Deep infection remains a serious complication of joint replacement surgery. The bacteria which cause most of these infections gain entry at the time of surgery and are dispersed from theatre personnel, particularly during periods of increased activity (Duguid and Wallace 1948). Most contamination is by an airborne route, either directly into the wound or indirectly on instruments or gloves (Whyte, Hodgson and Tinkler 1982; Lidwell et al 1983). The use of ultraclean air alone can reduce but not eliminate airborne infection as shown by the additional effects of prophylactic antibiotics and of the use of body-exhaust suits (Lidwell et al 1982). Rates of infection are associated directly with airborne bacterial contamination (Lidwell et al 1983), and bacteriological standards have been recommended for ultraclean-air operating theatres. There should be less than 10 colony forming units per cubic metre ($\text{CFU/m}^3$) within 30 cm of the wound, and not more than 20 CFU/m$^3$ at the level of the operating table in the remainder of the ultraclean-air enclosure (Whyte et al 1983; Holton and Ridgway 1993). Charnley described a system using a rapid-air-change enclosure, multiple instrument trays and a scrubbed, gowned leg holder (Charnley 1964), but this has not become standard practice.

Air contamination receives most attention when the wound is exposed, but an operation for joint replacement is preceded by skin preparation and draping, and the instruments are often exposed at this stage. Skin preparation and draping involve considerable activity, and there is often an ungowned assistant in the clean zone elevating the patient’s leg. During this period bacterial air counts may rise, and there is risk of contaminating exposed instruments. We have studied this possibly overlooked route of infection.

MATERIALS AND METHODS

We randomised patients scheduled for total hip or knee replacement using a random number chart, to derive two groups. One group had an unscrubbed, ungowned leg holder, the other had a scrubbed, gowned holder. All scrubbed staff wore occlusive gowns (Dermashield Proguard; Smith and Nephew, Cambridge, UK), double gloves and hoods (Surgine Barrier, Johnson and Johnson, Ascot, UK). The operating team and the theatre were the same for both groups.

We performed air sampling using a Casella 700 l/min slit sampler (Holton and Ridgway 1993) at a constant position,
50 cm into the ultraclean-air enclosure equidistant from right and left sides and 90 cm from the floor, to represent the usual position of instruments on a trolley during surgery. Timed air samples were collected during skin preparation and draping and again for a similar period, starting ten minutes after skin incision. In addition, ten air samples were taken over ten minutes at the same position with the ultraclean-air enclosure empty and a further ten in the outer turbulent-air zone of the theatre during operations.

The air samples were collected on 15 cm petri dishes containing nutrient agar and incubated aerobically at 37°C for 48 hours before colony counting; contamination was expressed as CFU/m$^3$.

Log transformation of the data produced normal distributions, allowing us to use parametric analyses. Air counts during skin preparation and draping were compared with intraoperative counts using the paired $t$-test. The influence of the attire of the leg holder was assessed for hip and knee replacements separately and for both combined using the unpaired $t$-test. Finally, the effects of using a scrubbed, gowned leg holder and of the type of operation were analysed using two-way ANOVA.

RESULTS

A total of 30 patients entered the study, but one was excluded because of contamination of the culture medium. The random allocations by a number chart, without blocking, failed to produce equal groups. Eleven cases had an unscrubbed, ungowned leg holder and 18 a scrubbed, gowned leg holder (Table I).

The air samples from the empty ultraclean-air enclosure grew no bacteria, while those taken from outside the enclosure during operations produced a geometric mean of 29 CFU/m$^3$ (range 20 to 70, 95% CI 22 to 40). We found no differences in the groups in relation to patient age or gender, time taken, or the number of personnel present during skin preparation and draping.

The attire of the leg holder during skin preparation and draping would not be expected to influence the intraoperative air counts and this was confirmed ($p = 0.88$). We therefore used the intraoperative counts as baseline readings. The geometric mean air counts during skin preparation and draping with an unscrubbed, ungowned leg holder were 4.4 times greater than that during the operation (95% CI 2.3 to 8.4, $p < 0.001$). With a scrubbed, gowned leg holder this difference was reduced to 2.4 fold (95% CI 1.5 to 3.8, $p = 0.001$). In two of the cases with a scrubbed, gowned holder, and two with an unscrubbed, ungowned leg holder the air counts exceeded the accepted theatre standard of 20 CFU/m$^3$. None of the intraoperative air counts exceeded this standard.

The geometric mean air counts during skin preparation and draping, for both groups together irrespective of the attire of the leg holder, differed in hip and knee replacement, being 2.5 and 6.5 CFU/m$^3$ respectively ($p = 0.034$).

The geometric mean air counts during skin preparation and draping, irrespective of the joint replaced, were 6.3 CFU/m$^3$ with an unscrubbed, ungowned leg holder but 3.2 CFU/m$^3$ when the leg holder was scrubbed and gowned ($p = 0.126$). The effect of the unscrubbed, ungowned leg holder was more pronounced in hip than in knee replacement with respective increases in the geometric mean air counts of 3.5 fold (95% CI 1.2 to 10.0, $p = 0.025$) and 1.8 fold (95% CI 0.4 to 8.3, $p = 0.377$).

Our attempt to determine the effect of the attire of the leg holder was confounded by the difference noted between hip and knee replacement, and consequently it was necessary to analyse the data by two-way analysis of variance to isolate the effect of the leg holder. In this analysis, the presence of an unscrubbed, ungowned leg holder during skin preparation and draping resulted in a 2.6 fold increase in air contamination compared with a scrubbed, gowned leg holder (95% CI 1.1 to 6.2, $p = 0.029$). The geometric mean air counts were 3.2 fold higher during skin preparation and draping for knee replacement compared with hip replacement (95% CI 1.4 to 7.4, $p = 0.008$).

DISCUSSION

The failure of ultraclean air to eliminate prosthetic infection implies that bacteria are still able to circumvent the system. Inappropriate practices may be responsible as has been shown by studies on the effect of interposition (Salvati et al 1982; Taylor and Bannister 1993). This suggests that in addition to ultraclean air, specific detailed protocols are
necessary for optimal efficiency.

In our study the highest air counts were found outside the clean zone, but even this air was still substantially cleaner than the median 164 CFU/m$^3$ noted for plenum ventilation by Lidwell et al (1982). This improvement is probably due to the rapid air turnover, but it is clear that instrument packs should be opened only in the clean zone.

We showed that air counts were higher during preparation and draping than during the operation; this can be explained by the increased activity of personnel (Duguid and Wallace 1948). In relation to this, we considered the numbers of personnel present, their movements within the enclosure, their position in relation to the air sampler, the vigour of skin preparation and draping, and also the numbers of towels and clips used. We can provide, however, no obvious explanation for the difference in air counts for hip and knee replacement during the skin preparation and draping.

Despite the improvement with the use of a scrubbed, gowned leg holder, the air counts during skin preparation and draping were more than double those during surgery, and on several occasions exceeded the standards for ultraclean air (Whyte et al 1983).

At present it is common practice to involve an unscrubbed, ungowned leg holder. This practice and the exposure of instruments during the phase of skin preparation and draping will then place the patient at increased risk of indirect wound contamination. This risk can be reduced at a cost of minimal additional time, by changes in theatre protocol. We consider that, first, the leg should be held by a scrubbed and gowned member of the team and, secondly and most importantly, instrument packs should be opened only after skin preparation and draping have been completed.

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