

Clean air and total hip arthroplasty

Carl L. Nelson, M.D.
Alan Seth Greenwald,
D.Phil. (Oxon)

Department of Orthopaedic Surgery

The concept of clean air is of common interest to the ecologist and the surgeon, although the adjective clean has a somewhat different connotation to each of these scientists. Attached to the concept of clean air and laminar air flow is an unfortunate emotional connotation. 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 orthopaedist's 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 site results in total failure of the operation. This is in contrast to the usually excellent results seen with this operation. Also, total hip 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 amount of living tissue in contact with the large endoprosthesis are factors that encourage bacterial growth. Furthermore, materials such as methyl methacrylate and high density polyethylene, which are not entirely inert, add to the likelihood of infection.

Historical considerations

In considering the merits of the clean air system as used in total hip replacement arthroplasty, the historical background of infections and past attempts to eradicate infection should be reviewed. Lister¹ proposed the concept of aseptic surgery, and with the application of these principles, the infection rate decreased. His concepts led to the present era of aseptic surgery, which includes preoperative skin cleansing combined with sterile scrub for 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 Moynihan² stated that two thirds of his patients died of infection after he had opened the belly. In 1915 Brewer³ showed that the infection rate after clean operations was 39%. In 1933 Meleney⁴ 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%, and of minor infection from 10% to 5.4%. In a similar study McKissock et al⁵ reduced the percentage of surgical infections from 15% to 1.1%. More recently Henderson and Kornblum⁶ kept the percentage of serious infections in 3,290 operations to 1.7%; Steel⁷ reduced the infection rate from 15% to 0.58%.

From these studies similar criteria for reducing the incidence of infection have been established: (1) rigid restriction of movement in the operating room, especially restriction of the inadvertent visitor; (2) careful, thorough

preparation of the patient and the operating room personnel; (3) gentle handling of tissue; and (4) an intangible—alerting everyone in the hospital to the problem of infection.

Sources of infection

Almost everyone agrees that surgical wounds can become infected at the time of operation. There is less agreement on 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, the number of bacteria deposited in the wound and, of course, there must be a chance deposition of bacteria into the wound for the development of infection.

A single individual will shed from 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 will directly affect the particle and bacterial counts and also affect 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 Eftekhari⁸ have shown that 50% of the surface of such gowns are contaminated at the conclusion of a total hip replacement arthroplasty. Since the surgeon and operating room personnel are sources of bacteria, and the activity pumps particulate matter

over the wound, there is little question that if particles with attached bacteria are released 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 amount 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 or 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.^{9, 10} 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. Overall, in this study there would have been 30 fewer deep wound infections if ultraviolet light had been used in ultraclean cases.

Therefore, data and logic in support of attempts to reduce airborne contamination exist. Altemeier and Levenson¹¹ have pointed out that infections developed postoperatively in an estimated 1,391,000 patients at a cost of \$7,000 per patient and an overall cost of \$9.8 million for the control of wound infections. This is a signifi-

cant 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 air flow systems

What is a laminar flow clean air system? Early in 1961 the aerospace industry realized that the control of airborne particles in certain manufacturing and assembly areas was critical. A single hydrocarbon particle impinged on a liquid oxygen valve seat could be the cause of a missile explosion. Single particles of any measurable size, especially if they display magnetic properties, can short circuit a microcircuit as well as slow or jam the gyro of a missile guidance system. Thus, in response to an obvious need for higher reliability in manufacture, laminar air flow systems came into use, pioneered by Whitfield.¹²

Laminar air flow can be described as a flow in which the entire body of air within a confined area moves at a uniform velocity along parallel flow lines. If one were able to follow the motion of a tracer substance injected into the flow, he would observe motion in the same direction as the fluid with no visible disturbance. In other words, there would be no velocity components perpendicular to the direction of flow. When such components are present, the flow is said to be turbulent. The difference between laminar and turbulent flow can be seen by watching the smoke rising from a cigarette in a still room (*Fig. 1*). The smoke rises from the ember first in a smooth stream with no velocity components perpendicular to the



Fig. 1. The difference between laminar and turbulent flows can be seen by watching the smoke rising from a cigarette in a still room.

flow. After the smoke has risen a certain height above the ember, the layer-like or laminar flow becomes unstable and there are obvious velocity components perpendicular to the main direction of flow. This later flow is turbulent.

Recently, laminar clean room technology has been extended to the operating room. In this environment, these systems filter out dust and microbial organisms before they enter the surgical area, and also effect a rapid purging of particles from this area by means of an essentially unidirectional air flow. The former is accomplished by means of high efficiency filters. The filtering systems now used in surgical suites provide class 100 air or better. This means

that each cubic foot of filtered air contains not more than 100 particles 0.5 microns in diameter (Fig. 2).

Federal standards suggest limits of 90 ± 20 feet per minute as an effective average air flow rate over a work area. The surgical clean rooms in use today maintain a somewhat higher air flow velocity over the surgical area. In discussing laminar flow clean rooms, the term "laminar" needs some qualification. The interposition of objects such as surgical tools or the surgeon's hands will disturb the air flow pattern over the surgical area. Thus in all laminar flow clean rooms, some air turbulence is present. The term laminar when applied to operating rooms is therefore inappropriate, and "clean air rooms" is a more accurate and acceptable description. In designing surgical clean rooms, it is necessary to define the environment of the surgical area so that small-scale turbulences may be reduced to a point that the purging qualities of the air flow are not altered, and the development of large scale turbulences such as recirculating vortices resulting from thermal fields or large objects such as people placed in the flow field are prevented.

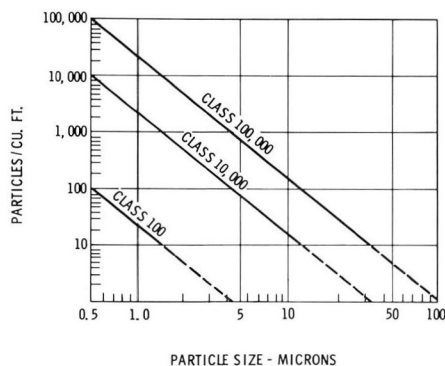


Fig. 2. Each cubic foot of filtered air contains not more than 100 particles 0.5 microns in diameter.

Rapid recovery from transient disturbances brought about by movement of personnel is also important. Users of laminar flow systems must recognize these facts and seek to achieve the best possible arrangement of equipment, personnel, and movement.

The clean air system used at the Cleveland Clinic is a wall-less horizontal type 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.¹³ 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. 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 achieved by the horizontal system are for the entire room; over the worksite there are about 500 changes of air per hour. The flow produced is similar to a piston of air forced across the room, and it sweeps particles shed by the surgeon and staff 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. This filter is 99.9% effective in removing particulate matter with attached bacteria and viruses, and bacterial contamination at the wound site may be decreased tenfold.

Effectiveness of clean air systems

Is there any proof that these systems have value? Studies of the clean air systems have shown a significant decrease in the number of organisms collected at the wound site. Charnley and Eftekhari¹⁴ have shown that with an increased air flow the infection rate was reduced from 8.9% to 1.3%. During this period no doubt they changed and improved their technique, altered the criteria for surgery, and more rigidly enforced the 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 to 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 some correlation with infection. Results of a study in Albuquerque, New Mexico showed a 0.79% wound infection rate in clean air systems compared with a 1.4% wound infection rate in a control group.¹⁵

Other studies have shown that clean air flow reduced bacterial counts at the wound site from a control level of 0.8 bacteria count to 0.19.¹⁶ Other studies using bacterial counts at the wound site show a 1.9 preremoval bacterial contamination count and a 0.8 count with a clean air system. Two other studies show an approximate four to eightfold decrease of bacterial contamination at the wound site,¹⁷ and from a control level of 8.0 to 2.3.¹⁸

Enneking¹⁹ reported that in 239 consecutive cases studied, 50% had bacterial contamination in the wound at the conclusion of surgery. He noted that in those cases which were con-

taminated at the end of surgery, there was a 7.9% infection rate, while in those that were not contaminated at the end of surgery, the infection rate was 6.0%. By applying a clean air system to his operating suite, he reduced his end of operation contamination rates to 21% and presently has a 0% infection rate. This is not statistically significant, but again shows a trend.

One of the few controlled studies was done using 300 total hip replacement arthroplasties, divided into two sections. One group of patients were operated on in a nonclean air environment under similar conditions, and with similar insertions. The infection rate was 3.6%. An equal number of patients were operated on in a clean air system, and in this group the infection rate was 0.6%. This, too, is not statistically significant at present, but again there appears to be a definite trend.

It is clear, then, at the present time there is very little hard, scientific data to prove that the use of the clean air system reduces infection. However, the system does reliably reduce bacterial contamination at the wound site. The absolute relationship between bacterial contamination and infection rate remains unanswered. To be dogmatically in favor of, or opposed to the clean air system in our present state of knowledge may be aptly characterized in one of Osler's aphorisms "The greater the dogma, the greater the ignorance." In our personal experience, the clean air system combined with rigid attention to tissue technique, careful preparation of the patient, control of activity in the operating room, and insistence on reliable housekeeping has enabled us to main-

tain an infection rate of five deep wound infections in more than 1,000 total hip replacement arthroplasties.

References

1. Lister J: On the antiseptic principles in the practice of surgery. *Lancet* 2: 353-356, 1867.
2. Moynihan BG: (quoted by Colebrook L) Infection acquired in hospitals. *Lancet* 2: 885-891, 1955.
3. Brewer GE: Studies in aseptic technique. *JAMA* 64: 1369-1372, 1915.
4. Meleney FL: The control of wound infections. *Ann Surg* 98: 151-153, 1933.
5. McKissock W, Wright J, Miles AA: The reduction of hospital infections of wounds: a controlled experiment. *Br Med J* 2: 375-377, 1941.
6. Henderson ED, Kornblum SS: Studies on the epidemiology of staphylococcal wound infection in previously clean surgical cases on an orthopaedic service. *Instruct Lect Am Acad Orthop Surg* 18: 282-287, 1961.
7. Steel HH: Surgical infections—Orthopaedic considerations. *Instruct Lect Am Acad Orthop Surg* 18: 288-293, 1961.
8. Charnley J, Eftekhari N: Penetration of gown material by organisms from the surgeon's body. *Lancet* 1: 172-173, 1969.
9. Hart D, Postlethwait RW, Brown IW Jr, et al: Postoperative wound infections: a further report on ultraviolet irradiation with comments on the recent (1964) National Research Cooperative Report. *Ann Surg* 167: 728-741, 1968.
10. National Research Council: Postoperative wound infections: the influence of ultraviolet radiation of the operating room and of various other factors. *Ann Surg* 160: Suppl. 1-192, 1964.
11. Altmeier WA, Levenson S: Trauma Workshop Report: infections, immunology, and gnotobiosis. *J Trauma* 10: 1084-1086, 1970.
12. Whitfield WJ: A new approach to clean room design. (SC-4673 RR), Albuquerque, New Mexico, Sandra Corp., March 1962.
13. Nelson CL: Experience with a wall-less horizontal clean air system during total hip replacement, p. 107-115, *In Symposium on Clean Room Technology in Sur-*

- gery Suites, Cocoa Beach, Fla., NASA, Midwest Research Institute, 1971.
14. Charnley J, Eftekhar N: Postoperative infection in total prosthetic replacement arthroplasty of the hip-joint. *Br J Surg* 56: 641-649, 1969.
 15. Whitcomb JG, Whitfield W, King JG, et al: Ultraclean operating rooms. *Lovell Clin Rev* 2: 65-69, 1965.
 16. Nelson P: Personal communication, April 27, 1972.
 17. Ritter M, Hart J: Evaluation of wall-less horizontal laminar flow clean air system for hospital operating rooms. Presented at Symposium on Bio-Clean Room and Its Application to Surgery Suites, San Francisco, Nov 1971.
 18. Herndon CH: Personal communication, Feb 24, 1972.
 19. Enneking WF: Bacteriological studies of alteration in operating room environmental contamination with "Clean Room." Presented at the Third American College of Surgeons Symposium on Control of Surgical Infections, Washington, D.C., Jan 1972.