Clean air symposium—Part II

Horizontal flow operating room clean rooms

J. Phillip Nelson, M.D.*
Alba R. Glassburn, Jr., M.D.*
Richard D. Talbott, M.D.*
James P. McElhinney, M.D.*

During the past several years there has been increasing interest, particularly among orthopaedic surgeons, in the application of clean room technology to the operating room. The stimulus for this interest can be attributed to Mr. Charnley,[1] who has demonstrated a marked reduction in infections in total hip replacement surgery using this technology. The more precise operative discipline which Mr. Charnley developed to complement this technology also appears to have contributed significantly to more efficient surgical asepsis.

It is the purpose of this paper to discuss our experiences with horizontal flow clean rooms during the past 18 months. We shall review the literature which contributed to our interest in operating room clean rooms, our reaction to utilization of such rooms and our experience with wound cultures, air bacterial sampling, and wound infections.

Literature review

In 1895 Brewer[2] reported that 39% of all clean surgical wounds became infected. Reviews of infection rates for all surgery showed a 9.4% rate in Great Britain[3] in 1960 and 7.5% in the United

* *Orthopedic Associates, P.C., Denver, Colorado.*

Table 1. Types of organisms found in operating room air[13]

Staphylococcus epidermidis	48.72%
Bacillus subtilis	36.63%
Sarcina lutea	6.59%
Fungal species	5.07%
Diphtheroid species	1.60%
Staphylococcus aureus	.50%
Aerobacter species	.49%
Micrococcus species	.16%
Achromobacter species	.14%
Neisseria species	.05%
Alpha hemolytic streptococcus	.03%
Streptococcus pyogenes	.01%

States[4] in 1964. Infections following hip surgery have been reported as 6.4%.[5] Early reports of series of total hip replacements not done in the clean room environment have indicated infection rates of 4% to 12%.[6-10] However, Coventry[11] reports an approximate 1% infection rate for his relatively large series done in a standard operating room. The figures serve to emphasize the diminished but still present threat of infection, particularly in extensive surgical procedures.

Wound contamination may occur endogenously from local or hematogenous sources. It may also occur exogenously from contact with contaminated hands or utensils or from airborne particulate matter.[12] Contact contamination has apparently been the most important source of surgical wound infection in the past.

Several investigators[13-15] have shown that the number of airborne microorganisms in standard, occupied operating rooms varies between 1.5 and 180 per cubic foot of air. In a modern, well-ventilated room this figure varies between 3 and 6 per cubic foot. The concentration of microorganisms varies directly with the number of people and their activity and whether or not the operating room door is open. Airborne bacterial counts in the wound vicinity may be twice as high as those peripherally because of the activity of the surgeons and scrub nurses. The organisms found are primarily derived from human shed, although a small proportion are of soil origin. *Table 1* indicates the types of microorganisms and their relative incidences in a standard operating room.

These organisms are generally occasional pathogens, and enteric organisms are relatively uncommon. *Staphylococcus aureus* is also relatively uncommon but its persistent occurrence in the operating room and in surgical wounds has been well documented.[16-18] Burke[17] has shown that essentially all large, clean surgical wounds are contaminated near the conclusion of the procedure and that cultures of these wounds will produce pathogenic organisms in most cases. Furthermore, he demonstrated by phage-typing that both scrubbed and nonscrubbed personnel contributed to the wound flora.

Man is a very prolific source of particulate matter in the air, and this material is composed of shed epithelial scales, fomites from the upper respiratory tract, and bacteria which are either free or associated with particles.[14, 19, 20] The average individual with normal skin sheds an average of 10,000 viable particles per minute.[21] With standard operating room attire, this figure is reduced to approximately 3,000 viable particles per minute. Ulrich[16] has shown that all human beings have essentially the same distribution of skin bacterial population. The greatest concentrations are found on the head and neck, axilla, hands, peri-

neum, groin, and feet. The angle of the jaw is the most highly populated area and it is usually uncovered by standard surgical masks. Bacteria shed into the operating room air from a small source can be detected in remote parts of the room in a few minutes. This occurs because of turbulent air flow, convection currents, and Brownian movement. Shedders of *S. aureus* are those relatively rare individuals who distribute increasing numbers of microorganisms in proportion to their activity; this is not the case with carriers.

The airborne microorganisms shed from operating room personnel reach the air from exposed skin, through operating room attire, and through surgical masks. The restraint to shedding provided by muslin gowns and caps is very ineffective.[22-24] In fact, standard gown pore size in relation to bacteria has been likened to the barrier effect of a tennis net on a BB. Regular surgical masks, particularly after more than 1 hour of use, are also relatively inefficient bacterial filters.[25]

The foregoing discussion indicates that infection of clean surgical wounds continues and that airborne microorganisms may contribute significantly to the production of these infections. The addition of clean room technology and improved gowning of operating room personnel to standard antiseptic techniques has been an attempt to provide better control of wound contamination both directly from airborne sources and indirectly from contact sources.

Several investigators[15, 18, 26, 27] have shown that the Class 100 Laminar Flow Room is effective in removing bacterial and particulate matter from the air. Microbial levels up to 200 viable particles per cubic foot and particulate levels of over 1 million per cubic foot have been reduced to essentially zero at the plenum and less than 0.3 microorganisms and 10,000 particles downstream from the work area.

Mr. Charnley[1] stimulated the application of this technology and the reduction of his infection rate from 8.9% under standard operating conditions to 1.3% in the clean room environment is well documented. The first truly operational vertical flow clean room was constructed at the Bataan Memorial Hospital in Albuquerque, New Mexico, and became operational in January 1966. Whitcomb and Clapper[28] and Whitcomb[29] have described this room and the drop in infection rate from 1.03% in 8,253 cases in two regular operating rooms to 0.79% for 3,408 operations in the clean room.

Fox and Baldwin[30] and Fox[31] proved the feasibility of horizontal flow clean rooms in surgery. Instruments on back tables remained sterile for 90 minutes compared to a 30% contamination rate in a regular operating room. Others who have contributed to the early development of clean room technology for operating rooms in the United States are Goodrich,[32] Beck,[33] Coriell et al,[14] and Bechtol.[34]

Special gown materials to prevent bacterial penetration and special hoods or helmets to prevent shed from the head and neck and nasopharyngeal expulsion have recently received considerably more attention. Finely woven materials with very small pore sizes and paper gowns with or without plastic backing are now available.[23, 24, 35] The use of pants and boots by all operating room personnel is recommended. Charnley,[36] Bechtol,[34] Lein-

bach,[37] and Goodrich[32] use hoods with plastic eye shields or helmets combined with a suction apparatus which draws through apertures at the side of the nose and mouth.

Our experience

A. General comments. At St. Luke's Hospital in Denver, our surgical team utilizes two horizontal flow clean rooms. The first is the Enviromatic model manufactured by the Envirco Corporation and it became functional on March 15, 1971. Its features have been described earlier in this symposium. The second module was constructed by the Martin-Marietta Company under contract to NASA. It was designed to meet the following criteria: (1) quick installation, (2) minimal operating room modification, (3) minimal maintenance, (4) portability and easy storage, (5) use of existing operating room lights, (6) use of existing air conditioning, (7) use of existing power supplies, (8) use of recirculated air, (9) minimal interference with operating room procedure, (10) reduced cost, and (11) self-contained suction and communications. The evaluation of this system has been published in a report to NASA.[38]

Both units have a 10-foot by 10-foot work area with a full wall plenum. Walls are transparent and retractable. *Figures 1 and 2* show the Envirco Room and *Figures 3 and 4* show the Martin-Marietta Room in both collapsed and functional positions.

To complement the Martin-Marietta Room, a bubble type "space" helmet with stabilizing yoke harness was designed. Ventilation is accomplished through a 1-inch hole in the top of the

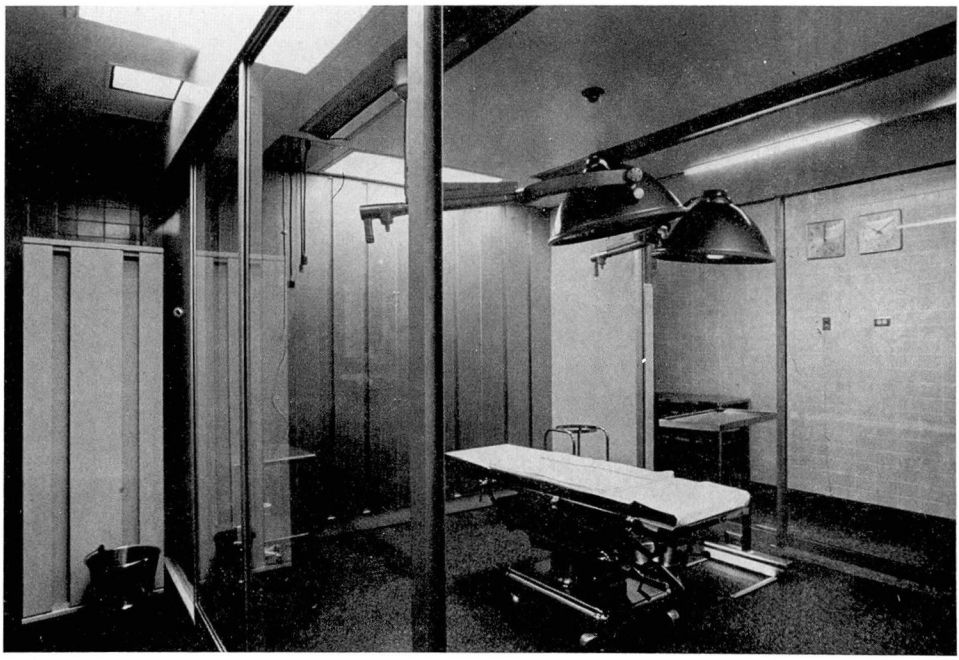

Fig. 1. Enviromatic Horizontal Flow Clean Room at St. Luke's Hospital. Plenum at rear and blowers at sides.

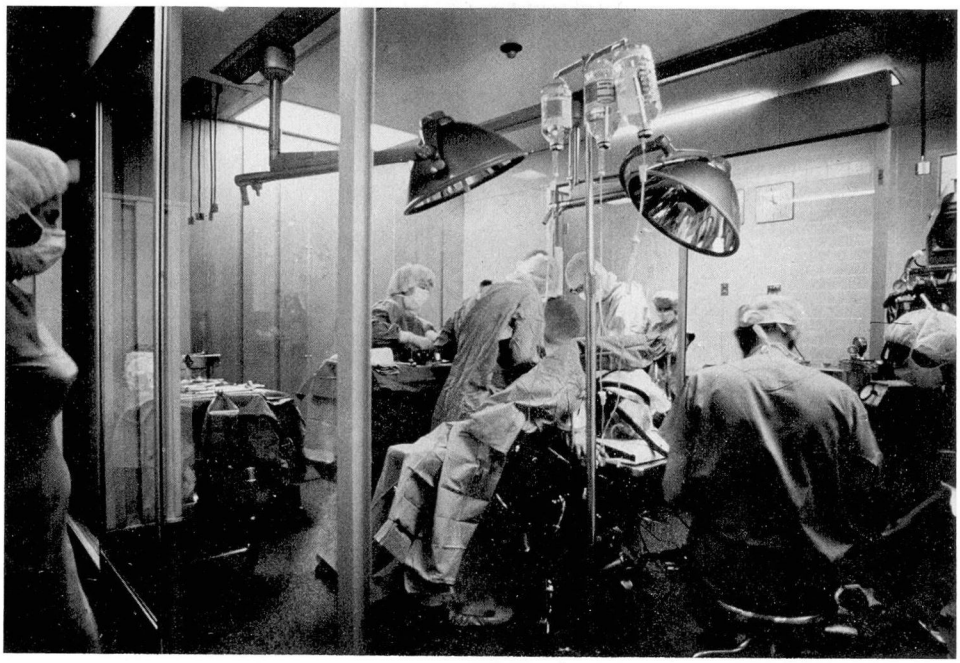

Fig. 2. Total hip arthroplasty in progress in the Enviromatic Clean Room. Note use of standard hoods, masks, and gowns.

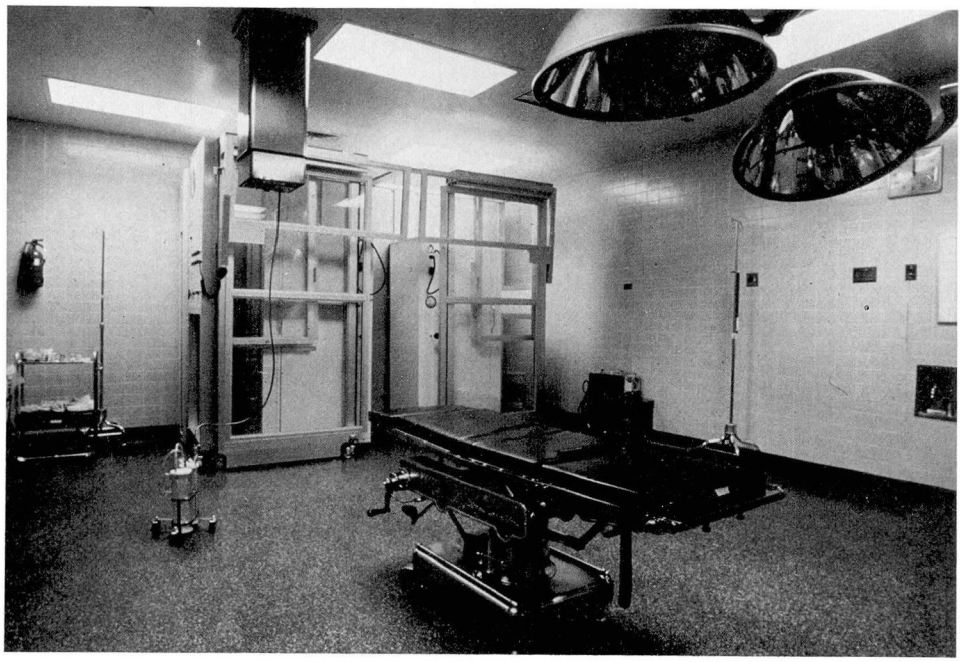

Fig. 3. Martin Clean Room in collapsed configuration.

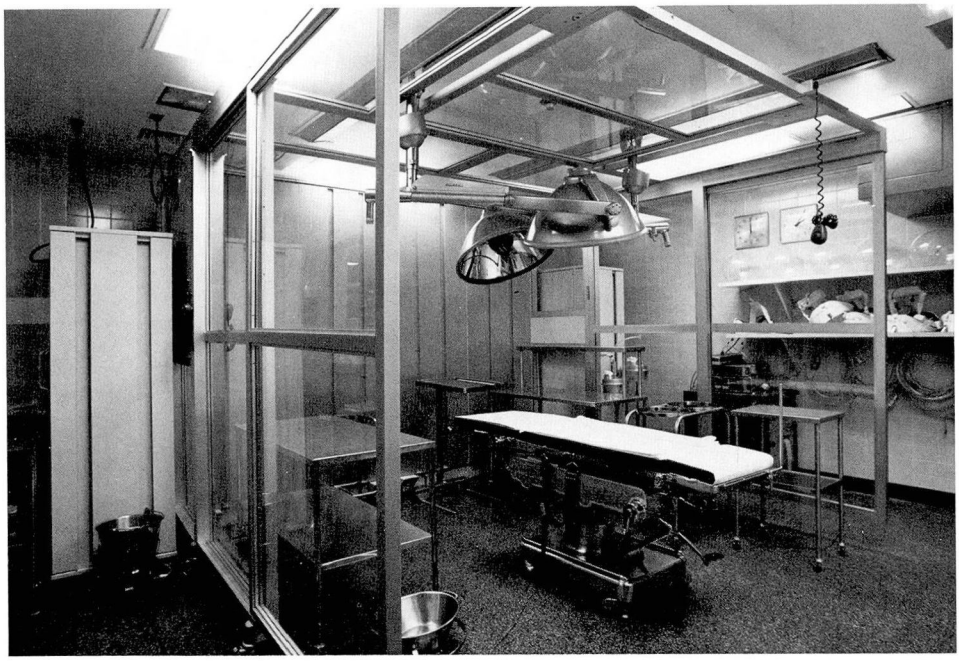

Fig. 4. Martin Clean Room in expanded configuration. Note helmets stored on far wall and back table with two tiers.

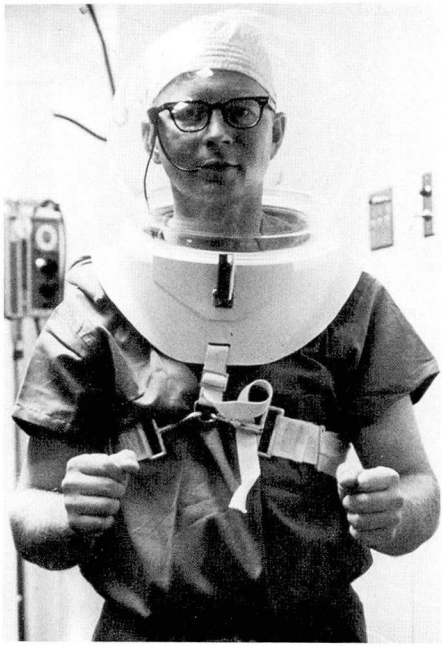

Fig. 5. Helmet and yoke before gowning.

helmet and a suction outlet for umbilical attachment on the back of the yoke. Communication requires use of an intercom system. The Johnson and Johnson Company fabricated paper gowns for use with the helmets. The paper-resin used in these gowns markedly reduces fluid and bacterial penetration of this material. *Figures 5 and 6* show the helmet and harness and several operators using the system in the clean room.

B. Technical evaluation. *1. Maintenance.* There have been no serious mechanical breakdowns. Prefilters are changed once monthly and the HEPA filters are tested semiannually for leaks and efficiency. There is minimal accumulation of dust on environmental surfaces.

2. Utilization. The systems are activated prior to opening sterile packs.

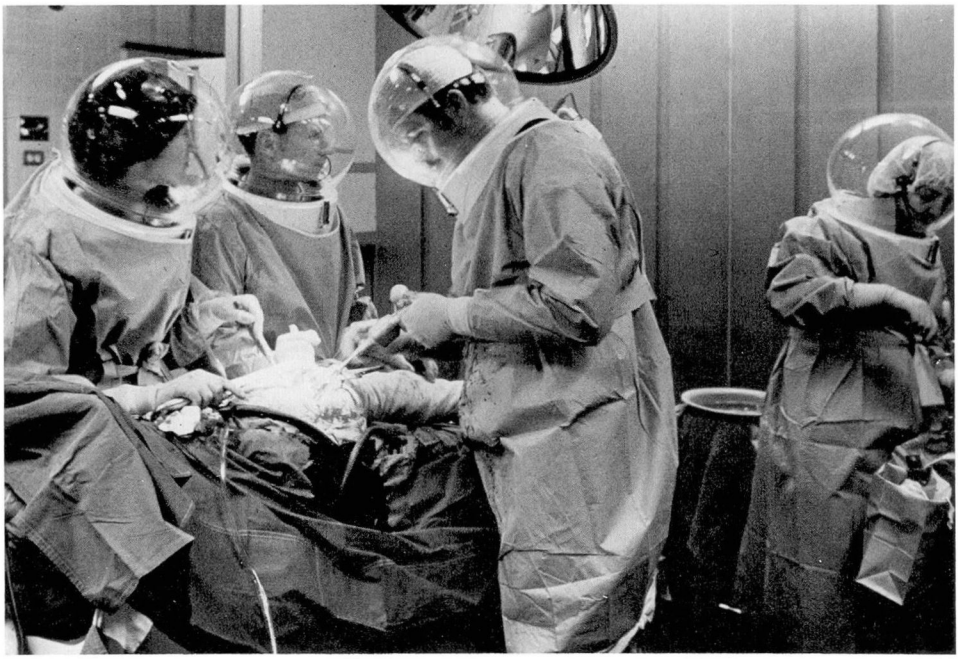

Fig. 6. Total hip arthroplasty in progress in Martin Room. All personnel are wearing helmets and paper gowns.

The sliding doors permit easy entrance and exit for patients. After induction of anesthesia, prepping and draping, the patient is moved to within about 3 feet of the plenum. Care is taken to allow no obstructions between the plenum and the table. It has been necessary to construct a double-tiered back table which, along with a Mayo stand and two wash basins, comprise our operating room furniture. Additional wall shelving for the cardioscope and emergency drugs have reduced space requirements. Biplane x-ray films during hip fracture nailing are possible by placing the table obliquely in the room. The 3-inch space between the bottom edge of the wall and the floor allows passage of tubes, cords, and wires. The 4-foot leeway between the enclosure walls and operating room walls is adequate for observation, personnel movement, and equipment storage. Our anesthesiologists are moderately cramped until the patient is moved deeper into the enclosure.

3. Noise. Noise levels range between 65 and 71 decibels. Communication in a conversational tone is possible except when helmets are used.

4. Temperature. Air conditioning is inadequate and temperatures rise to 80 F or more on warm days when the units are used for several hours. Therefore, additional air conditioning has been added.

5. Humidity. There is no specific control and it varies from 35% to 46%.

6. Turbulence. Our observations with a smoke gun indicate that floor level particles do not rise more than 15 inches.

7. Wound drying. This occurs significantly more rapidly in the clean room and wounds should be protected with frequent irrigations or moist packs.

8. Helmet-paper gown system. The helmets are made of plexiglass. They scratch rather easily, break at the top where they are quite thin, and there is a mild visual distortion around the inferior rim where they are thicker. There is moderate noise inside but communications are relatively good. The helmet-yoke assembly is comfortable and weighs about 2 pounds. However, after several hours of use, fatigue is noted, particularly by the nurses. There has been no difficulty with heat buildup or fogging, provided that the suction air flow is sufficient.

The gowns have been satisfactory and we have seen no gross leakage of fluid through the material. They come in only one size (large) and therefore are somewhat cumbersome for smaller personnel.

We believe that this system provides the optimum protection against shedding. However, it is experimental and cannot be recommended for general use at this time.

C. Studies. *1. Wound contamination.* Swab cultures of the subcutaneous tissues and deep tissues have been taken for the past 2 years from clean surgical wounds. These cultures are obtained shortly after making the incision, usually within 20 minutes. They are then sent to the bacteriology laboratory where they are plated on blood agar and inoculated into thioglycolate broth. Cultures are read at 48 to 72 hours. Additional deep cultures or tissue cultures have also been obtained on occasion. *Table 2* summarizes the results of these studies in a regular operating room, in the clean room alone, and in the clean room with personnel wearing helmets and paper gowns.

Since the overall series represents a heterogeneous series of orthopaedic cases, the same type of analysis was applied to our series of total hip arthroplasties and total knee replacements. *Table 3* summarizes these results.

The types of bacteria cultured and

Table 2. Wound contamination rates—overall

	Culture	No. cases	No. cultures	Positive cultures	Rate (%)
Horizontal flow plus helmets and gowns	Superficial	107	107	1	.43
	Deep	120	120	4	3.33
	Other	18	21	2	9.52
	Overall	122	248	7	2.82
Horizontal flow	Superficial	344	344	16	4.65
	Deep	551	556	32	5.76
	Other	27	29	1	3.45
	Overall	590	929	49	5.27
Regular OR	Superficial	56	56	10	17.86
	Deep	107	107	25	23.86
	Other	14	14	4	28.57
	Overall	108	177	39	22.03

Table 3. Wound contamination rates—total hip arthroplasty and total knee replacement

	Culture	No. cases	No. cultures	Positive cultures	Rate (%)
Horizontal flow plus helmets and gowns	Superficial	98	98	2	2.04
	Deep	99	99	2	2.02
	Other	9	9	1	11.11
	Overall	99	208	5	2.43
Horizontal flow	Superficial	121	121	4	3.31
	Deep	123	123	6	4.88
	Other	11	11	0	.00
	Overall	123	255	10	3.92
Regular OR	Superficial	38	38	6	15.79
	Deep	43	43	12	27.91
	Other	10	10	3	30.00
	Overall	43	91	21	23.08

Table 4. Types of bacteria cultured from clean surgical wounds and their relative frequencies

	Regular OR	Clean room
Staphylococcus epidermidis	72.5%	57.1%
Diphtheroid species	7.5%	19.0%
Bacillus subtilis	7.5%	0
Nonhemolytic streptococcus	0	16.7%
Anaerobic streptococcus	2.5%	0
Micrococcus species	2.5%	0
Enterococcus species	2.5%	0
Enterobacter hafnia	0	2.4%
Herellea vaginicola	2.5%	0
Clostridium perfringens	2.5%	0
Escherichia coli	0	2.4%
Moraxella species	0	2.4%

their relative frequencies are shown in *Table 4*. It appears that the great majority of these organisms were derived from the air and that the clean room reduced the rate of wound contamination by a factor of four. This rate is further reduced slightly by the use of helmets and paper gowns.

Table 5. Gelman air sampler studies

	Regular OR	Clean room at wound
No. cu ft sampled	678	204
Average colonies per cu ft	3.9	0.1

2. Airborne bacteria sampling. Our initial studies were done with a Gelman air sampler and results are tabulated in *Table 5*.

During the past 4 months, a team from Jet Propulsion Laboratories has been extensively studying the bacteriology and particle physics in our Martin Room under operating conditions. Airborne bacterial sampling has been done using both Reynier and Sartorius membrane samplers. All sampling was done just down stream of the wound. The results reported in *Tables 6 and 7* are preliminary findings and a much more detailed analysis of the Jet Propulsion Laboratories team's data will be forthcoming at a later date.

Table 6. Clean room airborne bacterial sampling at wound—Reynier

Operation		Colonies		Significance
1	2	1	2	No
—	—	—	—	
A (27)[a]	B (16)	3.55[b] (.10)[c]	4.12 (.12)	
C (6)	D (12)	2.05 (.06)	8.47 (.24)	Yes (.05)
A & C (33)	B & D (28)	3.28 (.09)	5.98 (.17)	Yes (.05)
A & C (33)	E (41)	3.28 (.09)	7.09 (.20)	Yes (.05)

A = total hip arthroplasty, experimental system; B = total hip arthroplasty, regular garments; C = total knee arthroplasty, experimental system; D = total knee arthroplasty, regular garments; E = varied, regular garments.

[a] = number of procedures; [b] = colonies/cu m; [c] = colonies/cu ft.

Table 7. Clean room airborne bacterial sampling at wound—Sartorius

Operation		Colonies		Significance
1	2	1	2	Yes (.05)
—	—	—	—	
A (15)[a]	B (12)	5.97[b] (.17)[c]	43.40 (1.23)	
A & C (20)	B & D (14)	8.92 (.25)	40.11 (1.14)	Yes (.05)
A & C (20)	E (25)	8.92 (.25)	27.86 (.79)	Yes (.05)

A = total hip arthroplasty, experimental system; B = total hip arthroplasty, regular garments; C = total knee arthroplasty, experimental system; D = total knee arthroplasty, regular garments; E = varied, regular garments.

[a] = number of procedures; [b] = colonies/cu m; [c] = colonies/cu ft.

Several conclusions may be drawn from these data. There is a marked reduction in airborne bacterial concentrations in the clean room compared to the regular operating room. The use of the helmet-paper gown system further reduces these counts. The Sartorius sampler is more efficient than the Reynier sampler.

3. Infections. We are currently involved in an extensive review of our infection rate for the past 4 years. We cannot make any definitive statements with regard to the effect of the clean room on our infection rate at this time. However, our preliminary data are summarized in *Table 8.*

Five of the seven regular operating room infections became apparent more than 1 month following surgery. Two cases in the regular operating room group and two in the clean room group appeared early and were caused by *S. aureus.* The remaining early appearance case was caused by *Escherichia coli* in a draining hematoma. The late cases were due to anaerobic micrococcus (3), Enterobacter, and mixed gram-negatives.

Summary

We have attempted to review the history of operating room clean rooms and to document our experience resulting from the use of two horizontal flow clean rooms. Wound contamina-

Table 8. Deep infection rate—total hip arthroplasty Nov 1969 to Sept 1972

	Regular OR	Clean room
No. operations	134	270
No. deep infections	7	3
%	5.2	1.1

tion rates, airborne bacterial sampling, and preliminary infection rates for both regular operating rooms and clean rooms have been presented. In addition, we have presented our initial experiences with a "space" helmet-paper gown system designed to further reduce operating room personnel shed. It is our opinion, based on this evaluation, that the clean room significantly reduces airborne bacteria and wound contamination rates. Addition of the helmets and paper gowns further reduces these parameters. We cannot make a definitive statement regarding infection rates at this time.

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