

more positive surgical site cultures with helmets and tape, but this was not statistically significant [22]. Direct contact with the sterile helmet is discouraged as a significant number may be contaminated during joint arthroplasty and sterility should not be presumed [11]. In a very large cohort of primary total hip arthroplasty, procedures where a body exhaust system was used showed a higher deep infection incidence, but this did not prove to be a risk factor in multivariate analysis [23].

Overall, the study quality on the subject of sterile surgical attire is low in most instances. Tangible conclusions on which type of attire, material, system and combinations leads to reduction of contamination or incidence of infection following TJA cannot be reached. There appear to be several reports of contamination using sterile helmet systems. Whether that leads to increased incidence of infection remains to be shown. In summary, a weak recommendation of sterile surgical gowns for TJA is put forward, as best “common sense” practice in the absence of robust evidence [24], but the use of modern helmet systems would not be recommended in preventing SSI.

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QUESTION 3: Does the use of personal protection suits (space suits) influence the rate of surgical site infections/periprosthetic joint infections (SSIs/PJIs) in patients undergoing joint arthroplasty?

RECOMMENDATION: In the absence of strong evidence, we believe the use of personal protection suits does not reduce the rate of subsequent SSIs/PJIs in patients undergoing joint arthroplasty.

LEVEL OF EVIDENCE: Moderate

DELEGATE VOTE: Agree: 87%, Disagree: 11%, Abstain: 2% (Super Majority, Strong Consensus)

RATIONALE

Initial personal protection suits, which aimed to protect the surgical site by reducing microbial contamination and subsequent infection from the operation staff, were negative pressure body exhaust suits

with inflow and outflow tubing creating a negative pressure inside the suit. Shed particles were vented away from the surgical site by the tubing. Due to the cumbersome nature of the tubing, more port-

able surgical helmet systems were developed. These helmet systems typically have an intake fan on the helmet, allowing the air to flow across the person's head and neck, and are exhausted by openings in the gown, usually through the lower portion of the gown or other potential openings.

A systematic review of helmet systems and body exhaust suits was published in 2016 [1]. Helmet systems or body exhaust suits were compared to conventional gowns for outcomes of (i) air contamination, (ii) wound contamination and (iii) deep infection. Sixteen articles met inclusion criteria for the various outcomes.

Air contamination: Four studies compared helmet systems to conventional gowns [2–5]. One study [4] reported reduced air contamination; the other three showed no difference [2,4,5]. Five [6–10] of seven studies comparing body exhaust suits showed reduced air contamination. Two studies showed no difference in air contamination compared to conventional gowns [11].

Wound contamination: A single study showed no statistical difference in wound contamination comparing helmet system to conventional gowns [4]. Two of four body exhaust suit comparison studies found a significant advantage to body exhaust suits with less wound contamination compared to conventional gowns [12,13]. The other two studies trended in favor of body exhaust suits [6,7].

Deep infection: Three registry data studies, reporting on four series of patients (two series of total hip arthroplasty (THA) and two series of total knee arthroplasty (TKA) patients), totaling just over 175,000 patients, compared helmet systems to conventional gowns and used reoperation for infection at 6 months [14] or one year as the outcome [15,16]. Hooper reported a statistically higher rate of reoperation for infection within the first six months when helmet systems were used: THA - 0.19% with helmet system vs. 0.06% conventional gown, $p < 0.0001$, and TKA - 0.24% with helmet system vs. 0.098% conventional, $p < 0.001$ [7]. Namba et al. showed no difference in reoperations for infection at one year when a multivariate analysis was used for both THA and TKA [8,9]. Pooled data from these four series showed a non-statistically significant ($p = 0.09$) increase in deep infections (risk ratio (RR) 1.67, 95% confidence interval (CI) 0.92, 3.05) [17].

In contrast, the four studies involving 3,990 patients comparing body exhaust suits to conventional gowns showed a decrease in deep infection when body exhaust suits were used [6–8,13]. The deep infection rate at mean 2.5 years follow-up was 0.17% (3 of 1,795) in the body exhaust group and 1.0% (16 of 1,604) in the conventional clothing group ($p < 0.01$). When data from the above studies was combined in a fixed meta-analysis model, body exhaust suits were associated with a significant reduction in deep infection rates (RR 0.11, 95% CI 0.09–0.46).

Following the publication of the helmet system systemic review, two additional New Zealand Joint Registry data studies have further analyzed the impact of surgical helmet systems on reoperation for infection at 6 and 12 months [18,19]. Multivariate analysis showed no statistical increase (or decrease) in reoperation for infection when surgical helmet systems were used for both primary hip and knee arthroplasty. In the primary knee study there was a non-statistically significant trend ($p = 0.052$) towards reoperation for infection at six months when surgical helmet systems were used (odds ratio (OR) 1.53, 95% CI 1.00 to 2.34) [18]. One additional study, comparing a helmet system to a conventional gown in a simulated surgical environment enclosure, used particle and microbiological emissions as the outcome. Particle counts were statistically higher, while microbiological emissions trended (but not significantly) higher in the helmet system experiments [17].

It is important to note that the type of helmet systems and gowns used were not reported in the above studies on deep infection. Helmet systems vary with respect to the fan type, fan speed, location of exhaust from the gown and material of the gown/toga used with the helmet system. These variables may also influence the potential for contamination. In a study by Fraser et al. one helmet/toga system showed significantly higher rates of contamination at the gown-glove interface relative to other helmet systems and a conventional gown [3]. The other helmet systems in that study showed no statistically increased rate of contamination compared to a conventional gown. The helmet system with the higher risk of contamination at the gown-glove interface used a toga with sleeves made of a stiffer, plasticized material that likely allowed for greater egress of particles at the gown-glove interface.

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