A study of the wound environment during total hip arthroplasty

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Summary

Two hundred and seventeen total hip replacements were performed during a trial designed to assess the influence of a surgical isolator upon postoperative wound infection. The trial was controlled by performing 108 of the replacements in a standard plenum-ventilated theatre with twenty air changes/hr, which also housed the isolator procedures. Comparative postoperative wound infection rates were 6.4% for the isolator patients and 4.6% for those operated on in the plenum-ventilated theatre. There was intra-operative wound contamination in both groups of patients and, although the isolator reduced wound contamination at operation, this bore no relationship to eventual wound sepsis.

Introduction

Published reports of major postoperative wound infection rates for total hip arthroplasty vary from 0.1% to 10%. The multi-factorial nature of such infection is emphasized by a variety of reports ranging from the influence of joint cement, prosthetic materials, prophylactic antibiotic therapy to both direct contact and airborne cross-infection. The advent of the surgical isolator (McLauchlan *et al.*, 1974) based on the plastic flexible film isolator (Trexler and Reynolds, 1957) provided an opportunity to evaluate some of these factors. The isolator, unlike any other ultra-clean air system, effectively blocks both the airborne and direct contact routes of cross-infection during operation. The effects of ultra-clean air conditions using the isolator have already been described (McLauchlan *et al.*, 1976). The following sets out the whole trial in more detail.

Methods

A controlled trial was set up using the isolator (Fig. 1) in a standard plenum ventilated theatre. Patients were randomly allocated to have their hip replacements with or without the isolator. Two patients were operated on each morning. The same procedure was employed by the same surgeon

(J.M.) throughout the trial. The patients were nursed and had their wounds dressed in an open Nightingale-type ward. No prophylactic antibiotics were used. Samples for bacteriological study were collected as set out in Table 1.

Classification of postoperative wound sepsis

The clinical examination of all wounds by the same observers (J.M. and J.R.C.L.) was correlated with the results of the bacteriological studies. The classification previously used (Davidson *et al.*, 1971) was followed.

Clean wounds

No clinical or bacteriological evidence of infection.

Infected wounds

(a) Major—those requiring further active treatment with antibiotics, wound exploration or irrigation, or removal of the prosthesis.

(b) Minor—those showing limited redness or discharge in relation to the suture line with evidence of pus and bacteria from wound swabs, but the wound healing without active therapy.

(c) Primary or secondary—both major and minor infections were sub-grouped 'primary' or 'secondary' when monitoring exposed an aetiological relationship to theatre or ward environments respectively.

Results

The patients

A total of 222 patients requiring total hip replacement were admitted to the trial. A fatal pulmonary embolus, fracture at operation, exposure of pus around an old Zimmer nail plate and on two occasions monitoring failure, resulted in the withdrawal of five patients. Of the remaining 217, 109 were operated on in the surgical isolator and 108 served as plenum theatre controls. The groups were discovered to be very similar in terms of age, sex, pre-operative diagnoses, previous surgical procedure, operative time and postoperative wound drainage

FIG. 1. Diagram of the surgical isolator fully inflated and in position on hip. Only the incised wound is exposed to the sterile interior of the isolator, the rest of the patient and all operators and assistants being external to the wound environment. Note the position of air sampling devices inside the isolator.

TABLE 1

Patient	
On admission	Swabs from nose, throat, and perineum.
At operation	Skin over operation site before and after disinfection. Skin edges after incision and before closure including biopsies. All layers of wound down to and back up from bone. All instruments in close and repeated contact with wound and scalpel blades. Joint cement, aerosol adhesives, adhesive drapes.
Blood cultures	At start of operation, 30 and 60 min later then 4 and 24 hr postoperatively.
Drainage fluid	At closure and on removal of drain at 48 hr.
Final bacteriological assessment of wound	At dressing 14 days postoperatively unless soakage of dressings by wound drainage fluid or pyrexia previously.
Theatre	
Nasal swabbing	Of all personnel weekly.
Glove and finger	Streak plating at end of operation.
Air hygiene studies	Inside isolator and in plenum-ventilated theatre by slit-samplers and 9 cm diameter settle plates.

(Table 2). Nor was there any major difference in bacteriological status on admission—there being nasal carriage rates for *Staphylococcus pyogenes* of 27% and 20.3% in isolator and control groups respectively, and no significant throat carriage of Group A *Streptococcus haemolyticus*.

The bacteriology of the operative procedure

Wound contamination during operation. *Staph. pyogenes* was isolated from the hip skin of four patients before disinfection on the table. Post-disinfection sampling on inhibitor media proved the

efficiency of 2.5% iodine in 70% ethyl alcohol, nearly all samples including those from skin carriers of *Staph. pyogenes* remaining sterile on incubation. Sampling of wound and instruments throughout the operative procedure revealed evidence of bacterial contamination of the wound in thirty-nine (36%) isolator patients and sixty-three (58%) plenum theatre patients. The bacteria were seen to be related to the linear impressions on the surface of bandage-agar sampling plates formed by the wound edges. Major bacterial contamination of the wound (more than 100 colonies/operation) was observed in

TABLE 2. Two hundred and seventeen total hip replacements

	Surgical isolator	Plenum theatre
Patients	109	108
Male	45	54
Female	64	54
Average age	67	67
Average operating time	71 min	72 min
Average wound drainage	556 ml	575 ml
Pre-operative diagnosis		
Osteoarthritis	98	95
Rheumatoid arthritis	6	6
Avascular necrosis	4	6
Steroid arthritis	1	—
Traumatic dislocation	—	1
Previous operation		
Osteotomies	10	11
Sliding nail plates	1	2
Smith-Petersen nails	2	3
Removal of nails	3	2
Bohlmans pins	1	—
Psoas tenotomies	2	1
Bone graft	1	—

twelve and eleven of isolator and plenum theatre operations respectively. In these patients, wounds were discovered to be contaminated at an early stage of the operation. They became more heavily contaminated as the operation proceeded. Sometimes by the end of the procedure both wound edge biopsies and the surgeon's knife yielded heavy growths on agar plates (Fig. 2). In seventeen of the heavily contaminated wounds the organisms were all

coagulase negative staphylococci, pigmented or non-pigmented or, as was often the case, a mixture of both. *Staph. pyogenes* was isolated from the cultures obtained from the remaining six patients (three isolator and three control) of whom four were nasal carriers. In only one instance was the pathogen the dominant wound isolate. This patient revealed no carriage of the pathogen in either nose, throat or perineum, and his wound, as in the case of the other five potentially highly infective contaminations, healed cleanly.

Skin biopsies taken at the start of operation and laid on to blood agar yielded cultures in 3.1% of isolator cases and 7.3% of control cases, while those taken at the end increased the percentage yield to 4.3% and 14.1% respectively. Agar impressions from the surface of the adhesive drape applied to the skin at the end of operation, yielded cultures of organisms from 19.6% of isolator cases and 29.2% of the control cases. Analysis of blood cultures revealed no instance of bacteraemia in any of the patients. Cultures of joint cement and aerosol adhesive revealed no evidence of wound contamination from these sources. Bacterial contamination of the surgeon's knife was found in relation to eight of the twenty-three heavier wound contaminations detected during the trial.

Wound infection

The comparative postoperative wound infection rates for the two groups of patients were 6.4% (seven) and 4.6% (five) for isolator and control series respectively, with only two major wound infections (1.8%) in each group (Table 3).

FIG. 2. Heavy bacterial contamination of both the wound edge biopsy taken immediately before wound closure, and the surgeon's knife—from Op. No. 190, an isolator procedure, and one of the twenty-four patients revealing heavy intra-operative wound contamination during the trial.

TABLE 3. Classification of postoperative wound sepsis occurring in 217 total hip arthroplasties according to their operative environment

No. of patients	Operative environment	Major infections		Minor infections	
		Primary	Secondary	Primary	Secondary
109	Surgical isolator	0	2 (1.8%)	0	5 (4.5%)
108	Plenum ventilated theatre	0	2 (1.8%)	0	3 (2.7%)

Major infections. In all four instances where major wound infection developed there was soakage of dressings by wound drainage fluid so that they had to be changed within the first or second postoperative day. All were due to faulty wound drainage. In three, wound haematomas occurred. Initially the wound discharges appeared sterile, but became infected at the end of the first postoperative week. Swabs then yielded a mixed growth involving various combinations of *Escherichia coli*, *Proteus sp.*, *Strep. faecalis*, *Pseudomonas aeruginosa* and diphtheroid bacilli. Still later, in one instance after a delay of 3 weeks from the start of proved mixed wound infection, *Staph. pyogenes* could also be isolated from these mixed growths. There was no strain similarity between these late isolates of *Staph. pyogenes*. Two were untypable but of differing antibiotic sensitivity pattern, and the other two strains were typed 42E/— and 29/62/77/—. The latter was present in the anterior nares of the affected patient. Two of the four major infections, one an isolator and the other a control procedure showed no operative wound contamination. In the other two, again one isolator and one non-isolator case, *Staph. epidermidis* was a heavy contaminant of the former wound and a light contaminant of the latter. In neither instance was this species isolated from the infective wound discharge.

Minor infection. Of the eight cases of minor wound infection only one was not a mixed infection. In this isolator patient the wound swab at the fourteenth postoperative day yielded only debris and aerobic spore-bearing bacilli. On the twentieth postoperative day repeat swabbing revealed pus and a growth of a penicillin-insensitive phage type 85/— *Staph. pyogenes*. The patient was not a carrier of this strain. The time taken to develop infection plus the absence of this strain among theatre isolates was highly suggestive of a ward rather than a theatre source. *E. coli* appeared as the dominant growth in the other mixed infections except in one patient when this was *P. aeruginosa*. Accompanying species were either *Proteus*, aerobic spore-bearing bacilli, *Strep. faecalis*, diphtheroid bacilli or, in one instance, *Clostridium welchii*. Only three of the minor infections (one isolator and two control procedures) suffered demonstrable wound contamination in theatre. *Staph.*

epidermidis was a light contaminant in the isolator and one of the control procedures, and a heavy contaminant in the other control case. *Staph. epidermidis* was not isolated from the infective wound discharges of these three patients.

The bacteriology of the operative environment

Air hygiene studies. Because every procedure was monitored by membrane sampler and settle plate it was possible to demonstrate the marked differences in standards of air hygiene between the two groups and also the regularity and steadiness of these standards within each group.

Bacterial counts. (1) *The surgical isolator.* So as to exclude the possibility of a dead space pattern of isolator ventilation two well spaced membrane sampling heads were used, one at the top end of the wound, the other at the instrument table. With each, a settle plate was placed. By this method, 5,321 cu. ft of isolator air were sampled in conjunction with 196 hr of settle plate exposure. The sampling periods employed ranged from 5 to 60 min. This resulted in the isolation of only two colonies by membrane sampling and six by sedimentation on the settle plates, a result well within the acceptable level of accidental handling contamination and proof of the constant sterility of the aerial environment. At intervals further checks on the validity of this result were carried out using a 'Casella Slit Sampler' for 1 min, 2 min and 5 min sampling periods. All plates exposed in this way to isolator air remained sterile.

(2) *The Plenum theatre. Membrane sampling.* During the control series of hip replacements performed in the plenum theatre, membrane sampling times were restricted ranging from 5 to a maximum of 30 min in order to cope with the expected concentrations of airborne bacteria. A total of 2,995 cu. ft of air was sampled demonstrating a mean average concentration of airborne bacteria-carrying particles of 6.2/cu. ft. There was no significant difference in the concentrations measured at the wound as opposed to the instrument table.

Settle plates. (a) *Theatre.* These were placed at opposite sides of the theatre for all 217 operations. They revealed a mean average sedimentation rate of 28.5 bacteria-carrying particles/plate/hr at one

side of the theatre and 14.2 at the other. The difference was expected since most of the movement of personnel and supplies took place at the side of the theatre showing the heavier rate of settle. There was no significant difference in sedimentation rates as between isolator and control series of operations.

(b) *Operating table.* The wound and instrument table settle plates, approximately equidistant and central to those at the sides of the theatre, revealed sedimentation rates of 19.4 and 19.8/hr respectively, approximately 4.7 particles/sq. ft/min. As the settle rate of such particles (average size 10–15 μ m) is such that the number settling per sq. ft per min is approximately equal to the number contained in 1 cu. ft of air, the rates observed would suggest the presence of four or five such particles per cu. ft of air at the wound. Apart from occasional aerobic spore-bearers and fungi, colonies grown were almost entirely saprophytic cocci, *Staph. pyogenes* being isolated (usually a single colony) during only eight of the control procedures. With a wound surface area of roughly 1/3 of a sq. ft approximately ninety such particles might be expected to reach the exposed tissues during operations. Despite this assumption nearly half the wounds made in the plenum ventilated theatre revealed no detectable bacterial contamination while a similar proportion of wounds exposed in the sterile aerial environment of the surgical isolator did. It appears, therefore, that wound contamination in both groups of patients was largely due to the release of resident skin flora from wound edges and not to bacterial 'fall-out' from theatre air, although this latter factor may have had a small part to play in the marginally higher contamination rates observed in the control series of patients.

Total particle counts. These were performed in both the surgical isolator and the plenum theatre by the Royco particle sampler with five channel digital read-out on the size range of 0.5 μ m, 1.0 μ m, 5 μ m, 10 μ m, and 15 μ m on twelve separate occasions. The results summarized in Table 4 along with bacteria-carrying particle counts from membrane sampling reveal bacterial contamination to be an infinitesimal part of the total particle content of the air in the plenum theatre and that when swabs were taken, bone sawn, and cement powder mixed, counts were as high and in some size ranges higher inside the surgical isolator.

The operating team

Of the regular members of the operating team 38.2% were nasal carriers of *Staph. pyogenes*. Throughout the trial period the surgeon and two of his assistants were heavy nasal carriers of strains exhibiting the usual hospital pattern of multiple antibiotic resistance, the former carrying a phage

type 29/52/80/ while the latter both carried a strain typed by nearly all of the phage Group III lysates.

Contamination of the operators' hands

From previous experience (Smylie, Webster and Bruce, 1959; Smylie, Logie and Smith, 1973) it was considered important to assess the bacteriological state of the outside of surgical gloves after wound closure and before removal. Plate-streak sampling was therefore carried out on members of the team firstly on their gloved hands as a test of intra-operative contamination and again after glove removal to assess residual disinfection of skin. Figure 3 demonstrates a typical result of such sampling. Both the inner and outer pairs of surgeon's gloves were punctured in 21.2% of operations but in only 2.4% of operations was this double puncture associated with a positive culture from the skin of the surgeon's hands, and in no instance were such organisms detected on the external glove surface. Bacteriological monitoring of the outside of the gloves and of the patient's skin was completed in ninety-five isolator and ninety-eight plenum theatre operations. This showed that contamination of the outside surface of the surgeon's glove at wound closure occurred in eighteen and thirty-four of these procedures respectively. Taking the surgeon's glove as the most relevant wound handling risk, and classifying wounds into those which remained clean throughout and those showing either light (<10 colonies isolated from the wound/operation), moderate (>10, <100) and heavy contamination (>100), it was seen that although sometimes the surgeon's gloves were found to be dirty when the wound was apparently clean and vice versa, in general his glove contamination increased in direct proportion to the degree of wound contamination (Fig. 4). Contamination of the surgeon's gloves was invariably accompanied by similar contamination of the gloves of one or more of his assistants. All such contaminants were morphologically identical to those found in the wounds handled.

Discussion

Although postoperative wound infection is recognized as multi-factorial in origin, argument continues on the relative importance of the sources of such infection in the total environment of the surgical patient. Since Lister, surgeons have concentrated upon control of the theatre environment as the best means of reducing infection in the wounds they create. Consequently, the architecture of the operating theatre has passed through many stages reaching the ultimate in ultra-clean environmental control systems such as the surgical isolator (McLauchlan *et al.*, 1974; Trexler and Reynolds, 1957) and the laminar flow-ventilated operating enclosure

TABLE 4. Prevailing standards of air hygiene during trial

Environmental state	Surgical isolator				Plenum ventilated theatre						
	Mean bacterial count/cu. ft.	Mean total particle counts/cu. ft in sizes (μ m)				Mean bacterial count/cu. ft	Mean total particle counts/cu. ft in sizes (μ m)				
		0.5	1	5	10	15	0.5	1	5	10	15
Empty:											
Non-pressurized	Nil	37	19	1	0	0	—	—	—	—	—
*Pressurized	Nil	463	189	3	0	1	2.2	286	2	0	0
Occupied:											
Quiet	Nil	11,025	2,299	110	71	40	4.2	11,772	693	146	105
† Busy	Nil	349,734	51,580	49,848	1,049	497	7.1	6,317	1,207	318	253

* Measurements taken immediately following inflation of isolator. Ten minutes later counts had dropped to 18 at 0.5 μ m and nil in the remaining size range.

† Much movement of personnel around sampler, or mixing of cement and swab shake-out around total particle sampler.

FIG. 3. Intra-operative wound contamination resulting in bacterial contamination of the external surface of the gloves of the operating team while skin of hands inside gloves remains clean. Postoperative plate streaks (case 190).

(Charnley, 1964). Moreover, progress in the control of direct contact cross-infection in theatre is now so sophisticated, that throughout even the longest operation bacterial recontamination of the skin of the operating hand inside its protective rubber glove can be largely abolished, thus reducing the bacteriological consequences of glove puncture to negligible proportions. All kinds of sterile supplies for the operative procedure are now guaranteed in most modern theatres via quality controlled Central Sterile Supply Departments, Theatre Sterile Supply Units and commercial suppliers all using the most advanced and efficient of modern sterilizing equipment. In marked contrast, scant attention has been

FIG. 4. The relationship between bacterial contamination of wounds and the surgeon's gloves during operations in the surgical isolator (a) and plenum ventilated theatre (b). The number of clean wounds and lightly, moderately or heavily contaminated wounds (see text) in each type of operating environment is demonstrated and the percentage of them associated with bacterial contamination of the operative surface of the surgeon's gloves. □, clean; ▨, light; ▩, moderate; ■, heavy; ■, contamination of surgeon's gloves.

paid to the ward environment. Therefore it was with great interest that we embarked on a trial of the surgical isolator for total hip replacement in patients nursed in multi-bedded wards.

The surgical isolator provided precise control of the sterile environment eliminating the airborne and direct-contact cross-infection hazards. In clean operations such as total hip arthroplasty the sources of wound contamination and their relationship to postoperative infection are not clear. One publication (Charnley and Eftekhari, 1969) assesses wound contamination at operation from airborne bacteria as of extreme importance in the aetiology of postoperative sepsis and attributes a drop in wound infection over 7 years to the use of an operating enclosure supplied with 300 air changes/hr and special exhaust-ventilated theatre clothing. Unfortunately, insufficient bacteriological monitoring in such studies still leaves considerable doubt as to the exact role of clean air.

Air sampling checks proved the sterility of the aerial environment of the surgical isolator. By contrast, the air of the plenum ventilated theatre used

for the control series of operations contained an average of 6.2 bacteria-carrying particles/cu.ft during procedures with a settle rate at the wound of between 4 and 5 particles/sq. ft per min. It therefore closely approximates the reviewed standard for efficient plenum ventilation of operating rooms (Blowers, 1962). Despite this difference in the aerial environments of the two operation systems wound contamination during operation was apparent in both 'isolator' and 'plenum theatre' patients. The levels of such bacterial contamination were frequently far in excess of any possible contribution from airborne bacteria. The frequency of contamination of the operative surface of the surgeon's gloves was in direct proportion to the degree of wound contamination, the bacterial species involved being exactly similar to those isolated from the wounds. In the absence of any proved bacterial leakage from the surgeon's glove, the only demonstrable source of these organisms, predominantly *Staph. epidermidis*, was the patient's skin. There was no aetiological relationship between wound contamination and recorded cases of postoperative wound sepsis and, to date, in a follow-up period of between 12 and 24 months, no patient has developed late infection. The aetiology of the major infections, two in each group, was related to heavy and immediate wound soakage and faulty drainage with the associated opportunities for bacterial invasion of the wound. Repeated sampling showed these discharges to be sterile initially, only yielding positive cultures after 7–10 days, predominantly of a mixed faecal type flora such as is commonly isolated from both the bedclothes and the perineal region of patients. Of the eight minor infections only one did not show a similar mixed infection. The exception developed infection on the twentieth postoperative day from a strain of *Staph. pyogenes* undetected during theatre monitoring. Consequently, all infections, whether major or minor, were classed as secondary, reflecting an aetiology which was properly related to the opportunities for infection in the ward rather than in the theatre.

In this trial we have shown that operating in a sterile environment reduces wound contamination at operation. It could be argued that a valid statistical

result would require a longer series of observations, but so far there appears to be no aetiological relationship between operative wound contamination and subsequent wound infection. Those patients whose wounds were heavily contaminated with *Staph. epidermidis* may be at risk to late infection. This organism is well documented as a cause of infection following heart surgery (Hoffman *et al.*, 1959). Whether or not infection occurs may be related to the type of micrococcus involved as shown by Selwyn and Ellis (1972).

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