Body-exhaust suit *versus* occlusive clothing

A RANDOMISED, PROSPECTIVE TRIAL USING AIR AND WOUND BACTERIAL COUNTS

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We randomly allocated 50 total knee replacements to scrub teams wearing body-exhaust suits (BES) or Rotecno occlusive clothing. The effectiveness of the clothing was assessed using air and wound bacterial counts.

Bacteria were recovered from 62% of wounds (64% BES, 60% Rotecno). The mean air count was 0.5 CFU/m³ with BES and 1.0 CFU/m³ with Rotecno (p = 0.014). The mean wound counts were 14 bacteria/wound with BES and eight bacteria/wound with Rotecno (p = 0.171). There was no correlation between the air and wound counts (r = -0.011, Spearman’s).

The higher air counts suggest that Rotecno occlusive clothing is less effective than BES, but wounds were equally contaminated with both types of clothing suggesting that at very low levels of air contamination the contribution of bacteria to the wound from the air is irrelevant. Even doubling the air counts from 0.5 to 1.0 CFU/m³ had no detectable effect on the wound.

This allows a reassessment to be made of other sources of contamination the effect of which would previously have been overwhelmed by contamination from air.

Infection can be a devastating complication of joint arthroplasty causing morbidity and mortality for the patients and distress for the surgeons and draining scarce resources. Prevention remains the goal.

Contamination of air plays a major part in the development of infection after arthroplasty. Charnley,1 by operating in a clean-air enclosure, reduced the infection rate from 10% to 1.0% and by wearing a body-exhaust suit (BES) reduced this further to less than 0.5%. Lidwell et al2 showed in a multicentre, randomised, prospective trial that the rates of infection using clean-air theatres, when compared with conventional plenum-ventilated theatres, were reduced from 1.5% to 0.6%. Although the trial was not randomised for types of clothing, wearing a BES in clear air reduced infection from 1.0% to 0.1%. They also showed that there was a correlation between bacterial air counts and rates of periprosthetic sepsis. Ultraclean air (UCA) in the operating theatre has been defined as that with less than 10 colony-forming units (CFU)/m³.3

BESs are uncomfortable, awkward to work in and expensive. Thus other types of occlusive clothing have been produced such as fabric 450 and polyester T85392 (Rotecno). None of these has been assessed as a part of a randomised, controlled trial using deep infection as an endpoint. With rates of infection of less than 1%, any such trial would require tens of thousands of patients and would be prohibitively time-consuming and expensive.

Surrogate measures of infection include air counts in a dispersal chamber, air counts in theatre and wound counts. Air counts can be measured accurately using a Casella slit sampler.4 In a dispersal chamber Rotecno has been shown to be as good as a BES, better than fabric 450 and vastly superior to cotton5 (Table I). Air counts less than 30 cm from the wound are an established standard measure of air cleanliness for testing new interventions in theatre.2,5-7 In 1991,
Newton et al\(^8\) used this measure as part of a randomised, controlled trial comparing Rotecno with Charnley type BES and concluded that there was no difference in air counts between the two types of clothing. The operative procedures were not standardised, however, since the study compared hemiarthroplasty for a fracture of the neck of femur in the Rotecno group with total hip replacement for the BES group in two different UCA theatres.

Numerous methods of counting bacteria in wounds have been described. They can be broadly divided into imprint and washout methods. Low-pressure and volume washout methods cause an unpredictable break-up of CFUs creating large variability. High-pressure and volume washout methods produce large quantities of fluid containing a few bacteria which are difficult to process and count.\(^9\) The tetrazolium-stained membrane imprint technique (TSMI) has been validated using a wound model and in plenum-ventilated theatres.\(^9,10\) It has not yet been used in UCA in which wound contamination may be too slight to detect.

In order to compare BES and Rotecno in such a clean environment, ideally as many variables as possible should be removed. This may be achieved by using the same operation, operating surgeon, theatre and scrub team.

Our study aimed to determine: a) whether the TSMI wound-counting method could detect bacteria in a wound created in UCA; b) whether there was a correlation between air and wound counts in UCA; and c) whether BESs were better than Rotecno occlusive clothing at controlling air and wound contamination in a UCA theatre.

**Patients and Methods**

We randomly allocated 50 patients undergoing primary total knee replacement to a scrub team wearing BES or Rotecno clothing using sealed envelopes which we opened just before surgery. The senior author (GJST) undertook all the operations using the same surgical procedure, instrumentation, scrub team and theatre.

**Air bacterial counting** We positioned a 700 l/min Casella slit sampler taking air at a standardised position within 30 cm of the wound. Colonies were counted after aerobic incubation at 37°C for 48 hours on large Petri dishes with nutrient agar. The results, expressed as CFU/m\(^3\), were calculated using the following equation:

\[
\text{CFU} = \frac{1000C}{RT} \text{per metre}^3
\]

where C is the number of colonies, R is the sampling rate in litres per minute, and T is the duration of sampling in minutes.

**Wound bacterial counting.** Wound counts used the TSMI method which involved pressing mixed cellulose acetate and nitrate membrane filters (Millipore (UK) Ltd, Watford, UK) measuring 47 mm in diameter with a pore size of 5 µm onto the wound for about 10 to 30 seconds, then transferring to diagnostic sensitivity test agar with β-lactamase (190 units/l agar) to neutralise the cefuroxime used for antibiotic prophylaxis. As in most other studies, the incubation of wound samples was aerobic.\(^2,6\)

Although anaerobic organisms can be identified in air,\(^11\) infection of implants by anaerobes is very uncommon.\(^11\) Incubation of samples was at 37°C. Previous experience has shown that culture for longer leads to intermittent overgrowth of the plates with *Bacillus* species, which prevents the counting of other colonies leading to lost data.\(^12\)

It also allows some comparison between studies since an incubation period of 48 hours is frequently used for aerobic culture. Staining the bacterial colonies with tetracycline (0.5 ml of 0.75%) allowed colonies to be distinguished from tissue.\(^9\)

**Clothing** All the theatre staff wore polycotton (50% polyester, 50% cotton) clothing (Standard Textiles, Lancaster, UK) and caps and masks (Surgikos, Livingston, UK). Depending on the randomisation, the scrub team wore either BES (DISP Barrier Hood/Gown U.V., DePay, UK) or Rotecno clothing (Logjigma International, Dunfermline, UK) with Fluidshield splash guard masks (Tecnol-Fluidshield; Kimberly-Clark, Brussels, Belgium). Rotecno clothing is made of a hydrophobic, spun-laced, 70 g/m\(^2\) polyester-pulp non-woven material. Masks are not required in a BES. Patients were covered by standard disposable drapes made of Fabric 450 (extremity drape; Allegiance, Swindon, UK). The operative site was also covered with an adhesive drape (Steridrape; 3M, Loughborough, UK).

**Theatre ventilation** A UCA system (Ultraflow; Medical Air Technology, Manchester, UK) provided the theatre ventilation. The system gives laminar vertical downflow ultraclean air at 0.38 m/sec, using high-efficiency particulate air filtration which removes 99.97% of all particles of 0.3 µm or more in size. Airborne bacteria carrying particles measure 4 to 20 µm. The recommended protocols for working in UCA were strictly followed.\(^13,14\) These included the exclusion of unscrubbed ungowned personnel from the laminar flow area at all times during the operation, no opening of instruments until after skin preparation and draping, and the keeping of instrument trolleys within the laminar flow. We avoided inter-position of personnel between the air source and the wound whenever possible.\(^15\)

**Experimental design** After skin incision we sampled the air for six periods of ten minutes. As a control, one large unused Petri dish with no exposure to air was processed in an identical manner to those used in the slit sampler.

Wound assessments were made at the end of each of the ten-minute periods after skin incision, namely at 10, 20, 30, 40, 50 and 60 minutes. Using six membrane filters for each assessment, four were pressed on the wound and two were passed over the wound to act as controls. Agar control plates, with added β-lactamase, were not opened, but transported and incubated in the same way as the test agar plates. All patients received 1.5 g of cefuroxime intravenously on induction.
Statistical analysis
For the comparison of types of clothing, analysis of air counts was by repeated-measures analysis of covariance with a Toeplitz covariance structure and of wound counts by a random-effects logistic regression model. For calculation we used the Bayesian statistical package WinBUGS (MRC Biostatistics Unit, Cambridge, UK). The non-parametric Spearman’s correlation coefficient assessed any correlation between air and wound counts. Statistical significance was at the 5% level.

Results
The TSMI wound counting method was effective in UCA. For analysis by patient, bacteria were detected in two of 50
control membranes (4%) and 31 of 50 wounds (62%). Contamination occurred in 64% with BES and 60% with Rotecno. For analysis by membrane filter, bacteria were detected in two of 600 control membranes (0.3%) and 101 of 1200 wound specimens (8.5%) (random-effects logistic regression model, \( p < 0.001 \)). There was no correlation between air and wound counts when both groups were combined (\( r = -0.011 \)), calculated separately for each ten-minute period or repeated separately for the BES and Rotecno groups. Statistically, none was significant (Table II).

As shown in Table III, the mean air count less than 30 cm from the wound was 1 CFU/m\(^3\) for Rotecno and 0.5 CFU/m\(^3\) for BES (Toeplitz covariance structure \( p = 0.014 \)). The mean wound count was 14 colonies for BES and eight for Rotecno (random-effects logistic regression analysis, \( p = 0.171 \)). Air and wound counts varied with time with no clear pattern during the operations for either type of clothing (Figs 1 and 2).

**Discussion**

Overall, air counts in our study showed very clean air (0.5 to 1 CFU/m\(^3\)). Only three of 300 (1%) were higher than the UCA theatre standard of 10 CFU/m\(^3\). These were 10.7, 10.7 and 10.8 and all were in the Rotecno group.

We used repeated-measures analysis of variance when comparing the clothing for air counts, since this allows for a wide range of patterns of correlation between consecutive measures. Although there was a statistically significant difference between the air counts, the distinction between 0.5 and 1 CFU/m\(^3\) may not be clinically important since both are very clean and did not influence the bacterial load in the wound.

In previous research in a plenum-ventilated theatre the TSMI wound-counting method provided a good catchment of bacteria,\(^{10}\) but it had not been tested in UCA in which air contamination is low. In a wound model the TSMI method showed a relatively low collection, but close relationship to control counts suggesting that it gave accurate results. When compared with control membranes the TSMI method successfully collected bacteria from the wound (\( p \leq 0.001 \) logistic regression).

Interposition of personnel between the UCA source and the wound can cause contamination of the wound.\(^{15}\) We chose TKR since interposition is likely to occur during surgery in vertical laminar flow. The senior author (GJST) chooses to carry out total hip replacement with the patient supine in order to avoid interposition of personnel and using this as the model wound may have underestimated contamination caused by interposition when the type of clothing would be highly relevant.

Although we followed strict UCA and aseptic protocols, we still identified bacteria in 62% of the wounds. Although this high percentage may sound alarming it represents a successful wound-counting method rather than major wound contamination. The concept of ‘sterility’ is relative. It may be that all wounds would be found to be contaminated if we had a sufficiently sensitive test for infection. The bacterial load recovered per wound was low (Table III).

A value of -0.011 represents a very low level of correlation. Initially, we expected air and wound counts to be related as in many previous studies. Our explanation of this unexpected finding is that at very low levels of air contamination bacteria in the wound are arriving from other routes. In plenum-ventilated theatres, where 98% of wound bacteria come from the air,\(^{16}\) any non-airborne route is difficult to evaluate. The findings of this study will allow all aspects of aseptic technique to be readdressed. In UCA with BES or Rotecno the contribution to wound contamination from the air can be disregarded when measuring bacterial load in a wound. The effects of such factors as skin preparation, adhesive drapes, suckers, light handles and double gloving can now be assessed for their contribution to wound contamination.

Bayesian logistic regression analysis was used to compare the clothing for wound counts because, in addition to the benefits of repeated measure analysis of variance, it is suitable for analysing the small numbers of bacteria involved. The lack of statistical difference between the two types of clothing suggests that a route other than air may be important and worth further investigation. This also suggests that the statistically significant difference in air counts is not clinically relevant. There is no way of knowing how many of the bacteria found in the wound came from the air in our study. The airborne route cannot be completely dismissed, but its contribution must be very low for there to be no correlation. We must point out that reverse contamination of surgeons has not been addressed in this study.

Rotecno is as good as BES, but more comfortable and economic. Wound counts using the TSMI method should become an essential part of research when comparing variables in UCA.

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**References**