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Do 'Surgical Helmet Systems' or 'Body Exhaust Suits' Affect Contamination and Deep Infection Rates in Arthroplasty? A Systematic Review

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ABSTRACT

This systematic review examined whether negative-pressure Charnley-type body exhaust suits (BES) or modern positive-pressure surgical helmet systems (SHS) reduce deep infection rates and/or contamination in arthroplasty. For deep infection, four studies (3990 patients) gave adjusted relative risk for deep infection of 0.11 (P = 0.09) against SHS. Five of 7 (71%) studies found less air contamination and 2 of 4 studies (50%) less wound contamination with BES. One of 4 (25%) found less air contamination with SHS and 0 of 1 (0%) less wound contamination. In contrast to BES, modern SHS designs were not shown to reduce contamination or deep infection during arthroplasty.

Early arthroplasty series reported deep infection rates as high as 9.5% [1], and operating room personnel are the primary source of microbial contamination in up to 98% of cases [2,3]. Charnley introduced the body exhaust suit [4] (BES) as a 'personnel-isolator' [5], aiming to protect the surgical site from microbial contamination from operative staff.

A key principle of BES is using aspiration tubing to create 'negative pressure' inside the suit [5], ensuring shed particles are removed from the surgical field. A 1979 paper identified approximately ten different BES designs on the market [6] and recommended exhaust aspiration of above 60 litres of air per minute per gown in order to maintain negative pressure. In 1982 a large randomised trial [7] reported BES resulted in a further 90% reduction in infection rate (0.7 vs 0.06%) in patients given prophylactic antibiotics and operated on in ultraclean theatres. These results led to the widespread introduction of BES.

However exhaust tubing is cumbersome in practice [8], and during the 1990s many companies introduced more portable 'surgical helmet systems' (SHS). SHS typically have an intake fan on the helmet itself, drawing air in using the hood material as a filter. The air is then blown across the surgeon's face and neck, creating a 'positive pressure' environment inside the gown [9]. Such suits are often described as 'personal protection systems' [8,10] for the surgeon's benefit, and recent registry data suggests that they may be associated with a paradoxical increase in deep infection rates [11].

Despite fundamental design differences between BES and SHS, no critical appraisal of the literature has analysed their effects separately. We aimed to perform a systematic review, addressing the question: does BES or portable SHS reduce contamination or clinical infection rates in hip and knee arthroplasty?

Methods

A methodology for the search, inclusion criteria, and analysis was specified in advance and documented in a protocol. As no study directly compares BES to SHS, inclusion criteria were studies comparing either BES or SHS to conventional clothing using one of three outcomes – clinical infection rates, wound contamination, or air contamination. Microbial wound contamination is typically assessed using techniques such as fluid washout and subsequent culture, wound swabs, or membrane based samples and culture. Air contamination is assessed using high-volume air sampling and culture or passive settle plates. Studies using sham operations or non-microbiological measures of contamination such as air particle counts were excluded, as these are known to have a poor correlation with bacterial contamination [12,13]. If suit type (SHS or BES) was not clearly documented the authors were contacted for confirmation. BES was defined as an aspirator system with external aspirator and tubing of the original Charnley type, SHS was defined as a helmet-based portable system.

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A primary search was performed employing the electronic databases of PubMed (1950 to May 2013), EMBASE (1950 to May 2013) and Cochrane databases (1980 to May 2013), searched via Ovid using the key words: body exhaust suit(s) or body exhaust system(s) or exhaust helmet or spacesuit(s) or space suit(s) or surgical helmet or garb or gown or body exhaust gown(s) or exhaust suit(s)or personal protection AND contamination or infection or dispersion. A secondary search assessed unpublished literature using the meta-register of current controlled trials for recently completed studies (http://www.controlled-trials.com/mrct/), and finally a search was undertaken using the reference lists of relevant papers to identify additional articles. Two reviewers performed eligibility assessment independently in an unblinded standardised manner; disagreements between reviewers were resolved by consensus. The search strategy was performed in accordance with the PRISMA statement [14] (Fig. 1, Appendix 1).

Data was extracted using a predesigned spreadsheet. One author extracted data from included studies and a second author checked the extracted data, disagreements were resolved by discussion between three reviewers. We contacted three study authors for further information. Two responded, one providing data on the suit type used and one provided additional numerical data presented only as a final calculation in the published paper [15]. Authors from one study did not respond to requests to clarify the suit type [16], however, based on the manufacturer reported it was analysed as an SHS. Data extracted from each study included study type, outcome measure(s) used, number of participants, allocation method, type of procedure, suit type evaluated, sampling methodology, ventilation type, and outcome (infection rate, wound contamination, or air contamination). Where a study compared more than one variable (e.g. operating room ventilation) we extracted the comparative data for surgeon clothing (suit vs no suit) where other such variables were held constant.

Methodological quality and risk of bias were assessed using the Quality Assessment Tool for Quantitative Studies, developed by the Effective Public Health Practice Project (EPHPP, McMaster University, Ontario, Canada) [17,18]. Studies were rated individually for selection bias, study design, confounders, blinding, data collection methods and withdrawals. The scores were combined to give an overall rating of 1–3; corresponding to 1 – "strong", 2 – "moderate" and 3 – "weak" (Appendix 2). Three reviewers performed quality appraisal and assessed risk of bias for each individual study independently; disagreements were resolved by consensus. Following the recommendation of the MOOSE study group [19], the quality scores were not used to determine weighting in the final analyses; instead, they were used in the sensitivity analysis by excluding articles with low quality scores.

Data from included studies was analysed in three groups, based on the outcome measure used: infection rates, wound contamination and air contamination. Pooled quantitative assessment (meta-analysis) was carried out on data from randomised controlled trials and large registry studies which used deep infection as an outcome. To assess heterogeneity, the Higgins I^2 index [20] was used to assess heterogeneity amongst original studies. We presented the overall effects and corresponding 95% confidence intervals obtained with the random-effects model or fixed-effects models as appropriate. Studies using air and wound contamination as an outcome differed in methodological aspects such as number and duration of sampling times, and therefore were analysed on a qualitative basis only.

As BES and SHS aim to reduce contamination and deep infection rates compared to conventional attire, each study was assessed as to whether it supported this conclusion, based on demonstration of a statistically significant improvement in outcome. In some older studies where a *P*-value was not explicitly reported, a determination of significance was made based on the data presented and the difference reported. In studies using deep infection as an outcome, meta-analysis was performed by computing odds ratios (ORs).

As part of the meta-analysis, which summarized the results of studies using deep infection as an outcome, we used standard statistical techniques to identify potential problems with the analysis. The potential for *publication bias* was examined by constructing a funnel plot in which log risk ratios were plotted against their standard errors [21]; the rank correlation test of Begg [22] was used to test for significance of publication bias; the trim-and-fill method to estimate and adjust for the potential effects that unpublished studies may have had on the measured outcome. Stata 10.0 (StataCorp, College Station, TX, USA) statistical software was used for data analysis. Statistical significance was set at a *P* value of ≤0.05.

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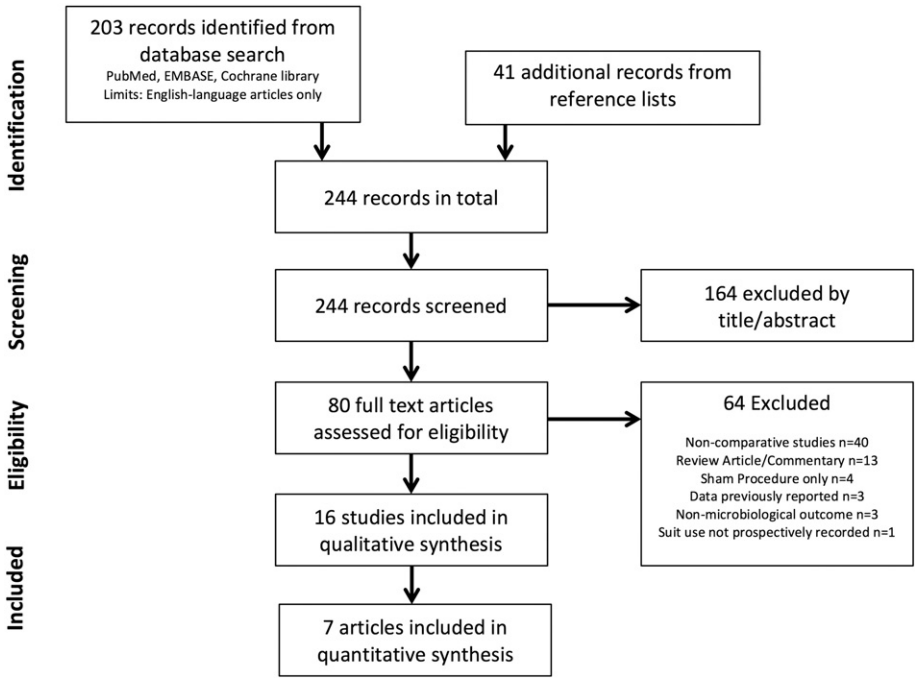

Fig. 1. Study selection for the review and meta-analysis.