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Clinical Orthopaedics and Related Research® A Publication of The Association of Bone and Joint Surgeons*

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CORR Insights[®]: Do Double-fan Surgical Helmet Systems Result in Less Gown-particle Contamination Than Single-fan Designs?

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Where Are We Now?

hen Sir John Charnley first began performing total hip replacement in the 1960s, the risk of prosthetic joint infection (PJI) was as high as 9.5% [1]. In an attempt to reduce this, he introduced the body exhaust suit to protect the surgical site from potential microbial contamination from operative staff [2].

Body exhaust suits originally used aspiration tubing to create negative pressure inside the suit, which would remove shed particles from the operation. Feagin [3] identified about 10 different

The author certifies that he has received personal fees from Stryker (Kalamazoo, MI, USA) and Smith & Nephew (London, UK). The opinions expressed are those of the writer, and do not reflect the opinion or policy of $CORR^{\textcircled{B}}$ or The Association of Bone and Joint Surgeons^(®).

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All ICMJE Conflict of Interest Forms for authors and *Clinical Orthopaedics and Related Research*[®] editors and board members are on file with the publication and can be viewed on request. body exhaust suit designs on the market in 1979 and recommended exhaust aspiration of 60 liters of air per minute per gown. Three years later, a large randomized trial [7] found that a body exhaust suit had a 90% reduction in PJI rate (0.7 versus 0.06%) in patients given prophylactic antibiotics and operated on in ultraclean theatres. These results led to the widespread introduction of the body exhaust suit.

More-portable surgical helmet systems were introduced during the 1990s. Such surgical helmet systems typically had an intake fan on the helmet itself, drawing air through the hood, which is then blown across the surgeon's face and neck, creating a positive pressure environment inside the gown [12]. A 2016 review found that in contrast to body exhaust suits, modern surgical helmet designs have not shown a reduction in PJI rates, with some studies reporting a paradoxical increase [13]. The positive pressure of modern surgical helmet systems has been implicated as a potential reason for these findings [4].

In the current study, Vermeiren and colleagues [11] performed a comparison between a standard single-fan surgical helmet systems, and a double-fan surgical helmet systems design. While the original aim of the two fans was to improve ventilation and surgeon comfort, the authors speculated that it may also reduce positive pressure inside the gown, thus reducing particle egress and contamination. In an experimental model using fluorescent particles and ultraviolet light, the authors found no difference in contamination between the single and double-fan surgical helmet systems designs [11].

Where Do We Need To Go?

Experimental models like the current study will be important in evaluating future suit designs, but clearly further clinical data are needed. Helmet fans are just one aspect of suit design—suit material, stitching at seams, speed of airflow, and sealant tape around the gloves may all affect contamination rates. The challenge when evaluating suits using experimental models, is that the relationship between the outcome measured (particle contamination), and the outcome of interest (PJI), is unclear.

While PJI remains the most common reason for premature revision following arthroplasty [6], the advent of prophylactic antibiotics has reduced rates to the level where prospective studies are difficult to power adequately. If an intervention (such as a surgical helmet systems) is hypothesized to reduce PJI rates from 1% to 0.5%, a study with 80% power to detect a difference at the 5% significance level would need more



This CORR Insights[®] *is a commentary on the article* "Do Double-fan Surgical Helmet Systems Result in Less Gown-particle Contamination Than Single-fan Designs?" *by Vermeiren and colleagues available at:* DOI: 10.1097/CORR.00000000001121.

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than 9000 patients; conducting such a study, obviously, would be difficult.

Currently, most contemporary information on PJI rates with the use of surgical helmet systems comes from joint registry data. However, not all registries record surgeon attire, and no registry records more-specific details such as the type of suit, airflow speed, or whether tape was used around the cuffs. Registry findings are mixed-the New Zealand Joint Registry was the first to report surgical helmet systems may be associated with a paradoxical increase in revision for PJI, whereas other registries report no difference [9], and a later multivariate analysis using New Zealand registry data could not confirm the association [10]. In order to determine the clinical effect of suit design aspects similar to the current study [11], future studies need large datasets with accurate recording of both surgeon attire and postoperative PJI rates using defined criteria.

How Do We Get There?

As resistance to prophylactic antibiotic resistance increases, it is possible to foresee a time where there is a renewed focus on reducing contamination in the operating field. Registry studies provide large numbers of patients and can be an important tool in studying rare endpoints like infection. However, national registries do not capture all infections, as surgery for PJI may not meet the registry definition of "revision" (change, removal, addition, or manipulation of a component) or procedures are performed urgently out of hours and data collection is compromised [14].

Combining data from arthroplasty registries with surgical site infection surveillance programs [5] may offer better insight into the effect of surgical helmet systems on PJI risk. Furthermore, there is potential for prospective-nested randomized controlled trials where individual hospitals are randomized to surgical helmet systems use, with PJI rates monitored by these surveillance programs. After appropriate ethical review, such studies do not require individual patient consent, which is expensive to obtain and typically requires paid researchers. Prospective-nested randomized controlled trials can reduce costs, while still providing the large numbers required for adequate study power. However, whatever the findings of future studies may show, many surgeons are likely to wish to wear surgical helmet systems because of the personal protection provided by such systems [8].

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