50 millimetres of mercury above the systolic pressure (to allow for fluctuations which may occur during the course of an operation). For the lower limb, where the cuff often has to be relatively narrow to permit adequate surgical access, twice the systolic pressure is sufficient provided the patient is not unduly muscular or obese (Klenerman and Hulands 1979). The pressure used should be recorded on the anaesthetic chart together with the times of application and release of the tourniquet. Special care is necessary for thin patients, and padding should be applied to protect the limb beneath the tourniquet. A tired assistant must not inadvertently rest on the cuff, since this may significantly raise the pressure applied. The gauge of the tourniquet should be inspected by a vigilant anaesthetist during the course of the operation and he should ensure that the pressure remains constant; on deflation it should be noted whether or not the dial indicator returns to zero.

The suggestion by Wheeler and Lipscomb (1964)

that the rocker valve of an ordinary pressure cooker should be inserted between the tourniquet gauge and the cuff has much to commend it, as it will not allow a predetermined upper limit of pressure to be exceeded. This pattern of safety valve is an integral part of every anaesthetic apparatus. A simple hand pressure pump with an accurate gauge is safer and preferable to more sophisticated and expensive tourniquets which may be inaccurate; at least the person using the pump knows by feel how hard he has to press to inflate the cuff and does not simply turn a switch unthinkingly. Nor should we forget that it is perfectly possible to operate without a tourniquet by suitable positioning of the limb.

The pneumatic tourniquet, common everyday instrument as it is, should not merely be taken for granted; it should be used with due consideration for the physiology of the limb to which it is applied, and with the same respect for pressure as for time.

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ANNOTATION

ULTRA-CLEAN AIR

The *British Medical Journal*, volume 285, published a report from the Medical Research Council giving the results of its randomised trial of ultra-clean air systems of theatre ventilation, compared with a control of standard theatre environments (Lidwell *et al.* 1982). This paper has been anticipated with eagerness and anxiety by all who are concerned with theatre asepsis, most particularly by those involved in major joint replacement.

Charnley believed, with justification, that the mechanical problem with regard to hip disease was solved and that the only threat to successful arthroplasty was

infection. He remained profoundly absorbed, not to say obsessed, with the prospect of providing a germ-free environment for the operation. Although Buchholz and others have demonstrated that infection need not necessarily be an unmitigated disaster, nevertheless it remains the principal threat to successful surgery and certainly leads to prolonged morbidity with repetitive revision operations. Charnley's observations led to the conclusion that the provision of clean air in the operating environment was an obligation upon everyone involved in this form of surgery. Few things concentrate the

surgeon's mind more than the prospect of an accusation of negligence. Charnley's experience was never subjected to a controlled trial and for this reason there has always been a certain scepticism about it. No-one has doubted his figures but many have considered that the provision of a "glass house" barrier was necessary only at Wrightington, where a constant flow of the world's surgeons perpetually peered over Sir John's shoulder, doubtless breathing out a variety of organisms. By contrast, more plebeian surgeons, not afflicted by such crowds, might feel better able to control their own theatre environment.

The MRC set about the analysis of some 8000 major joint replacement operations, chosen at random and at the last minute before operation as to whether the procedure was carried out in an ultra-clean air theatre or in a standard one. Every case from each group that came to revision during the following three years has been carefully studied, particularly bacteriologically. Furthermore, the series has been analysed for the presence of other factors which might have influenced the incidence of infection.

At the start of the presentation the authors describe precisely what is meant by ultra-clean air. Samples of theatre air were regularly analysed by passing them across gelatin filters and the number of bacterial colonies was counted in relation to each cubic metre so filtered. They concluded that an effective ultra-clean system would provide air bearing less than 10 bacteria-carrying particles per cubic metre. Several ventilating systems varied in their efficiency. Horizontal laminar flow performed less well than vertical downflow systems, and the provision of body-exhaust suits further improved the figures. The air present in conventional operating theatres bore more than 50 bacteria-carrying particles per cubic metre and some theatre suites as many as 500! The variation was wide and one of the so-called clean-air systems had to be relegated to the "control" group because the environment it produced contained 49 bacteria-carrying particles per cubic metre. The other four systems, comprising the series under test, gave figures of 22, 10, 2 and 0.5 bacteria-carrying particles per cubic metre. These measurements emphasise the importance of not blindly accepting trade descriptions, but subjecting so-called ultra-clean theatres to regular testing in this fashion.

Nineteen hospitals participated in this study and all the surgical procedures were carried out between 1974 and 1979. During the first four years after operation deep sepsis occurred in 63 cases out of 4133 operations in the controlled group (1.5 per cent) and in 23 out of 3922 operations in the ultra-clean air group (0.6 per cent). The significance of these figures can be appreciated at a glance ($P < 0.001$).

The mathematics is beyond reproach but knowledge and experience of surgical practice reveals an element of uncertainty. The value of figures is directly related to the

purity of data. Urgency required that many hospitals be enlisted for this study so that the series would be large enough to reveal a difference of less than one per cent. But this has multiplied the variables, many of which are hardly definable, and most unmeasurable. For example, surgeons vary in dexterity, speed, anatomical approach and countless details of procedure and skin closure; they vary in selection and rejection of patients, their preparation for operation and postoperative management. The individual patient varies with regard to age and obesity, anatomical dimensions and toughness of bone, immunological competence and health of skin and teeth. Peroperative accident affects blood loss and replacement, the size of dead spaces and retained haematomata. The list is endless. Eight thousand seems a significant series but with so many variables and unmatched controls, does not an element of doubt exist, bearing in mind how few become infected anyway?

The study from the Hospital for Special Surgery, New York (Salvati *et al.* 1982) quotes an incidence of infection for knee arthroplasty of 3.9 per cent in a laminar flow theatre as compared with 1.9 per cent in conventional ventilation. Statisticians claim significance, but does this recommend unclean air? No attempt has been made to eliminate from the MRC study all cases which from the very start presented an increased vulnerability to infection because of a preoperative condition, peroperative accident or postoperative complication. One would like to have a detailed retrospective analysis of each septic case to reveal any extraneous cause for infection other than the theatre environment.

Of course it goes without saying that cleaner air is preferred to less clean. The bacteriological evidence is undeniable. But are the systems under study the only, or even the principal factors operating? The study reminds one to limit theatre traffic to a minimum, not just forbid it but prevent it; the garrulous are urged to deny themselves; and those who make free use of the sucker are warned that the depths of the surgical wound are a filter for all the cubic metres of imperfect air. Everyone who has worked in a laminar flow theatre has been impressed by the discipline it imposes, no less upon the surgical team than the nursing. Such an expensive capital investment excites an aura of sanctity, a sort of tabernacular tension which must contribute to cleanliness. It follows that a superintendent is very unlikely to designate such an orthopaedic theatre to be used for acute purulent or bowel surgery.

The low incidence of infection found in the series from the ultra-clean air environment compares with the best figures of Sir John Charnley, who had quoted an incidence of 0.4 per cent. One might speculate as to whether one is approaching the point of perfection at this stage. It has always been presumed that deep infection developing during the first four years after major joint arthroplasty (the period is somewhat arbitrary) had gained entrance in the course of the operation,

but there are well-documented cases in which infections have developed quite acutely after a few years of trouble-free function and from which rather unusual and precisely definable organisms have been grown, identical with organisms grown simultaneously from distant intercurrent infections (lobar pneumonia, urinary tract infection, skin boils or dental sepsis). When such organisms can be very precisely typed, the case has been effectively made out that metastatic infection through late bacteraemia does occur, and therefore the "zero option" is not possible.

The principal question that hangs over this most impressive trial is not whether or not ultra-clean air is in fact clean, nor whether or not such demonstrably clean air leads to a lesser incidence of deep sepsis after arthroplasty, but rather whether this expensive technique represents the only way of achieving such excellent results.

The remit of the MRC trial did not include a randomised study of arthroplasties performed with the benefit of other special techniques for avoiding infection. The report does, however, give some valuable information about those cases which were given prophylactic courses of antibiotics. There was no attempt at randomisation of the antibiotic prescription but it is clear from the figures that very many surgeons did in fact employ some such technique in each group. Sepsis occurred in 34 out of 5831 cases given antibiotics prophylactically as compared with 52 cases out of 2221 operations in which antibiotics were not used. The two groups are unequal

but nevertheless there is a firm suggestion that this ratio of 4 to 1 is indeed significant compared with the ratio 2.6 to 1 for the rather better controlled ultra-clean air trial.

From this valuable contribution it emerges with great clarity that the standard environment of the operating theatre is unacceptable without some additional protection against infection. An element of doubt remains as to whether the improved cleanliness of the laminar flow theatre was due solely to the machinery, or whether other factors concerning theatre practice or obsolescence of the existing ventilation plant played a significant part. It is even less clear that the provision of ultra-clean air constitutes the only method of achieving an incidence of 0.6 per cent infection. Further studies of the same very high standard that the MRC team has demonstrated are called for in order critically to evaluate antibiotic prophylaxis in various forms. It may well prove that in huge numbers an incidence in the region of 0.4 per cent constitutes the best possible figure, bearing in mind the permanent danger of metastatic bacteraemia. The report does not support the contention that the provision of an ultra-clean air system is obligatory upon every hospital undertaking this type of surgery. This is perhaps as well in view of the very considerable expense that would be incurred from the limited budgets of so many hospitals throughout the country presently doing excellent work. The door remains open for continued study of current and newer techniques.

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