

The clean air operating room at University Hospitals of Cleveland

Charles H. Herndon, M.D.*

The control of infection following surgical procedures has been a major concern since anesthesia permitted operative intervention. Although tremendous progress has been made through aseptic technique, postoperative infections still are a major cause of increased morbidity and disability. A reassessment of further means of reducing the incidence of postoperative infections has been stimulated by the role infection may play in the success or failure of certain surgical procedures that have become possible through advances in surgical technology in recent years. Examples are whole organ allografts, installation of cardiac pacemakers, resections of tumors of the extremities with replacement by prostheses or allografts, total hip replacements and, more recently, total knee replacements. Although surgical techniques have made such procedures feasible, infection as a postoperative complication is a disaster and frequently will lead to total failure of the procedure. This is particularly true when artificial implants are involved.

It has been emphasized by Deryl Hart et al¹ as well as by many other investigators that although contamination of the wound at the time of surgery is the primary cause of postoperative wound infection, there are many other factors that influence the incidence of infection. These factors were well documented in the study of an Ad Hoc

* *Rainbow Professor of Orthopaedic Surgery, Director, Division of Orthopaedic Surgery, Case Western Reserve University School of Medicine, Cleveland, Ohio.*

Committee of the Committee on Trauma of the Division of Medical Sciences, National Academy of Sciences, National Research Council in 1964, and I need only to emphasize that older patients are more prone to postoperative wound infection, as are those patients who are obese, those who are malnourished, those who have diabetes, and those who are receiving steroid therapy. Another factor of major importance in postoperative wound infection is the insertion of inert foreign bodies in the wound. There are also numerous statistics to document the importance of the size of the wound, exposure time, and the effects of hematoma and traumatized tissues as factors influencing the incidence of postoperative infection.

It is apparent that some of the factors that may influence wound infection can be controlled; others cannot. We may be able to persuade an obese, elderly woman with a disabling osteoarthritis of the hip to lose weight over a period of time, but the age factor cannot be changed. Also, if we are to make available to the severely disabled rheumatoid arthritic receiving steroid therapy the advantages of a total hip replacement, we must recognize that there is a greater risk of infection than in a young, normal individual. We may, through meticulous attention to surgical technique, avoid excessive surgical trauma and hematoma, but if we are to utilize some of the major advantages in surgical technology we will leave behind in the wound large, inert implants or allografts. It therefore behooves the surgeon to search for every possible means of preventing wound contamination, which is a major factor that we should be able to control.

There are three major sources of contamination of a surgical wound.

Endogenous. It has been recognized for many years that an infection elsewhere in the body or bacterial contamination in the nasopharynx or urinary tract may produce a showering of bacteria into the blood stream either during or following a surgical procedure, with bacteria lodging in the hematoma at the operative site, thus producing a postoperative infection.

Contact. This is the simplest form of bacterial contamination of a surgical wound and has now largely been obviated through meticulous skin preparation and sterilization procedures.

Airborne. Bacterial fallout in the operating room during surgical procedures has been the subject of an intensive investigation for many years. This results from particulate matter in the air, caused by turbulence in the room or the ventilation system, by exhaled air from all who are in the operating room, and by bacteria and particulate matter shed from hair and skin of the operating team.

Recognizing that infection following major implant surgery, such as a total hip replacement, and also recognizing that such procedures would be commonly indicated in patients in a higher risk group, that is, the elderly patient, possibly obese, and possibly having been receiving steroid therapy, we have at University Hospitals of Cleveland carried out an extensive reevaluation of techniques to control postoperative wound infections.

An attempt to control the potential endogenous source of infection is made by careful evaluation of the patient preoperatively with a search for foci of infection. If such is found, surgery is delayed until the focus of infection

has been eradicated. We believe that the data presented by Fogelberg et al² on the use of prophylactic antibiotics in elective surgical procedures is valid, and we have therefore initiated the use of prophylactic antibiotics 12 hours prior to surgery in an attempt to prevent bacteremia.

The potential source of infection through contact has also been emphasized. Meticulous skin preparation over a period of 3 to 4 days before surgery has been established as a routine. All bed linens and equipment which are in contact with the patient are sterilized and meticulous aseptic technique is followed not only in the operating room but on the wards.

The most difficult potential source of infection to control is that of airborne bacterial fallout. It is for this reason that the clean air surgical facilities have been designed and their importance has been emphasized. Charnley^{3, 4} stimulated interest in the use of a clean air operating room when he demonstrated that he reduced his infection rate at Wrightington from 8% to 1% through the utilization of a glass-enclosed clean air operating room.

Theoretically, if an air filter system in the surgical facility filtered 100% of particles and bacteria, there would be zero bacterial fallout when the room was empty and there was no traffic. It is recognized, however, that any turbulence within the room will create increased bacterial fallout. There is constant shedding of bacteria from the skin and hair of an individual and there is a constant bacterial fallout from the exhaled air of everyone within the room. Therefore, the challenge was to exteriorize the individuals within the room by means of clothing

to prevent bacterial shedding and to evacuate their exhaled air. It was also essential to reduce turbulence within the room, which could be accomplished by a glass enclosure permitting traffic outside the enclosure but not within (*Fig. 1*).

Operating room supervisors designed the attire of the surgical team in cooperation with the personnel of University Hospitals sewing room. All individuals permitted in the room are dressed in specially designed sterilized jumpsuits, sterile boots, sterile gloves and helmet that is attached to an evacuation system which evacuates exhaled air (*Fig. 2*). Johnson and Johnson impervious disposable operating gowns are worn over the sterilized jumpsuits.

The ventilation filtering system of the operating suite was evaluated by our engineers. It was determined that 100% fresh air is applied to the system through a protected intake point. It passes through two prefilters before conditioning. The first filter is a 2-inch thick fiberglass prefilter pad, followed immediately by an American Air Filter PL-24 pleated fiberglass filter mounted in a metal frame. The PL-24 filter is 35% efficient in removing atmospheric particles of 0.3μ diameter and above. The air then passes through temperature and humidity conditioning stages and is terminally filtered by an American Air Filter "Dry Pack" Series 2000 filter, using a No. 100 media. This is a sock-type filter having an average efficiency of 93% to 97% in removing particles of 0.3μ diameter and above. All efficiency filters are based on American Filter dust spot method tests for atmospheric dust. Before installing a bio-clean surgical facility bacterial fallout studies were carried out in the closed



Fig. 1. The glass operating room enclosure at University Hospitals of Cleveland using shatter-proof glass. Vertical air flow about perimeter within the enclosure. Enclosure elevated 4 inches from floor to provide air outlet. Sliding doors provide entrance room for patient and surgical team. Sliding glass instrument pass window for circulating nurse.

operating room overnight. A total of 208 agar plates were exposed 8 to 12 hours in 104 tests. It was demonstrated that there was zero bacterial fallout under these controlled conditions. We were thus satisfied that the filter system was efficient in producing a bacteria free environment when other factors were not introduced.

Bacterial fallout studies were then carried out in the standard operating room under standard operating room conditions during a variety of orthopaedic procedures (*Table 1*).

The air is supplied to the operating room at the rate of 1,500 cubic feet per minute. It enters at ceiling level through a ring of diffusers having a surface area of 48 square feet, and the velocity of supply air is about 31.2 feet per minute. A glass enclosure was

designed to reduce the size of the actual operating area, exteriorize the anesthetist, the patient's head, students, circulating nurse, and other necessary traffic within the room (*Table 2*).

Helmets for the surgical team as designed by Charnley were obtained from Codman and Shurtleff, Inc.* The helmets were connected to a vacuum system (also obtained from Codman and Shurtleff) for the purpose of evacuating exhaled air and thus as nearly as possible exteriorizing the surgical team.

The details of the exhaust system are as follows: velocity and discharge rate at exhaust end in work room

* Codman and Shurtleff, Inc., Boston, Massachusetts.



Fig. 2. The vacuum tube is channeled through the lower support of the glass enclosure. Intercom wire is attached to vacuum tube.

Table 1. Bacterial fallout on exposed agar plates in standard operating room under standard operating room conditions—44 tests; average exposure time 74.5 minutes; variety of orthopaedic procedures

Site	Average colony fallout
Field	8.07
Mayo stand	5.4
Instrument table	6.5
Perimeter	5.3

where vacuum pump is located, taken at the open end of a 3 inch by 12 inch duct: 950 feet per minute = 10.8 miles per hour. Tests on the six vacuum outlets within the glass enclosed room were made at the connection points where the flexible hoses that lead to the masks and hoods are attached to the perimeter exhaust manifold (*Fig. 3*). Tests were made with all six exhaust ports open, because air speed with one port shut off exceeded the range of the meter. Average air volume

Table 2. Comparison of outer operating room and glass enclosure

	Sq ft	Cu ft	CFM supply	CFM exhaust	Air changes per hr	Rate of air change
Outer room (old OR 15)	415	3735	1500	985	24	Every 2.5 min
Inner room (glass enclosure)	168	1512	1500	985	51	Every 1.18 min



Fig. 3. Sterile instrument trays are opened as required.

exhausted from each of the 17/8 inch ports is 40 cubic feet per minute. This indicates an average velocity per outlet of approximately 2,100 feet per minute or 24 miles per hour. If only five ports are in use, this figure should be increased by 20%. Exact velocity of the air leaving the face mask when the system is in actual use with five persons present in the room, all fully clothed and connected, is a matter of conjecture. Because the hose diameters are decreased in size, velocity will increase, but friction created by the hoods and the added lengths of hose will decrease the air speed. It is simply our calculated guess that air velocity through the face masks with five masks in use will not exceed 30 miles per hour.

Results

Bacterial fallout studies as demonstrated on agar plates exposed during surgical procedures for total hip replacements were carried out under a variety of conditions. *Table 1* provides data from studies carried out in a standard operating room under standard operating room conditions during a variety of orthopaedic procedures. *Table 3* shows the results of studies carried out in the standard operating room but with the surgical team in special attire, and the vacuum system used to evacuate exhaled air. *Table 4* provides the results of studies carried out in the glass enclosure, the surgical team in special attire and helmets with the vacuum system in operation. *Table 5* gives a comparison of the different studies. It will be noted that the bacterial fallout is definitely reduced through the precautions taken as detailed above. The most effective is the utilization of the glass enclosure

Table 3. Bacterial fallout on exposed agar plates in standard operating room—doors locked; special attire; vacuum mask; low friction arthroplasty; 35 tests; average exposure time 127 minutes

Site	Average colony fallout
Field	3.5
Mayo stand	5.2
Instrument table	4.0
Perimeter	4.7

Table 4. Bacterial fallout demonstrated on agar plates exposed in glass enclosure during total hip replacement

Site	No. of tests	Average no. of colonies
Operative field	24	2.3
Mayo stand	24	3.6
Tray 3	19	2.6
Tray 4	19	1.3

Table 5. Comparison of bacterial fallout under varying operating room conditions

	Standard OR	Standard OR doors locked	Glass enclosure
Number of tests	44	35	24
Average length of exposure (min)	74.5	127	128
Field	8.07	3.5	2.3
Mayo stand	5.4	5.2	3.6
Instrument table or tray	6.5	4.0	2.5

combined with exteriorizing the surgical team through special attire and vacuum system (*Fig. 3*). In the standard operating room the bacterial fallout in the region of the operative

field was 8.07 bacterial colonies after an average exposure of 74.5 minutes, whereas in the glass enclosure with precautions as indicated above, the bacterial fallout in the region of the field was only 2.3 colonies after an average exposure of 128 minutes.

We have now performed 185 total hip replacements in the bio-clean surgical facility and have had no infections attributable to airborne infections to date.

Conclusions

The bio-clean modular surgical facility is an effective approach to reducing the airborne source of bacterial contamination of surgical wounds.

Further studies are indicated to determine the effective reduction in postoperative infections following implant surgery, joint replacements, prosthetic

replacements following major tumor excision of the extremities, and organ transplantation.

References

1. National Academy of Sciences—National Research Council: Report of an Ad Hoc Committee of the Committee on Trauma, Division of Medical Sciences: Postoperative wound infections: the influence of ultraviolet irradiation of the operating room and of various other factors. *Ann Surg* **160** (Suppl): 1–192, 1964.
2. Fogelberg EV, Zitzmann EK, Stinchfield FE: Prophylactic penicillin in orthopaedic surgery. *J Bone Joint Surg* **52A**: 95–98, 1970.
3. Charnley J, Eftekhar N: Postoperative infection in total prosthetic replacement arthroplasty of the hip joint with special reference to the bacterial control of the air of the operating room. *Br J Surg* **56**: 641–649, 1969.
4. Charnley J, Eftekhar N: Penetration of gown material by organisms from the surgeon's body. *Lancet* **1**: 172–174, 1969.