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A microbiological assessment of sterile surgical helmet systems using particle counts and culture plates: recommendations for safe use whilst scrubbing

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SUMMARY

Background: Infection occurs in 2–4% of arthroplasty cases, and identifying potential sources of infection can help to reduce infection rates. The aim of this study was to identify the impact and potential for the contamination of hands and gowns whilst scrubbing using sterile surgical helmet systems (SSHSs).

Methods: A colony-forming unit (cfu) is a pathogenic particle of 0.5–5 μm. Standard arthroplasty hoods and SSHSs, with and without the fan switched on, were tested for a 3-min exposure (to represent scrubbing time) on three subjects and a mannequin with concurrent particle counts and culture plates.

Results: All SSHSs were positive for Gram-positive cocci, with a mean colony count of 410 cfu/m^2. Background counts were lower for laminar flow areas [mean 0.7 particles/m^3; 95% confidence interval (CI) 0–1.4] than scrub areas (mean 131.5 particles/m^3; 95% CI 123.5–137.9; P=0.0003). However, neither grew any bacteria with a 2-min exposure. The background count increased 3.7 times with the fan switched on (total P=0.004, cfu P=0.047), and all helmets had positive cultures (mean 36 cfu/m^2). There were no positive cultures with the standard arthroplasty hood or the SSHS with the fan switched off. In laminar flow areas, all cultures were negative and particle counts were low.

Conclusions: Sterile gloves and gowns can be contaminated when scrubbing with the SSHS fan switched on. It is recommended that the fan should remain switched off when scrubbing until the hood and gown are in place, ideally in a laminar flow environment.

Introduction

Peri-prosthetic joint infection is a rare but serious complication of elective arthroplasty surgery, accounting for up to 4% of primary arthroplasty failures [1,2]. This is a devastating complication for the patient, who will require challenging, complex and multiple revision surgeries with compromised functional outcome. It also places a significant financial burden upon healthcare systems [3,4]. Sterile surgical helmet systems (SSHSs) are commonly used in arthroplasty to minimize the spread of infection.

Infection can be exogenous or endogenous to the patient. It is the surgeons' responsibility to identify and reduce the risks of infection. Pre-operative assessment to identify high-risk

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patients, routine infection screening tests, and subsequent optimization and treatment of patient co-morbidities are key to reduce the impact of patient factors [5]. There are four possible sources for surgical site infection: the patient, the instruments, the operative team and airborne particles. Airborne sources account for 95% of reported wound contamination [6]. Of the airborne sources, 15% are airborne floor particles, while the rest are related to microbial shedding (upper respiratory tract organisms from talking, and from the skin and clothes; 90% of the bacteria originate from below the level of the neck) [6].

Scrubbing reduces the normal transient bacterial floral load on the surgical team member's hands and forearms prior to commencing a surgical procedure. This is performed under aseptic conditions using approved cleaning products to clean the hands, followed by the placement of a sterile visor, gown and gloves, using open or closed gloving techniques [7]. For arthroplasty, either disposable arthroplasty hoods or SSHSs can be used, neither of which have been associated with increased infection rates [8–10].

An SSHS comprises an unsterile helmet with a built-in fan for ventilation (Figures 1 and 2). This is covered by a disposable sterile visor mask hood, which acts as a filter once in place, drawing particles towards the fan system. The unsterile helmet is donned before scrubbing, and the hood is connected to a separate battery to power the fan as there is no switch to control power to the fan manually. The fan consequently blows particles from the head area downwards.

It was hypothesized that use of the fan prior to visor placement may contaminate both the surgeon's hands and the scrub pack, and may desterilize this equipment. Therefore, the aim of this study was to identify the impact and potential for contamination of hands, gowns and gloves when scrubbing using an SSHS compared with a standard arthroplasty hood.

Materials and methods

Study design

In order to understand the potential for contamination of surgical gloves and gowns during scrubbing, background particle counts were taken in scrub areas. This enabled the change in particle count to be measured with a particle counter in order to assess the impact of scrubbing using either a standard paper arthroplasty hood or an SSHS with the fan switched on or off. Microbiological samples were also taken in the above conditions, and from the SSHS, to compare any organisms grown with known pathogenic organisms at the study institution and nationally.

Figure 1. Stryker Flyte Steri-Shield helmet personal protection system (re-usable) (Stryker Medical, Mahwah, NJ, USA).

Figure 2. Disposable sterile Flyte suit (Stryker Medical, NJ, USA).

Equipment and theatre setup

SSHSs (Stryker Flyte Steri-Shield helmet personal protection systems covered with a disposable Flyte suit; Stryker Medical, NJ, USA) are used for all arthroplasty procedures at the study institution (Figures 1 and 2). A standard disposable arthroplasty hood (Halyard Surgical Hood 69110; Halyard Health, Alpharetta, GA, USA) was used for comparison (Figure 3). The theatre layout at the study hospital consists of a communal cabin design (The Barn) with the scrub area outside the cabin but in

Figure 3. Standard disposable arthroplasty hood (Halyard Surgical Hood 69110; Halyard Health, Alpharetta, GA, USA).

the main room space (Figure 4). The operating space uses vertical ultra clean air laminar flow, but the scrub areas are outside of the laminar flow system.

Microbiological assessment

All microbiological samples were cultured in a standard fashion in accordance with the study hospital's microbiological protocol and interpreted by a consultant microbiologist (GH), recording micro-organisms and number of colony-forming units (cfus). Examples of the culture plates from the hoods are seen in Figures 5 and 6.

SSHS culture

To assess the presence of organisms on the SSHS hoods, five hoods were swabbed and cultured, both before and after being cleaned with alcohol preparation. The helmet systems are not normally cleaned between cases at the study institution.

Background particle counts

Microbiological assessment using a particle counter (APC ErgoTouch, Millipore Merck, Schwalbach am Taunus, Germany) was performed in all theatre areas to assess the particle counts of the scrub environment and operating room environment over a 24-h period, with normal day-to-day activity.

Assessment of SSHS fan usage

Three subjects and one mannequin were tested in scrub areas and theatre laminar flow areas with concurrent particle counts and 3-min exposure agar settle plates. A mannequin was used as a control by being cleaned with alcohol and swabbed prior to each test. Control samples were taken during experimental conditions.

Each subject gowned as normal in front of a scrub table with an agar plate, using either: a standard SSHS with the fan switched off; a standard SSHS with the fan switched on; or a standard paper arthroplasty hood. This was performed and repeated three times in scrub areas outside of laminar flow and

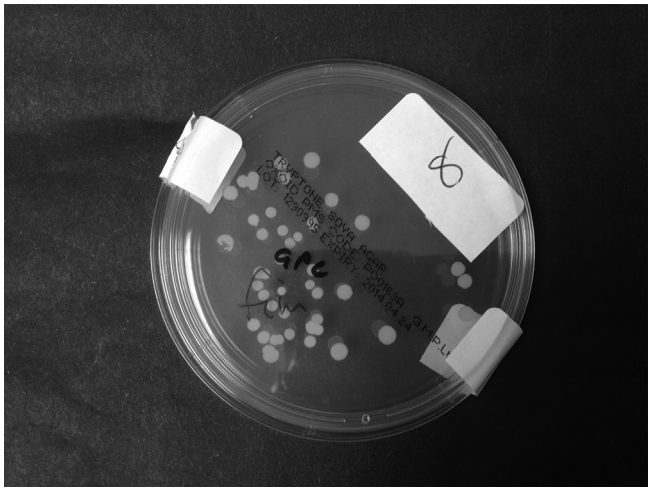

Figure 5. Example of cultures taken from sterile surgical helmet system hoods on agar plates before cleaning.

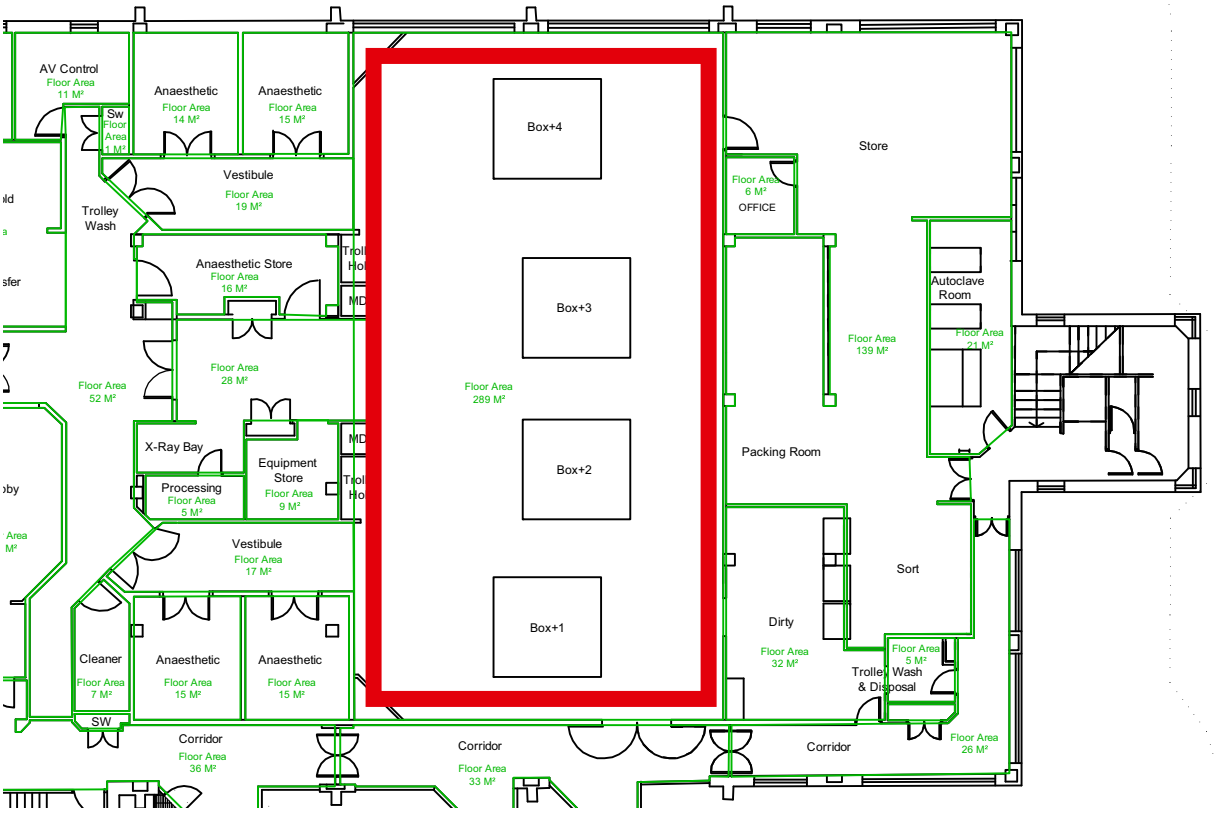

Figure 4. Blueprint floor plans of the theatre complex in the study hospital, nicknamed 'The Barn'. The red outline highlights the theatre complex.

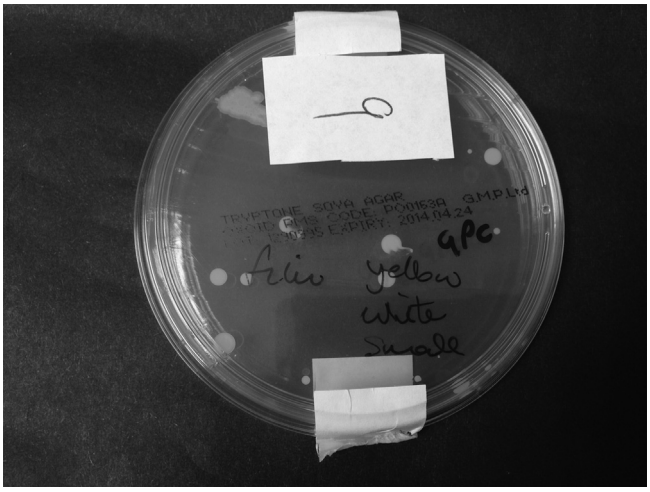

Figure 6. Example of cultures taken from sterile surgical helmet system hoods on agar plates after cleaning.

in an area inside of laminar flow. Agar plates placed on the scrub table were exposed at the same time as particle counts were taken from the level of the scrub table, for a total of 3 min. This duration was chosen for exposure time to represent the standard scrubbing time [7].

Surgical site infection

Public Health England has a database for all surgical site infections (SSIs), with local microbiology departments being responsible for reporting all operative infections [11]. This database was accessed for all confirmed infective organisms for hip and knee arthroplasty surgery at the study centre between January 2010 and December 2013. Furthermore, data for SSI rates in the same date range were obtained to compare the study centre with national figures.

Statistical analysis

All data were collected in Excel Version 15.13.3 (Microsoft Corp., Redmond, WA, USA) and analysed using SPSS Version 22.0 (IBM Corp., Armonk, NY, USA). The change in particle count for each test scenario from the baseline level in the scrub and laminar flow environments was assessed using *t*-tests. $P<0.05$ was considered to indicate statistical significance.

Results

SSHS culture

The micro-organisms present on the SSHSs, both before and after cleaning, are shown in Table I.

Background particle counts

In the communal theatre suite, the laminar flow cabins are suspended, allowing air to travel to the floor and out, and also through the doorways. The scrub area is located next to the doorway, with the background particle count increasing as the counter moved further away from the doorway of the cabin.

Table I
Summary of micro-organisms cultured from five sterile surgical helmet systems (SSHSs)

Micro-organism	Mean number of colonies (unit)	
	Uncleaned SSHSs	Cleaned SSHSs
Staphylococcus aureus	24	16
Staphylococcus epidermidis	15	12
Staphylococcus capitis	8	6
Micrococcus spp.	3	9

There was a significant difference in background particle counts ($P<0.01$) between laminar flow areas [mean 0.7 particles/m^3; 95% confidence interval (CI) 0.0–1.4] and scrub areas (mean 131.5 particles/m^3; 95% CI 123.5–137.9]. However, no bacterial growth was obtained at any site with a 3-min exposure. Increased counts were noted if there was a disruption to air flow, including the opening of theatre doors or movement past the scrub area. In the doorway of a cabin, the particle count was equivalent to the laminar flow particle count, with a mean of 1 particle/m^3 (95% CI 0–3). However, 50 cm away from the door, this increased to 113 particles/m^3 (95% CI 98–144), and at 100 cm away from the door, this increased further to 2566 particles/m^3 (95% CI 198–3446) ($P<0.01$). Scrubbing takes place 50–100 cm from the door; a distance within this range was used for the next phase of tests.

Assessment of SSHS fan usage

The results for microbiological assessment of the agar plates on the scrub tables are given in Table II. Of note, there was no significant increase in the mean background particle count when using a paper arthroplasty hood or an SSHS with the fan switched off. This correlated with no growth on culture plates. When the SSHS fan was switched on, there was a significant increase in the mean particle count from background for both the control mannequin ($P=0.042$) and the three subjects ($P=0.004$). When the three test conditions were performed in laminar flow areas, there was a significant increase in particle count; however, the mean count was lower than outside the laminar flow areas, and no positive cultures were obtained.

Surgical site infections

Table III shows the SSI rates at the study centre for all primary arthroplasty procedures performed between January 2010 and December 2013, compared with national rates. *Staphyloccus aureus* and *Staphylococcus capitis* were the most common species isolated (Table IV).

Discussion

To the authors' knowledge, this is the first study to demonstrate that there is a potential for contamination at the time of scrubbing when using an SSHS with the fan switched on in a non-laminar flow environment.

The study centre has reported SSI figures of 0.8% and 0.7% for primary hip and knee replacements, respectively. These figures are below the reported rates of 2–4% for prosthetic joint infection [2]. These low figures are possibly due to careful

Table II
Summary of microbiological results

Environment		Arthroplasty hood		SSHS, fan switched off		SSHS, fan switched on	
		M	H	M	H	M	H
Scrub area: mean background count 113.5 particles/m^3 (95% CI 123.5–137.9)	Mean change in background count (%)	103	116	141	233	150	373
	P-value	0.636	0.425	0.611	0.123	*0.042	*0.004
	Culture result (colonies grown)	No growth	No growth	No growth	No growth	13	36
Laminar flow area: mean background count 0.7 particles/m^3 (95% CI 0.0–1.4)	Mean change in background count (%)	123	637	533	744	844	1152
	P-value	0.531	*0.037	*0.048	*0.020	*0.018	*0.016
	Culture result (colonies grown)	No growth	No growth	No growth	No growth	No growth	No growth

SSHS, sterile surgical helmet system; M, mannequin; H, human; CI, confidence interval.
Asterisk refers to significant results.

pre-operative optimization, control of the surgical environment, aseptic techniques, antibiotic prophylaxis, surgical technique and postoperative wound care [5,12,13].

During surgical procedures, members of the surgical team wear protective sterile clothing that aims to prevent direct transmission of micro-organisms to the surgical site. The National Institute for Health and Clinical Excellence recommends double gloving as this has been shown to reduce perforation and potential contamination of the surgical wound in arthroplasty procedures [14,15]. Furthermore, changing gloves regularly is also associated with lower SSI rates; the contamination rate of gloves is as high as 33%, with the highest rates seen after draping [16]. The purpose of scrubbing is to decrease the bacterial load on the hands prior to wearing sterile protective clothing. Washing the hands and forearms decreases the transient microbes, and the aqueous- and alcohol-based antiseptic solutions further destroy or inhibit bacterial growth. This would minimize direct transmission of microbes to the surgical site if there was a perforation in the protective clothing compromising the surgeon's sterility [17].

Arthroplasty surgeons also wear specialized headwear: either a disposable hood, a mask, an SSHS or a body exhaust system. SSHSs can use either a complete suit covering or have a sterile hood over the helmet. These are associated with reduced infection rates, and SSHSs are reported to be comfortable for the surgeon [8–10]. The sterile covering has been shown to become contaminated over the course of arthroplasty surgery in laminar flow [9,17]. Therefore, if the sterile cover is touched, gloves should be changed because the suits and SSHS covers act like filters and cannot be presumed to be sterile [18].

The results suggest that SSHSs harbour infective micro-organisms consistent with the natural flora of the hair and scalp. These are common SSI bacteria, with *S. aureus* and coagulase-negative staphylococci being cultured in high concentrations from the test SSHSs [19]. Once the SSHS fan is switched on, the number of cfu-sized particles increased significantly from the background rate, with positive cultures for the exposed plates consistent with organisms cultured

Table III
Surgical site infection (SSI) rates at the study centre compared with national figures, between January 2010 and December 2013

	Hospital	Total no. of primary arthroplasties	All SSIs	
			No.	Rate (%)
Hip	RJAH	5626	44	0.8
	All	225,417	2741	1.2
Knee	RJAH	5259	37	0.7
	All	233,653	3955	1.7

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Table IV
Details of micro-organism isolates causing infections in the study centre between January 2010 and December 2013

Micro-organism	Total no. of isolates	
	Hip arthroplasty	Knee arthroplasty
Staphylococcus aureus (MSSA)	16	5
Staphylococcus aureus (MRSA)	3	3
Staphylococcus capitis	8	7
Staphylococcus epidermidis	1	2
Staphylococcus haemolyticus	1	0
Staphylococcus lugdunensis	2	0
Enterococcus faecalis	4	3
Bacillus spp.	0	1
Clostridium perfringens	1	0
Coliforms (unspecified)	1	1
Corynebacterium spp.	1	1
Diptheroids	0	2
Enterobacter aerogenes	0	1
Enterobacter cloacae	1	1
Escherichia coli	0	1
Klebsiella spp.	1	2
Proteus spp.	1	0
Pseudomonas aeruginosa	2	2
Serratia spp.	1	1
Streptococcus – other aerobic spp.	0	3
Streptococcus viridans group	0	1
Total	44	37

MSSA, meticillin-susceptible *S. aureus*; MRSA, meticillin-resistant *S. aureus*.

from the SSHS cultures. With such a short exposure time (3 min) for the culture to settle, the agar plates suggest a highly significant result because routine exposure for background rate analysis is of the order of 30–60 min. However, this represents a real-world estimate of the level of exposure that would happen during scrubbing. The use of an alcohol-sterilized mannequin to eliminate the effect of normal microbial shedding confirms the increase in particle count when using an SSHS with the fan switched on. The positive cultures suggest that the fan directs bacteria present within the SSHS or within the air.

If the fan was not switched on or a disposable hood was not worn, the background rate was not affected significantly and there were no positive cultures. This suggests that sterile clothing in the scrub area would not be contaminated. Kearns *et al*. suggested that contamination of sterile surgical clothing starts whilst scrubbing and gowning. The exact point of contamination is unknown, but the use of an SSHS with the fan switched on during scrubbing may contribute [18].

Contamination may occur from airborne particles because the background counts in non-laminar flow scrub areas for cfu-sized particles are statistically higher compared with cfu particle counts in laminar flow areas ($P<0.01$). Airborne particles are known to cause contamination in up to 95% of SSIs [6]. No positive microbial cultures were obtained even with the fan switched on in the laminar flow areas. Therefore, a combination of cfu-sized particles from the air and the hood may be responsible for contamination of scrub areas. The background particle counts increased further away from the laminar flow source. This, coupled with increased theatre traffic and disturbances to air flow (doors opening), which are associated with higher SSI rates, may cause contamination of the scrub table and the opened sterile surgical clothing [20]. Therefore, the risk of contamination of the surgical clothes is greater if they have been opened and left out on the scrub area for a longer period, compared with being opened when the wearer is about to put them on [20,21].

Similarly, Young *et al*. performed a fluoroscopic study to track possible sources of contamination using SSHSs. In a simulated environment, they demonstrated that the highest amount of powder migration (particle migration) was seen in the SSHS group, compared with no powder migration in the standard gown group. This gives a plausible explanation for the increased infection rates seen with the use of SSHSs [11]. The results of the present study can be extrapolated to suggest that this is likely to be related to fan use.

The main limitation of this study is that it is a model to assess particle counts and to identify a potential cause of contamination of scrub areas. As it is a model, the microbiological culture results cannot be correlated directly with the reported SSIs. Further studies are required to determine if these microbes are the source of SSI or prosthetic joint infection.

In conclusion, SSHSs may become colonized with micro-organisms that commonly cause prosthetic joint infection. Having the fan switched on whist scrubbing directs the micro-organisms towards the scrub table, and can potentially contaminate gowns and gloves that should be sterile. These results suggest that even short exposures with the fan switched on may be sufficient to contaminate the wearer and their sterile clothing. Therefore, sterile surgical gowns and gloves should be opened only when the wearer is ready to put them on. In addition, gowns and gloves should be worn in the laminar flow area.

It was also noted that no micro-organisms were grown when the SSHS fans were switched off or if a disposable arthroplasty hood was used. As such, it is recommended that if an SSHS is used, the fan should be switched off until the surgeon is completely gowned in order to prevent contamination of the sterile surgical pack, and should only be switched on when the wearer is fully dressed. In laminar flow areas, no exposure plates were positive for a micro-organism, suggesting that laminar flow offers an advantage in reducing contamination whilst scrubbing. Scrubbing in a laminar flow environment could further reduce the potential for contamination of the sterile surgical pack, and should be a consideration in future theatre designs for arthroplasty.

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