound may be inhibited by local application of antiseptics or by local or systemic antibiotics.

There are, therefore, not only many ways by which a dose of infection may build up in a surgical wound, but an even larger variety of procedures which might be applied to reduce it. As an additional complication, it is rather unlikely that the relationship between the size of the bacterial dose received by the wound and the risk of infection or sepsis will be anything like a proportional one. Very wide variations in the susceptibility of the population at risk will lead to a situation in which large reductions in dose lead only to a small reduction in the risk. Figure 1 may serve as an illustration

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to make even more apparent a number of obvious consequences. If the dose to the wound via contact and/or autogenous routes is fairly high, e.g., the uppermost horizontal line in Figure 1, then only if the air is very dirty will improved ventilation or reduction in dispersal lead to any reduction in the dose to the wound with a possible fall in the risk of sepsis. If the infectious

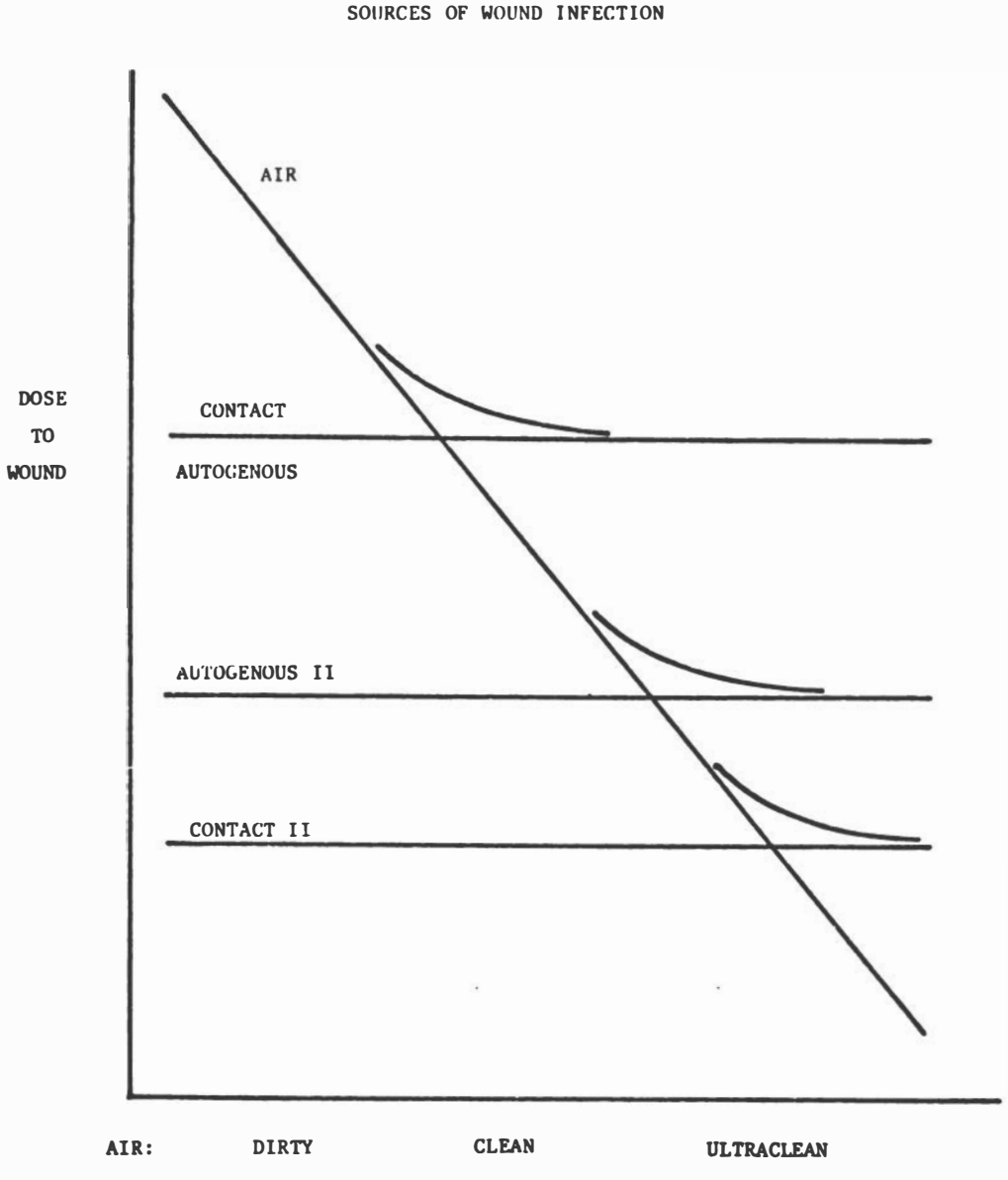

Fig. 1.

dose is delivered simultaneously by the contact route and an autogenous source, control methods applied to either of these separately will have little effect. If, however, substantial improvements can be made in relation to both these routes, i.e., the dose transmitted falls to the lower two horizontal lines, then measures to provide a cleaner air environment may result in improved clinical results. The advantage obtained will, however, be limited by the highest level of dose resulting from any other route. Only if this is reduced still further will the attainment of the cleanest atmospheres bring clinical benefit.

A fundamental difficulty in reaching a decision as to which preventive measures should be applied, and which would merit clinical evaluation, lies in our almost complete ignorance as to the relative dose levels arising in the different possible ways.

BACTERIOLOGICAL EVALUATION

The first step towards evaluating a control procedure is to establish that it is effective in its purpose, e.g., that a suit of protective clothing does indeed prevent or very substantially reduce dispersal of microorganisms into the environment by the wearer. Laboratory tests should be followed by in-use tests both in order to ensure that some circumstance in the operating room situation does not vitiate the method used, and to establish that it is compatible with the other requirements of surgical operation procedure.

Evaluations of this kind can establish an order of effectiveness among different methods applied to the same point in one of the routes of possible infection, e.g., methods of skin disinfection for the surgeon's hands. Some estimate of the relative reduction in the dose which might reach the wound as a result of replacing one procedure by another can also be made. If this reduction is only small, then there is little likelihood of any clinical benefit. However, for reasons discussed above, even if the relative reduction bacteriologically assessed in this way is very large, there is no guarantee that significant reduction in the rate of wound sepsis would follow.

A more direct approach is to study the contamination actually reaching the wound itself. Although this is by no means a simple procedure, it is

probably a good deal less exacting than attempting a full clinical assessment of the basis of change in the rates of wound infection and sepsis.

There has been a sufficient number of such studies carried out to demonstrate the feasibility of this approach, and to establish that there is a significant correlation between the finding of microorganisms in the wound at the end of an operation and the risk of subsequent development of wound infection. Thus, in a study of over 1,000 surgical operations (Table 1), the risk of subsequent wound infection exceeded 25 percent for the wounds from which Staphylococcus aureus was recovered by bacteriological examination of washings taken from the wound at the end of the operation (6). The rate of subsequent wound infection was less than two percent for those wounds from which this organism was not so recovered. If all kinds of microorganisms were considered, then the rate of wound infection was greater than five percent for those wounds yielding washings positive for any bacteria, compared with about one percent for those wounds yielding apparently sterile washings. This study was part of an investigation into the value of ultraviolet irradiation of the air of the operating room. In the hospital (No. 4 in the study) carrying out wound washings, approximately 40 percent of the operation wounds yielded bacteria on culture of the washings when there was no irradiation. The irradiation produced only a modest reduction in this fraction, to just under 30 percent, and no significant difference in the risk of wound infection was observed.

Table 1. Infection in Wounds Found Contaminated with Staphylococcus aureus
(Number infected/total number)

Wound classification	Staph. aureus recovered	Not recovered
clean	2/12	9/812
clean contaminated	2/9	10/289
contaminated	2/4	1/31
dirty	2/4	2/25
total	8/29	22/1157
percentage	27.6	1.9

Derived from Postoperative Wound Infections (6).

This correlation between bacterial contamination of the wound and subsequent infection did not imply that the infection was necessarily, or even usually, caused by a strain isolated from the washings. The sampling process is necessarily inefficient. If this were not so, it would itself be a potentially highly effective measure for control of infection. The possibility that the sample method may itself affect the prognosis needs, however, to be considered seriously. In addition to the removal of bacteria, probably ineffectively, it may also remove blood clots and small pieces of tissue which might influence the chance of infection developing. In an attempt to assess the effect of moving from an old hospital into new buildings, Davidson, Smith, and Smylie (1) also examined over 1,000 operations bacteriologically by a swab and contact plate technique. Some seven percent of the wounds were found to be contaminated with "pathogenic" species at the end of the operation. This proportion did not differ appreciably in the two environments. Multi-regression analysis by Davidson, Clark, and Smith (2) showed that bacterial contamination of the wound was by far the most important factor in determining the outcome (Table 2). In conforming with the similarity of the rates of contamination

Table 2. Coefficients of Regression Equation for Risk of Wound Sepsis

	Factor	Coefficient	Standard deviation
1.	Positive wound swab	0.364	0.043
2.	Dirty operations	0.106	0.026
3.	Old hospital, pre Sept. 1966	0.105	0.021
4.	Age over 60	0.091	0.020
5.	Surgical team A or C	0.089	0.028
6.	Duration over 60 min	0.069	0.018
7.	Emergency	0.062	0.037
8.	Glove puncture	0.058	0.025
9.	Patient a nasal carrier of Staph. aureus	0.058	0.031

Data from 1,000 operations performed by three surgical teams, half before and half after moving into a new hospital.
After Davidson, Clark, and Smith (2).

found at the end of operation, the infection rates for primary infection with Staphylococcus aureus were indistinguishable in the two environments. The difference between the total infection rates was entirely due to secondary (or late) infections presumed to have developed after return to the ward (Davidson et al.) (3). Jepsen (4) has carried out a similar study in Denmark.

CLINICAL EVALUATION

Demonstration of a reduction in the rate of wound infection is the only fully convincing evidence of the value of any control measure. For assessment of antibiotic therapy, or treatment of the wound with antibacterials, it may be the only approach. If infection rates are very high then the statistical problems are not too great. Thus, Lister, when he introduced the use of antiseptic carbolic acid dressings for covering the wound after limb amputation, was able to show a convincing effect after fewer than 50 operations with the new technique (5) (Table 3). Although he himself stated that these numbers were too small for statistical significance they do show a probability of over 98 percent by the χ^2 test. Fortunately for the patients, the infection rates in clean elective operations, which are those for which the provision of air, free from microorganisms, might seem most likely to be of value, are very much

Table 3. Deaths Following Limb Amputation
(deaths/number of amputations)

Year	All amputations	Upper limb only
1864	7/17	
1866	9/18	
1864 and 1866	16/35	6/12
1867	0/7	
1868	3/17	
1869	3/16	
1867-1869	6/40	1/12

Antiseptic procedures using carbolic acid were in use from 1867 onwards.
After Lister (5).

lower. As a consequence, the numbers of operations that must be studied in order to demonstrate a significant difference between two or more procedures are usually very large. From Figure 2 it can be seen that when the control infection rate is about 10 percent, more than 3,000 operations must be studied in each group to determine, at a reasonable level of significance, whether or not there is a reduction of 25 percent in this figure, i.e., to 7.5 percent. A similar number would be required to show in the same way a fall to one

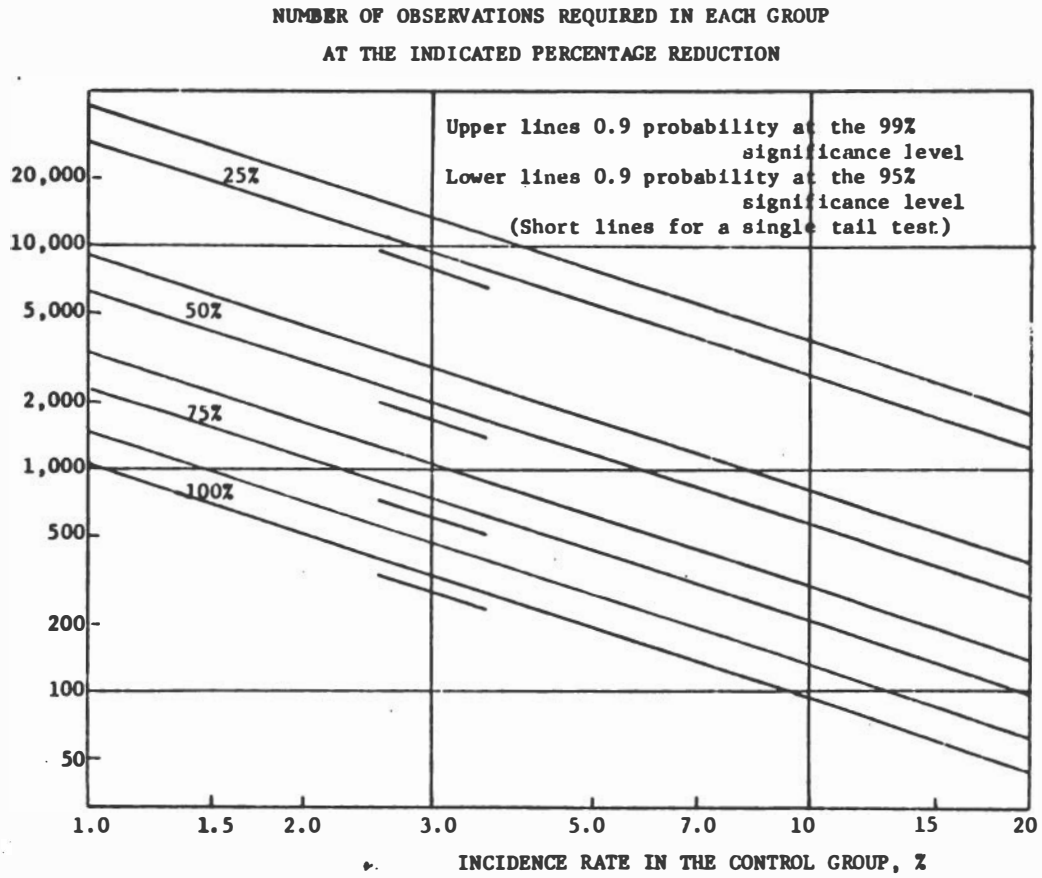

Fig. 2

percent, from an initial infection rate of two percent, i.e., a reduction of 50 percent. A simple rule is that the expected number of infections in the control group must be at least 1,000 $(200-a)/a^2$, where a is the percentage reduction chosen as critical. The above numbers are those required in order to have a 90-percent chance of demonstrating at the 95-percent level of significance that the procedure being investigated is effective.

It is clear that in addition to the effort required to collect records from such numbers of operations, there are also likely to be difficulties in ensuring comparable conditions throughout the investigation. Since, (in addition to possible changes in staff and technique), there are undoubtedly secular changes in the bacterial environment in any hospital, it is essential that operations are carried out throughout the same period of time under all the various conditions to be compared. Table 2 also shows another obvious requirement. There was a substantial difference in the rates of infection following operations performed by the different surgical teams. Whether this was due to different carriage rates associated with the members of the teams, variation in surgical technique, or to other factors, it is clear that comparisons between environmental conditions or procedural differences can only be made if each surgeon operates equally under both control and trial circumstances.

PROPOSED INVESTIGATION OF THE VALUE OF ULTRACLEAN AIR IN SURGERY

The practical consequences of some of the points discussed above can perhaps be best seen in a brief description of an investigation planned to start in 1975.

Any benefits of operating in an ultraclean air environment are most likely to be apparent in those operations for which the risks of autogenous and contact infection are lowest. In view of the considerable interest among orthopaedic surgeons, and because most of the operations they perform fall into the clean-elective group and include large numbers of similar operations, e.g., total-hip replacement, it was decided to study these last.

The term ultraclean air may be considered to imply a level of airborne contamination at least 10 to 20 times less than that attained by conventional

positive pressure turbulent ventilation, i.e., below 10 bacteria-carrying particles per cubic meter of air (0.3/ft^3) during operations. These levels can be obtained by a variety of installations, and provided a satisfactory level of air contamination is achieved, there seemed to be no reason to specify the type of equipment. A further reduction in the exposure to microorganisms arising from the surgeon and his assistant can be obtained by the use of protective garments of the Charnley body-exhaust type. Three conditions have therefore been chosen for comparison:

1. Conventional positive pressure ventilation with clean air at not less than 0.5 m^3/sec (1,000 ft^3/min).

2. Ultraclean air systems, e.g., horizontal or vertical unidirectional flow systems or the Charnley enclosure. Both of these are to be used with the surgeon and staff wearing conventional operating room dress.

3. Ultraclean air systems with the surgeon and his assistant(s) wearing a body exhaust system.

All surgeons taking part would have to operate under both conventional and ultraclean air conditions.

The number of observations required depends both on the infection rate in the control group, and on the reduction in this rate which would be considered worthwhile, and therefore must be detectable with reasonable confidence by the study. Observations on between 2,000 and 3,000 operations in each group would be needed if reduction of five percent to three percent or two percent to one percent were to be shown. There is no precise way of determining these figures, so it has been decided to plan for approximately 3,000 operations per year over a study period of two and one-half to three years. Observations will be made of both deep and superficial infection. The latter is perhaps more relevant to the conditions in other types of surgery, especially where there is no foreign body implanted in the tissues. The long delay period sometimes associated with deep infection around the artificial hip joints means that observations must be continued for up to two years after the last operation,

but for a three-year study period over 80 percent of the deep infections should be recorded before the end of the fourth year.

The numbers of operations performed annually in representative centers ranges from approximately 100 to over 400. To observe 3,000 operations per year requires 12 to 15 participating hospitals. It is thought that sufficient bacteriological data on wound contamination at the end of the operation can be obtained from approximately 2,000 observations in all, and these could be obtained from only five to six centers, each of which would observe approximately 150 operations per year.

This leads to the organizational plan sketched in Figure 3. Members of the working party will be able to exercise a general oversight of the investigation in each area, and in some cases the microbiologists will carry out the detailed bacteriology in a hospital making studies of wound contamination at the end of operation. They, and the other microbiologists engaged in this

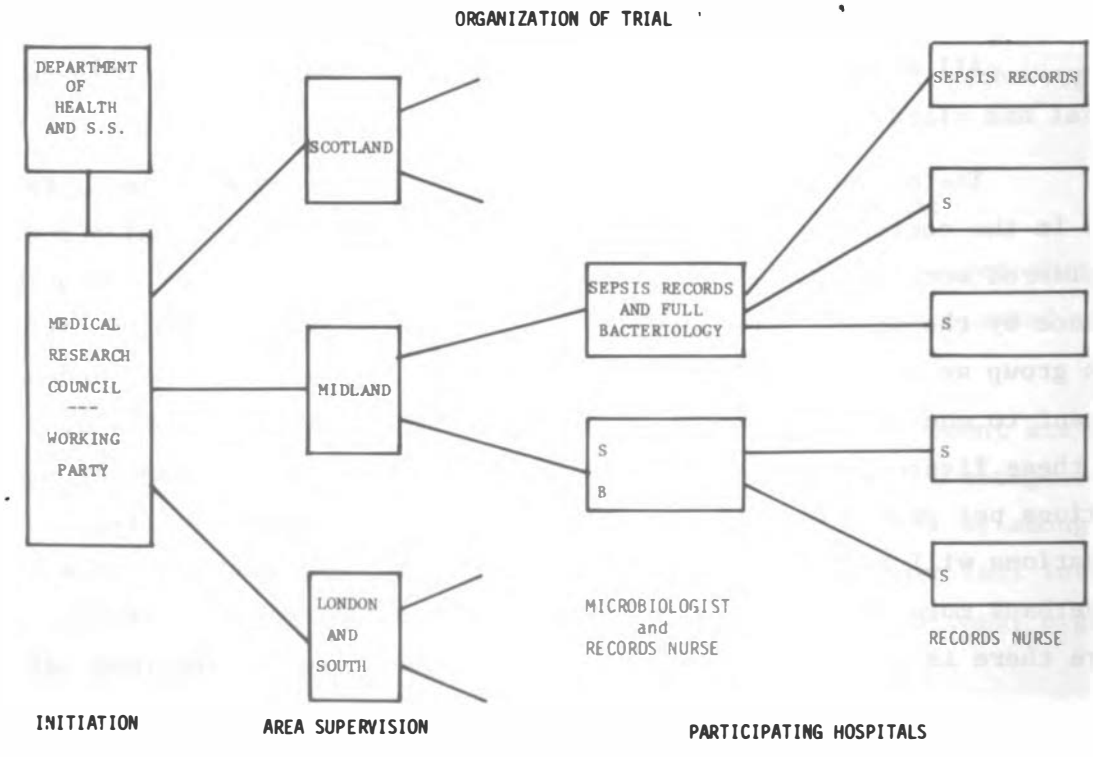

Fig. 3.

work, will also be responsible for establishing that the clean air installations in their own and selected other hospitals are functioning correctly throughout the period of the study. Further, they will examine, bacteriologically, specimens from clinically infected wounds in these other hospitals. In their own hospitals, they will also monitor, with respect to Staphylococcus aureus, the preoperative carriage state of the patients, and the carriage state of the operating room staff. In order to obtain comprehensive and consistent recording, and the systematic collection of bacteriological specimens, each participating hospital will have a records nurse, usually part-time. All records will be returned to the working party for assessment and analysis.

CONCLUSIONS

The statistical, ethical, and logistical problems associated with establishing the value, or non-value of medical procedures are often very great. They are especially so when the chance of the occurrence of the event to be prevented is small, and the consequences of it to the individual patient are great. The development of scientific medicine has brought us now to the situation where only a proportion of the competing demands for resources can conceivably be met. It is, therefore, as important to decide when a possible treatment, though harmless, is ineffectual, as it is to establish the value of one that is effective. This will demand a greater investment of effort than we have, perhaps, previously thought desirable in such laborious evaluative studies as I have discussed.

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PROPOSAL FOR AN INVESTIGATION OF THE EFFECT OF ULTRA-CLEAN AIR IN OPERATING ROOMS ON SURGICAL SEPSIS*

O. M. Lidwell

1. INTRODUCTION

Experience has indicated that the introduction of positive-pressure ventilation for operating rooms has led to substantial reductions in the numbers of airborne microorganisms, and has been accompanied by a reduction in the frequency of wound sepsis. Methods for still further reducing the air contamination by a factor of ten or more ("ultra-clean air") depend on the introduction of sophisticated ventilation systems, and the use of special clothing worn by the surgical team. The claim is made that their use would be accompanied by a further reduction of wound sepsis, at least in some kinds of surgery. However, ultra-clean air systems are expensive, and controlled assessment of their value seems desirable before they are taken into extensive use.

1.1. Orthopaedic Surgery

A major study of sepsis after toal-hip replacement, by Professor John Charnley, shows a nearly ten-fold drop in sepsis rates after the introduction of his ventilation system. There has, therefore, been a considerable demand for the installation of ultra-clean air ventilation.

As is inevitable in such a sequential study, there were changes during the period of study. There are those who challenge the assertion that the improvement was wholly or substantially due to the cleaner air, and believe that a conventional plenum system would have given comparable results.

Published series of observations after hip-replacement operations performed during the last ten years, record infection rates ranging from 0 to 10 percent on numbers of operations between 100 and several thousand. In most of these studies, the recording of sepsis was a secondary interest, and the only consistent criterion of sepsis was breakdown of the joint, presumptively related to deep infection. These deep infections often become apparent only after a considerable period.

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*Prepared by a working party set up by the Medical Research Council, London, England, as a basis for a controlled study. Chairman, Dr. O. M. Lidwell.

Apart from the data given by Charnley, there is no substantial series that gives any direct comparison between the rates of infection in operations conducted in normally ventilated operating rooms and those performed under "ultra-clean" air conditions, although there have been a few smaller sequential studies with similar conclusions.

In particular, there are no reports of studies in which substantial numbers of operations have been carried out over the same period of time in either ultra-clean air conditions or with conventional ventilation, all other circumstances being similar.

1.2. Prerequisites for an investigation

Infection of the surgical wound may arise from the patient's own organisms, from contact with contaminated objects - including the members of the operating team - or directly or indirectly from airborne bacteria in the operating room. The provision of cleaner air can directly affect only the last of these. Any study of ultra-clean air should, therefore, be made on operations in which the risks of autogenous and contact infection are as low as possible in relation to the risk of airborne infection, i.e., clean elective operations lasting at least 45 minutes. Because the risks of wound infection vary between different surgical procedures, it is important that the groups be comparable in this respect. In view of the interest of orthopaedic surgeons, and of the fact that most of the operations they perform fall into the clean-elective group and include many similar operations (for example, total-hip replacement) it seems convenient to study these operations. Because of the many variables that may differ between surgical teams, control observations would have to be made by each team with each individual surgeon operating under control and ultra-clean air conditions.

The studies referred to earlier suggest that for hip-replacement operations, the incidence of deep infection, as defined above may be as low as two percent or even less for operations performed with good conventional ventilation, and that this rate is dependent on several factors, e.g., prophylactic antibiotic therapy, previous operation on the joint, and whether the joint disease is rheumatoid or osteoarthritic.

Although deep infection is of particular importance in total-hip replacement, the genesis of "superficial" infection is probably closer to the conditions relevant to infection in other types of surgery, especially those in which there is no foreign body implanted in the tissues. Rates for "superficial" infection in substantial series of orthopaedic operations of less than two percent have been reported, but the criteria employed are not well defined. Charnley has estimated that the incidence of superficial sepsis in his series was rather more than five percent, assessed at 14 days.

The extent of the reduction in the incidence of wound infection that can be considered useful is a matter for judgement at a particular time, and depends on the consequences of infection. In determining the size of the investigation necessary, reasonable criteria might be those that would give an 80-percent chance of demonstrating at the 99-percent level of significance - or a 90-percent chance at the 95-percent level - a reduction of one percent in the incidence of deep infection, e.g., from two percent to one percent, or a reduction of two percent in the incidence of superficial infection, e.g., from five percent to three percent. At these levels, the number of observations required under the control conditions and under any other circumstances to be compared with this, would be at least 2500 for the "deep" infections and 1500 for the "superficial" infections.

Because any one surgical team is unlikely to perform more than about 200 hip replacements in any year with, perhaps, an equal number of other suitable elective operations, the study will have to be multicentered. In view of the inevitable uncertainties involved in the above estimates of the numbers of operations needed to obtain a reasonably conclusive result, analysis of the records will be made at intervals as the investigation proceeds. It will be possible to obtain much more realistic estimates after a relatively short time, and to modify the study accordingly.

1.3. Wound contamination

Wound infection directly derived from air contamination in the operating room must result from microorganisms deposited in the wound during operation. Several studies have shown good correlation between bacteriological

contamination of the wound, as determined by samples taken at the end of the operation, and the risk of subsequent sepsis. If ultra-clean air systems are of any value this should be evident in a reduced amount of wound contamination.

Experience has shown that samples from operation wounds are highly variable in this respect, but any difference in bacterial contamination levels under ultra-clean air conditions should be apparent in far fewer examinations than those necessary to determine variations in the level of sepsis.

1.4. Sepsis

In view of the difficulties involved in setting out a consistent agreed-upon definition of "sepsis," it will be necessary to record objective descriptive criteria for the progress of the wound after operation.

2. THE PROPOSED INVESTIGATION

2.1. Operating Conditions

There are a variety of ventilating systems and other circumstances that influence the bacteriological cleanliness of the air over the surgical field. Some of these are:

2.1.1. None or only extract ventilation: air bacteriologically dirty.

2.1.2. The accepted present-day standard of positive pressure ventilation: air fairly clean.

2.1.3. Professor Charnley's method of high rate of ventilation in an enclosure containing only the surgeons and part of the patient: air very clean.

2.1.4. So-called "laminar-flow" ventilation systems, whole or part room: air can be very clean.

2.1.5. Special clothing ventilated and impermeable to bacteria-carrying particles; at present associated with Professor Charnley's system.

2.1.6. Enclosure of the surgical field within a ventilated plastic envelope, e.g., the Trexler surgical isolator.

Type 2.1.3. and the many variations of 2.1.4. are the ultra-clean air systems. Because it is the effect of the degree of bacterial cleanliness of the air that is the object of the

investigation, it should be possible to group all the ultra-clean systems together if they attain comparable standards. It is not necessary to include "dirty air" conditions in the study.

We therefore, have the following four sets of conditions:

I. "Clean" air - standard positive-pressure ventilation.

II. Ultra-clean air - Charnley-Howorth or unidirectional ("laminar") airflow.

III. As II but with special clothing.

IV. Plastic isolators.

The first of these can conveniently be taken as the control condition to be employed in a proportion of the operations performed by every team. It seems improbable that the 1000-2500 operations required for statistically significant evaluation of the rates of sepsis in each group can be obtained for the plastic isolators, at least in the near future, so that only bacteriological evaluation may be practicable for this procedure. The use of special clothing in a conventionally ventilated operating room is not included because to produce a major effect on air contamination every person in the room would have to be dressed in this way. In the ultra-clean air system only the surgeon and his assistant intrude into the air mass that comes into contact with the wound. Such clothing might, of course, contribute to reducing the risk of sepsis by reducing the probability of contact transfer of microorganisms but this lies outside the scope of the present study.

Therefore, the total number required, divided between conditions I, II, and III, is approximately 7500 observed operations, corresponding to 40 team-years. With 15 teams this would take about 2 1/2 years.

2.2. Selection and allocation of patients

The types of operation that will be included in the study are:

2.2.1. Total-hip joint replacement.

2.2.2. Replacement of knee joint.

Other clean elective operations may be included if convenient.

It is important that patients are distributed between the three test conditions without bias. Strictly random allocation is probably impracticable,

and the method to be used will have to be agreed upon locally with the surgeons concerned and the hospital ethical committee. In most places, it will probably be convenient for each surgeon and team to alternate between the test and control circumstances. If this is done, the conditions should be changed at intervals of no more than seven days to minimize the influence of secular changes in the bacteriological environment. Alternatively, where several operating rooms are in use, each for a different condition, the surgeons and teams may move at similar intervals from one operating room to another.

2.3. Clinical records

Clinical and operation details for each patient included in the study will have to be recorded to check the comparability of the test and control series. These data should also provide the opportunity to evaluate the significance of some of the potentially significant variables. The progress of wound healing and the subsequent experience of the patient will be recorded in terms of objective descriptive criteria. An assessment of the incidence of differing grades of sepsis will then be made on the basis of these observations.

2.4. Bacteriological studies

2.4.1. Airborne bacteria

Because the object of this investigation is the influence of clean air on sepsis, it will be important to measure the air contamination for each set of conditions. It will not be necessary to do this for every operation, but only often enough to obtain a good estimate of the mean and variation for each set of circumstances in each place.

2.4.2. Wound contamination

Infection derived from the air of the operating room must relate to bacteria already in the wound when it is closed. If the ultra-clean-air systems are superior, there should be less wound contamination at the end of the operation. By washing out the wound at this time, and culturing the wash fluid, an estimate of this can be obtained. As detected by this method, differences between the performances of the various systems may be apparent after many fewer observations than are necessary to establish differences in the rate of sepsis. Wound-washing observations made after operations performed by no more than six teams should furnish ample data.

2.4.3. Wound infection

Bacteriological specimens should be taken from all wounds that show any departure from normal at any time they are examined. These observations can then be related to the clinical observations to obtain information on the species of microorganisms responsible, and to throw some light on the disputed role of bacterial infection in delayed breakdown of hips after joint replacement.

It is tempting to attempt to relate the strain of organisms found in each infected wound to those recovered from it at the end of operation, and to those carried by patient or staff, or found in the air of the operating room at that time. Reduction in the rate of infection due to contaminated air might be expected to be accompanied by an increasing proportion of infections due to strains carried by the patient before operation. But experience has shown that such a complete bacteriological picture is very difficult to obtain, and even a limited attempt involves a very large amount of bacteriological work. It will be useful, however, to obtain preoperative specimens from patients and from the scrubbed surgical team in those centres where wound washout is to be done, and to compare typable organisms with any found in the wound, either at the end of the operation or from the abnormal wounds.

2.5. Types of centres

As has been indicated in the above description, it is proposed that the observations shall be made at two kinds of centres.

2.5.1. Sepsis and Bacteriology (SB) Centres which will: keep clinical and bacteriological records of wounds, record wound contamination (washout) for all wounds, record preoperative bacteriology of nose and perineum for all patients, record nose carriage of swabbed staff at regular intervals, and record physical and bacteriological conditions in their own operating rooms.

There should be at least six SB centres, preferably, at least two for each ventilation system, e.g., Charnley or some type of laminar-flow. At each SB centre, the staff will include the local surgical and bacteriological consultants who will need to be assisted by:

one full-time graduate microbiologist;
one part-time laboratory technician;
one part-time infection-record nurse.

These centres would also make environmental bacteriological observations at the second type of centre and, where practicable, carry out or oversee the bacteriological observations made at those places using the Trexler plastic isolator.

2.5.2. Sepsis Centres (S) which will keep clinical records of all wounds and bacteriological records of septic wounds. There should be at least nine S centres in all for the Charnley and the laminar-flow systems. At each centre, the local surgical and bacteriological consultants will need the assistance of one part-time infection-record nurse, as well as the help provided by the microbiologist from the associated SB centre.

The precise number and distribution of the centres, of both types, and the times at which they can be brought into the investigation must depend on negotiation with the individual hospitals. Preliminary enquiries suggest that it should be possible to find enough centres willing to take part, but that some provision of special equipment, e.g., ventilation and special clothing is likely to be required to set up a well balanced investigation within a reasonably short time.

2.6. Outcome

This investigation could give one of three kinds of answers:

a) The infection rate after operation in conventionally ventilated operating rooms is appreciable, and is significantly reduced when ultra-clean air systems are employed.

b) The infection rate is appreciable and is not significantly different if ultra-clean air is provided.

c) The infection rate is, in any case, very low under the best circumstances with conventional ventilation so that the effect of ultra-clean air, if any, is too small to be demonstrable.

All these outcomes give an answer to the practical question as to whether ultra-clean air systems are of value, i.e., a) yes, b) no, and c) the effect is too small to be demonstrable.

EXPERIENCES WITH ULTRAVIOLET LIGHT IN OPERATING ROOMS

J. Drennan Lowell *

The Peter Bent Brigham Hospital is a relative newcomer to the use of ultraviolet light as a method of reducing airborne bacteria in the operating room while a surgical procedure is in progress.

We have used ultraviolet light at the Peter Bent Brigham for years as a method of improving the bacteriological isolation of our operating suites from the corridors of the hospital, and we have used similar lights to help isolate patients with known infections from uninfected patients on the wards and from the superimposition of additional infective organisms. We use them in our critical care unit for burn patients, and on occasion for patients on immunosuppressives.

Among the problems encountered with installation of the lights in the operating room were those of personnel acceptance, especially by the Departments of Anesthesia and Nursing. A solution comprising some six steps was successfully employed to solve the problem.

The first of these was a test of their effectiveness. A non-pathogenic E. coli was nebulized in two of the four operating rooms equipped with ultraviolet light, and air samples were taken with and without lights. When the lights were not illuminated, the concentration of organisms recovered was 930/5 ft^3 in one room and 310/5 ft^3 in the other. When the lights were turned on, even though the nebulizer was not turned off, there was essentially instantaneous removal of 100 percent of the organisms in one room and 99.7 percent in the other.

Because their effect was so immediate, we felt we could take a second step and modify the Duke protocol, and our lights are now not illuminated until the patient is anesthetized, prepped and draped. This made the logistics of their use much simpler and much more acceptable to the Anesthesia Service whose personnel had vastly easier access to the patient during the induction period. We turn them off at the completion of wound closure and application of the final dressing.

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The third step was installation of an autotransformer inside the operating room, by which the intensity of output from the lights could be regulated.

A fourth step was to teach our circulating nurses how to monitor the intensity of the lights, using a germicidal photometer, compact in size and portable. Once instructed in the technique of monitoring, the circulating nurses can then make adjustments as needed. The technique was easily learned, gave them a significant role in the use of the lights, and had a very positive effect in reducing not only their apprehension but that of the other operating room personnel as well. The lights are tested with each procedure at time of illumination, and are spot-checked at numerous times throughout their period of illumination. Changes in the autotransformer are not often, but occasionally, required. The intensity of light recommended is 25-30 microwatts/cm^2/second and is the intensity we use.

The fifth step consisted of monitoring a series of four total hip-replacement procedures with and without lights, then circulating the results accompanied with photographs of the fallout plates, the plates from the volumetric air samples and the Rodac agri-contact plates. The fallout plates showed a range of 4-8 organisms/ft^2/minute in each of the rooms before the lights were turned on. In the room without ultraviolet light, this remained at 4 throughout the procedure and after wound closure. In the rooms with ultraviolet light, there was a 20-fold drop in organisms while the lights were on. Even at the end of the procedure, when the drapes were removed and there was a general stirring up of the air in the operating room, fallout never rose to the earlier levels. The accompanying photographs graphically illustrated these findings. One of the patients done in the room without lights had had a renal transplant and was on immunosuppressives. The problem that arises for patients on immunosuppressives is well known to our hospital staff and, I expect, to those in most other teaching hospitals. It was a very happy coincidence that one of the patients monitored during a procedure with lights was a member of the anesthesia staff at the Brigham, and it was quite easy for the operating room personnel to identify with this individual.

Experiences with Ultra Violet Light in Operating Rooms

The sixth and final step was to develop a protocol for the use of the lights for protection of patient and personnel. The protocol consists of the wearing of goggles, not unlike ski goggles, which are commercially available and regularly used in industry, or the use of a gambler's-type eye shade in association with ordinary eye glasses, temporarily equipped with side shields. The skin is protected either by the use of fire-resistant paper hoods covering the exposed areas of the face and neck, or by the use of a Benzophenone-containing suntan lotion, such as UVAL or SOLBAR, both of which are commercially available in any drug store.

Similar precautionary measures may be taken for patients, although usually the patient is shielded from the lights by the surgical drapes held away from the face and anesthetic equipment by conventionally shaped metal supports. Lights are turned on at the time of incision and off at the completion of wound closure.

In our review of the National Academy of Sciences--National Research Council study on the subject of postoperative wound infections (1), we found that no mention was made of the influence of humidity on the role of ultraviolet light effectiveness as a bactericidal agent. The role is a significant one and must be recognized and appreciated by any who might consider this method of reducing bacteria in the air. Observations relative to this were made by William Wells (2,3), who stated that when the humidity is above the 60 percent level, the bactericidal power of ultraviolet radiation is critically affected and drops off very rapidly.

Our experience has paralleled that of the group at Duke University in that we have found that ultraviolet radiation is an extremely effective method of reducing the numbers of viable airborne bacteria in the operating theater. To date, using this technique in conjunction with preoperative and intraoperative antibiotics, we have experienced no infections in patients undergoing total-hip or total-knee replacements at the Peter Bent Brigham Hospital since the ultraviolet lights were installed. Prior to that time, our infection rate was 1.5 percent.

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ONE CLINICIAN'S THOUGHTS UPON ATTENDING THE WORKSHOP ON CONTROL OF OPERATING ROOM AIRBORNE BACTERIA

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Airborne bacteria are part of the wound infection problem.

Sources can be identified and include the patient, scrubbed members of the surgical team, unscrubbed members of the surgical team, and other personnel incidentally present in the operating room area.

The numbers of bacteria can be quantified in some measure, by a variety of methods which allow assessment of techniques used to reduce airborne bacterial counts within the framework of one institution, but do not allow easily compared conclusions between institutions, and some standardization of these methods between hospitals is critically needed.

Methods are available to reduce the numbers of airborne bacteria in the operating room environment.

At the very least, it would appear that a relationship can be shown between the quantity of bacteria in the operating room air and the incidence of postoperative infection in clean surgery.

The quantitative or qualitative relationship between organisms found in the air to those found in the operative wound and subsequently found in infected wounds is inadequately defined. At least a part of this problem lies in the deficiency which exists in our being able to culture organisms in the operative wound with uniform success in all investigating centers. There is one report (Burke) in which wound culturing was 100 percent successful in recovering organisms, whereas most other reports given at the meeting or cited elsewhere report only a 20 percent success.

Until such a time as wound culturing can be done more successfully, any conclusion as to the existence of an incontrovertible relationship between observed airborne organisms and observed infection must be inferential, even though this inference may be remarkably strong.

Until it is incontrovertible, our recommendations must be accordingly tempered, particularly with reference to the employment of air handling techniques and cannot be in the form of a mandate.

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Although all of us urge continued effort along any reasonable line to solve the problem of wound infection, I would specifically recommend that one area of endeavor should be along the lines of developing a more successful method of intraoperative wound culturing.

UNIDIRECTIONAL AIRFLOW IN HOSPITAL OPERATING THEATERS

George F. Mallison*

Airborne microbial contamination in operating theaters may contribute, in part, to the risk of surgical wound infection; but endogenous infection, infection acquired postoperatively, and infection transmitted by contact are of greater importance. Other factors such as operative technique and host susceptibility also have major influences on the risk of acquiring wound infection. Unidirectional airflow (UAF) systems in operating theaters have a potential for reducing the risk of wound infection in selected circumstances, but there are no controlled studies to support their efficacy thus far. Hospitals are not encouraged to install these systems until controlled clinical trials document a significant reduction in patient disease, and until population groups that might benefit from these systems are more precisely defined.

Air filtration and delivery systems that are apparently far more efficient than traditional air conditioning systems in reducing airborne particulate and microbial contamination have recently become available for use in hospitals (11). These systems incorporate ultra-high efficiency particulate filters and high rates of air change in an attempt to achieve clean, relatively unidirectional airflow. They have been variously described as laminar, linear, or unidirectional airflow (UAF) systems, but the latter term appears more descriptive of their effects in hospital operating theaters (5,21). Several investigators have enthusiastically recommended conversion to UAF in operating theaters (11,21), but others have questioned the value of such systems for routine use (7,9). A hospital's decision regarding installation of UAF systems should be based upon an assessment of the epidemiology of surgical wound infections and data concerning the efficacy of these systems.

THE EPIDEMIOLOGY OF SURGICAL WOUND INFECTIONS

Airborne contamination in the operating theater is but one of the many factors influencing the risk of surgical wound infection.

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Surgical wound infections may be acquired from numerous potential human and extra-human reservoirs both at time of operation and in the post-operative period (16,18). A patient's own flora is one potential reservoir: normal fecal flora is responsible for a substantial proportion of infections following intra-abdominal procedures (24); nasal carriers of staphylococci appear to have a higher risk of acquiring staphylococcal wound infection than non-carriers (25); and transient bacteremia at the time of operation may seed a surgical wound and result in subsequent wound infection (13). Exogenous reservoirs such as contaminated air, surgical instruments, medications, or colonized personnel are frequently implicated in outbreaks of wound infection (20,22).

Pathogenic microorganisms may be transmitted to a surgical wound by direct contact, by contamination of a common vehicle, or indirectly by airborne spread. Despite numerous attempts to document the role of airborne transmission in the acquisition of surgical wound infection, its relative importance is still uncertain. Burke demonstrated that air adjacent to open wounds at the time of operation is often contaminated with potential pathogens, and he considered the air to be the final common pathway responsible for much of the universal contamination of clean wounds that he demonstrated (4). Howe and Marston, on the other hand, demonstrated no relationships between variations in airborne contamination and the incidence of infections in clean surgical wounds in a large uncontrolled study (14). Ultraviolet (UV) light is effective in reducing airborne microbial contamination (17), but a large and well-controlled study of the effects of UV light in the operating room showed a statistically significant reduction in infections only in very clean surgical wounds when UV light was used at the time of operation; and UV light had no influence on the incidence of wound infection in other types of surgery (17).

Contamination of a surgical wound with pathogenic organisms is necessary but not sufficient for development of a clinical wound infection (10); from 30 percent to 100 percent of wounds of clean surgical procedures have been shown to be contaminated at the time of closure (4,17), and most healed without evidence of wound infection. Factors influencing the risk of infection include alterations in host susceptibility, surgical technique, and patterns of antimicrobial usage (8,17).

EFFECTIVENESS OF UNIDIRECTIONAL AIRFLOW

Valid environmental testing of UAF systems requires sophisticated techniques and careful study design (15); many environmental studies purporting to demonstrate reductions in airborne contamination with UAF provide little meaningful data because of invalid sampling techniques or test conditions that are not applicable to the operating theater. Nonetheless, airborne microbial counts are probably reduced by these systems. However, current practices in operating theaters in the United States generally result in very low levels of airborne contamination. The benefits resulting from a further lowering of this contamination level by use of UAF must be measured by effects on patient disease; expensive or complicated alterations do not seem justified unless the incidence of infection is significantly decreased.

Charnley and associates pioneered the clinical use of UAF in total-hip replacements. As they introduced progressively sophisticated measures to reduce airborne contamination, they noted a definite trend towards a reduction in surgical wound infections (6). However, changes in operative technique, alterations in surgical skill, variations in patient selection, and changes in ward care activities occurring concurrently were not evaluated and played an unmeasured role in these uncontrolled studies. Furthermore, they also introduced measures to minimize direct contact transmission. While some investigators have noted high infection rates following total-hip replacement (19,26), others have apparently achieved infection rates comparable to Charnley's excellent results without use of UAF systems (23,26). In a controlled clinical trial, Alpert reported a threefold reduction in surgical wound infections with use of a patient surgical isolator, but the study design was insufficiently described to allow interpretation of these data (1).

DISCUSSION

The exact proportion of surgical wound infections resulting from airborne contamination in the operating theater is unknown (25), but we believe that other factors are generally of greater importance. A higher relative risk of acquiring airborne infection may occur in certain populations (the very old or young; patients with impaired immune systems, or those undergoing prolonged procedures that result in extensive tissue damage, or that implant a foreign

body). In these select populations, UAF has theoretical advantages. However, trials such as the UV light study (17) suggest that UAF alone may have only minimal effect on the incidence of wound infection, even in select populations. Thus, until the effectiveness of UAF in reducing patient disease is documented in controlled clinical trials, we do not recommend that hospitals routinely install UAF devices.

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PERSONAL ENVELOPE SYSTEM IN THE CONTROL OF OPERATING ROOM AIR CONTAMINATION

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John Prentis*

It is now a well-established fact that, in the modern operating room, the large majority of airborne microorganisms emanate from the skin and respiratory tracts of the surgical team, including the circulating nurses, the anesthetists and other personnel. This air contamination is of particular concern to the orthopaedic surgeon, as it represents one of the sources of wound contamination which may lead to infection, particularly in the presence of the large implants used in major joint reconstruction. There has been considerable interest in controlling the level of this air contamination, and for the past decade most of the attention has been directed towards the use of so-called "laminar flow" clean rooms. These installations do not completely eliminate the problem, but they appear to reduce the level of air and wound contamination (8,10,19,23), and have, for the moment, gained considerable acceptance, in spite of the fact that they tend to be cramped, noisy, hot and expensive. More recently, attention has been devoted to other somewhat more simplistic approaches in an attempt to reduce air and subsequent wound contamination.

We have postulated that if the "spilling" into the air of organisms from the skin and respiratory tract of the surgical team could be prevented or blocked at its source by the use of new highly specialized operating room costumes, then the level of air contamination and the degree of risk to the surgical wound would be markedly reduced. It is the purpose of this paper to present the preliminary results of research in this regard.

REVIEW OF THE LITERATURE

The surgical operating room of the modern hospital is synonymous with cleanliness and sterility, but complicating infection persists as a problem, involving 3-10 percent of all elective operations (1,22,25), and the availability of antibiotics has not changed the overall incidence of this problem in

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recent decades. Altemeier (1) states that the average cost for sepsis complicating elective surgery is $7,000 per patient, and the cost to the North American community probably exceeds ten billion dollars a year.

It is probable that sepsis originates, in the large majority of cases, with contamination occurring during the course of surgery (4). It is now recognized that airborne microorganisms in the operating room are an important source of contamination and a threat to the clean surgical wound (9,14, 15, 23).

Many studies have shown that the air in the empty operating room is almost free of organisms (10,21), but becomes increasingly contaminated as the room is occupied by the surgical team. It is obvious that most of the contaminating organisms originate from the skin and respiratory tract of the people who staff the room (3,9,11). There is great variation from individual to individual in the number and character of organisms released into the air. Some individuals described as "shedders" or "dispersers" may release unusually large numbers of Staphylococcus albus, the organism most commonly found on the skin, while others may release significant numbers of very virulent pathogens, either because this is "normal" for that person or because of the presence of a local purulent lesion.

The normal individual sheds many thousands of viable particles per minute (26), and this desquamation is in no way controlled by the caps, masks and gowns in current use (7,12,13,16,20) which are essentially identical to those used 60 years ago (17,24). Some studies have suggested that closely woven or impervious fabrics might be of some value (7,13,20).

Some effort has been made to identify the exact portion of the body responsible for the major part of air contamination (20), and some new types of attire have appeared designed to control the problem. These include hoods of various designs, new masks with or without exhaust systems, and gowns of synthetic fabrics, which are said to be more impervious than those of standard cotton fabric.

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THE PREVENTION OF AIR CONTAMINATION

It is postulated that if the spill of microorganisms from the surgical team into the air is to be prevented, two requirements must be satisfied: the first is that costumes must be designed to cover all parts of the body which are sources of bacterial contamination; and secondly, that a material must be used which is completely impervious to airborne organisms. This leads to a third requirement: that moisture and heat accumulating beneath the costume must be carried away, and to satisfy this, a total-body exhaust system would be essential. An additional advantage of an exhaust system is that it produces a negative pressure within the costume, so that at the points where essential parts, such as arms, protrude from the costume, the flow of air will be from outside in.

METHODOLOGY

The experiments to be described were all carried out in an empty operating room of standard dimensions, supplied by filtered outside air, with approximately twenty changes per hour. The room was subjected to routine cleaning by the operating room housekeeping staff each day preceding the experiments. The air in the operating room was sampled using a Casella sampler which passes 25 cu/ft of air per minute over a bacteriological culture plate. Each of the sequential plates represented a five-minute period of sampling.

A "mock operating room team" was assembled, made up of a small number of individuals who took part in most of the experiments. A standard activity pattern was developed which yielded reproducible results in terms of air contamination, providing a consistent baseline upon which the investigations were superimposed.

In all experiments, the operating room was allowed to stand empty for 15 minutes, followed by the introduction of the "mock operating room team" which carried out its assignments for a period of 5 minutes. Following this, the room was once again allowed to "rest" for 15 minutes with air sampling before the next experiment was carried out.

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OPERATING ROOM CHARACTERISTICS

The air in the empty operating room was found to be virtually free of organisms, but the entrance of personnel was always attended by a sharp increase in contamination; within 15 minutes after the room was vacated the counts returned again to the baseline. These findings were consistent and reproducible from day to day.

Reservoir Effect

It was postulated that organisms introduced into the operating room air during one experiment might settle onto various surfaces, and might be remobilized by activity and turbulence during a subsequent experiment, resulting in artifactual data. To explore this point, the operating room was occupied by the "mock operating room team" dressed only in standard scrub suits, caps and masks; they pursued the standard activity pattern for five minutes with the expected increase in air contamination. The room was then vacated and allowed to remain empty for 15 minutes, at which time large fans which had previously been placed in the room were started in order to produce air turbulence. This failed to produce an increase in the level of airborne microorganisms. It appears, therefore, that there is no reservoir effect, and that organisms introduced into an operating room are either carried away by the airconditioning, or settle out on surfaces, and are not effectively remobilized.

Opening and Closing of Doors

It has been said that the opening and closing of doors in operating rooms produces turbulence which increases the level of air contamination. With samplers functioning in an empty operating room, the doors were opened and closed repeatedly <u>from the outside</u> without any increase in the level of air contamination. When the experiment was repeated by <u>individuals inside</u> the operating room opening and closing doors, there was a significant rise in the air count. Obviously, the opening and closing of doors and the attendant turbulence in itself is not of importance.

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Number of People and Level of Activity

Studies were carried out to document the relationship between the number of people in the operating room, their level of activity, and the associated level of airborne organisms. In sequential experimental periods, increasing numbers of people followed the standard activity pattern in the operating room with air sampling. Figure 1 indicates the direct relationship between the number of people and the level of air contamination.

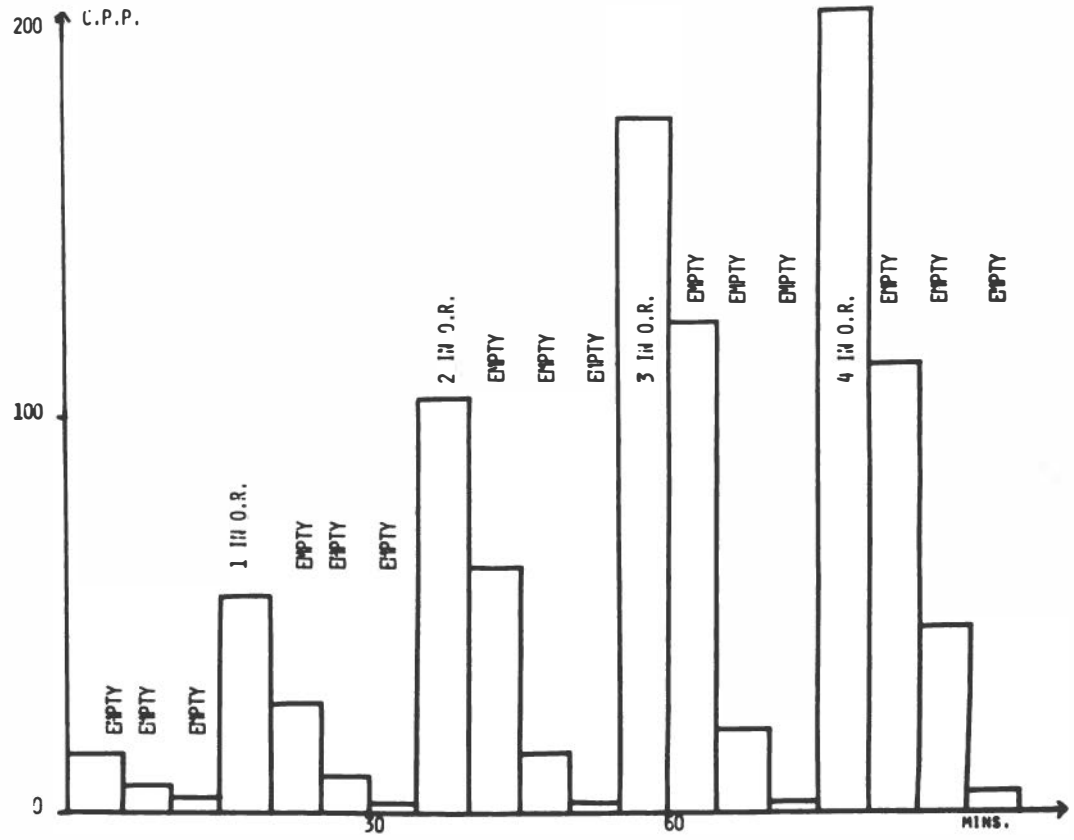

Fig. 1. This histogram summarizes the relationship between the number of people in the operating room and the level of air contamination. As in all of our studies, the "mock operating room team" occupied the room for five-minute experimental periods, divided by 15-minute intervals, during which time the operating room was empty. Air sampling continued throughout.

In sequential experimental periods two members of the "mock operating room team" pursued increasing levels of activity, with proportional increases in the level of air contamination, as summarized in Figure 2.

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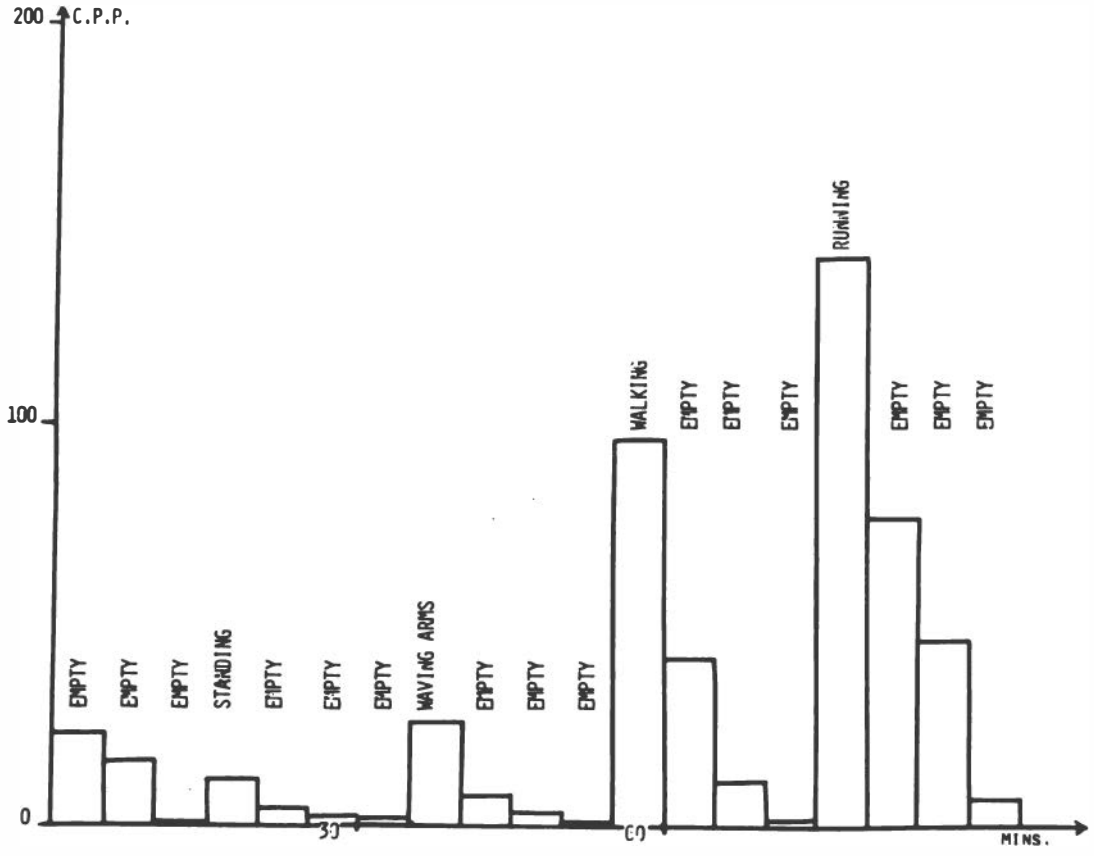

Fig. 2. The relationship between the level of activity of the "mock operating room team" and the concentration of airborne organisms is summarized in this histogram.

THE COMPLETELY OCCLUSIVE "ENVELOPE" SYSTEM

A relatively crude experiment was devised to establish whether or not the operating room environment could be protected from the organisms normally released from the skin or respiratory tract. A large occlusive polyethylene "bag" (Fig. 3) was devised with legs, but no openings for arms and head. Members of the "mock operating room team," dressed in this costume, entered the operating room and pursued a standard activity pattern for five minutes. Fifteen minutes later, as a control, the same members entered dressed only in scrub suits, caps and masks, and again pursued the same activity pattern for five minutes.

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Fig. 3. Occlusive polyethylene "bag" used experimentally. Mock operations carried out with the team dressed in these garments resulted in no increase in airborne organisms.

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Fifteen minutes later, the same group re-entered the operating room, once again dressed in the polyethylene bags. The findings are summarized in Figure 4, which shows the members of the operating room team did not contaminate the air when dressed in plastic bags, but, in contrast, produced heavy contamination when dressed in scrub suits. It is interesting to note that 15 minutes later, when they re-entered the operating room in plastic bags, they were unable to re-mobilize the organisms released during the scrub suit phase moments earlier, once again verifying that there is no reservoir effect in the well-maintained operating room.

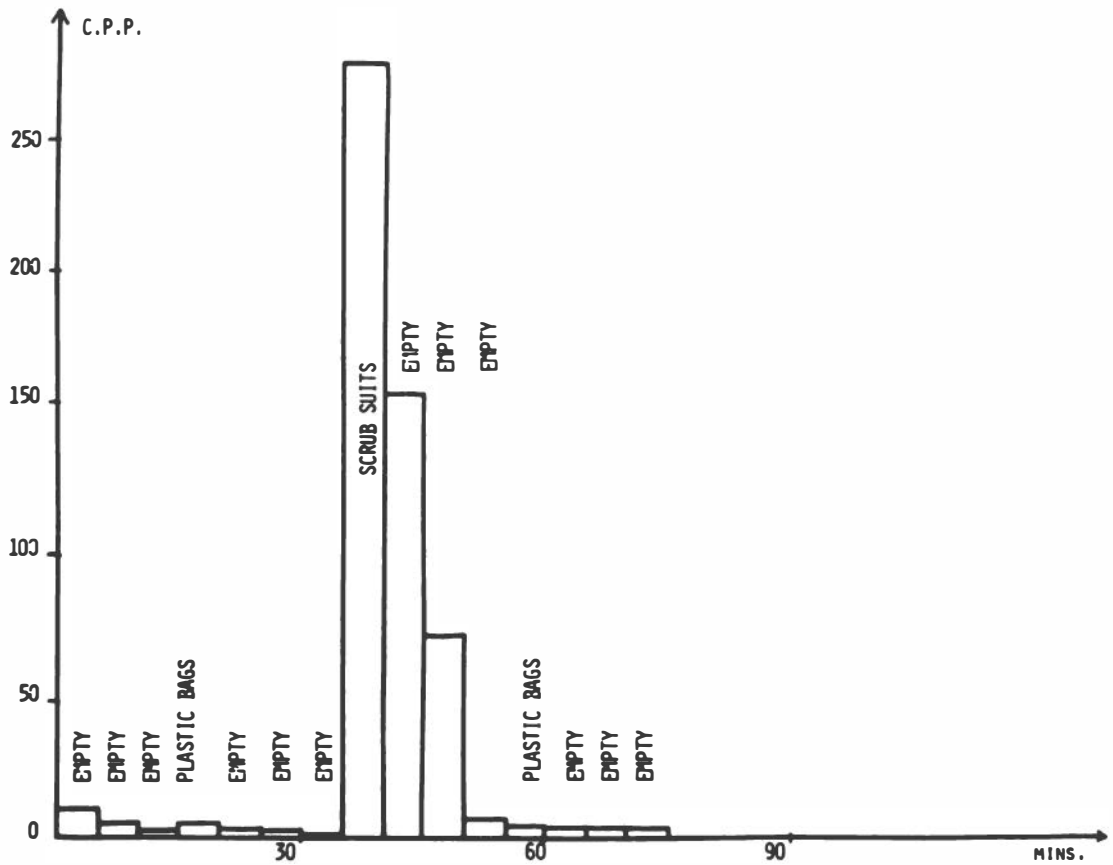

Fig. 4. "Mock operating room team" dressed in plastic bags produced no increase in the number of airborne organisms, in contrast to heavy increase when they wore standard scrub suits, caps, masks and gowns.

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FABRIC STUDIES

The occlusive bag was utilized as a vehicle to study the effectiveness of various fabrics which are commonly used in the manufacture of operating room costumes. Bags were made of operating room cotton (Fig. 5), a patented closed woven fabric, and disposable paper fabric. The same members of the "mock operating room team" wore these costumes in sequential experiments, and the findings are summarized in Figure 6. The degree of air contamination is directly proportional to the inadequacies of the material in containing desquamated organisms. The fabric is, of course, subjected to the various deformations, stresses and local pressure differentials which would be generated in any costume in common operating room usage.

Fig. 5. Experimental costumes were also manufactured from cotton and other fabrics.

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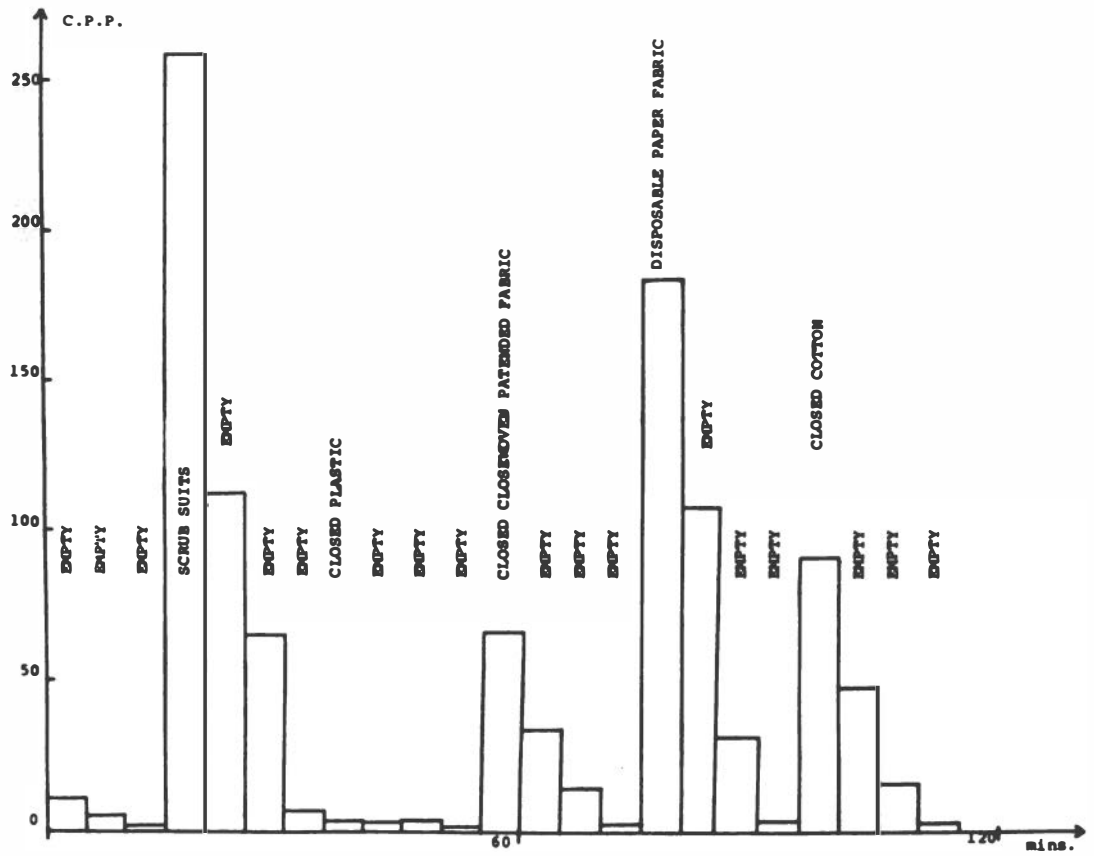

Fig. 6. This histogram summarizes the effectiveness of different materials in containing desquamated and expired micro-organisms.

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To compare the effectiveness of these bags with the jump suits worn over street clothes by visitors and with scrub suits, studies were carried out which are summarized in Figure 7.

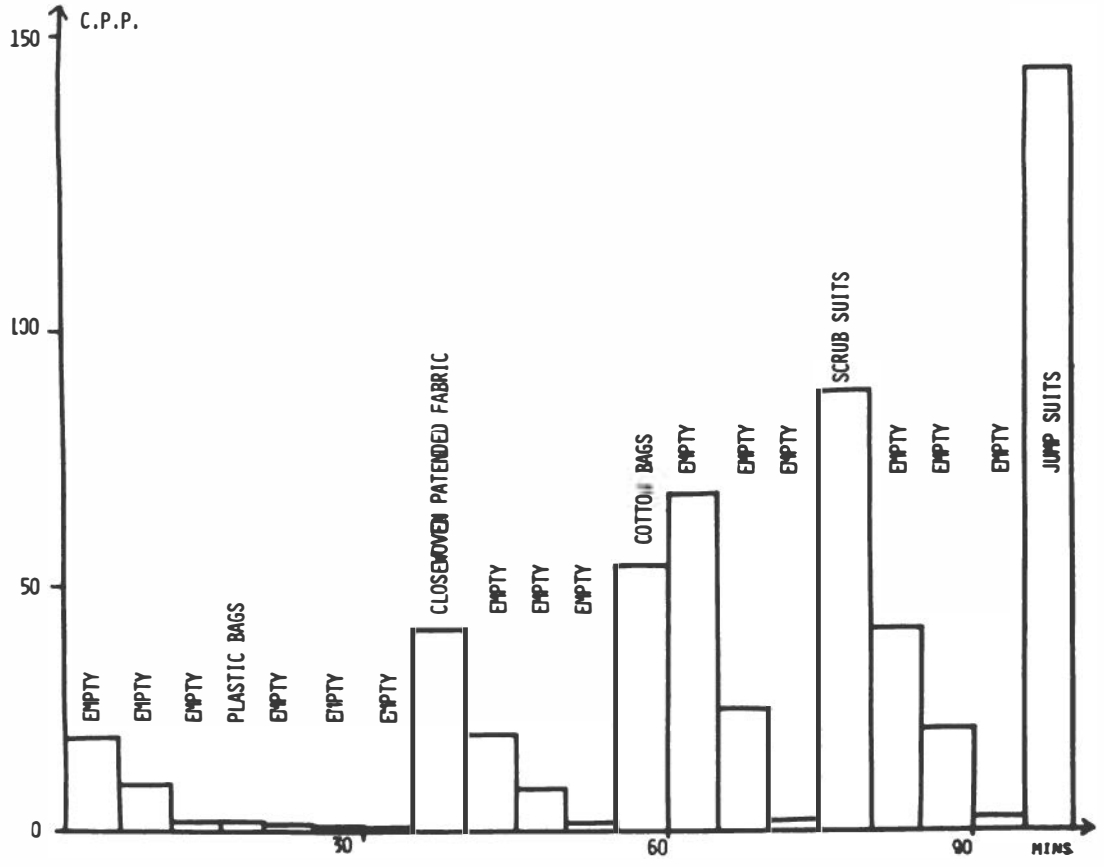

Fig. 7. The effectiveness of various materials in containing microorganisms is contrasted in this histogram with the effectiveness of scrub suits, and with jump suits over street clothes.

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SUMMARY AND CONCLUSIONS

The results of the experiments reported here indicate that the empty operating room is a suitable "laboratory" for the study of air contamination emanating from members of the operating room team. This contamination can, in the experimental setting, be controlled by the use of a completely occlusive and impervious costume. Various materials have been evaluated and have been shown to be more or less effective with respect to their ability to contain organisms from the skin and respiratory tract. Studies are continuing and involve the development of a practical one-piece scrub suit, with arms protruding, made of impervious material, and used with a total-body exhaust system.

All individuals in the surgical operating room will be required to wear this garment, which may diminish markedly the level of air contamination during the course of surgery. The surgeon, his assistant and the scrub nurse will, as at present, use the sterile gown to prevent contamination by contact. The importance of an occlusive head gear is still being studied.

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CLEAN AIR SYSTEMS

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One of the most controversial issues in surgery today is the use of laminar airflow systems in the operating room. The controversy and misunderstanding are compounded with the term "laminar flow" since there is no really true laminar flow as it is used in the operating room.

Many statements have been made concerning laminar airflow systems, or, more precisely, clean air systems. Questions have been raised regarding the design of units, the direction of airflow, premarketing testing, the federal role in legislation, and the medico-legal implications of infection as related to clean air systems. Unfortunately, because of these implications and a lack of information regarding clean air systems, the issue has become almost too controversial to discuss. Therefore, only meager information on clean air systems has been available to the orthopaedist. Rumor, impression, and dogma have been substituted for the scientific study and statistical evaluation that we usually rely upon.

The concept of clean air is of common interest to the ecologist and the surgeon, although the adjective "clean" has somewhat different connotations to each of these scientists. Attached to the concept of clean air and laminar airflow is an unfortunate emotional reaction. One must separate fact from hypothesis and attribute to these clean air systems only those facts we know. If unproved features are dogmatically attributed to the clean air systems, they will detract from what appears to be a logical, useful, and efficient adjunct in reducing bacterial contamination of surgical wounds.

The orthopaedists' interest in clean air was further stimulated when total-hip replacement arthroplasty was developed for the treatment of diseases of the hip. An infection in the total-hip replacement arthroplasty or total-knee arthroplasty sites may result in failure of the operation. This is in contrast to the usually excellent results obtained with these operations. Also, total-hip and total-knee replacement arthroplasty may be a more sensitive indicator of infection than many commonly used laboratory bacterial testing systems. The large dead space surrounding the operative area and the small

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amount of living tissue in contact with the large endoprosthesis are factors that encourage bacterial growth. Furthermore, materials such as acrylic bone cement and high density polyethylene, which are not entirely inert, may also increase the likelihood of infection.

HISTORICAL CONSIDERATIONS

In considering the merits of the clean-air system in total-hip replacement arthroplasty, the historical background of infections and past attempts to eradicate infection should be reviewed. Lister (16) proposed the concepts of antiseptic surgery, and with the application of these principles the rate of infection decreased. His concepts led to the present era of aseptic surgery, which includes preoperative skin cleansing combined with a sterile scrub of the operating room personnel, sterile rubber gloves and masks, sterile draping equipment, sterile clothing, and sterile instruments. One must concede that there is no substitute for strict adherence to standard aseptic surgical techniques. In 1888, Moynihan (20) stated that two-thirds of his patients died of infection after he had opened the belly. In 1915, Brewer (4) showed that the infection rate after clean operations was 39 percent. In 1933, Meleney (18) reported that adherence to aseptic technique, rigid restriction of movement within the operating room, careful preparation of the patient, and gentle handling of tissue reduced the incidence of serious wound infection from 4 to 1.7 percent and of minor infection from 10 to 5.4 percent. In a similar study, McKissock *et al.* (17) reduced the percentage of surgical infections from 15 to 1.1 percent. More recently, Henderson and Kornblum (12) were able to hold the percentage of serious infections in 3,290 operations to 1.7 percent; Steel (29) reduced his infection rate from 15 to 0.58 percent.

From these studies, similar criteria for reducing the incidence of infection have been established: rigid restriction of movement in the operating room, especially restriction of the inadvertent visitor; careful, thorough preparation of the patient and the operating room personnel; gentle handling of tissue; and an intangible -- the alerting of every one in the hospital to the problem of infection.

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SOURCES OF INFECTION

Almost everyone agrees that surgical wounds, at the time of operation, can become infected. There is less agreement whether most infections are endogenous or exogenous, animate or inanimate. However, certain facts are known. Wound infections are directly related to the type of organism that may find its way into the wound, the host's ability to combat infection, and the number of bacteria deposited in the wound; and of course, there must be a chance of deposition of bacteria into the wound for the development of infection.

A single individual sheds 5,000 to 55,000 particles per minute, depending on how recently he showered and on the kind of clothing worn. The physical activity of the surgeon and others in the operating room directly affects the particle and bacterial counts and also affects the circulation of bacteria in the air. Conventional operating room air may contain as many as 10 to 15 bacteria per cubic foot and as many as 250,000 particles per cubic foot.

The fine cotton surgical gowns and drapes have apertures large enough to allow particulate matter and accompanying bacteria to pass through. Charnley and Eftekhar (6) have shown that 50 percent of the surface of such gowns is contaminated at the conclusion of a total-hip replacement arthroplasty. Since the surgeon and operating room personnel are sources of bacteria, and since the activity pumps particulate matter over the wound, there is little question that if one releases particles with attached bacteria above the wound, they will be deposited into the wound. Even the most staunch nonbeliever in airborne contamination will agree that bacteria should not be deposited into an open wound. In light of the knowledge of airborne contamination of the wound site, what attempts have been made to eradicate contamination and clean the air of the operating room?

Ultraviolet light has been used to reduce the incidence of wound infection by reducing the number of airborne bacteria. The results are interesting. Ultraviolet light does decrease the amount of bacterial contamination in the operating room, but a double blind study, using dummy lamps in one room,

showed that the infection rate was almost identical with and without the ultraviolet light. In reviewing the results of this study, it is clear that all the cases in this portion of the study were the so-called unclean cases (11,21). When only ultraclean cases were considered such as those in reconstructive surgery, the difference in the two groups was statistically significant. Cleaning the airborne contamination by ultraviolet light reduced the infection rate. In general, in this study there would have been 30 fewer deep wound infections if ultraviolet light had been used in ultraclean cases.

Therefore, there are data and logic in support of attempts to reduce airborne contamination. Altemeier and Levenson (1) have pointed out that infections developed postoperatively in an estimated 1,391,000 patients at a cost of $7,000 per patient, with an overall cost of 9.8 billion dollars for the control of wound infections. This is a significant sum, but only the individual affected and the surgeon can truly understand the suffering and disability that occur with serious deep wound infection. Monetary and humanitarian needs justify all rational attempts to reduce wound infection.

LAMINAR AIRFLOW SYSTEMS

The first use of laminar airborne contamination control was by the aerospace industry in the early 1960s. It was noted that any small particulate matter could contaminate gyroscopic equipment in missile guidance systems and cause malfunction. Particulate matter as small as that in cigarette smoke could be responsible for contamination. Whitfield (31) pioneered the use of laminar airflow systems to reduce contamination.

Laminar airflow can be described as the flow in which the entire body of air within a confined area moves at a uniform velocity along parallel flow lines. This principle was mechanized and then applied to the aerospace industry. Recently this type of clean air technology has been applied to the operating room. In this type of environment, the system filters out particulate matter with attached microbial organisms before it enters the surgical area. This is done by a high efficiency filter system. The filter system now used in surgical suites provides what is known as Class 100 air. Class 100 air is one in which each cubic foot of air contains not more than 100 particles 0.5 micron or larger in diameter.

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Laminar flow clean air really does not exist in the operating room. Persons or objects in the room, such as the surgeon or surgical tools, disturb the airflow pattern, and the air becomes turbulent. Thus, in all laminar clean rooms the air is turbulent. "Clean air room" is a more accurate and acceptable description than the term "laminar." It is also clear that in designing and using clean air systems, it is necessary to properly plan and use the surgical area, so that any turbulence or eddying of current is reduced, and does not occur over the surgical site.

One type of clean air system that has been used is a wall-less horizontal system consisting of two parts - a self-contained blower filter system, which propels a horizontal flow of Class 100 air, and a vacuum aspirator system for the surgeon (22). A blower module placed at one end of the operating room propels a flow of clean air across the operating room. The horizontal system sends airflow in one direction, and in this manner particles are removed from the operating area. This system produces approximately 200 air changes per hour in the room, compared with 12 air changes in the standard operating room. The 200 changes developed by the horizontal system are for the entire room; over the work site there are about 500 changes of air per hour, and particles shed by the surgeon and staff are swept away from them and across the room. The air then rebounds from the opposite wall, turns laterally along the wall and enters the filtration system, the module, at the side. A high efficiency particulate air filter lies in the front of the module behind the perforated metal cover. The filter is 99.9 percent effective in removing particulate matter with attached bacteria and viruses.

A bacteriological study was designed to determine the effectiveness of a horizontal-wall-less clean air system in reducing bacterial contamination in the operating theater. One operating theater was chosen for study and all investigations were done in this room. The same surgeon, number of operating room personnel, and nursing staff were used for each clinical evaluation. Patients undergoing total-hip replacement arthroplasty were chosen for clinical study, none showing evidence of previous or secondary infection. The patient and operating room personnel were identically prepared prior to surgery, and all personnel in the operating theater wore hoods, gowns and foot coverings. The doors of the operating theater were taped closed and any entry was noted.

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Five TDL slit samplers were positioned in specified locations and labeled A,B,C,D, and E. The letters designated the following sites: A - instrument table; B - side opposite surgeon; C - anesthesia area; D - wound site; E - clean air filter exit (see schematic representation). The sampler at the wound site was somewhat differently positioned from the rest. A metal tube 4½ inches by 15/16 inches was connected to the slit sampler which was attached to a tigon tubing 21 inches by 1 6/16 inches and a metal tube 9 6/16 inches by 15/16 inches. The metal tube and flexible plastic tube were passed beneath the surgical coverings, incorporated into the drapings and taped into position. The tube did not directly contact the patient's skin and was positioned only after adhesive skin covering had been applied to the thigh.

Three tissue samples were taken at surgery, incubated in blood agar plates at 35° C and colony forming unit (CFU) counts made at 48 hours.

The TDL slit sampler used in this study was made by Engineering Development and Products, Incorporated, Decatur, Georgia. The sampler is a spring drive model-A which operates by a simple gear mechanism. A plastic Petri dish (100x15 millimeters containing 10 cc of blood agar medium) was placed on an adjustable stage which rotated at a speed of one revolution per hour. The medium did not touch the sampler except at the level indicator, which is a contact point in the center of the Petri dish. The top edge of the indicator is the point of reference used in determining the starting point from the dish. A witness mark on the dish is matched to the reference indicator. All samplers were calibrated with a Wright's respirometer, and were found to draw one cubic foot, plus or minus 100 cubic inches of air per minute (including the sampler with tubing attached).

The plates were collected after surgery and placed in a 35° C incubator for approximately 48 hours. The plates were examined with a Quebec colony counter, and the colonies counted counter-clockwise in twelve equal divisions on the plates. Each division represented a five-minute period. The colony counts were recorded in colony forming units per minute per cubic foot of air. The presence of lint on the plates is also recorded, and indicated as

degree by either scattered lint (which means slight) or distinct lint (which means a definite line of lint.)

RESULTS

The operating theater studied showed the following levels of bacterial contamination when the operating room was completely empty (Fig. 1).

Figure I

Clean Air Unit Off
Room Empty

A = 2.4 CFU/CU FT /MIN
B = 1.8 CFU/CU FT /MIN
C = 1.9 CFU/CU FT /MIN
D = 2.2 CFU/CU FT /MIN
E = 2.0 CFU/CU FT /MIN

The same empty operating room showed a significant decrease in the levels of contamination of air sampling when a clean air system was turned on (Fig. II).

Figure II

Clean Air Unit On
Room Empty

A = 0.2 CFU/CU FT /MIN
B = 0.1 CFU/CU FT /MIN
C = 0.2 CFU/CU FT /MIN
D = 0.4 CFU/CU FT /MIN

The bacteriological contamination of the operating theater was sampled in five different sites during total-hip replacement arthroplasties in a standard operating theater without the clean air system functioning. The levels were significantly high (Fig. III).

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Figure III

AVERAGE CFU/CU FT/MIN AT 5 SITES
DURING TOTAL HIP REPLACEMENT
STANDARD O.R.
(15)

A	7.2
B	9.9
C	8.5
D	6.3
E	9.8

Under identical conditions, the sampling was performed during total-hip arthroplasty when a clean-air system and an aspirator system were turned on. The levels of bacterial contamination were significantly lower (Fig. IV).

Figure IV

AVERAGE CFU/CU FT/MIN AT 5 SITES
DURING TOTAL-HIP REPLACEMENT
CLEAN AIR SYSTEM ON
(15)

A	0.1	$p < 0.02$
B	1.24	$p < 0.02$
C	2.32	$p < 0.05$
D	1.4	$p < 0.001$
E	0	$p < 0.001$

A third portion of the study was performed when the clean air system was functioning during a total-hip replacement arthroplasty, but the aspirator system was shut off. The bacteriological levels were statistically unchanged.

PART II

The data in Part I showed that the use of an aspirator system did not further reduce the level of bacterial contamination. The aspirator system was then replaced with a prototype surgical isolator-aspirator system, consisting of a self-contained aspirator vacuum, and a one-piece Barbac surgical gown with face shield that completely covered the surgeon to the knees. There was a further significant reduction in the bacterial contamination (Fig. V).

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Figure V

AVERAGE CFU/CU FT/MIN AT 5 SITES
DURING TOTAL-HIP REPLACEMENT
CLEAN AIR SYSTEM ON & SURGICAL ISOLATOR
(6)

A	0.6	
B	0.88	
C	0.71	$p < 0.02$
D	0.43	$p < 0.05$
E	0.	

The surgical isolator-aspirator system alone was then used during total-hip replacement arthroplasty in the standard operating room without a clean air system. The data in a small number of cases showed a difference at the wound site (Fig. VI).

Figure VI

CLEAN AIR UNIT
OFF
SURGICAL ISOLATOR
3 PATIENTS AVERAGE CFU/CU FT/MIN AT 5 SITES

A = 4.2 CFU/CU FT /MIN	
B = 3.7 CFU/CU FT /MIN	
C = 3.7 CFU/CU FT /MIN	
D = 1.9 CFU/CU FT /MIN	$p < 0.05$
E = 3.6 CFU/CU FT /MIN	

Eighty-two different colony forming units were surveyed and morphologically identified (Fig. VII).

Figure VII

BACTERIA IDENTIFIED

Staphylococcus Coagulase Negative	52%
Diphtheroids	44%
Bacillus Species	2%
Yeast Forms	1%
Staphylococcus Coagulase positive	1%

Figure VIII

FOURTEEN PATIENTS WITH INFECTED TOTAL-HIP REPLACEMENT ARTHROPLASTY

Staphylococcus Coagulase Negative	6
Staphylococcus Coagulase Positive	1
Beta Hemolytic Streptococcus	1
Gamma Streptococcus	1
Enterococcus	1
Klebsiella	1
Pseudomonas Aeruginosa	3

This study confirms the findings of Charnley, Ritter, and Herndon (7,13,14,27,28) that clean air systems do significantly reduce bacterial contamination, and points out the importance of containment of the bacterial contamination produced by operating room personnel at the time of surgery.

EFFECTIVENESS OF CLEAN AIR SYSTEMS

Is there any proof that these systems have value? Charnley and Eftekhar (7) have shown that with an increased airflow the infection rate was reduced from 8.9 to 1.3 percent. During this period, no doubt, they changed and improved their technique, altered the criteria for surgery, and more rigidly enforced aseptic technique. Nevertheless, this significant decrease in the incidence of wound infection combined with the other data, suggest that the clean air system is a valuable adjunct in reducing operating room infection. The results of the other studies point out the capabilities of these systems in reducing the amount of bacterial contamination and, in turn, infection. Results of a study in Albuquerque, New Mexico, showed a 0.79 percent wound infection rate in clean air systems compared with a 1.4 percent wound infection rate in a control group.

One of the few controlled studies that has been done involved 300 total-hip replacement arthroplasties, divided into two groups (25). One group of patients were operated on in a nonclean air environment under similar conditions, and with similar insertions. In 134 patients operated in nonclean air room, the infection rate was 5.2 percent. In 270 patients operated on in a clean air system, infection rate was 1.1 percent. This, too, is not statistically significant at present, but again, there appears to be a definite trend.

DISCUSSION

There was a statistically significant difference between a standard operating room, and the same operating room with the clean air system functioning. When both rooms were empty, there was approximately a ten-fold decrease in bacterial contamination in all areas sampled.

There was also a significant difference between the standard operating room and the clean room when tested during total-hip arthroplasty. A significant difference was found in all areas measured. It was interesting that the aspirator system furnished with the unit did not cause a significant difference in the bacterial contamination level whether the aspirator system was on or off. This was, in part, due to the fact that the system did not cover the neck and, consequently, did not efficiently aspirate the particulate material from the body.

The addition of a surgical isolator-aspirator system in place of the standard aspirator system showed a statistically significant difference in areas C and D ($p<0.02$ $p<0.05$ respectively). When the operating room personnel used the surgical isolator-aspirator in a standard operating theater, there was a statistically significant decrease in bacterial contamination at the wound site. The data point out the importance of isolating the surgeon, since the addition of a more effective "packaging" of the surgeon further reduced the bacterial contamination, even though the ventilating environment had not been changed. It should be pointed out that the limited number of samplings in the study may underlie the lack of a statistically significant effect for the surgical isolator at some sites.

None of the patients studied became infected. The bacteriological identification settle plates show that the majority of organisms identified were those usually found on the skin.

The organisms found in the wound were not in the same proportion as those found in the infected cases (Fig. VIII). This finding has been previously noted.

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Charnley (5), who has popularized the concept of reduced airborne contamination, has recently reported his results as well. In 5,800 total-hip replacement arthroplasties done between 1960 and 1970, the incidence rate of infection fell from 7 to 0.5 percent. It is his feeling that reduced exogenous infection in the operating room resulted from measures taken to eliminate airborne contamination. Charnley has stated that of all the precautions taken against infection in the operating room, the most important was clean air, but this measure alone did not reduce the infection rate below 1.5 percent. He has stated that a reduction below 1.5 percent in 1969 through 1970 was due to measures taken to avoid penetration of bacteria through the surgeon's gown. His studies are some of the longest with the largest numbers and longest follow-up of those yet published.

At present, there are no hard statistical data universally agreed upon that either prove or disprove the decrease in the infection rate when using a clean-air system. Perspective can be gained when one considers operating rooms of fifty years ago. In looking at the operating theaters of fifty years ago, one wonders how one could possibly operate under these surgical conditions and not expect a relatively high infection rate. In the future, one will look upon our present system and wonder how one could expect to implant large prostheses and not have high infection rates.

In summary, there is little accepted scientific data that prove the effectiveness of clean air in reducing infection although Charnley's experience appears to offer support for this relationship. The expectation of decreased bacterial contamination by improved mechanical barriers and clean air systems seems reasonable. Certainly it is not harmful to use a clean air system when it is employed properly. It is also acceptable to reduce bacterial contamination at the wound site; in fact, this has been a Listerian principle known to surgery since the 1800s. Lastly, the systems that are available are capable of reducing bacterial contamination of the wound site not only through the use of clean-air systems, but through improved methods of surgical isolation (2,3,8,9,10,13,14,23,24,26,27,28,30).

The absolute provable data regarding infection may not be available for the next ten years. Even at the end of ten years, the answer may not be irrefutably settled statistically. It becomes apparent that each surgeon must identify the problems in his operating room technique, in the type of surgery he does, and then choose whether an improved barrier system or clean air system is necessary in his environment.

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HORIZONTAL FLOW OPERATING ROOM CLEAN ROOMS

J. Phillip Nelson*

INTRODUCTION

Our experience with operating room clean rooms at St. Luke's Hospital in Denver, Colorado began in March 1971, with the installation of what is believed to be the first functional horizontal flow class 100 operating room clean room (5). A second horizontal flow class 100 clean room was installed nine months later for purposes of evaluation of the effectiveness of the clean room and a helmet-aspirator-paper gown system. This second clean room was constructed by the Martin-Marietta Corporation under contract to NASA (6) and included portability and communication features. Since their installation, these rooms have been used for essentially all of our orthopaedic procedures, and the helmet-aspirator-paper gown system has been used for the majority of major joint implants. Two other helmet-aspirator-paper-gown systems have also been evaluated. Figures 1 through 6 illustrate the clean rooms and personnel isolator systems.

Our studies (2,3,4,7) have included measurement of airborne bacterial and particle concentrations, wound contamination rates, sterile surface contamination rates, and continuing analysis of deep wound infections following joint implants. In addition, we have evaluated the effect of substituting 99.0 percent High Efficiency Particulate Air (HEPA) filters for 99.99 percent HEPA filters on the bacteriological and particle characteristics in a functional operating room (OR) clean room (1). Credit for a substantial amount of this work is given to Mr. Michael Wardle and his associates from the Jet Propulsion Laboratory.

AIRBORNE BACTERIAL SAMPLING

Table 1 summarizes our experience with airborne bacterial sampling in a horizontal flow class 100 operating room clean room using a Sartorious Membrane Sampler at the wound. In general, there is a significant reduction in airborne bacterial concentrations when comparing the clean room to the regular operating room, which is enhanced by improving the scrubbed personnel barrier system. These trends were also corroborated using a Reyniers slit sampler. The bacteria cultured were predominantly Staph epidermidis, diphtheroids and micrococcus.

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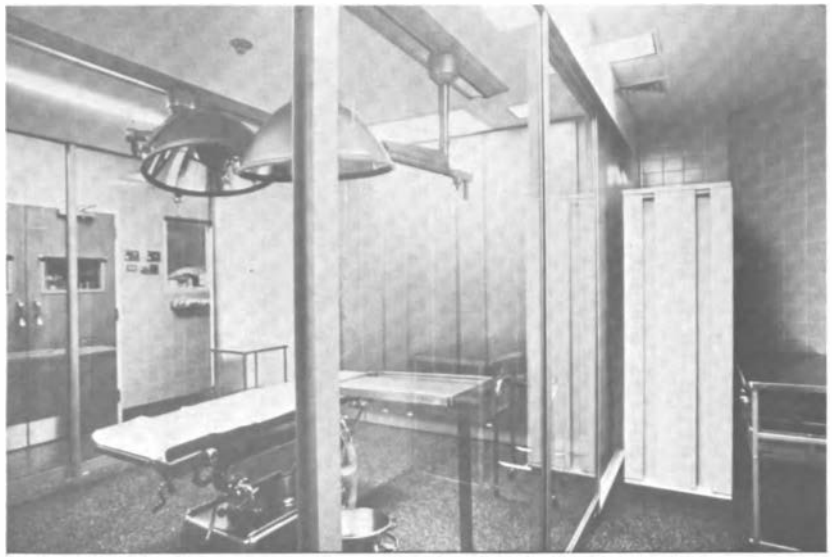

Fig. 1. Envirco Class 100 horizontal flow operating clean room.

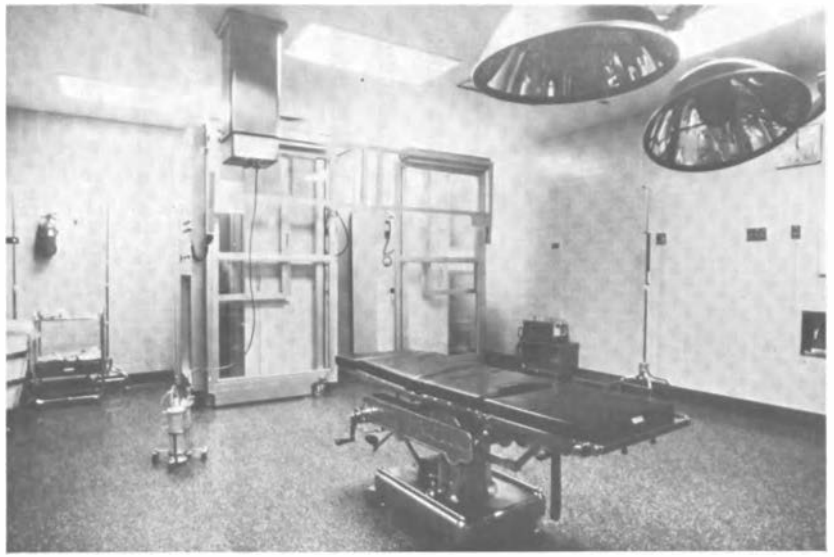

Fig. 2. Martin-Marietta Class 100 horizontal flow operating room clean room collapsed.

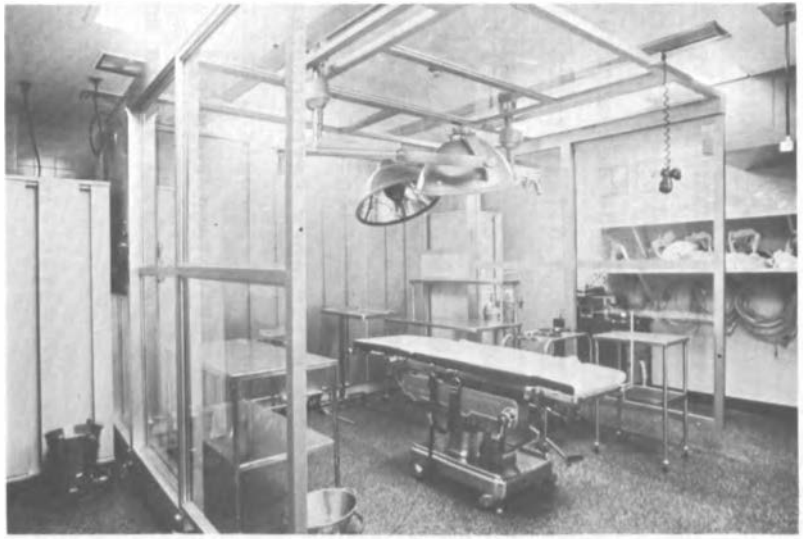

Fig. 3. Martin-Marietta Class 100 horizontal flow operating room clean room.

Fig. 4. Martin-Marietta bubble-helmet-aspirator system.

Fig. 5. Laminair personnel isolator system.

Fig. 6. Envirco-Hutter personnel isolator system.

Horizontal Flow Operating Room Clean Rooms

Table 1. Airborne Bacteria Sampling at Wound

OPERATING ROOM TYPE	GARMENT	PROCEDURE (No.)[3]	BACT./CU.FT.
Standard	Cotton	Hip Nail - Prosthesis (6)	3.87
C.R.[1]	Cotton	THA[4] (30)	.84
C.R.	H-A-P[2]	THA (14)	.11
C.R.	Cotton	TKA[5] (2)	.56
C.R.	H-A-P	TKA (11)	.48
C.R.	Cotton	THA + TKA (32)	.84
C.R.	H-A-P	THA + TKA (25)	.27

1. Clean Room
2. Helmet-Aspirator-Paper Gown
3. Approximately 50 cubic feet of air sampled per case
4. Total Hip Arthroplasty
5. Total Knee Arthroplasty

PARTICLE COUNTS

Table 2 demonstrates that the Clean Room with standard garments markedly reduces the level of 0.5μ and 5μ size particles at the wound. The level is further reduced by improving the effectiveness of the personnel barrier system.

WOUND SAMPLING

Tables 3 and 4 reflect our experience with swab wound sampling in the regular operating room, clean room, and clean room with Helmet-Aspirator-Paper Gown (H-A-P) system. The data indicate that the clean room reduces wound contamination and this effect again is enhanced by the H-A-P system. Table 5 indicates the types of bacteria cultured from wounds, and these types and their distribution correspond to those found in the airborne sampling data.

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Table 2. Volumetric Air Sampling of Surgical Field Airborne Particulates in Horizontal Flow Class 100 Clean Room Operating Room

GARMENT	PROCEDURE (No.)	MEAN NO. PARTICLES/CU.FT. 0.5	0.5μ	5μ
Cloth	THA and TKA (65)	3,108		266
H-A-P	THA and TKA (55)	1,830		197

Table 3. Wound Bacterial Contamination Rates - Total Experience

	CULTURE	NO. CASES	NO. CULTURES	POS. CULTURES	RATE (%)
REGULAR O.R. PLUS COTTON	SUPERFICIAL	56	56	10	17.9
	DEEP	107	107	25	23.4
	OTHER	14	14	4	28.6
	OVER-ALL	108	177	39	22.0
CLEAN ROOM O.R. PLUS COTTON	SUPERFICIAL	344	344	16	4.7
	DEEP	551	556	32	5.8
	OTHER	27	29	1	3.5
	OVER-ALL	590	929	49	5.3
CLEAN ROOM O.R. PLUS H-A-P	SUPERFICIAL	107	107	1	.9
	DEEP	120	120	4	3.3
	OTHER	18	21	2	9.5
	OVER-ALL	122	248	7	2.8

Horizontal Flow Operating Room Clean Rooms

Table 4. Wound Bacterial Contamination Rates
Total Hip and Total Knee Surgery

	CULTURE	NO. CASES	NO. CULTURES	POS. CULTURES	RATE (%)
REGULAR O.R.	SUPERFICIAL	38	38	6	15.8
PLUS COTTON	DEEP	43	43	12	27.9
	OTHER	10	10	3	30.0
	OVER-ALL	43	91	21	23.1
CLEAN ROOM O.R.	SUPERFICIAL	121	121	4	3.3
PLUS COTTON	DEEP	123	123	6	4.9
	OTHER	11	11	0	0
	OVER-ALL	123	255	10	3.9
CLEAN ROOM O.R.	SUPERFICIAL	98	98	2	2.0
PLUS H-A-P	DEEP	99	99	2	2.0
	OTHER	9	9	1	11.1
	OVER-ALL	99	206	5	2.4

Table 5. Types of Bacteria Cultured from Clean Surgical Wounds

	REGULAR O.R.	CLEAN ROOM
STAPH. EPID.	72.5%	57.1%
DIPHTHEROIDS.	7.5	19.0
BACILLIS SUB.	7.5	0
NON-HEMO. STREP.	0	16.7
ANEROB. STREP.	2.5	0
MICROCOCCUS	2.5	0
ENTEROCOCCI	2.5	0
ENTEROBACT. HAFINA	0	2.4
HERELLEA VAG.	2.5	0
CLOSTRIDIUM PERFRINIG.	2.5	0
E. COLI	0	2.4
MORAXELLA	0	2.4

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STERILE SURFACE SAMPLE

Table 6 reflects our experience with glove and drape bacterial sampling at the conclusion of the procedure. The improved personnel barrier system significantly reduces the rate of this contamination.

Table 6. Microbial Sampling of Surgical Gloves and Drapes in a Clean Room

SURFACE	SYSTEM	NO. OPERATIONS	NO. SAMPLES	% POSITIVE
Gloves	Cotton	22	98	20
	H-A-P	31	180	3.2
Drapes	Cotton	57	57	23
	H-A-P	36	36	8.3

99.99 PERCENT HEPA FILTERS VS 99.0 PERCENT HEPA FILTERS

Tables 7 and 8 summarize our studies with regard to use of the less efficient filters under operating conditions, and the data indicate that the less efficient filter is as effective in providing particulate and microbiological control at the wound as the 99.99 percent filter.

Table 7. Comparison of Particle Counts in Horizontal Laminar Flow Surgery Room with 99.99% and 99.0% Filters

	MEAN NO. PARTICLES/FT^3			
	99.99% FILTERS		99.0% FILTERS	
	0.5μ[1]	5.0μ[1]	0.5μ[2]	5.0μ[2]
Wound Site - THA	2159	238	2410	40
Back Table	-	-	2436	9
Upstream of Activity	1	1	1328	1

1. Particle counts taken with Model 540 Coulter Counter.
2. Particle counts taken with Model 550 Coulter Counter.

Horizontal Flow Operating Room Clean Rooms

Table 8. Comparison of Airborne Bacterial Counts in Horizontal Laminar Flow Surgery Room with 99.99% and 99.0% Filters

	MEAN NO BACTERIA/FT^3		
	99.99% FILTERS	99.0% FILTERS	
Garment	HAP-1* (No.)[1]	HAP-1 (No.)	HAP-2** (No.)
At Wound - THA	.11 (14)	.12 (5)	.08 (18)
At Wound - TKA	.48 (11)	------	.35 (5)

* Bubble helmet-aspirator-paper gown system.
** Hood helmet-aspirator-paper gown system.
1. Number of cases. Approximately 50 cubic feet of air sampled per case using Sartorius membrane sampler.

INFECTION STUDIES

We have kept careful records of deep wound infections following total-hip and total-knee replacements. Table 9 summarizes our results with a follow-up of at least six months on all cases. There have been changes in our technique, such as consistent use of perioperative antibiotics, and use of two different operative exposures. However, draping, operative time, use of irrigation solutions, closure and the use of tube drains and dressings have all remained constant. A thorough analysis of these infections, including their economic significance is now in progress.

Table 9. Total-Hip and Total-Knee Deep Wound Infections

	Regular O.R.	Inf.	%	Clean Room O.R.	Inf.	%
THA	131	8	6.10	466	4	.86
TKA	1	0	0	90	1	1.11
THA + TKA	132	0	6.06	556	5	.90

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CONCLUSIONS

The Class 100 Horizontal Flow Clean Room is effective in substantially reducing ariborne bacterial and particle concentrations at the site of the wound, and wound contamination. Sterile surface contamination, wound contamination, and airborne bacterial and particle concentration rates are further reduced by use of an improved scrubbed personnel barrier system. The 99.0 percent filter is as effective as the 99.99 percent filter in maintaining these reductions. The deep wound infection rate in our series of total-joint replacements is lower in the Clean Room Environment as compared to the Regular Operating Room.

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HELMET ASPIRATOR SYSTEMS

J. Phillip Nelson*

INTRODUCTION

Since the great majority of airborne bacteria originate from operating room personnel, improved personnel barrier garmenting should result in reduced numbers of bacteria in the ambient air. Helmet aspirator systems represent a significant advance in our ability to prevent shed bacteria from reaching the operating room air. The principles of these systems are:

1. Full-length gown made of wetting-resistent, small porosity materials.
2. Helmet or mask assembly with clear plastic face plate.
3. Yoke for shoulders of head harness to support helmet or mask.
4. Hood for head which fits beneath neck portion of gown or one piece hood-gown.
5. Tubing in helmet or hood which connects to a long, pliable, lightweight tubing.
6. Suction pump for aspiration of air.

Ideally, the gown should fit loosely so that a negative pressure may be maintained in the gown-body space. Air is sucked from the floor upwards around the body and is exited with air from the head region through the helmet tubes. Not only does this air movement evacuate shed bacteria, but it also provides significant cooling through increased evaporation. Air movement at a rate of approximately 6 cfm has been found to be most comfortable in terms of cooling effect and noise level. The umbilical tubing traverses down the wearer's back and then proceeds along the floor to the suction manifold. It is desirable to have the hood or helmet portion sterilizable so that procedures wherein there is considerable activity or wherein bone chips might fly about may be done more safely. Evacuated air is usually recycled through the clean room High Efficiency Particulate Air (HEPA) filter system. Exhaust tubing is made of pliable plastic with metal wire helical reinforcement and it is usually one inch in diameter.

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The sequence for putting on the assemblies is usually:

1. Head harness prior to scrub.
2. Hand scrub.
3. Hood or hood faceplate in operating room.
4. Gowning.

PROBLEMS WITH DESIGN INCLUDE:

1. Faceplate scratching. This occurs if faceplates or helmets are used repeatedly and because materials are soft plastics. Harder plastics such as Lexan might resolve this problem.

2. Visual distortion. In some models there is a significant curvature in the faceplate and difference of thickness of the plastic which causes mild distortions about the periphery.

3. Discomfort from head harness. This usually occurs if the faceplate harness is too heavy or if the headband is too tight. If a shoulder yoke-bubble helmet is used, the assembly is too heavy and often causes fatigue rapidly.

4. Faceplate fogging. Insufficient air exchange is the cause of this problem.

5. Noise from air movement. This is unavoidable but since the frequencies are of low intensity and if tubing is of sufficient diameter, noise is usually neither irritating or distracting.

6. Communication. Because the entire head is enclosed either with plastic or fabric and because of the air movement noise, hearing is impaired and one must use either an electronic communication system when the head is enclosed in a bubble or speak in a louder voice with the cloth system.

7. Mobility and agility. The ability of team members to move about is reduced to some degree with all systems. This effect is greatest with the Charnley and bubble helmets and least with the standard gown helmet systems.

8. Sterility. Care in putting on the units is necessary, particularly in the Charnley over-the-head type and in applying sterile faceplate hoods.

Helmet Aspirator Systems

TYPES OF SYSTEMS

1. Charnley -- Loose fitting full-length, one-piece gown and hood. Head harness with cheek exhaust tubes and clear plastic faceplate. Necessitates overhead donning with potential for contamination (Figs. 1 and 2).

2. Martin-Marietta Bubble Helmet -- Plexiglass space-type helmet resting on shoulder yoke. Special paper gowns. Heavy, easily scratched (Figs. 3 and 4).

3. Goodrich -- Open faceplate, plastic helmet with aspirator. Neck relatively unprotected. Standard-type gown (Fig. 5).

4. Bechtol, Leinbach -- Head harness, cheek tubes and clear plastic faceplate. Requires use of hood and paper or finely woven gown (Figs. 6 and 7).

5. Laminair -- Welder's mask with metal cheek tubes. Replaceable plastic shield. Hood and paper or finely woven gown. Relatively heavy (Figs. 8 and 9).

6. Envirco-Hutter -- Lightweight plastic head harness with face shield incorporated in hood. Face shield snaps onto hood harness. Face shield head-hood assembly may be sterilized (Figs. 10 and 11).

OUR STUDIES

Our studies, comparing the Helmet-Aspirator-Plexiglass system (H-A-P) to cloth gown systems, have indicated an approximate ten-fold reduction in particle generation and an approximate three-fold reduction in airborne bacteria and sterile surface contamination. In addition, wound contamination rates in the clean room have fallen from 5.3 to 2.8 percent using the H-A-P system as opposed to the standard cloth garments.

CONCLUSIONS

Comfortable, functional helmet-aspirator low-porosity gown systems which appear to significantly reduce release of shed particles and bacteria from scrubbed operating room personnel are now available.

Fig. 1. Charnley Head Harness and Assembly.

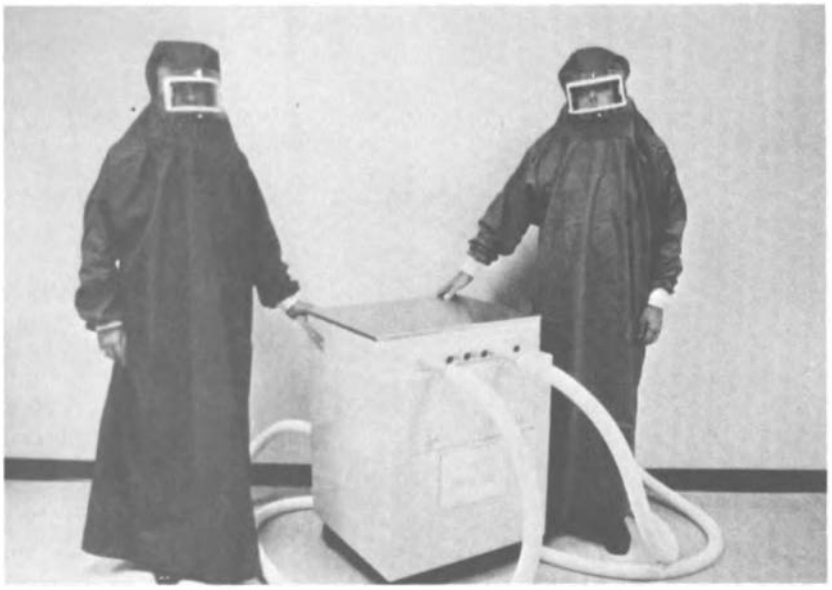

Fig. 2. Charnley Head Harness and Full Body Gown.

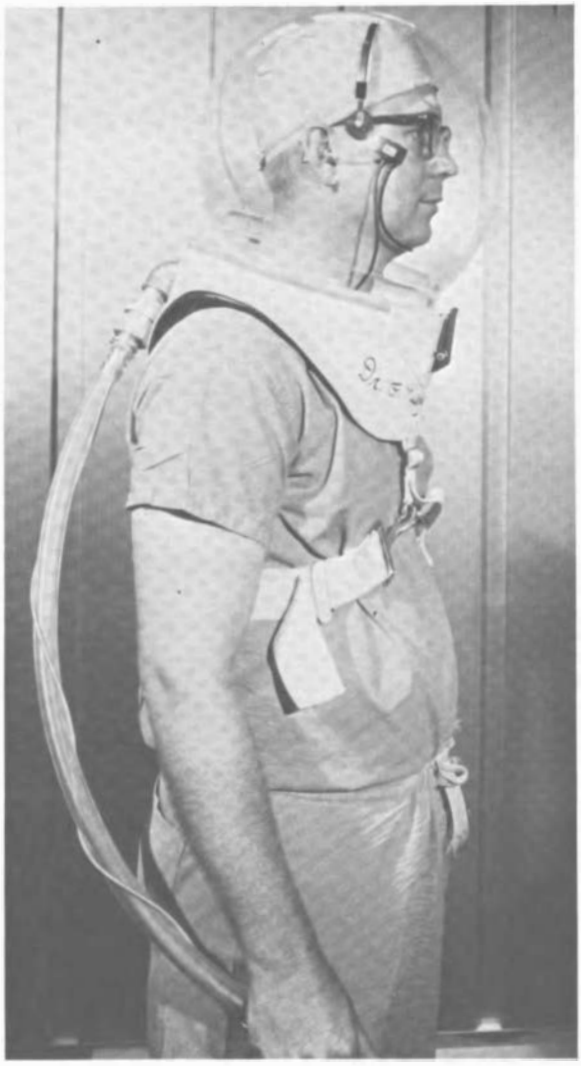

Fig. 3. Martin-Marietta Bubble Helmet and Shoulder Yoke.

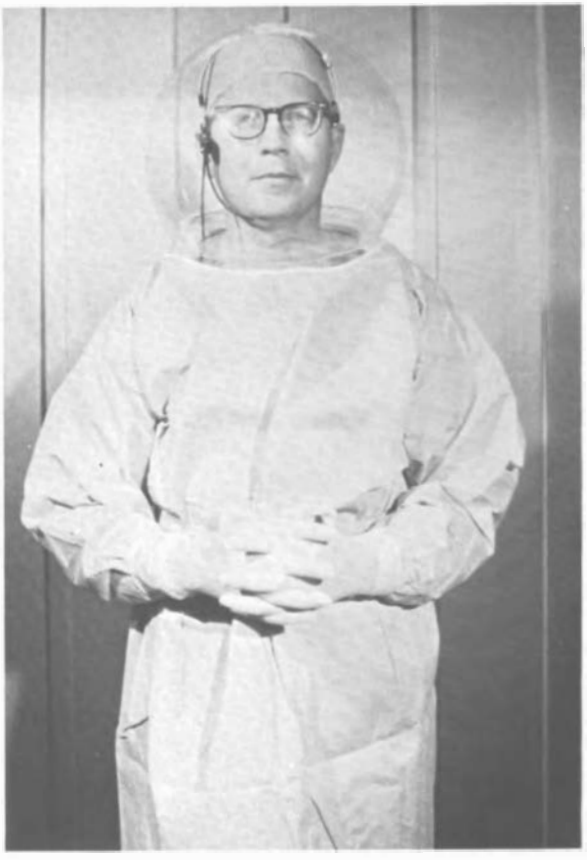

Fig. 4. Martin-Marietta Bubble Helmet and Gown.

Fig. 5. Goodrich Helmet

Fig. 6. Bechtol Aspirator System

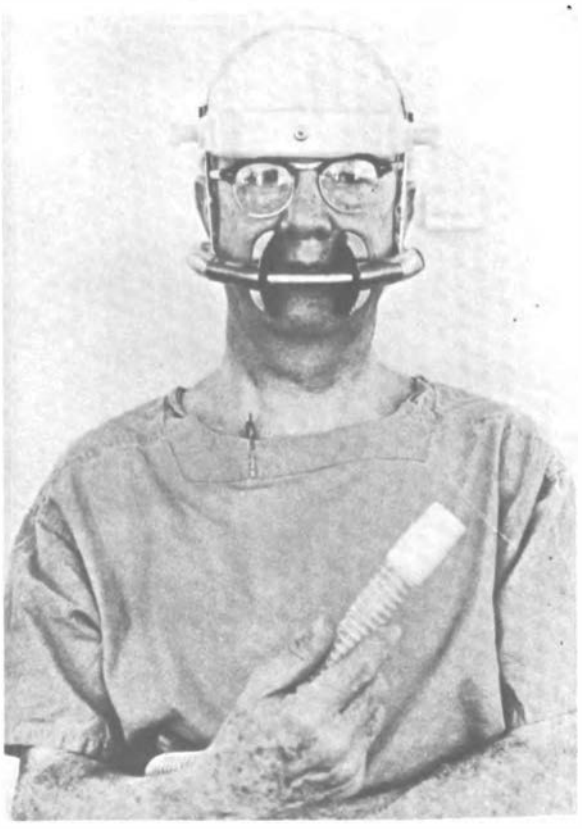

Fig. 7.
Leinbach Aspirator System

Fig. 8. Laminair Head Harness Assembly

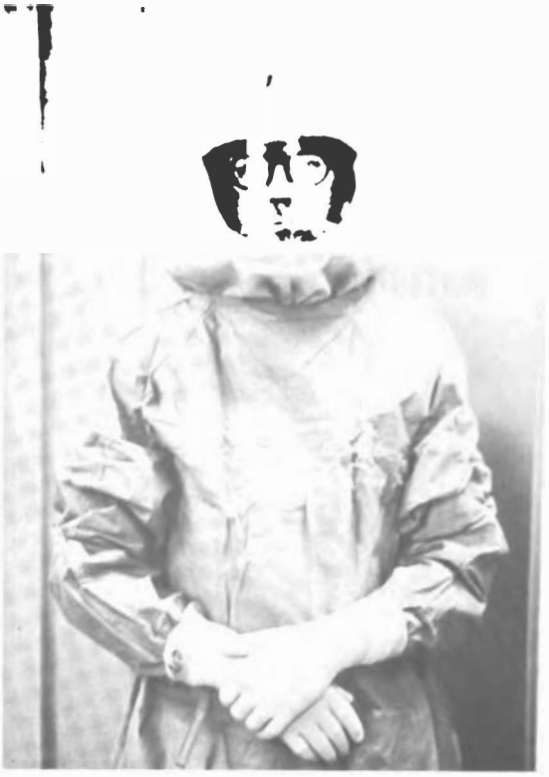

Fig. 9. Laiminair Head Harness, Hood and Gown.

Fig. 10. Envirco-Hutter Head Harness Assembly.

Fig. 11. Envirco-Hutter Head Harness, Hood and Gown.

FACTORS TO BE CONSIDERED IN ANALYZING POSTOPERATIVE CLEAN, REFINED WOUND INFECTIONS

J. Phillip Nelson*

The following outline was constructed in an attempt to organize acquisition of information which might contribute to defining the etiology of postoperative wound sepsis, particularly in the clean, refined wound. The outline is meant to give general guidance to those who wish to develop a protocol for the investigation of wound sepsis. Modification of the outline by addition or deletion of certain factors thought to relate to wound sepsis may be necessary. Since large numbers of patients and a vast amount of information would be required to achieve statistical significance for a single variant with regard to the incidence of wound sepsis, it is suggested that an adequate information handling system, plus the assistance of an infection control nurse and microbiologist be enlisted.

I. The Patient.
   - A. Statistical Information.
     1. Name or initials and date of admission.
     2. Hospital and Hospital Number.
     3. Age, Weight, Sex.
   - B. Diagnosis.
     1. Primary - reason for surgery.
     2. Secondary - all other recorded diagnoses.
   - C. History.
     1. Previous surgery - should include all surgery and complications thereof.
     2. Medicines - should include all medicines taken on regular basis during preceding year.
     3. Allergies.
   - D. Laboratory.
     1. Blood - CBC, Sed Rate and other indicated tests.
     2. Urine - analysis, culture and sensitivity for pus cells.

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3. X-rays - appropriate results.
4. Cultures - appropriate results such as urine, joint aspiration, etc.
    a. The results of preoperative nasal, perineum and skin at the operative area may give useful information relative to the carrier state and for correlation with postoperative sepsis.

E. Infection.
1. Specific inquiry by history and examination should be made for evidence of infection in teeth, respiratory system, urinary system, and skin.
2. Specific inquiry should be made for history of any type of previous bacterial infection.

II. Preoperative Preparation.
A. Preoperative hospital days.
B. Intestinal preparation.
C. Urinary or intravenous catheters.
D. Skin preparation.
1. Shave or depilatory - method, time before surgery.
2. Washing.
    a. Area.
    b. Number of times.
    c. Length of wash.
    d. Materials used for wash - i.e., soap, hexachlorophene, iodoform, etc.

III. Antibiotics
A. Local or Systemic.
B. Specific type.
C. Administration.
1. Route.
2. Schedule relative to surgery.
3. Dose.

IV. Operating Room.
A. Personnel.

1. Names for each case including:
    a. Surgeon(s).
    b. Anesthesiologist.
    c. Circulating nurse.
    d. Scrub nurse.
    e. Visitors.
2. Bacteriology of each member of the O.R. team, specifically with regard to carriage or shedding of certain types of bacteria.

B. Air Handling System (Conventional and Clean Room).
1. Air mix - i.e., recirculated vs. fresh air.
2. Air exchanges per hour.
3. Filter condition.
4. Filter efficiencies.
5. Temperature.
6. Humidity.

C. Other Antibacterial Systems.
1. Local air exchange systems - describe.
2. Ultraviolet light - describe.

D. Barrier Technique.
1. Describe type of:
    a. Hood or cap.)
    b. Helmet or mask.) Specific brand name with type
    c. Gown.) of generic named material for
    d. Drapes.) each.
    e. Gloves.)
2. If aspirator system used, describe.

E. Physical Layout of Operating Room.
1. Doors and windows.
2. Relationship to corridor and other rooms.
3. Size.
4. Lighting.
5. Cabinetry.

F. Surgical Procedure.
   1. Type.
   2. Implant.
   3. Length in time.
   4. Irrigation - amount and type.
   5. Closure.
   6. Dressing.
   7. Drains.
   8. Unusual occurrences - i.e., break in technique, violation of contaminated viscus, etc.

G. Bacterial Sampling
   1. Surface.
      a. Wound and sterile surfaces.
         (1) Method - i.e., swab, irrigation, tissue.
         (2) Timing.
         (3) How handled in laboratory.
         (4) Time of reading.
         (5) Results - qualitative and quantitative.
   2. Airborne.
      a. Method.
         (1) Type of sampler.
         (2) Placement of sampler.
         (3) Rate of sampling.
         (4) Results - qualitative and quantitative in viable organisms per cubic foot.
   3. Personnel.
      a. Area - i.e., nasal, perineum, skin or clothes.
      b. Method.
      c. Results.

H. Sterilization.
   1. General methods of sterilization (i.e., steam with pressure, gas, irradiation, soaking) should be recorded for differing types of materials.

V. Postoperative Care.
   A. Area - i.e., recovery room, ICU, ward, or private room.
   B. Dressing changes - when, where, and by whom.
   C. Activity.
   D. Wound complications.
      1. Dehiscence.
      2. Hematoma.
   E. Drains, catheters and IV's removed.
      1. Cultured?
   F. Anticoagulation.
   G. Antibiotics.
      1. See III.
      2. Other antibiotics - define some parameters and reason for use.
   H. Other infections - i.e., respiratory, urinary, etc.
      1. Record time of onset, appropriate diagnostic procedures, results of cultures and sensitivities.

VI. Wound Infection.
   A. Define with regard to:
      1. Location - i.e., superficial or deep to deep fascia.
      2. Time of appearance.
      3. Local signs of inflammation.
      4. Systemic signs of inflammation.
      5. Laboratory signs of inflammation.
      6. Drainage and sinus tracts.
      7. Special diagnostic procedures - i.e., arthrogram or sinogram.
   B. Cultures.
      1. How obtained?
      2. How handled in laboratory? - i.e., methods of culturing including aerobic and anaerobic.
      3. Result of culture.
      4. Sensitivities of organisms.
      5. Bacterial typing.

C. Treatment.

1. Antibiotics - dose, route, interval and duration.

2. Surgical - describe.

D. Outcome of infection.

HUMAN BACTERIAL SHEDDING

Dick K. Riemensnider*

Studies, ranging from very simple to complex, of bacterial skin population and their dissemination have been conducted by numerous investigators. Two efficient methods for recovering airborne bacterial particles shed from individuals are volumetric air sampling and a total rinse procedure in a sterile environment.

Work by Duguid and Wallace, Ulrich, and others showed that large numbers of microorganisms can be shed into the environment by individuals as they carry out daily work routines.

While at the Center for Disease Control in Atlanta, the author conducted many experiments on bacterial shedding. The Microbiotank, a large 7 ft X 3 ft cylindrical stainless steel chamber capable of being sterilized, was used in studying individuals for different time periods in various modes of dress to determine their bacterial shed rate. Bacteria were collected by a rinse procedure of sterile buffered water and a refrigerated continuous flow centrifuge. Enumeration was done with the pour-plate technique. This work showed not only that large numbers of microorganisms were shed, but that proper dress reduced shedding.

Most individuals were quite consistent in their shedding rate. Daily, weekly, monthly, and yearly, the number of organisms shed was within the same log. One individual studied over a two-year period had the same shed rate each time.

Shed rates were in the range of 5^3-5^5 viable particles per minute. The author believes that, as a result of the collection method, skin scale clumps were broken up into smaller aggregates than those recovered by volumetric air sampling.

One series of studies undertaken to reduce shedding demonstrated the effectiveness of changing the type of clothing and the clothing materials. In

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all instances, sterile clothing was used to assure that the bacteria were coming from the subject. In comparing a Dacron coverall with a hood and sterile scrub suit, the T test at five percent level showed a statistically significant reduction with the Dacron suit. A nonwoven material produced an even greater reduction.

In a study with conventional operating room garb, increased reductions occurred as mask, surgical gown, and gloves were added, i.e., the more body covered with sterile clothing, the more reduction.

Studies were done with various bathing procedures and it was found that hexachlorophene soaps, upon prolonged usage, definitely decreased the shed rate.

The shed rate was decreased to almost zero in a study using both the Gemini and the Apollo space suite, where air was exhausted outside the sterile environment.

This investigator believes that proper operating room clothing together with adequate air handling systems (filtered air and good peripheral exhaust) can control bacterial shedding problems in the operating room.

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HORIZONTAL LAMINAR AIRFLOW - ITS EFFECTS ON REDUCING POSTOPERATIVE WOUND INFECTIONS

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Harold Eitzen**
Morris L. V. French**
Jack B. Hart***

Since the development of the unidirectional filtered air (laminar airflow) for use in operating rooms, four prime questions have arisen as to its beneficial effect when compared to a conventional air handling system:

1) Does laminar airflow reduce the amount of bacteria about the wound site?

2) Does laminar airflow keep the surgical instruments cleaner?

3) Does laminar airflow reduce wound contamination?

4) Does laminar airflow reduce infection rates?

METHODS AND MATERIALS

Seven hundred and twenty-one consecutive clean orthopaedic cases have been evaluated microbiologically (1), 167 without laminar airflow, 377 with a horizontal wall-less unit (A)[1] and 177 with a horizontal walled (walls retractable) unit (B)[2]. During the evaluation of unit B we randomly determined whether or not the side walls were pulled out, for only total-hip and total-knee arthroplasty cases. This unit, which was capable of higher speeds at either end, was not installed as such, so that with the walls out there was an even flow of air through the tunnel as noted in other walled units. During the study we also evaluated the effect of a body exhaust system[3].

During and before this time, total-hip arthroplasty cases have been cultured upon opening the wound and just before closure. Infected cases have

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all been identified. Ninety-two total-hip arthroplasty cases were performed in a conventional operating room without laminar airflow, 278 total-hip arthroplasties in the wall-less laminar airflow unit A, and 87 in the unit B. Seventy-three total-hip arthroplasties were in unit A before our microbiological studies began. Three hundred and seventy have been followed for more than one year.

To evaluate the problem of instrument contamination, two studies were undertaken. The first study evaluated 20 open heart surgeries in a conventional operating room, whereby hemostats were removed from a rack on the sterile instrument table and placed into jars of thioglycolate broth every 15 minutes, and tested for both aerobic and anaerobic bacteria. In ten cases the hemostats were placed in the jars by the gloved scrub nurse's hand and in ten cases with sterile pick-ups. Each case was continued for only three hours. There were 20 bilateral total-hip operations evaluated in the horizontal laminar airflow operating room over a three-hour period. In ten cases the hemostats were removed from the instrument table located next to the laminar airflow unit with a gloved hand and ten with sterile pick-ups.

The second study evaluated both skin and deep knife blades. There were 102 skin and 209 deep knives from cases in a laminar airflow room versus 106 skin and 165 deep knives from cases in a conventional operating room evaluated for contamination by dropping them into the test tubes of thioglycolate broth after their normal usage. Both the jars and test tubes were evaluated for contamination over a 14-day period.

RESULTS

All three types of laminar airflow reduced the airborne contamination in the operating room statistically ($p.<0.005$). Of interest was unit B without walls, which gave just as good control as it did with walls, or as did unit A. This was surprising because the velocity at the wound site (midway between the two ends of the unit and six feet from the filter bank) without walls was about 85 feet per minute, but zero from there out laterally at the six-foot mark. The plates around the operating team and room illustrate that the room itself was cleaner.

Horizontal Laminar Airflow

Table 1 presents the number of colony forming units (CFU)/ft^2/hr for cases in a conventional operating room, a Horizontal Wall-less Laminar Airflow (LAF) unit A and a Horizontal Wall unit B with and without walls. The sites of air settle plate (ASP) sampling were adjacent to the wound, on the back instrument table; plates one through four were four feet above the floor and directly behind the surgical team; plates five and six were at the periphery of the room, four feet high.

Table 1. Airborne Contamination Levels in Operating Rooms Equipped with Conventional and Laminar Airflow Handling Systems

Air Settle Plates	Conventional Oper. Room	Wall-less LAF	LAF with Walls	LAF without Walls
Wound	293	22	16	26
Back Table	312	8	2	1
1	261	90	2	2
2	250	87	4	7
3	315	133	35	58
4	298	117	24	86
5	190	54	116	135
6	259	70	84	99

To evaluate the problem more specifically, Table 2 summarizes only total-hip arthroplasty cases. Even though fewer cases had been done in unit B, there seemed to be little difference beween the two units or three types of laminar airflow rooms.

Contamination levels as seen in Table 3, even though not statistically significant, and definitely not yet affecting the infection rates, showed that a body exhaust system further reduced the environmental contamination around the operating site.

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Table 2. Airborne Contamination Levels During Total-Hip Replacement Surgery Utilizing Laminar Airflow

	Wall-less LAF	LAF with Walls	LAF without Walls
No. Cases	205	50	37
Air Settle Plates			
Wound	16	18	17
Back Table	6	2	1
1	100	2	2
2	90	4	7
3	147	35	58
4	124	24	86
5	60	116	135
6	81	84	99

The number of CFU/ft^2/hr for just total-hip arthroplasty cases. The areas of ASP sampling were as described in Table 1.

Table 3. Effect of a Body Exhaust System Used in Conjunction with Laminar Airflow on Airborne Contamination Levels

Set Up Evaluated	Colony Forming Units/ft^2/hr			
	Body Exhaust Off		Body Exhaust On	
	Instrument Table	Wound Site	Instrument Table	Wound Site
Without Walls	2 (38)*	25 (37)	0.5 (38)	17 (38)
With Walls	4 (40)	20 (40)	1 (71)	15 (77)

* ( ) Number Tested

Horizontal Laminar Airflow

The effectiveness of laminar flow on the surgical instruments (Table 4 and Table 5) was exemplified by the reduction in the number of contaminated hemostats per case and per 15 minutes in the room with laminar airflow versus the conventional ventilation ($p < 0.05$). In the conventional operating room, the number of contaminated hemostats was statistically ($p < 0.05$) less when removed with sterile pick-ups. There was no statistical difference between the number of contaminated hemostats in the laminar airflow room whether they were picked up with the gloved hand or sterile pick-ups. Spearman's correlation coefficient revealed a correlation between time and the number of contaminated hemostats picked up by the gloved hand (.7517).

Table 4. The Effect of Different Air Handling Systems on Hemostat Contamination

	Conventional Operating Room	Laminar Airflow Operating Room
Scrub Nurse's Gloved Hand	6.4	1.1
Sterile Pick-Ups	4.3	0.5

The average number of contaminated hemostats per case (12 sampled/case).

Table 5. The Effect of Different Air Handling Systems On Hemostat Contamination

	Conventional Operating Room	Laminar Airflow Operating Room
Scrub Nurse's Gloved Hand	5.33	0.92
Sterile Pick-Ups	3.58	0.49

The average number of contaminated instruments per fifteen minutes for ten cases.

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Table 6 revealed a statistically significant reduction in the number of contaminated skin and deep knife blades in a laminar airflow operating room versus those from the conventional operating room. There was no statistical difference between the skin and deep knife blades contaminated from either group.

Table 7 revealed a statistical reduction in not only the number of positive opening ($p < 0.05$) and closing cultures ($p < 0.001$), but also the number of infections ($p < 0.05$) in total-hip arthroplasty cases done in a laminar airflow operating room.

Table 6. The Effect of Different Air Handling Systems on Knife Blade Contamination

Microbial Contamination of Knife Blades					
	Laminar Airflow On		Laminar Airflow Off		Probability
	No. Tested	No. Contaminated	No. Tested	No. Contaminated	
Skin	103	3 (3%)	106	16 (15%)	P < 0.005
Deep	209	9 (4%)	165	33 (20%)	P < 0.005
Total	311	12	271	49	P < 0.005

The number of contaminated skin and deep knife blades tested from clean orthopaedic cases done in a conventional operating room with and without the laminar airflow system in use.

Table 7. The Effect of Different Air Handling Systems on Opening and Closing Cultures and Postoperative Infections During Total-Hip Surgery

		Conventional Operating Room		
	No. Tested	No. Positive	Percent	Probability
Opening Cultures	92	11	11.4	P < 0.05
Closing Cultures	92	22	23	P < 0.001
Infections	92	6	6.5	P < 0.05
		Laminar Airflow Operating Room		
Opening Cultures	225	8	1.3	P < 0.05
Closing Cultures	225	15	6.6	P < 0.001
Infections	278	3	1.07	P < 0.05

The number of positive opening and closing cultures and infections in 370 total-hip arthroplasties done with and without laminar airflow for more than one year.

DISCUSSION

The data most interesting to laminar airflow skeptics are now becoming available, as noted in the answers to the previously posed questions:

1. Several horizontal laminar airflow units have reduced environmental airborne contamination more than 93 percent ($p < 0.005$) and is further aided by the use of a body exhaust system.

2. Surgical instruments (hemostats, 82 percent, and knife blades, 80 percent) are kept statistically cleaner ($p < 0.05$) by the addition of laminar airflow in the operating rooms.

3. Opening and closing cultures both show a statistically significant ($p < 0.05$ and $p < 0.001$) reduction of 69 percent and 72 percent respectively in the number of contaminated wounds treated under laminar airflow conditions.

4. Our infection rates have been statistically ($p < 0.05$) reduced from 6.5 percent to 1.07 percent for total-hip arthroplasties done under horizontal laminar airflow conditions.

CONCLUSION

Not only does horizontal laminar airflow control and keep the environment cleaner, but it also reduces the contamination of surgical instruments and wounds, thus lowering infection rates.

REFERENCE

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LOCALIZED SURGICAL ISOLATORS
(Sterile Environment Capsule)

Dana M. Street*

The most sterile operating theater might be found on the moon but is still too inaccessible. One can clean the air of the entire room as in our laminar flow rooms, or the immediate area of the patient including the surgeon and assistants but excluding the anesthetist as in the "greenhouse," or just the region of the operative field excluding the surgeon with a localized surgical isolator. The smaller the space, the easier it is to obtain sterility and the less the cost.

My first experience with the use of isolators in surgery was in 1962 when associated with Jerome Landy who was using isolators for breeding germ-free research animals at the University of Arkansas. An isolator was exhibited at a meeting of the American Academy of Orthopaedic Surgeons in 1963, and a movie depicting intramedullary nailing of the humerus in an isolator was shown at the meeting in 1964. The isolator, measuring five feet long by three feet in diameter, was constructed of flexible but heavy transparent vinyl, and incorporated two pairs of long-sleeved, heavy, black rubber gloves (Fig. 1). The isolator or capsule was inflated by air passed through a High Efficiency Particulate Air (HEPA) filter. The undersurface of the capsule was cemented to the prepared operative field with Vi-spray, and the incision made through the floor of the capsule. The surgeon and assistants scrubbed their hands, but no other sterile precautions, such as gowns and masks, were considered necessary. A pass-through port was located at one end, but most of the instruments, towels, and sponges were placed inside and gas sterilized with the capsule prior to surgery.

While the above arrangement functioned satisfactorily, there were a number of disadvantages. The large capsule of heavy vinyl was cumbersome and expensive as were the long, thick, rubber gloves. The air blower and filter also were costly items.

Therefore, in 1963, the feasibility of a light-weight, inexpensive, disposable capsule was investigated. The patient was prepared and draped in the usual fashion, and the team gowned and gloved, so that the capsule could

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be removed at any time during the procedure if necessary. Wearing the usual operating gloves, the arms were introduced through sleeves in the capsule eliminating the heavy rubber gloves. The capsule was at first inflated with nitrous oxide from the anesthesia machine eliminating the air blower and filter. Later, less expensive nitrogen was used.

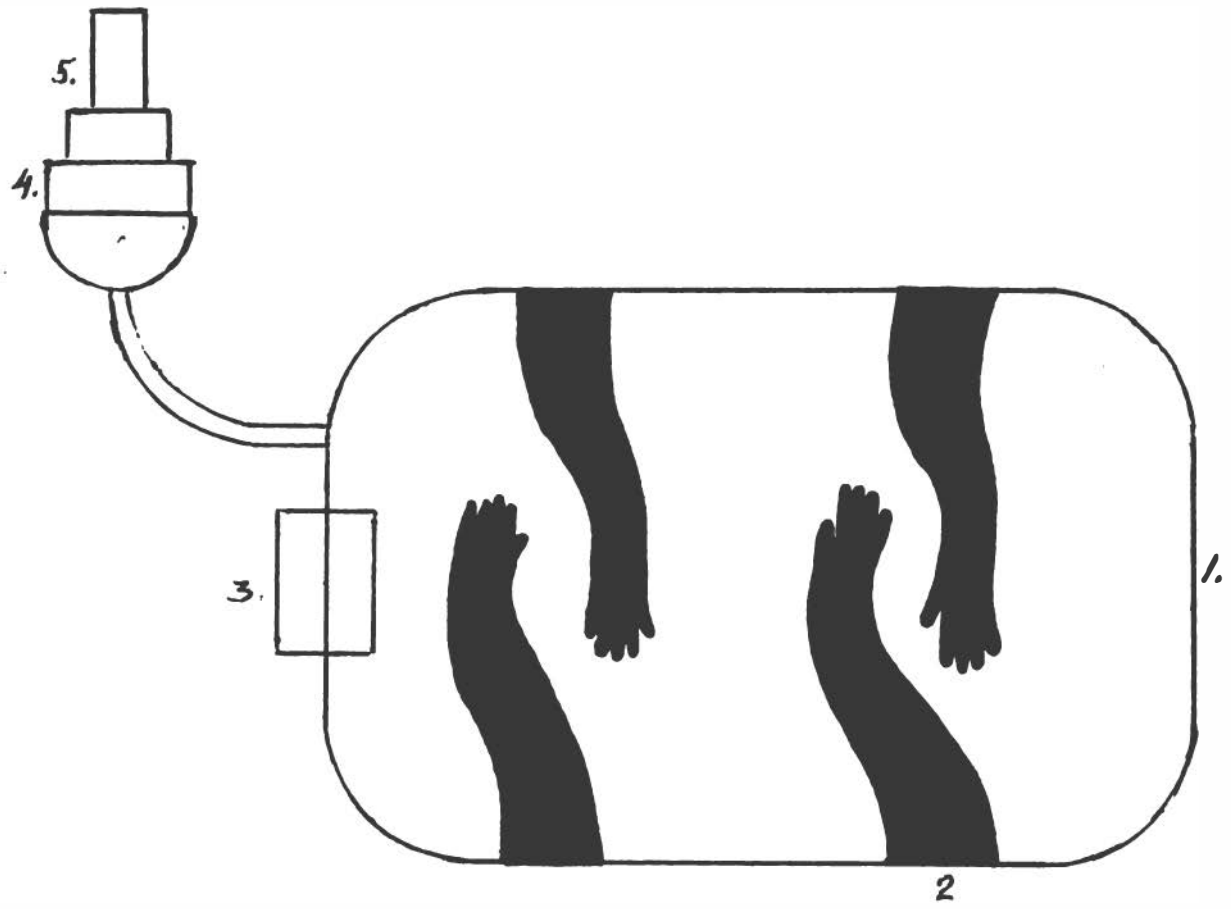

Fig. 1. Isolator for Germ-free Animals.
1. Heavy vinyl capsule; 2. Heavy, black, rubber gloves; 3. Pass-through port; 4. HEPA filter; 5. Blower.

Localized Surgical Isolators

The first capsules were kitchen table fabrications of Saran Wrap and Scotch Tape, which built up an electrostatic charge attracting dust and lint. Later experimental models, by Aeroplast in 1965, were of a conductive film (Fig. 2). While designed to be disposable, the supply was limited, and they were used repeatedly by placing a large Vi-drape patch in the floor. New capsules were cemented to the field using Vi-spray, the patched ones by the usual application of the Vi-drape which held somewhat better.

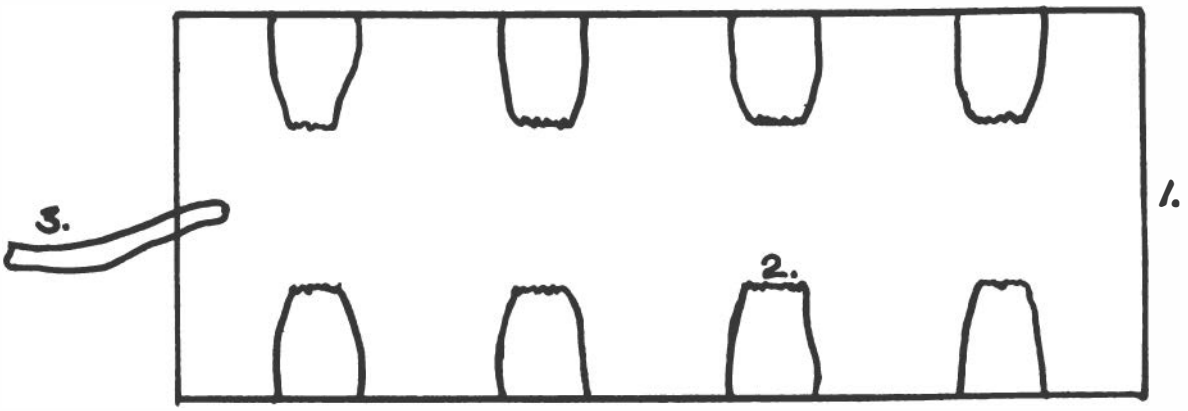

Fig. 2. Modified Isolator - Disposable, Germ-free Environment Capsule. 1. Lightweight plastic capsule; 2. Elastic in sleeves; 3. Snorkle intake.

Gas from the N_2O or N_2 tanks was thought to be sterile, but was passed through cotton plug filters in the intake tube which could catch any possible oil droplets, and also could be cultured for organisms. The cotton plugs tended to slow the rate of inflation.

At first, the instruments were placed in a tray and covered with a separate plastic bag which was cemented underneath the nurse's end of the capsule and the floor was incised to get to them (Fig. 3). Later, it was found satisfactory for the nurse to pass them in through one of her sleeves, wrapping the sharper ones in a towel. The Bovie cord, suction, and fiber-optic cord were also carried in through sleeves. The seal between the end of the capsule sleeves and the surgeon's gloves was held by elastic around the wrists. When the nurse withdrew one arm in order to introduce an

instrument she would close the empty sleeve with her other hand to prevent escape of gas and collapse of the capsule. Still another method for larger cases was to open the end of the capsule, introduce a tray of instruments, then seal it again.

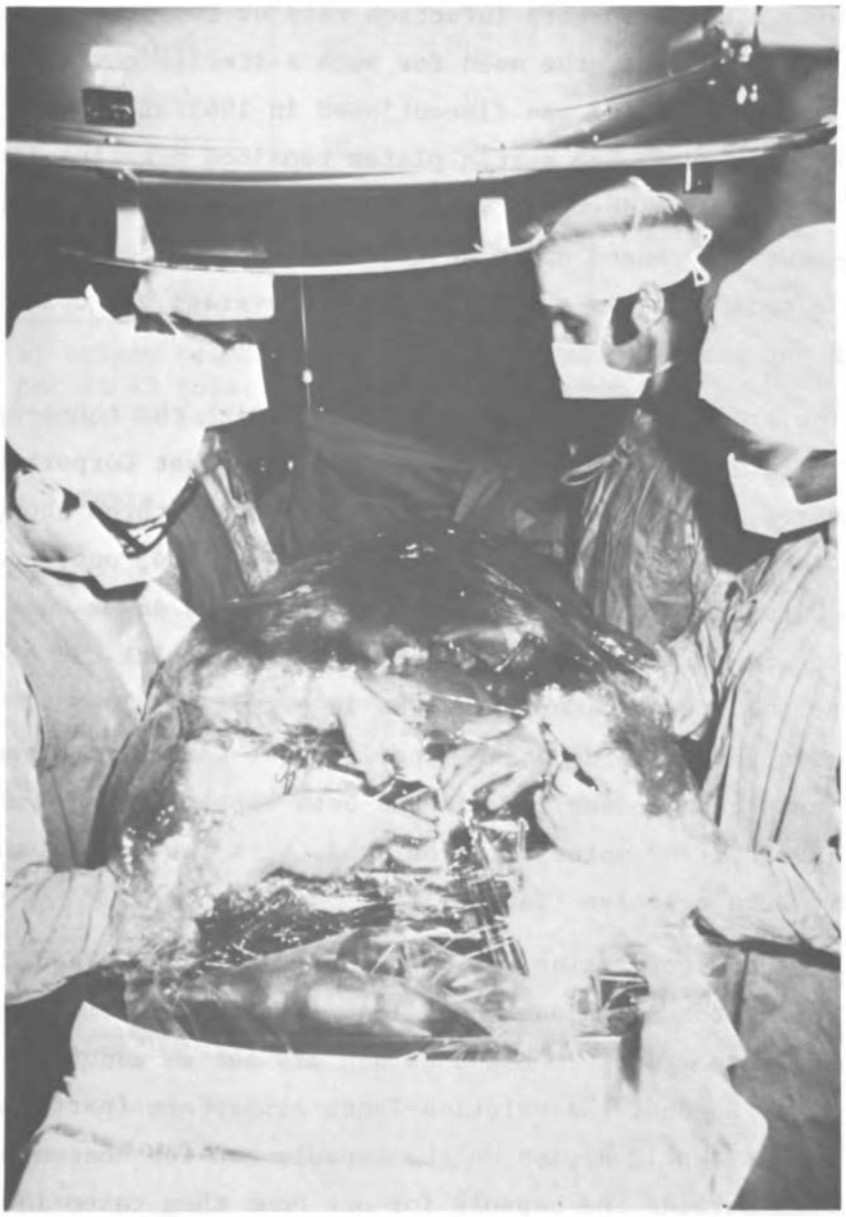

Fig. 3. Capsule in use. Standard draping and gowning. Instruments introduced through floor from tray in separate bag.

Localized Surgical Isolators

Settle-plate cultures were obtained from various locations in the operating room outside of the capsule, and from two plates inside - one at the head end and one at the foot end near the nurse's sleeves. The wound was cultured just prior to closure in some cases, as was the surface of the capsule, inside and out.

With a clean surgery infection rate of two percent and before the advent of the total hip, the need for such a sterile environment was not so pressing, and the project was discontinued in 1965 after only a handful of cases. In these cases the settle plates remained negative inside, positive cultures of Staph. epidermidis were obtained from the top of the capsule and plates outside ranged up to 40 colonies. Colony counts vary with location in the room and over a wide range, but average ten colonies per hour in most of our rooms.

The project was reactivated in 1970 with the total-hip procedures, using the original supply of capsules from Aeroplast Corporation. In the next ten cases, using gas only filtered by cotton, three showed positive plates of three, ten, and nine colonies after three, one, and six hours of surgery. Unfortunately, the cotton plugs in these cases were not cultured. Also, plates freshly poured in surgery were used which did not have time to demonstrate their prior sterility. No infection developed. However, there was sufficient cause to doubt the sterility of gas taken directly from the tank. In subsequent cases the gas has been bubbled through a 1/4 percent Neomycin in distilled water solution, and, with few exceptions, cultures inside have been negative (Table 1).

Besides sterilizing the nitrogen, passing it through an antiseptic solution introduces additional benefits. First, the humidity is raised 75 to 85 percent; and the wound does not dry out as under a draft of low-humidity air. Second, the solution-laden atmosphere (particle count 300,000) may have an antiseptic action on the capsule and its contents (a settle plate exposed outside the capsule for one hour then taken inside for one hour was reduced to three colonies, while a plate beside it outside grew 46 colonies using 1/4 percent Neomycin. Other more effective solutions are shown in Table 2).

Dana M. Street

Table 1. Colony Counts Inside Capsule

Case #	Col.	Case #	Col.	Case #	Col.
7	0-0	24	0-	36	0-0
8	0-	25	0-0	37	1-0
9	10-10	26	0-	38	0-0
10	0-0	27	0-	39	0-
11	0-0	29	0-	40	0-
12	0-0	30	0-	41	0-
13	0-0	31	0-	42	0-
14	9-	32	1-0	45	0-
15	1-0	33	0-		

Total colony counts on settle plates in 26 cases in which counts were recorded out of 45 total surgeries ranging from 1-6 hours. Known technical break in cases 9, 14, & 32. No infections.

Table 2. Effect of Solution on Colonies

Solution	Gas N_2	Gas Humid.	Caps. Hum.	Vapor	Control Pl.	15 min	30 min	45 min	60 min
1/4% Neo.	Y_1	21%	62%	41%	6	8	6	2	6
"	G	53%	81.5	28.5	8	13	21	10	7
"	Y_1	27%	85	64	13	10	14	6	
35% Alc.	G	53	86	33	8	10	4	3	6
4% Neo.	Y_2	15.5	83	67.5	15	8	6	5	4
70% Alc.	"	"	73.5	58	39	10	9	0	0
						10 min	20 min	30 min	40 min
" + I_2	"	"	75.5	60	5	5	2.7	0	0
						10 min	20 min	30 min	40 min
" + I_2	"	"	"	"	3.3	2.3	1	0	0

Settle plates exposed in operating room then brought inside capsule and exposed for stated periods.

Disadvantages of the surgical isolator are:

1. A sense of claustrophobia on the part of the surgeon.
2. Visual impairment
    a. from reflective glare (eliminated by fiber-optic lamps near or inside the capsule.
    b. from blood splatter on the inside surface (cleared with a damp sponge). Fogging has not been encountered

The disadvantages are minor compared with the advantages of true sterility and lack of dehydration.

While admittedly this was a preliminary study with only 51 experiences involved, it demonstrates great potential for sterility at the wound site at the very low cost of an estimated $20-$30 per patient.

VERTICAL LAMINAR AIRFLOW SYSTEM

Robert S. Turner*

INITIAL SURGICAL APPLICATION

William Randolph Lovelace II, co-founder of the Lovelace-Bataan Medical Center, and Willis Whitfield, discussed applications of laminar airflow rooms in December, 1961.

Bacteriologic studies were started in April, 1962, in a laminar airflow room at Sandia Laboratories. On the basis of the studies, it was concluded that a laminar airflow operating room would reduce the possibility of airborne contamination from pathogenic bacteria. The vertical laminar airflow system was then installed in an existing operating room in the Bataan Memorial Hospital in Albuquerque, and has been used since January 3, 1966 (Fig. 1).

Because of operating room regulations and the permanent flooring in the existing operating room, it was necessary to adopt an outflow system of peripheral vinyl drapes (Fig. 2).

After the vertical laminar airflow system was installed, air sampler bacterial counts were compared in a conventional operating room identical in dimensions to the laminar airflow operating room (Talbe 1). Settling plates were also used to compare bacterial colony counts in the conventional operating room with the vertical laminar airflow operating room (Table 2).

Air sampler studies demonstrated that almost no bacteria existed on the floor at the foot of the operating table, even though no hoods or special aspirating devices were used, when the vinyl drapes were closed (Fig. 3). The incisional area was noted to be nearly free of viable bacteria particles during these air sampler studies (Fig. 4).

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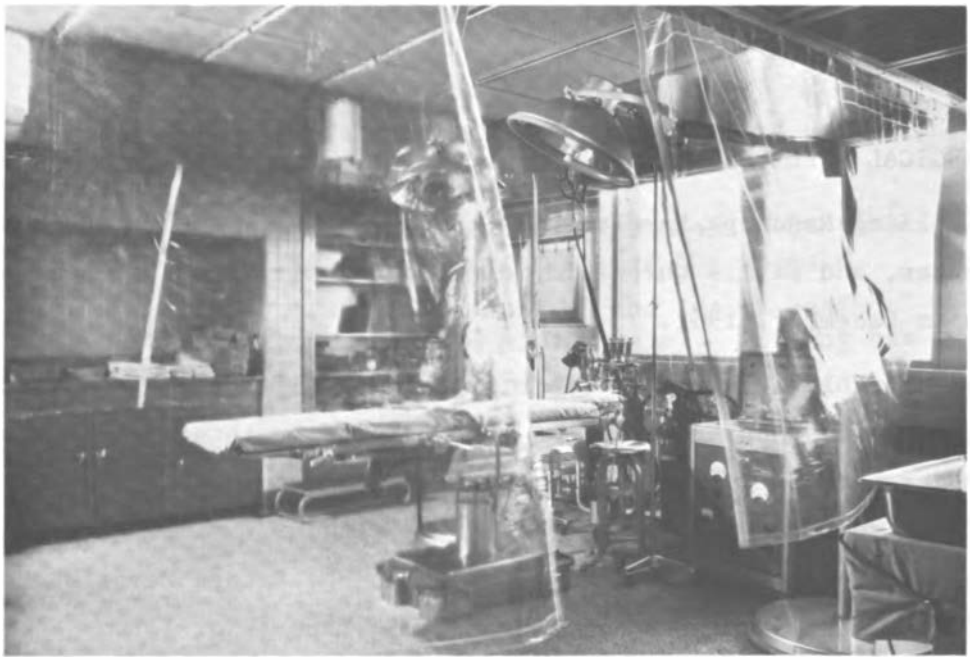

Fig. 1. Vertical Laminar Flow Operating Room, Bataan Memorial Hospital, Albuquerque, used since January 3, 1966. High Efficiency Particulate Air (HEPA) filters remove particulate matter 0.3 microns or greater in diameter.

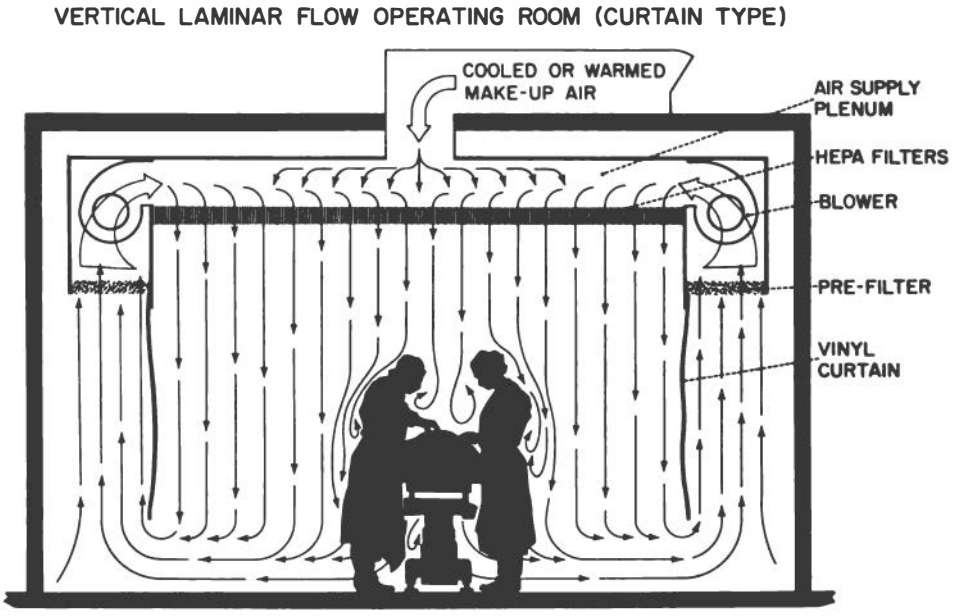

Fig. 2. Functional diagram of the Vertical Laminar Air Flow Operating Room adapted to an existing operating room. Note the pre-filters, and the introduction of fifty new air changes to the recirculating system, allowing a total of 600 air changes per hour.

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Table 1.

COMPARATIVE BACTERIOLOGICAL STUDIES

Andersén Sampler Technique

Bacterial Count per Cubic Foot of Air per Min.

Time	Conventional O.R.	Ultra-Clean O.R.
Pre-op. determ.	3.0 bact. per cu. ft./'	0.3 bact. per cu. ft./'
1st 10 minutes	15.4 " " " "	1.3 " " " "
2nd " "	15.1 " " " "	0.4 " " " "
3rd " "	10.0 " " " "	0.7 " " " "
4th " "	15.7 " " " "	0.4 " " " "
5th " "	11.3 " " " "	0.4 " " " "
6th " "	23.4 " " " "	0.6 " " " "
7th " "	16.0 " " " "	0.3 " " " "
8th " "	10.5 " " " "	0.4 " " " "
9th " "	9.3 " " " "	0.2 " " " "
AVERAGE	14.4 bact. per cu. ft./'	0.5 bact. per cu. ft./'

Table 2.

COMPARATIVE BACTERIOLOGICAL STUDIES

Settling Plate Technique

	Conventional O.R.	Ultra-Clean O.R.
Anesthesia table	4 colonies/plate	0-1 colony
Top of cautery unit	9-14 " "	0 colony
Operative field	12 " "	0 colony
Sterile Mayo stand	11-19 " "	0-1 colony
Sterile back table	7-21 " "	0 colony
Open room	7-10 " "	0 colony
AVERAGE	9-12 colonies/plate	0 colony

Vertical Laminar Airflow Systems

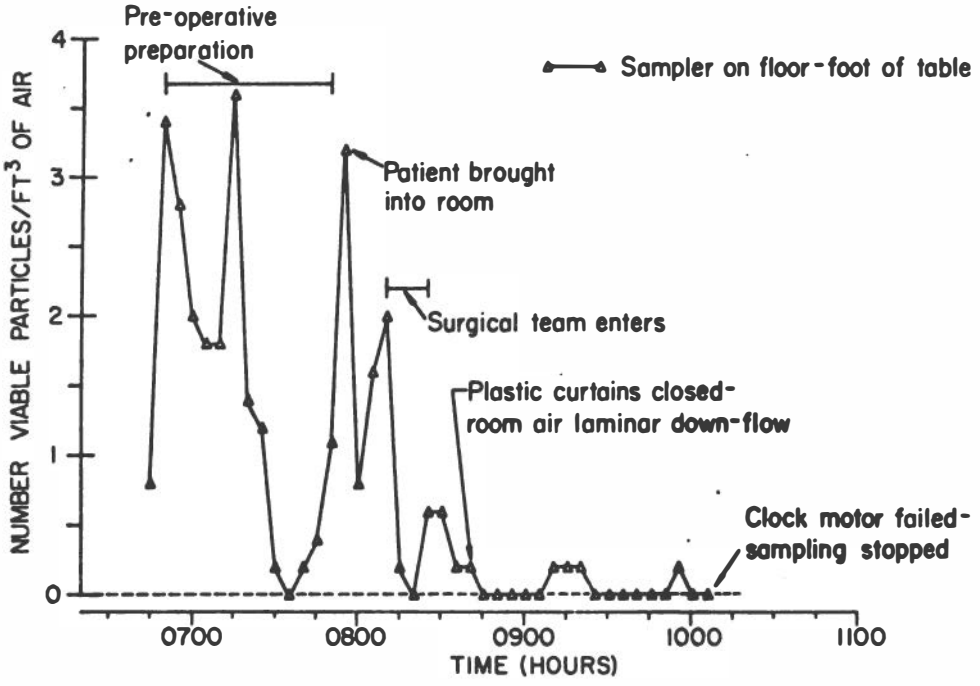

Fig. 3. Aortic Vascular Surgery Case. Note the marked decrease of the viable particle count when laminar airflow was obtained with closure of the vinyl drapes.

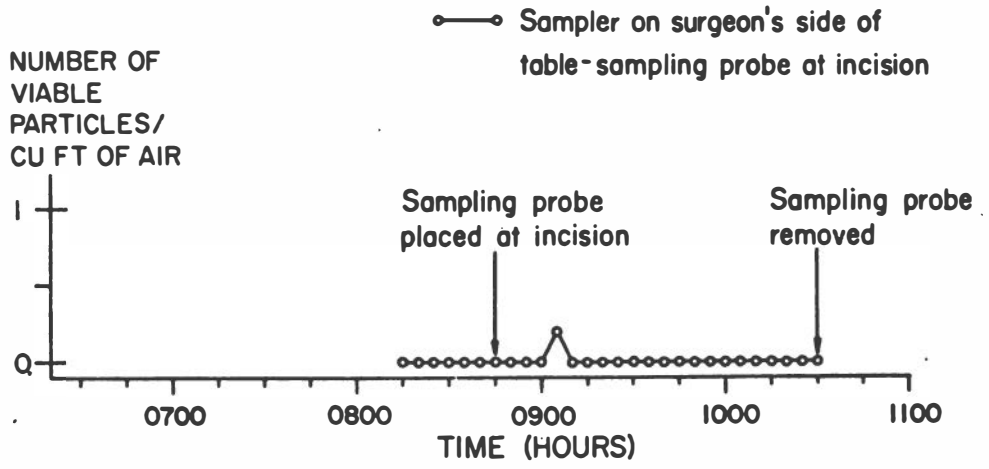

Fig. 4. Aortic Vascular Surgery Case. Note the near absence of viable particulate matter at the wound site even though no operating hoods or aspirating devices were used.

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REVIEW OF RESULTS (POSTOPERATIVE INFECTION RATES)

The postoperative surgical results were those obtained in a community service-type hospital, with approximately 25 to 30 percent of the patients referred from outside the Albuquerque community. The laminar airflow room has been used predominantly by several surgical specialists in a multispecialty group practice in a medical-center-type setting.

There has been a definite tendency to use the laminar airflow operating room for major cases requiring considerable operating time.

Over a 54-month period, from October 1966 to March 1971, there was a postoperative infection rate of .79 percent after 3,408 operations performed in the vertical laminar airflow operating room. The infection rate was also low for two control operating rooms, as there was a .93 pecent postoperative infection rate after 4,162 operations in one control room and a 1.14 percent postoperative infection rate after 4,091 operations in another control room. Thus, there was a 1.04 percent postoperative infection rate following the 8,253 operations in the two control rooms (Table 3).

Table 3.

VERTICAL LAMINAR FLOW OPERATING ROOM
October 1966 - March 1971
54 Months

			% Rate
Room #1 (Lam. Flow)	3408 operations	27 infections	0.79
Room #2 (Control)	4162 operations	39 infections	0.93
Room #3 (Control)	4091 operations	46 infections	1.14

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These figures were collected on a monthly basis on a confidential report form that listed the operations done during a specific month by a specific surgeon. The surgeon graded the operation as to whether it was a clean or contaminated procedure, and stated the outcome of the operative wound healing. The figures were tabulated monthly. No reports were entered in the patient's clinical chart. This form of reporting was started by Whitcomb, and is being continued with the full cooperation of the surgical staff.

Bataan Memorial Hospital expanded its surgical suite in 1971, and a horizontal laminar airflow operating room was constructed with dimensions of 7.92 meters by 6.70 meters (26 by 22 feet). The horizontal laminar airflow operating room has been used since May 24, 1971, and its recent use has been much more intensive than the vertical laminar airflow room, because its larger dimensions allow better surgical working conditions.

From January 1, 1966 to January 1, 1973, there were 284 spine fusions performed in both laminar airflow operating rooms, with one postoperative infection. During the seven-year time interval from January 1, 1966 through January 1, 1973, 207 hip arthroplasties and total-joint replacements, as well as 45 knee arthroplasties and total-joint replacements, were performed in the laminar airflow rooms with five postoperative infections. The postoperative infection rate for these selected 536 major orthopaedic procedures performed in the laminar airflow operating rooms was 1.12 percent.

From January 1, 1966 to January 1, 1973, there were 28,485 surgical operations at the Bataan Memorial Hospital with 334 postoperative infections for an overall postoperative infection rate of 1.17 percent.

The postoperative infection rate of .72 percent following 4,400 operations performed in both laminar airflow operating rooms from January 3, 1966 to January 1, 1973 compared with the postoperative infection rate of 1.205 percent after the 24,085 operations performed in all of the conventional operating rooms in the Bataan Memorial Hospital during the same time period, is significantly different at the $p \sim 0.05$ competence level. The validity of this comparison is questionable, however, because of the numerous variables involved.

Vertical Laminar Airflow Systems

PROBLEMS WITH USAGE OF THE VERTICAL LAMINAR AIRFLOW OPERATING ROOM

Portable lighting was necessary for use as the high efficiency particulate air filters were located in the ceiling. Usually two portable operating room lights were required. This increased the amount of congestion in the 10 by 12 foot work area.

Circulating nurses had to open and close the vinyl drapes for ingress and egress. There was a definite tendency to leave one or more of the drapes partly open to facilitate this activity. Often, an exterior door would be left open for the same reason, and this would obviously alter the effectiveness of the airflow system.

Working space was found to be rather cramped as anesthesia equipment and the instrument tables were all placed within the enclosure. Surgical nurses felt ill at ease, for fear of contaminating their work areas through contact with the adjacent vinyl drapes or other equipment in the working area.

The vinyl drapes are placed on a track so that they can be opened and closed. When closed, some personnel had a "closed in" claustrophobic-type feeling. The vinyl drapes only partially obscured visibility.

PROBLEMS OF ACCEPTANCE OF THE VERTICAL LAMINAR AIRFLOW ROOM BY PERSONNEL

Almost all personnel were immediately aware of the sound level of approximately 65 decibels (A scale). Many nurses, anesthetists, and anesthesiologists expressed reluctance to work constantly in the room because of the sound level.

As personnel turnover occurred through the years, it was noted that constant re-education was needed for the operating room staff to aid in understanding the principle of how the vertical laminar airflow system worked. This re-education was also necessary to aid the personnel in understanding the potential significance of eliminating airborne pathogenic bacteria.

SPECIAL CONSIDERATIONS

A few patients with scientific background who live in the Albuquerque area are aware of the laminar airflow operating room system and have inquired as to whether their surgery would be performed in such a room.

Robert S. Turner

Lawyers in the Albuquerque area are also aware of the potential significance of laminar airflow operating rooms. To the best of my knowledge, no decision has been made by any court in New Mexio relating to the use of, or failure to use, a laminar airflow operating room.

MICROBIOLOGY OF HUMAN SKIN AND ITS RELATION TO POSTSURGICAL INFECTIONS

John A. Ulrich*

The work of numerous investigators has supported the observation that the surgical team is the primary source of microbial aerial contamination in the operating room. During the pandemic of Staphylococcus aureus, 80/81, infections in the late fifties, it was believed the nose was the prime site in which this organism was carried. It is true that Staphylococcus aureus did reside and was found in the nares of many operating personnel. However, after carrying on a project for more than two and one-half years, sampling the personnel in surgeries at least once a week, and after more than 14,000 cultures, we had a correlation of only .13 between nasal carriers and infections originating in the surgeries. It was obvious that this was not the major source of the organism causing our problem, so we sought elsewhere for the real source. The most obvious source was one of the largest organs in our body which is in constant contact with the environment: the skin. Thus, we began to study the skin to see if it was one of the problem sources of potential pathogens in surgery.

The human skin is an involved structure with a complex bacteriology. It is more than just a contaminated surface. First, there are microbial populations classified according to source which can be divided into two different types, transient and indigenous. A transient population is one you pick up from contaminated external sources and then transfer elsewhere; it can be washed off rather easily. Secondly, there is also an indigenous population which is always with us. It is one of our important main lines of defense against other invading organisms. Therefore, we do not want to destroy these bacteria; we only want to control them in operating rooms and other sensitive areas.

Most of this population does not grow on the surface of the skin. It comes from a deeper source, usually the sebaceous glands and the ducts of the sebaceous glands. It is expressed to the surface via the hair follicles. We use a number of techniques to track down the dynamics of the bacterial population of the skin. The contact plate method is very simple and gives good reproducible

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data. It is nothing more than an aluminum milk-bottle cap filled with agar. The agar is placed in contact with the skin, immediately removed and incubated, and then quantified after incubation.

Using this technique we can develop full-body patterns for the human being (Table 1). Notice that the bacterial colony counts on the forehead, temple, eye, nose, upper lip, cheek, jaw, ear, chin, back of the neck and the neck are relatively high counts. Since these are total colony counts on a plate the size of a milk-bottle cap, it indicates that the skin has a high density of the bacterial population in these areas. The axillary population is much higher in most people than indicated here. The use of underarm deodorants controls and reduces the population in this area. Normally, without the use of deodorants, the bacterial population of the axilla is a little higher than around the head and the neck. The trunk and the outer arms have relatively low populations. The hand is high. This is due not only to the indigenous population, but also to the transient population. Generally, most of the lower parts of the trunk and the legs are relatively low in microbial population. Areas which are high include the groin, perineum, navel, and buttocks. The inner thigh, the ankles and feet, although not listed, are found to be high population areas. In summary, each human being has essentially the same pattern of distribution with very high bacterial populations on the head and the neck, the axilla, the hands, the perineum, the groin, and the feet. The other areas are less heavily contaminated or populated. Note that one of the most highly populated sites is the angle of the jaw.

Whereas everyone has essentially the same pattern of bacterial population on the skin, each of us is individual in the number of bacteria per square centimeter that we carry. Table 2 is a compilation of data gathered from a number of individuals, both males and females. Some have relatively high counts; some have relatively low counts. Whatever the level of the count, it remains at the same level for long periods of time. It can be changed from time to time by special techniques which I will not discuss. The important aspect is that each person has a unique and stable microbial level which can be shed into the air in the operating room. Usually an individual who has a very high skin count is also a good shedder. Each of us constantly sheds into the air.

Microbiology of Human Skin

Table 1. Bacterial Skin Populations
(Contact Plate Method: Right Side)

Body Region	Site	Plate Count
Head and Neck	Forehead	348
	Temple	560
	Under eye	TNTC*
	Nose	TNTC
	Upper lip	TNTC
	Cheek	584
	Angle of jaw	TNTC
	Behind ear	TNTC
	Under chin	TNTC
	Back of neck	211
	Neck	316
Upper trunk and arms	Axilla	106
	Upper arm--lateral	42
	--volar	8
	Elbow --lateral	8
	--volar	24
	Forearm --lateral	41
	--volar	11
	Wrist --lateral	TNTC
	--volar	53
	Hand --lateral	224
	Palm	Pseudomonas
Lower trunk and arms	Shoulder	43
	Subclavicular	83
	Breast	50
	Lateral chest	15
	Lateral waist	15
	Groin	TNTC
	Perineum	TNTC
	Navel	TNTC
	Subscapular	128
	Buttock	TNTC
	Hip	104
	Lateral thigh	232
	Inner thigh	TNTC
	Popliteal space	241

*Too numerous to count

Table 2. Bacterial Skin Populations in Different Individuals (Contact Plate Method)

	1M	2M	7M	4F	5F
Jaw	TNTC*	TNTC	145	94	TNTC
Arm	2	26	109	13	**
Breast	6	86	11	8**	278
Abdomen	47	219	29	8**	121
Groin	128	132	Cont.	74	113
Buttock	248	207	TNTC	106	52

*too numerous to count
**spore formers

We cannot scrape or wash these organisms away because of the subsurface replicating population. The technique by which deep or subsurface populations are studied is called tape stripping. A sticky sterile tape, made by the Minnesota Mining Company, called Tape No. 850, is used. Regular Scotch tape cannot be used as it contains antibacterial agents. The sterile tape is removed from the roll by the operator and pressed onto the skin, smoothed over with a sterile applicator, and removed, put into a Petri dish, agar poured over it, incubated and quantified.

Each time one of these tapes is applied to the skin and pulled off, it removes a layer of cells and any bacteria that happen to be in that layer. Normally 20 layers of cells are removed serially in these studies. You cannot remove further layers, because minimal bleeding occurs. The type of data obtained using this technique is shown in Table 3. These are bacterial counts from the tape strips. Note again, the varying bacterial levels among subjects. Some people are relatively low-level carriers; some are relatively high; and some are intermediate in levels of populations they carry. After removing ten layers of cells, relatively large numbers of bacteria are still present in the skin. Thus, the bacteriology of the skin is not only a surface phenomenon, but much more complex. In between tape 10 and tape 11, a series of six two-minute surgical scrubs were performed, and yet we continued to find demonstrable

numbers of bacteria 20 cell layers down. These subsurface organisms cannot be controlled at the present time. These are the organisms that repopulate us and that we want to maintain.

Table 3. Deep Bacterial Skin Populations
(Bacterial Colony Counts per Tape: Tape-Stripping Method)

	Subject and Sex			
Tape	XII M	XIV M	XV F	XVI F
1	72	157	167	35
2	36	145	182	36
3	31	167	260	88
4	51	115	201	46
5	23	160	215	41
6	20	42	132	27
7	29	39	86	10
8	29	56	101	42
9	23	58	61	43
10	43	55	57	37
11	4	24	5	10
12	1	20	3	7
13	5	12	5	11
14	14	8	6	13
15	3	8	8	6
16	8	6	7	12
17	8	10	5	8
18	5	3	7	6
19	6	10	5	7
20	5	6	5	15

The next technique is known as the Price technique and it is a modified surgical scrub. When Price first published this technique, he performed ten two-minute surgical scrubs. The amount of time to put on the detergent, to scrub, and to flush are checked by a stopwatch. After the two minutes, the detergent is flushed from the skin into the measured amount of

water and the bacteria are quantified from the basin contents. Table 4 is a compilation of the type of data gathered by this technique.

Table 4. Removal of Bacteria from Hands and Arms
(Mean Bacterial Count per Basin: Price Technique)

	Subject, Sex, and Number of Tests			
Basin	XIII M (43)	XIV M (18)	XV F (25)	XVI F (29)
1	40*	465	194	196
2	64	295	182	219
3	71	214	156	210
4	65	183	133	175
5	62	154	129	170
6	44	147	124	151

*Multiply by 10^5 for total count in basin

Each one of these basins represents an individual surgical scrub. After the first two-minute scrub, subsequent scrubs are done consecutively, one right after the other. These particular data were gathered while using castile soap without a germicide. The observation that is important and interesting is that skin bacteria cannot be completely removed even through six serial scrubs. One of the reasons is the deep population. The ducts and the glands act like little tubes of toothpaste; and as you scrub, massage, and squeeze, bacteria are expressed onto the skin surface. Eventually, the surface population will be reduced to a minimal level, but it will continue at that level through subsequent scrubs. Apparently a triggering mechanism takes place as bacteria are expressed from the deeper sources and rapid reproduction commences. This indicates, even with the use of germicidal soaps, that this population cannot be destroyed. It remains in the deeper sites, and the surface population is replaced in a short period of time.

Microbiology of Human Skin

Microbial shedding from humans is more germane to the intent of this meeting. The discussion on skin microbiology is to indicate what happens to these bacterial populations that are normally on skin. Some of them die off, but most of them are shed (6).

The average individual with normal skin sheds on the average 10,000 viable particles every minute (2-8). With abnormal skin such as an eczematoid process or folliculitis, the shedding rate increases tremendously.

Fortunately, in surgery, barrier techniques are employed. Gowns, caps, gloves, and shoe covers are worn and these barriers reduce the amount of material shed into the air. Cotton gowns are imperfect barriers, and examination of these cloths with a magnifying glass shows large openings through which bacteria may penetrate. A number of layers form a somewhat better barrier. Even though gowned and draped, personnel still shed bacteria into the air, and these must be controlled in another way.

Surface sampling of floors in surgical suites indicates that the majority of bacteria recovered are human skin types. Gram-positive cocci and diphtheroids are most common, but gram-negative bacteria are noted by their absence. Most of the bacteria on the floor arrive by the airborne route.

We should know more about airborne bacteria in surgery. Figure 1 shows data gathered using slit-type quantitative samplers. Two samplers were used simultaneously. This operating room did not have laminar airflow, but had an ordinary turbulent type of air delivery. Counts from the samplers followed one another closely, even though they were placed in different sites in the room.

The level of organisms in the air before the surgical team came in was one organism per cubic foot. This was a low level with only the Casella operator in the room, and a few other personnel in and out. The symbol "S" signifies a coagulase (+) Staphylococcus on that particular plate.

After the team arrives and begins work on the patient, the airborne bacterial count increases. The data in Figure 2 were gathered at a time when one surgical case was being finished and another started. There is an average of ten surgical personnel moving about the surgery suite. The patient has undergone surgery and he is undraped at this point, and of course the activity in a surgery increases greatly at this time. Nurses move around, picking up the

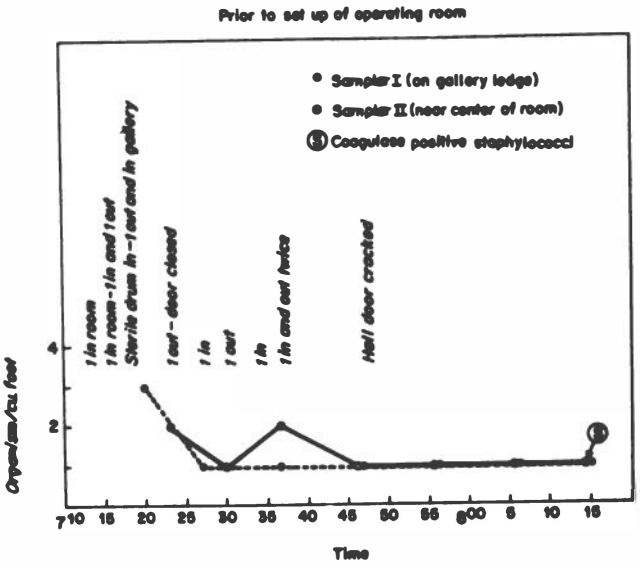

Fig. 1. Preoperative microorganism levels.

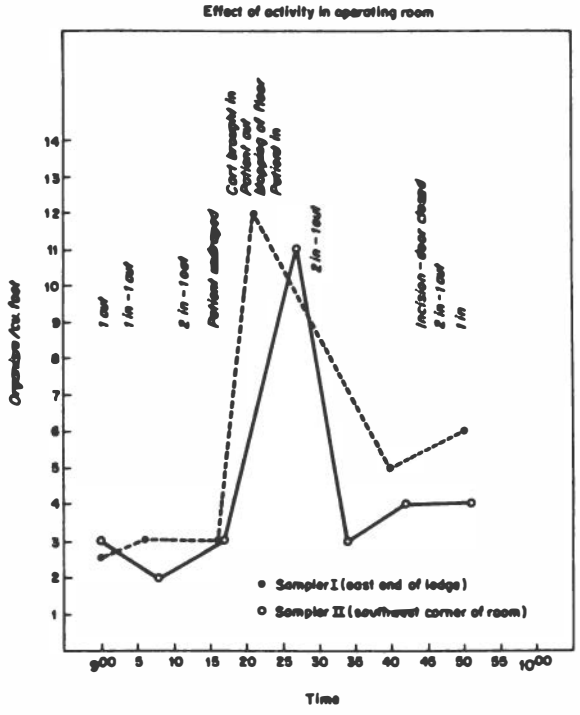

Fig. 2. Effect of activity in operating room on microorganism levels.

dirty instruments; the patient is undraped, picked off the table, and put back onto the cart. The floor is mopped. There is an excellent correlation between the degree of activity and the airborne bacterial population. This is probably due to two causes: we are scuffing up settled organisms from the floor, and probably more important, as our activity increases, our clothes rub and contact the skin and we break off more skin particles.

The legend indicates one patient is taken out and another brought in. When a patient is brought in the activity is very great (moving him to the table, scrubbing and getting him draped). New instruments are brought in and tables set up. There is a great deal of movement and so the airborne bacterial population stays high. As soon as personnel activity slows down, the number of organisms in the air drops rather dramatically. The samplers, in spite of being in different parts of the room, collect similar numbers of organisms in the same time periods. One of the important aspects in maintaining low aerial counts is to reduce personnel activity as much as possible. Once surgery is in progress activity goes down and again we reach a level of one organism per cubic foot.

Another important factor is the number of people present during the surgery. The data in Figure 3 show that more airborne microorganisms are released if more people are present. These data were gathered during an interesting case which had an increased number of spectators. Normally, the surgical teams comprise about ten people, but in this case there were about double that number. These observers were standing quietly. The airborne bacterial levels, instead of being around one per cubic foot, averaged at least ten times the expected number. In an ordinary turbulence air system operating room, it does not matter whether these people are sitting in a gallery or standing around the table. Bacteria, being the size that they are, follow the gas laws and diffuse much as gas does. Although there may be a point source, these organisms will fill the room in a relatively short period of time. The above is true in any conventional turbulent flow surgery, but not in the laminar flow type that we will be discussing during the meeting.

The levels of airborne bacteria in operating rooms are usually very low compared to other hospital areas. Figure 4 shows the microbial aerial combination in a surgical hall. It is of interest that the number of people

traversing a certain point is much greater than expected. The levels in the hall average 15 bacteria per cubic foot. Many coagulase (+) Staphylococci are present in the hall air. Most of the organisms found in hall samples were human skin bacteria.

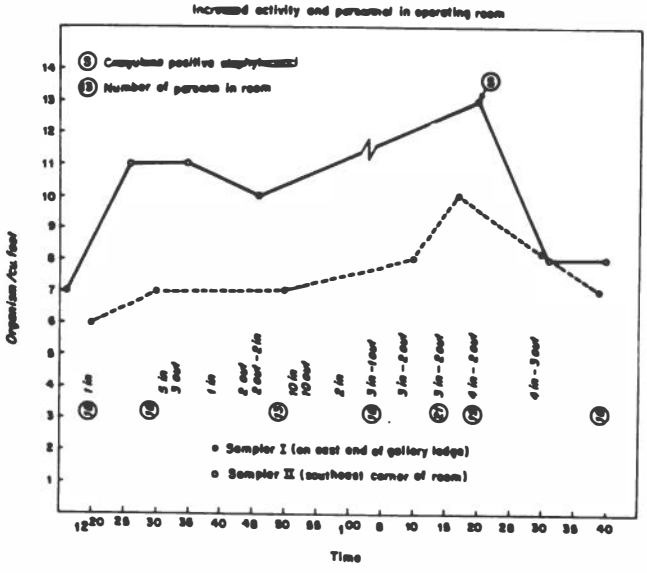

Fig. 3. Increased activity and personnel in operating room.

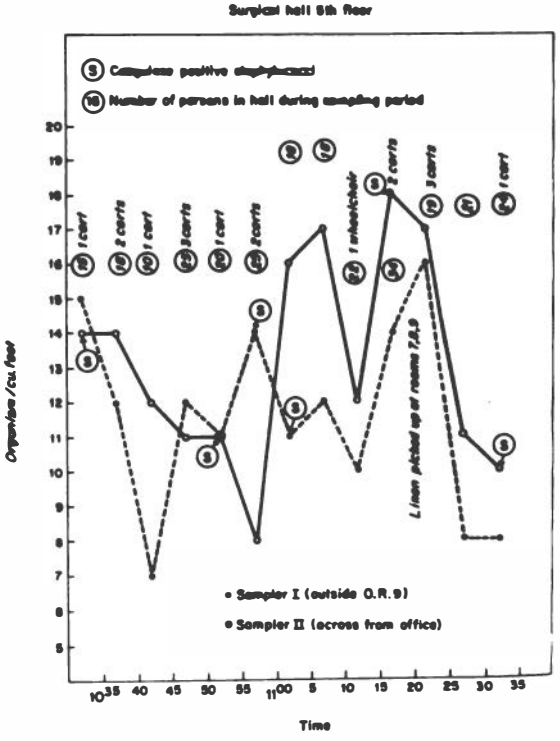

Fig. 4. Levels of microorganisms in surgical hall.

Microbiology of Human Skin

The data in Figure 5 indicate what happens when an infected patient is brought into surgery. This was a patient with a severe staphylococcal infection. Within a minute and a half after arrival (the bandages were not yet removed), the samplers began to pick up the phage-type of staphylococci found in his wound. He continued to shed these organisms all during the procedure in relatively large numbers. Interestingly enough, two minutes after the patient was removed from surgery, we could not find the organisms in the operating room (walls, floor, or air). They had most likely been swept out in the exhaust air.

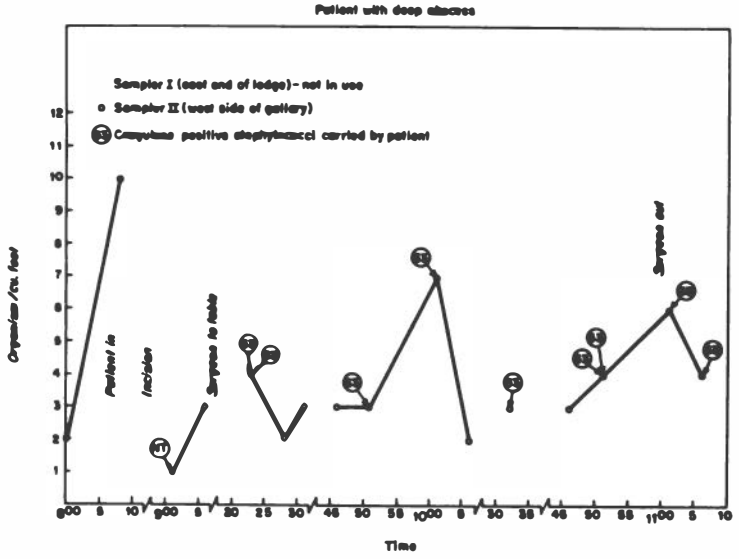

Fig. 5. Patient with deep abscess.

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The rapidity with which microorganisms can be disseminated is indicated in Figure 6. This was a rather fortuitous-type of situation in which the surgeon happened to cut into a deep abscess of which he was not aware. One minute after the incision the phage-type of organism that was isolated from the abscess was demonstrated on the sampler plates. Despite complete removal of the abscess, the organism was present in the operating room air as long as the patient was present. As soon as he was removed from the room the staphylococcus disappeared. The important aspects are the speed with which the organism disseminates, and that it is present in sufficient numbers for easy sampling.

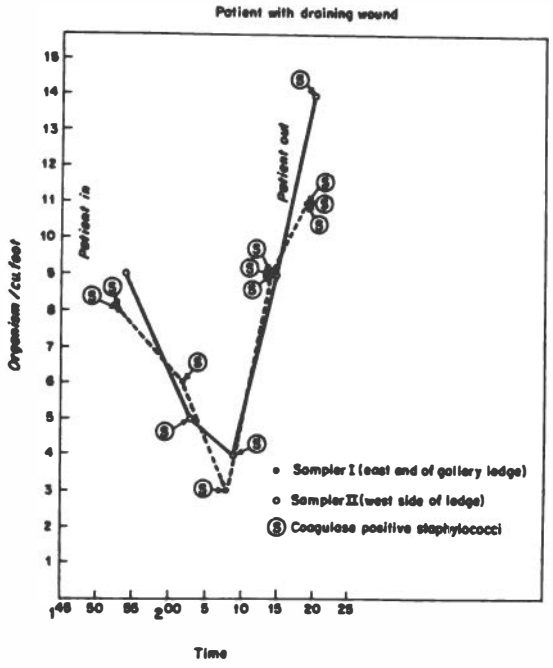

Fig. 6. Patient with draining wound.

Table 5 shows data that relate surgical team personnel to infections originating in surgery. Twelve patients were infected by one surgeon in a period of two weeks with the same phage-type staphylococcus. The surgeon had subsurface boils that had not yet erupted, but he was shedding large numbers of organisms. His skin was checked using contact plates and in Table 6 it was noted he was colonized with the proper phage-type of staphylococcus. Every site sampled during the third week was positive. At five weeks the jaw was negative, but the other sites were positive. At six weeks some sites became negative, and at nine weeks the 80/81 staphylococci remained only in the area where the boils originated. During this period of time he received autogenous vaccine because the staphylococci could not be controlled or removed with antibiotics.

Table 5. Surgical Infections Related to a Shedder

Surgical Schedule					
Thursday	Tuesday	Thursday	Friday	Saturday	Thursday
Pt. 1, Sa_1	Pt. 2, Sa	Pt. 3, Sa Pt. 4, Sa Pt. 5, Sa Pt. 6, Sa Pt. 7, Sa Pt. 8, Sa	Pt. 9, Sa	Pt. 10, Sa Pt. 11, Sa	Pt. 12, Sa_2

Table 6. Colonization of a Staphylococcus Aureus Shedder

	Duration Weeks			
Site	3	5	6	9
Nose	80/81	52/52A/80/81	52/52A/80/81	47/53/54
Jaw	80/81	Negative	Negative	Negative
Arm	80/81	80/81	Negative	Negative
Shoulder (front)		80/81	Negative	
Lesion (rt. chest)		80/81	80/81	Negative
Back (midline)	80/81	80/81	Negative	
Waist				80/81

The fact that he carried these organisms on the skin is not of prime importance. The important aspect is the shedding of the pathogen into the air. We differentiate between carriers and shedders, and find that carriers, by and large, in surgery are not dangerous. It is only when they become shedders that they become dangerous. The shedding studies shown for this individual in Table 7 were performed three weeks following the outbreak. In doing a shedding study the individual is placed in a small room with an air sampler, and the air is sampled for three different ten-minute periods. First of all, he sits quietly, then he moves around the room rather moderately, and finally he moves about rapidly. Some non-typable staphylococci and some not related were isolated from the room before the subject was allowed to enter. When sitting very quietly he was not shedding. When he started to move about, he began to shed and we began to pick his organisms out of the air. The same tests were repeated at six weeks when his skin became negative (except around the waist) and he was not shedding. He was allowed to go back into surgery with no further problems, even though he did continue to carry the 80/81 staphylococci on the skin in the area of the healed boils.

Table 7. Shedding Studies

Activity	Total Count/ Cubic Feet	Phage Type
Room only	6	47/53/83, no type
Sitting	13	No type
Moderate movement	41	80/81
Rapid movement	51	80/81 (2)
	Six Weeks	
Room only	3	
Sitting	6	No type
Moderate movement	12	No type
Rapid movement	10	

In summary, the human being is the important source of airborne organisms in surgery. It is very rare that the mechanical equipment, the walls, or the instruments are sources if they are cared for properly. Most of the airborne organisms in surgery are gram-positive.

What has been discussed here refers only to an operating room and not to other parts of the hospital, such as nursing stations where direct contact of individual to individual, nurse to patient, and then on to another patient, is probably the prime method by which organisms are spread. In an operating room, the use of barriers indicate the airborne route to be the most important.

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LOCAL CONTROL OF AIRBORNE BACTERIA

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E. J. Synek
P. Neals

AIRBORNE CONTAMINATION IN POSTOPERATIVE WOUND INFECTION

The Significance of Airborne Contamination

The relative importance of airborne bacteria contamination in causing postoperative wound infection cannot be settled with any finality since it depends on local operating room conditions, and the techniques and discipline of a particular operating team. The better these are, the more relatively important will be the danger from airborne contamination. Even under standard conditions for general surgery, however, it is indisputable that airborne contamination can result in infection, and the author has yet to hear any other acceptable explanation for the development of streptococcal infection derived from the anus of the anaesthetist (8,14,15,19).

Whatever may be its relative importance under specified conditions, an analysis of the possible causes of exogenous infection makes it clear that airborne bacteria cannot be safely ignored. The basic facts are simple.

For postoperative wound infection to occur, bacteria must reach the wound. They may do so either endogenously or exogenously. The former cannot be prevented by aseptic technique, the latter can. Bacteria from the external environment can reach the wound only if carried on some object which makes physical contact with it. The number of objects making such contact is limited and the possible mechanisms for their contamination are also limited. They may be listed as follows:

1. The skin of the patient

   Ineffective sterilization or isolation of the patient's skin may lead to direct or indirect contamination of the wound. An integral part of aseptic technique entails measures to prevent this occurrence.

2. The hands of the operating team

   These are isolated by impervious sterile surgical gloves subject to only four routes of contamination:

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a. Sterilization failure.

b. Puncture due to faulty manufacture or damage during the operation.

c. Contact with a contaminated object. If the object is external this is a breach of aseptic technique. Contamination by contact with the surgeon's gown (3,4) through which skin bacteria have penetrated is a case in point. If the contaminated object is within the wound, then endogenously derived bacteria are already present.

d. Airborne.

The remaining objects which can act as vehicles for wound contamination are the instruments, towels and drapes, sponges, suture material, irrigating fluids, dressings, topical applications, and air. These are subject only to three possible routes of bacterial contamination - sterilization failure, contact with hands or body of scrub-nurse or surgeon, and via the air.

This list may not be exhaustive, but the message is plain. Apart from the special risks of puncture of the operating team's gloves and failure to protect from the patient's own skin, only three sources of contamination can be identified and the first two of these represent breaches of standard aseptic technique. The third is the air.

In fact, if standard technique is effectively carried out, then the airborne route of contamination, either directly to the wound itself or indirectly through the various intermediaries listed constitutes the only means by which bacteria from the external environment can reach the wound.

Under these circumstances, it is clearly necessary to examine the sources from which the air itself derives its contamination, and there is no question that in the operating room, the source of primary importance is the operating team itself. Riemensnider and Sciple (17,20) have shown the startling degree to which the human body sheds bacteria-laden particles, and more recent studies (1,2,12) have demonstrated that these are mainly derived from the

perineal area, which is not only the external "cess-pit" of the human body with regard to enteric bacteria, but is also one of the primary sites of Staphylococcus aureus carriage. It was Charnley's recognition of the overwhelming importance of people as the source of dangerous contamination in the operating room that led to his success in controlling wound infection by physical isolation of the operating team (3,5).

If it be accepted that the argument so far presented is soundly based and logically developed, then two conclusions are inescapable:

1. When standard aseptic technique is effectively applied, the airborne route is the only remaining one by which bacteria from the external environment may reach the wound.

2. The air is the only unsterile object permitted to make unrestricted contact with the wound and with every other object contacting the wound.

To these conclusions may be added the observation that they are not wholly theoretical, since episodes exist even in general surgery which can be explained in no other way than by airborne contamination.

If it be granted that the air is in fact a vehicle for bacterial contamination, one must decide whether it should be controlled and, if so, how?

Techniques of Air Handling

Modern technology has made the production of adequate quantities of sterile air a simple matter so that the achieving of a bacteria-free environment at the wound site has become simply an exercise in ventilation technique. In the classical approach, filtered air is introduced peripherally to the operating room, and is also scavenged peripherally. With turbulent ventilation, about 60 percent scavenging efficiency is the effective limit, but the introduction of the laminar-flow ventilation principle has raised this limit too close to 100 percent provided that a rectilinear space is maintained without physical interruption of the airflow. The room must in fact be rectangular or cylindrical and empty. Any departure from these conditions will disrupt the laminar-flow pattern, and tend toward turbulent ventilation. Clearly, the ideal cannot be achieved in an operating room. Furthermore, any ventilation

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system in the operating room relying on the peripheral introduction of sterile air leaves the operating team the main source of contamination, because of its location between the sterile air supply and the wound site which is to be protected. Not only does the latter represent a ventilation deadspace, but it is also the seat of rising convection currents, termed "wound thermals," and demonstrable by Schlieren photography, whose velocity exceeds that of achievable laminar-flow systems (9). It was the recognition of the surgical team as the major source of bacterial contamination, and the impossibility of achieving laminar flow, that led Charnley to advocate the complete isolation of each member of the team with an individual airflow vented to the exterior.

Despite these limitations, a tremendous amount of work has been put into the application of laminar-flow ventilation to surgery, with marked and clearly demonstrable reduction of bacterial air loading even at the wound site (6,7,13,16,18,21).

In 1968, Marsh and Beck (11), recognizing the primary source of contamination and the consequent basic weakness of any ventilation system relying on a peripheral source of air, introduced the logical concept of generating the supply of sterile air at the wound site itself. Under these conditions, an expanding bubble of sterile air would be generated between the critical area to be protected and the surgical team, so that contamination from the latter, and from any other source in the operating room would continuously be driven away from the wound, which would itself be constantly bathed in the flow of sterile air. Furthermore, the rising column of sterile air is aided rather than opposed by the "wound thermals."

The work of my colleagues and myself represents an independent development of this concept to the point of practical applicability under operating room conditions. In the system which we have developed, sterile air is introduced from a simple fan-filter unit into a cloth channel sewn into the final surgical drape so that the wound site is surrounded by a diffusing collar. Sterile air emerges from this diffusing collar at a velocity of 100-200 ft/min, and effectively isolates the wound from external airborne contamination at

challenge velocities up to 300 ft/min. At this breakthrough point, quantitative assessments have shown a penetration of one particle in 20,000. Under normal conditions of operating room contamination, this would permit 70 hours of continuous operating time in a three-mile-an-hour wind for each viable particle penetrating. Under operating room conditions, this approaches complete protection.

As an adjunct to the wound-site diffuser or isolator, it is also necessary to protect the instruments and other paraphernalia on the instrument trolley and Mayo stand, and the hands of the operating team. This is achieved by means of a modified "clean station" providing sterile air, which sweeps over the instrument trolley and unites with that from the wound-site diffuser, to give a sterile air corridor within which the surgical team operates. It should be emphasized that in the absence of the wound-site diffuser the clean station cannot give effective protection at the wound site.

In our present design the two fan-filter units are housed in a single cabinet but operate independently, and either can, in fact, be used without the other. In an operating room already supplied with a laminar-flow sterile-air ventilation system, the clean station would be superfluous, and the wound-site isolator alone would be required. This could be housed in a unit of about 2 ft x 2 ft x 2 ft 6 in.

The system is flexible, relatively inexpensive, and mobile. While its main value would appear to lie in critical orthopaedic or cardiovascular prosthetic surgery, it could also provide an inexpensive means for upgrading substandard surgical facilities, and would be capable, in addition, of providing class 100 operating room facilities under field conditions in military or disaster emergency hospitals.

In conclusion, we would like to express a personal opinion. Whatever may be the virtues of one ventilation system over another, there can be no justification in critical surgical procedures for tolerating evident hazards which can be eliminated by simple existing technology. The American College of Surgeons has recently taken the position (10) that "there is no convincing evidence at this time that laminar, clean airflow, in itself, has a favorable influence on the incidence of surgical wound infections." We would like to

J.C.N. Westwood
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P. Neals

suggest that the issues with which we are now concerned no longer lie, for logistical reasons, within the realm of effective statistical evaluation, and statistical impotence is not a valid excuse for the rejection of simple conclusions based on known facts. More legitimate is their rejection on grounds of cost benefit--that the benefits to be gained do not justify expenditure on special air-handling systems. Compromise between the desirable and the practical is a familiar situation, but should be accepted for what it is, and should not be shrouded in political smoke screens aimed at facilitating evasion of the issue.

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PRINCIPLES OF HIGH VELOCITY DIRECTIONAL AIRFLOW SYSTEMS

Willis J. Whitfield*

I was asked to speak on the "Principles of High Velocity Directional Airflow Systems." First, I shall define "high velocity" and "directional" airflow as they are related to these types of clean rooms.

"High Velocity Airflow" is high velocity only when compared to the "low velocity" (20-30 ft/min) systems that you heard reports on earlier today. Airflow velocities of the system that I will be describing operate over a range of 80 to 100 ft/min, or about one mile per hour. These must also be considered low velocities when compared to other velocities with which we are familiar.

"Directional" airflow means that the entire body of air in the room is moving in a single direction, either ceiling-to-floor (vertical flow) or one wall to the opposite wall (horizontal flow). A better description might be "unidirectional turbulent flow." Also, an adequate description is contained in Federal Standard 209B for this type of airflow, designated as "Laminar Airflow."

I shall be very brief in describing the principles of the unidirectional airflow system as many of you have been working with these systems for a number of years. Very likely the rest of you have been exposed to the idea many times. More information is contained in Sandia Laboratories Report SC-M-69-1291.

The basic idea is a straightforward one, and may be described as "the entire body of air in a room that flows uniformly in the same direction throughout the room." Several elements are necessary to achieve this action including a filter bank, plenums, blowers, a containment system and temperature control. Figure 1 depicts one arrangement of those elements which provide very rigid control over airborne particle contaminants of which microbes are a part. This system is commonly referred to as the vertical downflow type. Air enters the room through the entire ceiling and exits the room through the entire floor. This arrangement provides a very short path for

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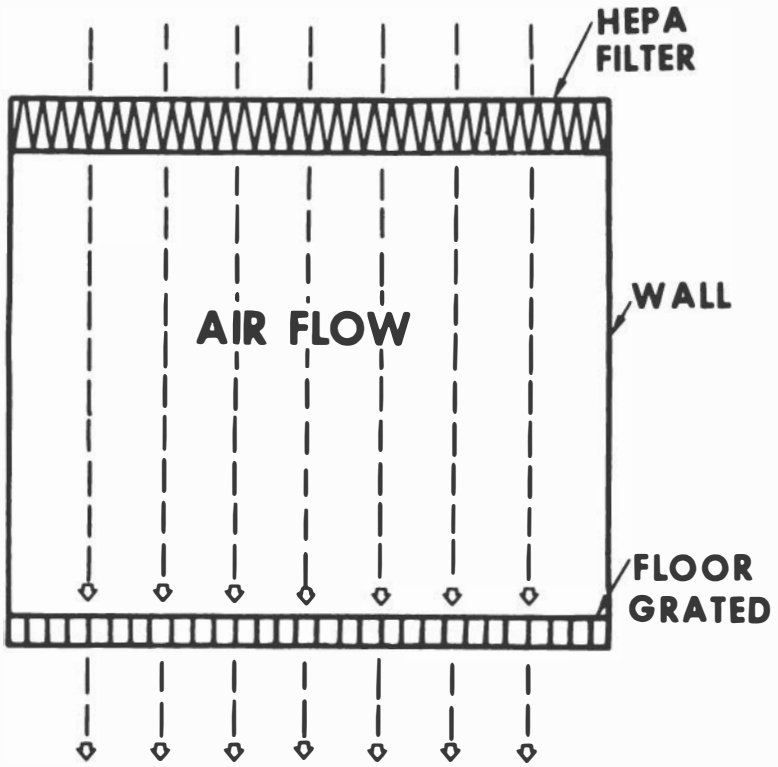
removal of contamination from the room, and offers a high degree of isolation for any given location within the room. Usually, this type of room is the most expensive to install.



BASIC LAMINAR AIR FLOW CONCEPT

Fig. 1.

The same principle is applied to the curtain unit except that air exits beneath the curtain instead of through the floor.

Another variation of the basic principle is the crossflow, or horizontal flow room. In this case, air enters the room through one entire wall and exits through the opposite wall. A variation of the horizontal flow idea is the "tunnel" room which is the same as the horizontal unit, except the air exits through an open end of the room.

Principles of High Velocity Directional Airflow Systems

The unidirectional systems described here have the capability of maintaining close control of airborne microbes, thereby, drastically limiting microbial fallout onto surfaces within the room. This has been shown by Turner (2), McDade (3), and others with a large number of tests in operational surgical suites.

RELATIONSHIP OF AIRBORNE CONTAMINATION TO PATIENT CONTAMINATION

In order to better understand the need for a clean room in surgery, a review is presented here of common modes of microbial contamination transfer to a patient. Such a transfer becomes of concern when the contamination affects the patient in a damaging manner, such as by infection or allergy.

1. Self contamination occurs when the patient's microbial flora cause problems as a result of surgery or medical treatment.

2. Direct transfer is a high probability mode of transferring contamination directly to the patient by contact with surgical instruments, the surgical team or monitors. The clean room has the potential of preventing airborne microbial contamination from collecting or "settling out" on the surgical instruments, personnel, trays, or clothing which can be transferred directly or indirectly to the patient.

3. Direct fallout or impingement is the mode by which airborne microbes are transferred directly from the air to a patient. The clean room eliminates this mode of contamination transfer to the extent of air cleanliness immediately surrounding the patient. Air cleanliness near the patient depends upon:

   (a) the clean room's filtration capability of cleaning the air entering the clean room;
   (b) clean room air velocity, direction and patterns in the immediate vicinity of the patient to provide fast removal of microbial particles shed by personnel and instruments. Also, correct airflow characteristics will reduce cross-transfer of contamination within the clean room;

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(c) the amount of contamination generated or carried to the immediate vicinity of the patient;

(d) clean room work procedures, which can reduce microbial contamination brought near the patient.

It should be emphasized that even though direct fallout or impingement rates are small, the indirect effects of airborne contamination are serious. It is for this reason that airborne contamination must be controlled before very clean surfaces can be obtained and maintained.

Very often the effects of contamination can be greatly reduced with extreme care without the use of clean rooms. However, techniques involving extreme care in cleaning, sequencing of procedures, and trial and error methods used to lessen the danger of contamination without a clean room, many times cost more in time, effort, and risk than a clean room would cost.

DETERMINING THE NEED FOR CLEAN ROOMS IN SURGICAL SUITES

For low-risk surgery where infection rates are low to begin with, the benefits of the clean rooms will also be low. For high-risk surgery the clean room will likely be of much greater benefit. Unless clean rooms are used for all types of surgery, decisions must be made as to which surgical cases require the microbial control provided by a clean room.

The surgeon is the most logical person to make these decisions since he can best assess the risk of a given surgical procedure, the condition of the patient, and determine the selection of instruments and other equipment for his personal use.

One thing is missing that is necessary for the surgeon to make such decisions - discrete airborne microbial levels or standards. Standardization is needed to provide the surgeon with a method of designating airborne microbial levels for operating rooms to meet specific surgical procedure needs. I am convinced that the technology exists today to create such standards.

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ULTRACLEAN ENVIRONMENTS - A BRITISH POSITION

William Whyte*

INTRODUCTION

It is my intention in this paper to report on the basic design data that exist at the present time in the United Kingdom on ultraclean systems. I shall not consider the way in which conventional turbulently ventilated operating rooms are designed to prevent airborne infection: firstly, because of the time available and, secondly, I would be repeating what has recently been reported in the UK by a Joint Working Party (7). All current thinking on the design of ventilation systems and air movement control in the operating suite has been incorporated into this report.

It is natural that this paper will draw heavily on my own research work, but I should also like to report on some of the work carried out in the small number of UK centers where there are ultraclean systems. This does not, however, include any more than a fleeting reference to the extensive work of Professor John Charnley whose research it is hoped, will be well known by, and extensively referred to, by others at this workshop. It is worth noting that although the number of ultraclean systems in the USA must be counted in their hundreds, there must certainly be no more than twenty in the UK at the present time.

To prevent airborne contamination of the wound, three methods of approach are possible:

1. to protect the wound so that airborne bacterial particles cannot get to it;
2. to wear impervious clothing to prevent bacteria being liberated at the source; and
3. to dilute and, if possible, remove all bacterial particles by ventilation.

The contention that the solution to wound contamination lies in protecting the wound is held by the exponents of the plastic film isolator system, a modification of systems built to produce germ-free animals. However, the other approach to the ultraclean environment, which has at the present time in

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in the UK the greatest number of adherents, is the use of unidirectional or laminar flow systems (to dilute or remove bacterial particles) with or without the use of special clothing (to prevent the dispersal of bacteria).

I propose to discuss what has been done and what is known about these two approaches, firstly, by discussing the plastic film isolator type of system, and then, in more depth, the unidirectional systems and the role of clothing in reducing the chance of wound contamination.

PLASTIC FILM ISOLATORS

For many years large quantities of animals have been born and raised germ free by the use of the plastic film isolator technique. Instinctively one would expect such a successful system would have an application to the operating room, and this is so, having been applied recently in the UK to surgery and now on sale commercially. This system has recently been described by the pioneer of notobiotics, Trexler (8), and its application to orthopaedic surgery is described by McLauchlan *et al*. (6).

Shown in Figure 1 is the diagram of the apparatus used by McLauchlan and his colleagues, its function and use being more fully described in their paper. Simply, it consists of a thin-film plastic bag which is inflated by a continuous supply of sterile air supplied by a blower unit through a filter unit. The bag is stuck to the skin at the wound site and an incision made from the inside of the bag through the isolator wall and patient's skin. The operation is carried out by the operating team using the access sleeves for their arms. Instruments and materials are passed through the entry port and along with the operating wound are isolated from outside contamination. Various ingenious methods are used to ensure the integrity of the system against bacterial contamination and to keep its use as convenient as possible. Airborne bacterial sampling has demonstrated the sterility of the system.

These units are commercially available in the UK and are presently being used in several centers in the UK. Hundreds of hip arthroplasties have been carried out under their protection.

UNIDIRECTIONAL FLOW SYSTEMS AND OPERATING ROOM CLOTHING

It has been explained above that the plastic isolator system will protect the wound so that no airborne bacteria can be deposited in it. There

are, however, two other distinct ways of preventing airborne contamination. On the correct assumption that in modern operating theaters almost all the airborne bacteria in the area of the wound are derived from operating room personnel, it is possible either to prevent the bacteria being dispensed by them using occlusive clothing, or to dilute and hopefully remove them from the air by ventilation.

Unfortunately for reasons which are explained below, it is not possible at this time to produce a completely sterile environment by either method alone. It is necessary to use both methods.

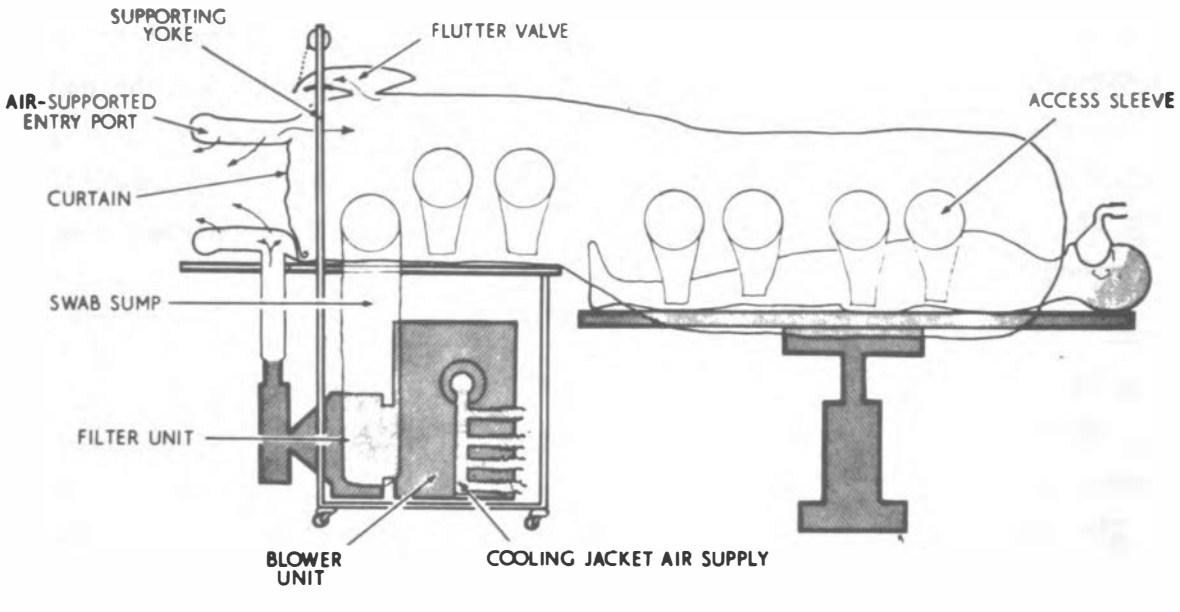

Fig. 1. Diagram of plastic film isolator.

DILUTION BY UNIDIRECTIONAL FLOW SYSTEMS - AVAILABLE DESIGN DATA

Over the last few years at Glasgow we have been assembling research data on the performance of laminar flow systems in an attempt to optimize their performance. Shown in Figure 2 is a sectional drawing of our laminar flow system as installed in Gartnavel District General Hospital, Glasgow. This is a slightly modified version of the system which was first installed four years ago in another hospital (10). It should be noted that this system has the facility for changing both air direction and velocity during an operation.

There were a number of problems which existed, indeed still exist, on the design of these systems and I should like to consider in turn the problems as I see them.

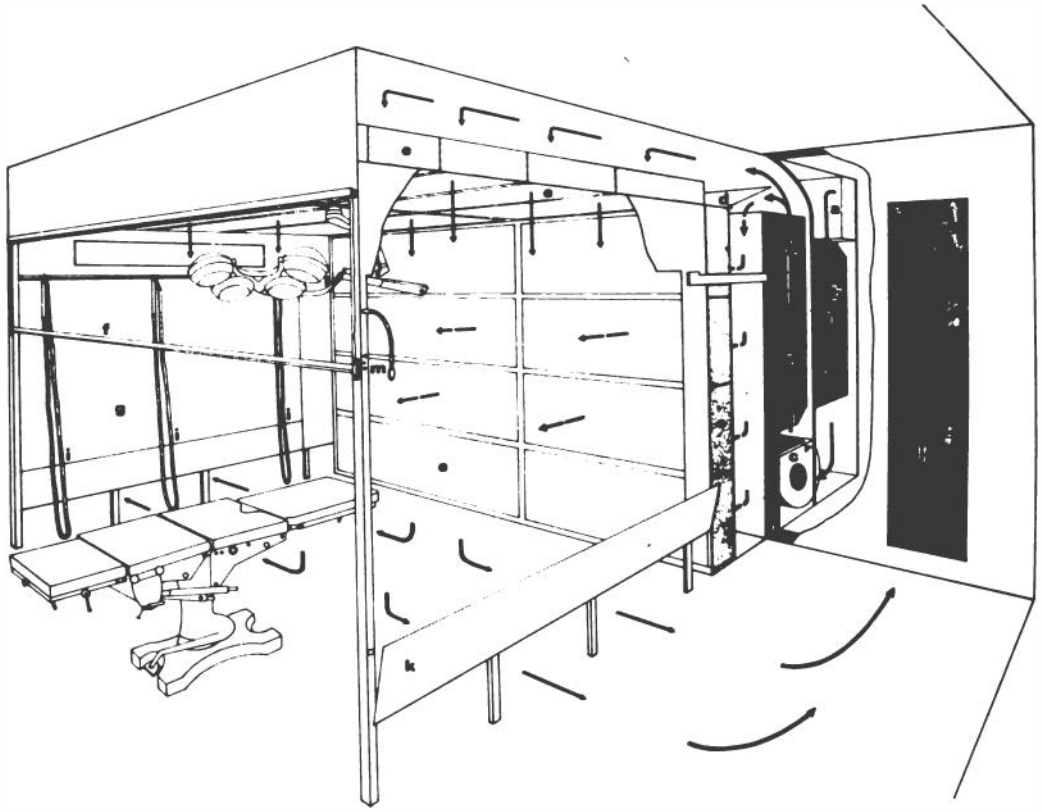

Fig. 2. Sectional drawing of optional-direction, variable speed, laminar-flow system: a. primary filters; b. silencers; c. variable speed fan; d. variable direction flap normally either up or down; e. High Efficiency Particulate Air (HEPA) filters; f. front plastic curtain; g. laminated glass; h. body-exhaust duct; i. personal exhaust tubes; j. return air grill; k. side flap; l. skeletal lamp; m. audio controls.

1. Downflow or crossflow? One of the basic questions we set out to solve was whether or not crossflow was better or worse than downflow in terms of airborne bacteria at the wound site. The crossflow system is in general cheaper to build and install and because of the open end there is better communication and accessibility. Unfortunately, our studies showed that using conventional operating clothing the downflow system was around five times better in terms of airborne bacteria at the wound side during major orthopaedic surgery. By measuring the airborne bacterial count within 10 cm of the wound site by means of a specially adapted Casella high-volume sampler drawing 700 l/min. (25 cfm) of air, the counts as shown in Figure 3 were ascertained. Sampling was carried out for up to 10 minutes and then either the air velocity or direction was changed. This was carried out through the entire operation and it may be clearly seen

from this strictly controlled experiment that downflow, in terms of airborne bacterial particles sampled at the wound, was around five times better than crossflow at 0.3 to 0.5 m/s (60-100 ft/min). The full results of this experiment are contained in our paper (12).

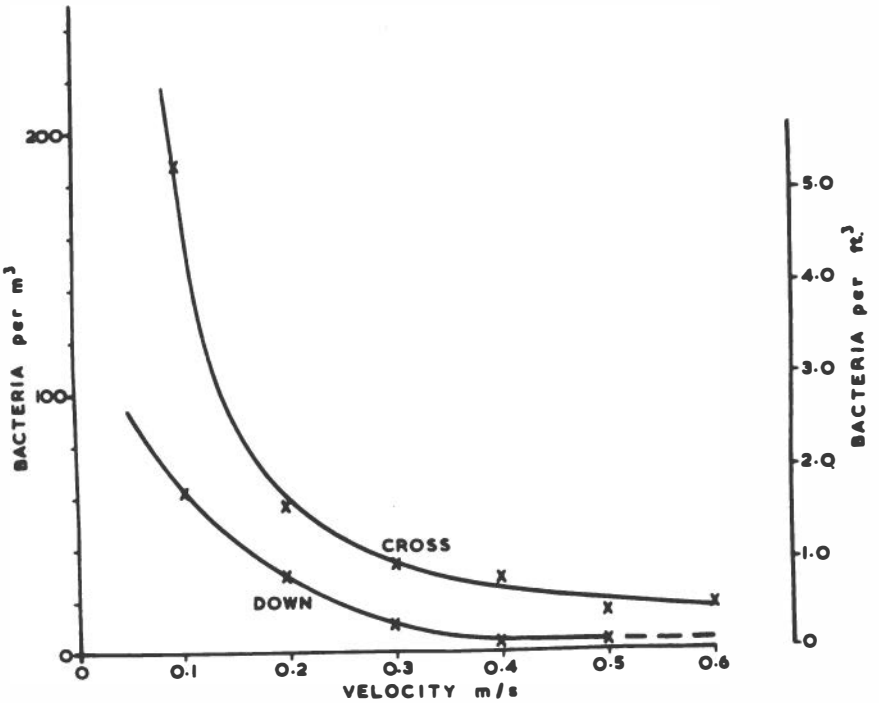

Fig. 3. Airborne bacterial counts at different velocities under cross- and downflow conditions.

2. Velocity requirements. Also shown in Figure 3 is the bacterial concentration to be found at the wound site at velocities varying from 0.1 m/s to 0.6 m/s (20-120 ft/min). As seen from this graph, the higher the velocity of the unidirectional airflow the lower the bacterial count. However, as in so many situations, the effort (and hence cost) expended in achieving very low airborne bacterial counts in an operating room is not proportional to results. This means that a point must be drawn where moderate effort and good design will achieve a highly efficient system. A study of Figure 3 will show this point to be around 0.3 m/s (60 ft/min). Allowing a small margin of safety, we now run our system at 0.35 (70 ft/min) using a downflow of air.

3. Walls or no walls? Unfortunately, although a downflow system of air movement is the best bacteriologically, it is not the best in terms of access or freedom of communication. Because of the apparent necessity of having walls to prevent entrainment of air from outside the clean area, the operation team is shut in and communication and access for X-ray equipment, etc. is very difficult. The access problem may be overcome by removable walls, but this cannot be considered a fully satisfactory solution. We have studied this problem and suggest as a possible solution the use of a downflow partial-walled system. These partial walls replace the full walls being located around the periphery of the clean area, and hang down to head height. A photograph of a partial-walled system at the London Hospital is shown in Figure 4.

Fig. 4. Partial-walled system at the London Hospital.

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By constructing a 1/10th scale water model and ensuring the Reynolds number to be the same in the water model as the airflow in the laminar flow operating room, it was possible to predict the type of flow and the effectiveness of the system in preventing penetration by contamination from the outer dirty area (15). This effectiveness is assessed by injecting dye as a challenge to the system, an example of this being shown in Figure 5.

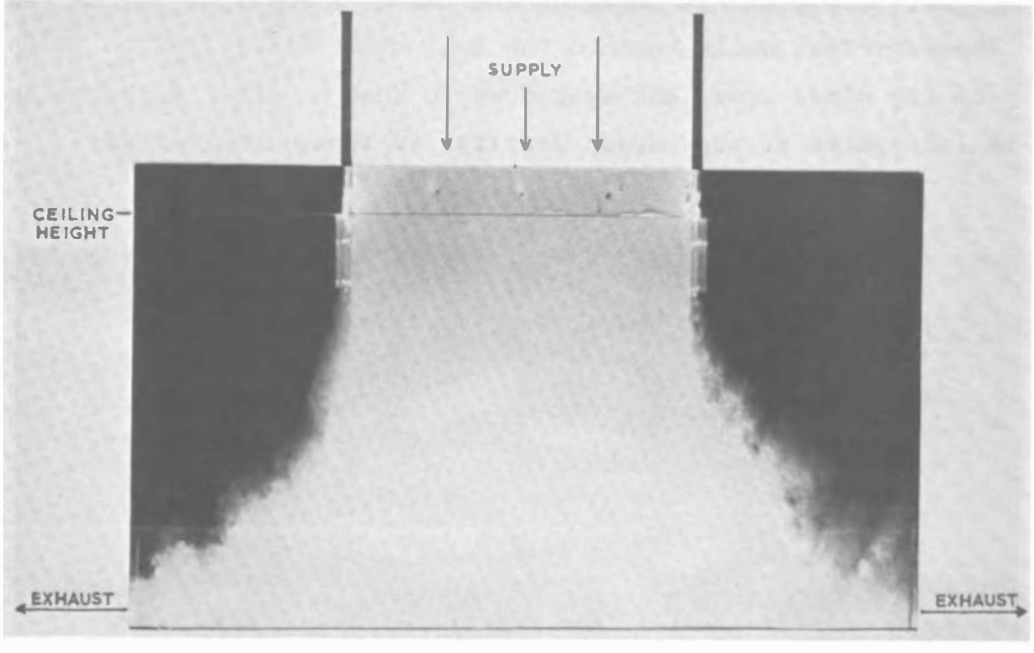

Fig. 5. Dye challenge of partial-walled, water-model system.

We also have had the opportunity of studying at the London Hospital (14) a partial-walled operating room. An assessment of this system highlighted some design faults, but by means of bubble generators, smoke challenge tests and velocity readings it was possible to show that:

a. the type of airflow was similar to that of the water model;

b. the partial wall was preferable to no wall;

c. entrainment was possible but the amount of contamination which reached the operating table was very small--about 1/10,000th of that on the outside area, but it was 1/100th at the periphery of the clean area where the instrument trolleys could be sited;

d. in order to achieve the same airborne bacterial concentrations

as the full walled system, the airflow would require to be increased by 25 percent because of the air moving sideways (as shown in Fig. 3) instead of being forced down by the constraining walls.

4. Obstructions and thermals. Low-speed unidirectional flow systems, as suggested by Blowers (2), have been shown to be disrupted by thermals rising from operating room personnel and operating lamps. On studying this problem in the higher speed laminar flow systems by means of Schlieren photography (an optical method by which hot air may be seen), it was possible to demonstrate (13) that the most intense heat source in our system, which was a quartz-halogen operating light giving off 1 kw of heat, would be overcome by the downflow of air at speeds over 0.3 m/s (60 ft/min). It is therefore apparent that the airflow in laminar flow systems will not be disrupted by thermals.

Investigations were also carried out on obstructions of the laminar flow system by use of bubble generators which produce small neutral-buoyancy detergent bubbles. Shown in Figure 6 is the effect on unidirectional airflow of the large lamp of the type used in the great majority of British operating theaters. The air in the turbulent area behind this lamp will have high concentrations of contamination if it is in contact with bacteria being dispersed by the operating team. In a similar fashion if it is in contact with the wound site, it will subject the wound to high concentrations of bacteria. Such obstructions should be kept well clear of the operating site, reduced in size or completely removed.

5. Filter efficiency and noise levels. It is common practice to fit filters that are of an efficiency greater than 99.9 percent against 0.3μ particles. This practice is obviously a direct copy from the industrial situation where these HEPA filters are required to contend with dust particles of 0.5μ and greater in size. As the size distribution of bacterial particles in hospital areas is much larger than this (the average size being around 12 to 13μ), it would appear that there is reason for considering filters that are less efficient. As these industrial type HEPA filters have a high pressure loss, they require large fans which, in turn, generate a great deal of noise if situated close or near to the operating theater. Use of less efficient filters would be of much benefit.

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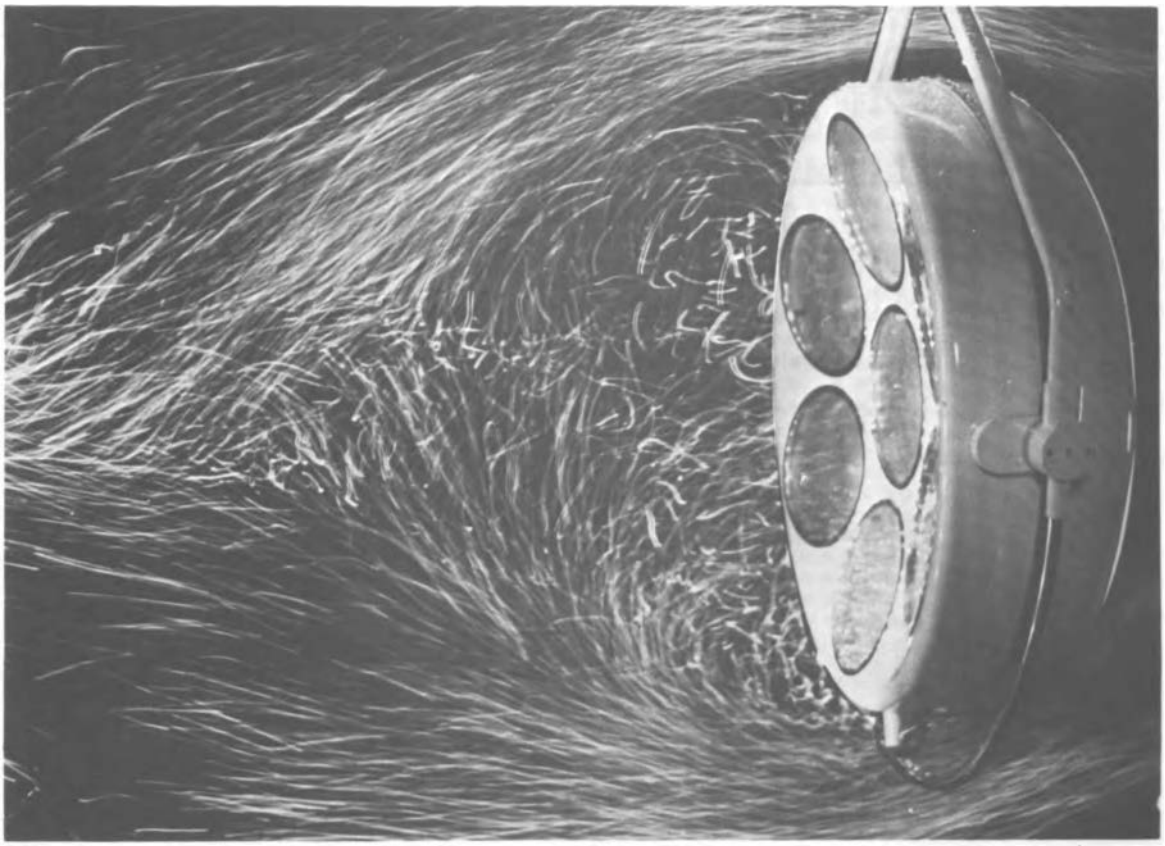

Fig. 6. Airflow around operating room lamp.

I have studied (9) the efficiency of airconditioning filters in a hospital ward when air was being recirculated. As it was a hospital ward, very high efficiency filtration was not considered a priority and HEPA filters were not used, but when a final filter around 80 percent against 0.5μ particles was installed, the bacterial count in the recirculated air was reduced from 1.93 bacterial particles/ft^3 before the filters, to 0.013 ft^3 after the filters--a 99.3 percent reduction. Considering the always present possibility of contamination which could account for at least part of the final bacterial concentration and also that any particles passing through this final filter would not be of the size that would deposit in the wound, it would appear that there is an excellent indication that HEPA filters are not essential.

A standard has now been accepted by the DHSS (7) for filtration of recirculated air in the operating theater of 90 percent against 0.3μ to 0.5μ particles.

Use of these filters would approximately halve the pressure drop at the filter and hence reduce the noise level but, notwithstanding this, it would appear that a great variety of systems are on sale which suffer from excess noise, and it would be an advantage that noise standards be worked toward the achievement of acceptable noise levels. This may be impracticable at the present time, but we should insist that noise levels, as measured in the operating area, be quoted for a given air velocity.

PREVENTION OF DISSEMINATION OF BACTERIA BY CLOTHING

It has been well established that people disseminate large numbers of bacteria into the air. Duguid and Wallace (4) estimated indirectly that a person with ordinary clothing would, during vigorous activity, disperse 10,000 bacterial particles per minute and that ordinary operating room clothing did very little to prevent this.

The importance of this lies in the fact that, in an operating room which is plenum ventilated by filtered air, almost all of the bacteria to be found in the air are derived from the operating team and that Staphylococcus aureus is given off into the air in large numbers by carriers of this pathogenic organism (1).

It seems obvious that operating theater clothing should be designed to prevent dissemination. Unfortunately, materials which are impervious to bacteria also prevent exchange of heat and water vapor from the body and, hence, are intolerable to wear. The present approach is either to produce clothes which are more impermeable to bacteria yet not uncomfortable to wear, or to use impermeable clothing and ventilate the person. There are also some intermediate stages between these two possibilities. In a series of as yet unreported experiments, we have compared, in a dispersal chamber, several types of gowns and trousers. We attempted to simulate both conventional turbulent and laminar-flow ventilation in the chamber but, for the purposes of this paper, I should like to mention only the results obtained in the laminar flow situation. Three subjects were used, and it was demonstrated that, by using disposable gowns of a conventional pattern made from nonwoven fabric instead of conventional linen gowns, the airborne bacterial counts could be reduced by 60 percent; but by using total-body exhause systems of the Charnley style, the count could be

reduced by over 98 percent. In order to test the validity of these experiments, as carried out in the test chamber, a comparison was made in the operating room between 1) ordinary linen gowns, 2) nonwoven fabric disposable gowns, and 3) Charnley-style total-body exhaust gowns. These showed in the laminar flow unit a very similar drop in airborne concentration when nonwoven fabric gowns were used, but the total-body exhaust gowns did not give quite as good a performance as in the dispersal chamber. There was some evidence that this slightly smaller drop was due to bacteria being dispersed from the patient on the operating table.

The bacterial count in the air of our laminar flow system when the total-body exhaust gowns are being used is around $0.63/m^3$ which is a reduction by a factor greater than 650 in airborne count at the wound site compared to our plenum ventilated conventional operating room when linen clothes are being used.

AIRBORNE COUNTS, WOUND CONTAMINATION, AND INFECTION

It is obvious from the results cited above that both the plastic film isolator type of ultraclean system and the laminar flow type, substantially reduce the number of bacteria in the air and, therefore, ipso facto must also reduce the number of bacteria to be found in the wound after surgery. The evidence for this statement may be ascertained by washing the wound after surgery and counting the number of organisms isolated. A standard technique has been suggested by the Medical Research Council's Working Party on Ultra-Clean Air in Surgical Operating Rooms for use in clinical trials of ultraclean systems, and is being used by several centers in the UK. The results of one such comparison will be presented by Mr. George Bentley during this workshop. He compared a conventionally ventilated operating room with an ultraclean one with respect to the number of bacteria in wounds after surgery.

The question still remains, however: Will the number of bacteria in the wound be reduced to a level sufficient to affect the incidence of infection? Or to pose the question another way: Is airborne contamination important? It should not be necessary at this workshop to remind the participants of the excellent work carried out by Professor Charnley in the UK. He maintains that a substantial reduction in deep infection after hip arthroplasties will be gained

by use of ultraclean air in operating rooms (3). Equally well, it should not be necessary to mention the criticism of the sequential method of his trial where variables other than a reduction of airborne bacterial particles, were introduced and the low infection rates obtained by many other orthopaedic surgeons in conventionally ventilated operating rooms (see Journal of Clinical Orthopaedics and Related Research, September 1973). Unfortunately in the UK there are relatively few centers with ultraclean systems, and even fewer with the years of experience, or number of operations, where Charnley's work could be confirmed. We ourselves, to date, have been more concerned with an assessment of the system from a bacteriological standpoint, rather than from a clinical one, and have only recently started a fully controlled clinical trial. This trial is being run according to the protocol set up by the Medical Research Council Working Party on Ultra-Clean Air in Surgical Operating Rooms for a multicentered clinical trial of ultraclean systems in the UK. How this trial will be run, and an outline of the protocol will be reported by Dr. Lidwell at this workshop. It will, therefore, not be necessary to duplicate such information. However, it is worth reporting the clinical results obtained in Edinburgh by Dr. Gould and his colleagues. They have now for several years been comparing a laminar flow system with an unventilated operating theater. Shown in Table 1 are the results reported for the years 1971-72 and 1972-73 (5). It should be reported that a perfect balance between surgeons operating on one system or the other was not obtained, but it would appear there is an indication from these results that deep infection will be reduced by ultraclean systems. A complete answer must await the results of the multicentered clinical trial.

William Whyte

Table 1. Infection of Hip Arthroplasties

	No. of operations	No. of superficial infections (%)	No. of deep infections (%)
1970 - 1971			
Unidirectional flow	80	5 (6.2)	0
Without unidirectional flow	110	5 (3.7)	3 (2.8)
1972 - 1973			
Unidirectional flow	104	2 (1.0)	0
Without unidirectional flow	76	5 (6.3)	3 (4.0)

SUMMARY

This paper reports the known basic design data that are available at present in the UK for producing ultraclean environments for the operating room. Two systems are considered. These are the plastic film isolator which is used to protect surgical wounds from environmental contamination and unidirectional flow systems, with or without special clothing. The plastic isolator system is briefly described. Most of the remainder of the paper discusses the effect of different unidirectional flow systems and operating room clothing on reducing airborne contamination. The main effects are summarized in Figure 7. These data were gathered by us at two different times. The data on the effect of clothing in the downflow system were collected some time after the comparison of downflow with crossflow so that the data do not quite intermesh, and averages have been taken.

Other subjects considered are:

1. velocity requirements; 0.35 m/s (70 ft/min) being suggested;
2. the use of partial walls for theaters with communication or access problems;
3. less efficient filters than at present (90 percent efficiency against 0.3μ to 0.5μ particles);
4. noise standards;

5. the non-influence of thermals;
6. obstructions; and
7. comparative sepsis figures, the lack of which should be overcome by a multicentered trial to be mounted in the UK.

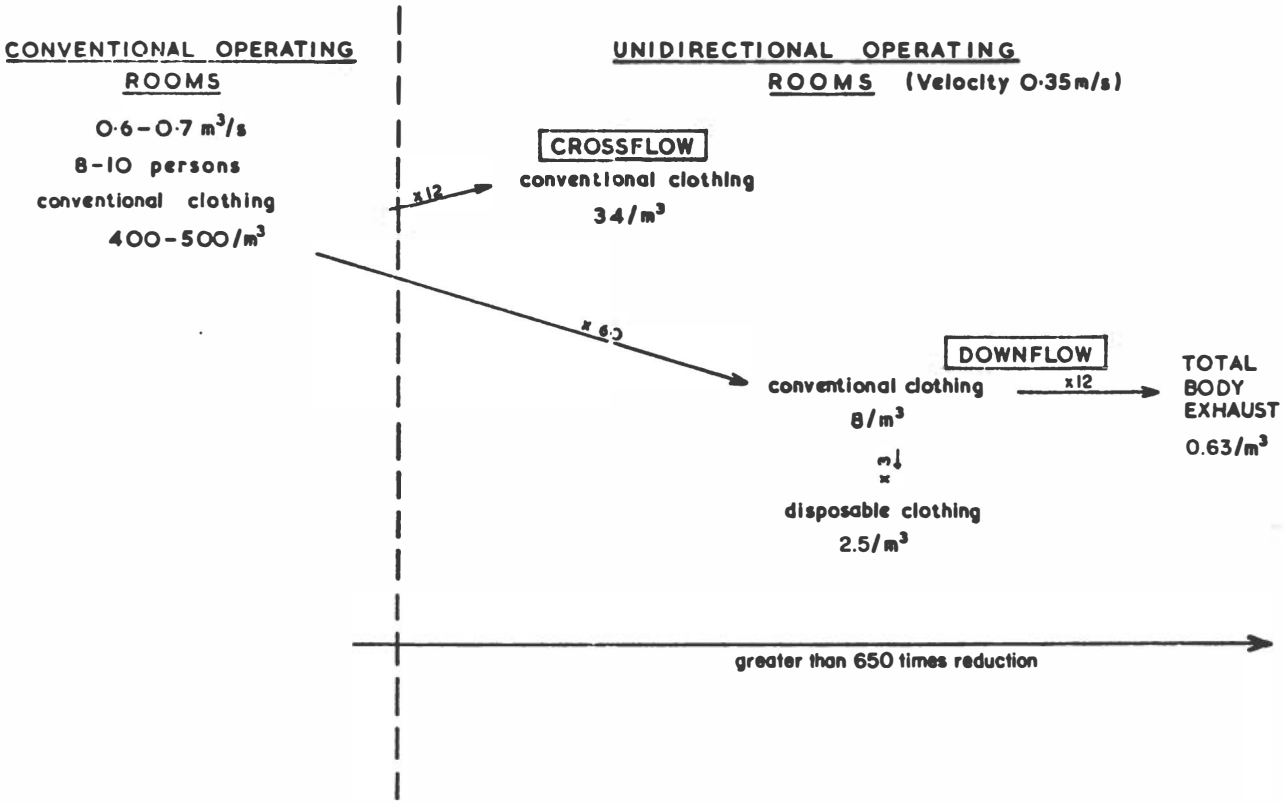

Fig. 7. Vector diagram of the influence of unidirectional system and clothing on airborne contamination.

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APPENDIX A

AGENDA

WORKSHOP ON CONTROL OF OPERATING ROOM AIRBORNE BACTERIA
COMMITTEE ON PROSTHETICS RESEARCH AND DEVELOPMENT

November 8-10, 1974
National Academy of Sciences
Washington, D.C.

George T. Aitken, Chairman

Friday, November 8		Lecture Room
	Moderator - George T. Aitken	
8:30 am	Welcome American Academy of Orthopaedic Surgeons	John C. Wilson, Jr.
8:40 am	Introduction and Objectives	George T. Aitken
8:50 am	Review of Postoperative Wound Infections	William A. Altemeier
9:05 am	The Orthopedist's Special Interest in Surgical Infection	Mark B. Coventry
9:20 am	Operating Room Air as a Source of Wound Contamination and Infection	Ruth B. Kundsin
9:30 am	COFFEE	
	Moderator - John C. Wilson, Jr.	
10:00 am	Operating Room Bacteriology Carriers versus Shedders Skin Carriage Sampling and Significance Physics of Operating Room Air Bacteria Types of Operating Room Air Bacteria	John A. Ulrich
10:20 am	Human Bacterial Shedding	Dick Riemensnider
10:30 am	Current Operating Room Air Handling Standards	Kenneth L. Credle
10:45 am	Standard Techniques to Reduce Operating Room Bacteria	Howard P. Hogshead
	Moderator - Jo Miller	
10:55 am	Ultraclean Environments - The British Position	William Whyte
11:15 am	The Case for Clean Air--Results of Three Years of Airborne Monitoring	John A. Feagin, Jr.

11:30 am	Culture Plate Studies in the Orthopaedic Operating Room	A. M. Wiley
11:40 am	Airborne Bacterial Contamination in the Operating Room	Robert H. Fitzgerald, Jr.
11:50 am	Experiences with Operating Room Environment at UCLA	Harlan C. Amstutz
12:00 noon	DISCUSSION	
12:30 pm	LUNCH	
1:30 pm	Participants in five multidisciplinary groups will discuss the morning's work	
	Moderator - John A. Ulrich	
4:00 pm	Plenary session for group leaders to present conclusions of group. Discussion	
5:30 pm	ADJOURN	

Saturday, November 9 — Lecture Room

Moderator - Philip D. Wilson, Jr.

8:30 am	Improved Operating Room Barrier Materials	Peter Dineen
8:45 am	Personal Envelope Systems	Jo Miller
8:55 am	Helmet Aspirator Systems	J. Phillip Nelson
9:05 am	Ultraviolet Light	J. Leonard Goldner
9:20 am	Low Velocity Unidirectional Ultrafiltered Air Systems	Lewis L. Coriell
9:35 am	COFFEE	

Moderator - Harlan C. Amstutz

10:05 am	Principles of High Velocity Directional Airflow Systems	Willis J. Whitfield
10:15 am	Vertical Laminar Airflow System	Robert S. Turner
10:25 am	Horizontal Flow Operating Room Clean Rooms	J. Phillip Nelson
10:35 am	Horizontal Laminar Airflow - Its Effects on Reducing Postoperative Wound Infections	Merrill A. Ritter
10:45 am	Bacteriological Evaluation of Clean Air Systems	Carl L. Nelson
10:55 am	Local Airflow as a Means of Protecting Surgical Wounds from Airborne Contamination	William E. Anspach, Jr.

11:05 am	Local Control of Airborne Bacteria	J.C.N. Westwood
11:15 am	Localized Surgical Isolators (Sterile Environment Capsule)	Dana M. Street
	Moderator - William A. Altemeier	
11:25 am	A Controlled Comparison of Air and Wound Contamination in Conventional and Vertical Laminar Flow Operating Theatres	George Bentley
11:45 am	Evaluation of Methods for the Control of Surgical Sepsis	Owen M. Lidwell
11:55 am	What is the Hard Evidence on the Role of Airborne Bacteria in Wound Infection?	Harold Laufman
12:05 pm	Defining Biologic Clean Air and Its Clinical Significance	William C. Beck
12:15 pm	Summary of Proceedings of the International Symposium on Contamination Control: Microbiological Aspects of Clean Room Technology as Applied to Surgery--with Special Reference to Unidirectional Airflow Systems	Michael D. Wardle
12:25 pm	Two Considerations in the Application of Laminar Clean Air	Edward O. Goodrich, Jr.
12:35 pm	Experiences with Ultraviolet Light in the Operating Room	J. Drennan Lowell
12:45 pm	LUNCH	
1:30 pm	Group discussions of the morning's session	
	Moderator - Kenneth L. Credle	
4:00 pm	Plenary Session	
5:30 pm	ADJOURN	

Sunday, November 10		Lecture Room
9:00 am	Plenary Session	
	Report of the Moderator of Plenary Session on Basic Data	John A. Ulrich
9:30 am	Discussion	
10:00 am	COFFEE	
10:15 am	Report of the Moderator of Plenary Session on Practical Application	Kenneth L. Credle
10:45 am	Discussion	
11:15 am	Summary, Conclusions, and Recommendations	George T. Aitken

APPENDIX B

PARTICIPANTS

WORKSHOP ON CONTROL OF OPERATING ROOM AIRBORNE BACTERIA

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