AN ANALYSIS OF BIOAEROSOL EMISSIONS FROM ORTHOPAEDIC SURGICAL CLOTHING

Dr Praveen Vijaysegaran

MBBS/B Med Sci (University of Melbourne)

Orthopaedic Registrar, Royal Australasian College of Surgeons

Submitted in fulfilment of the requirements for the degree of Master of Applied Science

> Institute of Health and Biomedical Innovation Queensland University of Technology

> > 2016

Keywords

Orthopaedics, space suit, clean air, arthroplasty, prosthetic joint infection

Abstract

Introduction: The role of space suits in the prevention of orthopaedic prosthetic joint infection remains unclear. Recent evidence suggests space suits may in fact contribute to increased infection rates, with bioaerosol emissions from space suits identified as a potential cause. This study aimed to compare the particle and microbiological emission rates from space suits and standard surgical clothing.

Methods: A comparison of emission rates between space suits and standard surgical clothing was performed in a simulated surgical environment during five separate experiments. Particle counts were analysed with two separate particle counters capable of detecting particles between 0.1 and 20 µm. One microbiological sampler was used, with culture counts performed at 24 and 48 hours.

Results: Four experiments consistently showed statistically significant increases in both particle and microbiological emission rates when space suits are used compared with standard surgical clothing. One experiment showed inconsistent results, with a trend towards increases in both particle and microbiological emission rates when space suits are used compared with standard surgical clothing.

Conclusion: Space suits cause increased particle and microbiological emission rates compared with standard surgical clothing. This finding provides mechanistic evidence to support the increased prosthetic joint infection rates observed in epidemiological studies.

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Statement of Original Authorship

The work contained in this thesis has not been previously submitted to meet requirements for an award at this or any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made.

I undertake to retain the original collated data on which this thesis is based for a minimum of five years, in accordance with University ethics guidelines.

QUT Verified Signature

Signature:

August 2016

Date:

Acknowledgements

First and foremost, I would like to thank my principal supervisor Professor Ross Crawford, for all your support and guidance, and for constantly serving as an inspiration. I would not be where I am today if it was not for you. To Dr Luke Knibbs, thank you for being so accommodating and always having a solution to all my problems. You have been my go-to guy over the last few years. Professor Lidia Morawska, thank you for this opportunity and your encouragement.

To all my family and friends who have supported me throughout, particularly my parents and in particular my father Vijaysegaran Shanmugam who spent many long hours experimenting with me, thank you. Almost everything I do is for you, and to make you proud. Kathleen Capehart and Navina Vijaysegaran, thank you for getting me over the finish line and all your help with editing.

I would also like to express my gratitude to all my other colleagues at QUT and elsewhere who have helped over the last few years. Dr Sarah Whitehouse, Dr Graham Johnson, Dr Timothy Kidd, Chantal Labbe and Monica Warzywoda, this research would not be possible without your help.

And to everyone else who played a role, however trivial or insignificant, your efforts have been much appreciated.

Chapter 1: Introduction and Literature Review

1.1 Total hip and knee joint arthroplasty

Hip and knee osteoarthritis are causes of significant pain and disability¹. Multiple treatment modalities exist for these conditions with total joint arthroplasty often being the final option^{2, 3}. Total joint arthroplasty is one of the most successful commonly performed orthopaedic procedures and an effective method of alleviating symptoms associated with hip and knee osteoarthritis³. In 2013, 43,826 primary total knee replacements and 29,080 primary total hip replacements were performed in Australia⁴. This demand is only expected to grow with an ageing population, with projections estimating the demand for primary total hip replacements and total knee replacements to grow by 174% and 673%, respectively, from 2005 to 2030^5 .

Multiple studies have shown excellent short- and long-term satisfaction rates after total hip and total knee replacement. Satisfaction rates in the early postoperative period (between three months to two years) of more than 90% have been reported while longer term follow-up of more than 15 years has reported satisfaction rates up to $96\%⁶⁻⁹$. Despite the success of total joint replacement, multiple associated risks exist. These include bleeding, thromboembolic events, prosthetic joint infection, aseptic loosening and periprosthetic fracture which often necessitate further surgery and can sometimes result in death.

1.2 Prosthetic Joint Infection

Prosthetic joint infection is a particularly concerning complication of total hip and knee replacement, with reports of mortality following prosthetic joint infection ranging from 2.5 to 8% ^{10, 11}. In 2014, The Australian National Joint Registry listed infection as the second most common cause of revision for primary total knee replacements with 3,038 cases reported in 2013, and the fourth most common cause of revision for primary hip replacements with 1,534 reported cases in 2013^4 .

Prosthetic joint infection is also associated with a substantial economic cost. The literature estimates that the average cost of uncomplicated primary total hip replacements and total knee replacements is roughly USD \$30,000 and \$25,000, respectively. The cost of total hip prosthetic joint infection increased from USD \$73,000 to USD \$94,000 over the decade, whereas the cost of total knee prosthetic joint infection rose from between USD \$59,000 to USD \$75,000 over the same period¹²⁻¹⁵. From 2001 to 2009 the annual cost of revisions due to infection in the United States increased from USD \$320 million to USD \$566 million, and is projected to exceed USD $$1.62$ billion by 2020^{13} .

Important predisposing factors for modern prosthetic joint infection can be divided into patient preoperative factors, surgical factors and postoperative factors. Patient preoperative factors include a higher body mass index, a history of rheumatoid arthritis, anaemia, venous thromboembolism or dementia as well as an American Society of Anaesthesiologists grading of more than two. Surgical factors include total knee arthroplasty, a longer operative time or inpatient stay and simultaneous bilateral procedures. Postoperative factors include allogenic blood transfusion, myocardial infarction, atrial fibrillation, urinary tract infection, wound drainage and haematoma formation¹⁵.

Clinically, pain is the single most frequent symptom of prosthetic joint infection and is often exacerbated by motion. Local warmth, tenderness, wound drainage, and joint effusions are also helpful in diagnosing infection. A normal erythrocyte sedimentation rate, along with a normal C-reactive protein level, would suggest a very low risk of infection. The most frequently recovered isolates are *Staphylococcus aureus* and *Staphylococcus epidermidis* in prosthetic joint infections, while gram-negative bacilli are also known to contribute 11 .

Treatment is generally guided by the chronicity and severity of infection. Options include washout and debridement procedures versus single or two staged revision procedures with appropriate antibiotic administration. Generally, two-stage revision is superior to singlestage revision or to debridement with prosthesis retention. Long-term antibiotic suppression and/or arthrodesis are useful for patients too frail to undergo extensive surgery 11 .

Current rates of prosthetic joint infection have been estimated to be anywhere between 2.0% to 2.4% over an eight year period in the $USA¹⁵$. Yearly postoperative infection rates have been estimated at approximately of 0.7% ¹⁶. This is a significant improvement compared to early arthroplasty series in the 1960s that described rates as high as 10% ¹⁷. This reduction in infection rates has been attributed to a number of measures that were introduced at the time, including the use of prophylactic antibiotics and the formulation of the clean air hypothesis $17-19$.

1.3 The clean air hypothesis

The clean air hypothesis suggested that the prosthetic joint might constitute a system uniquely sensitive to infection by a very small bacterial inoculum, and that this inoculum might be derived from airborne particles¹⁸. A multifaceted approach involving both refined room air ventilation systems incorporating laminar flow and modified surgical clothing consisting of body exhaust suits were introduced in an effort to reduce infection rates^{17, 18}. These body exhaust suits (Figure 1) incorporated both inlet and outlet tubing, which was designed to extract potentially infectious bioaerosols produced by the surgeon and theatre staff away from the surgical field. Studies performed subsequently in the 1960s showed a very strong *prima facie* case for the value of clean air systems, but they were not statistically robust and the conclusion that clean air was responsible for the improvement in infection rates was strongly challenged²⁰. By the 1970s there was still no consensus on the clinical value of either the clean air hypothesis or the use of prophylactic antibiotics in joint replacement surgery²¹.

This uncertainty led to a large prospective multicentre study of sepsis after total hip or knee replacement. The study was conducted by the Medical Research Council in Europe from 1974 to 1979 and was based on records from over 8,000 total joint replacements^{21, 22}. The study's results, reported by Lidwell in 1982, found the use of body exhaust suits led to a statistically and clinically significant reduction in infection rates from 1.5% to 0.6% and led to their widespread use. The study also showed a correlation between bacterial air counts and rates of periprosthetic sepsis, which has also been shown in subsequent studies^{23, 24}.

Multiple clinical and non-clinical studies on the impact of various forms of surgical clothing and the use of body exhaust suits have since been published. Both have used air and wound bacterial counts as surrogate markers for infection, as the number of samples or participants required in a study of statistical significance with the current low prosthetic joint infection rates would be in the thousands and logistically very difficult²⁵⁻³⁹. The use of air particle counts as a surrogate marker for bacterial contamination in operating theatres, and thus infection rates, has also been validated $40-42$.

Since Lidwell's landmark trial, other studies assessing various forms of clothing with particular reference to body exhaust suits and the clear air hypothesis have shown benefits with the use of body exhaust suits. A non-clinical study published in 1975 assessed the effect of body exhaust suits in a simulated surgical environment and found a significant reduction (up to tenfold) in bacterial dispersion when body exhaust suits were used²⁹. A clinical study published in 1983 showed a reduction in airborne bacteria and bacteria cultured from adhesive surgical drapes when body exhaust suits were used during total hip arthroplasty, supporting the use of these suits³⁰. More recent studies conducted in the last decade have similarly supported the use of body exhaust suits $^{31, 32, 37}$.

Figure 1 – Sir John Charnley in a body exhaust suit

Body exhaust suits were designed with both air inlet and outlet tubing to create negative pressure inside the gown, ensuring any shed particles are extracted via the outlet tube and released in a controlled manner away from the surgical field, preventing any contamination. However, such tubing is cumbersome, which led to the development of more portable 'space suit' systems such as the T4 Steri-Shield (Stryker Instruments, Kalamazoo, MI, USA), the Provision Surgical Helmet (DePuy, Warsaw, IN, USA), and Stackhouse FreedomAire (Stackhouse Incorporated, Palm Springs, CA, USA). Space suit systems have an intake valve on the helmet itself, which draws air in from outside using the hood material as a filter. The air is then blown down across the surgeon's face and neck, creating positive pressure inside the surgeon's gown and potentially expelling contaminated particles onto the surgical field²⁵. With the added benefit of being splash resistant and serving as a form of selfprotection for the surgeon, space suits have now become the most common form of clean air clothing systems used 43 .

In contrast to the proven effectiveness of body exhaust suits, the impact of space suits on infection rates remains unclear. Only one study has shown any benefit; a recent analysis of air bacterial colony forming unit (CFU) counts of twelve simulated hip arthroplasty operations using the Stryker T4 hood/helmet versus a normal gown, which found a five-fold increase with normal gown use³². Most of the other literature which comprises both clinical and non-clinical studies has shown no significant reduction in particle and bacteria counts, reflecting other findings showing no difference in infection rates when space suits are used compared to conventional surgical clothing^{34, 36-38}.

Recent reports based on nationwide registry data looking at infection rates specifically rather than surrogate markers such as particle or bacterial counts have shown a potentially harmful effect of space suits. A large registry study from New Zealand in 2011 analysed more than 51,000 total hip replacements and 36,000 total knee replacements. This study, although not a randomized control trial, found a significant increase in the rates of early revision for deep infection for those procedures performed with the use of a space suit when compared with those without (0.186% vs. 0.064%). Additionally, there were 23 surgeons who performed at least 50 total knee replacements both with and without a space suit. There was almost a tenfold increase in the rate of early revision because of deep infection in those who used a space suit $(0.251\%$ compared with 0.028% ⁴⁴. These findings were particularly compelling because of the large sample size, specific focus on infection rates, and ability to account for the surgeons' experience. A summary of the key findings and other pertinent literature is presented in Table 1 below²⁵.

Table $1 - A$ summary of the space suit literature²⁵

1.4 Causes of increased infection rates

Various hypotheses have been put forward to explain these increased rates, including decreased spatial awareness, which makes it easier to contaminate oneself, and the exhaust emissions of space suits. Surgeons surveyed in the 2011 New Zealand registry study agreed with the spatial awareness issue. Studies have also shown that these suits regularly become contaminated with bacteria capable of causing prosthetic joint infections during the course of surgery and routine contact with all parts of the suit including headgear should be avoided^{27,} 28 . Recent studies looking at the gown/glove interface have shown that it is prone to particle contamination and may serve as a route for particles on the surgeons hand to escape onto the surgical field $^{25, 26}$.

Despite these numerous hypotheses and the strong epidemiological evidence linking space suits and infection, to date no studies have compared particle or microbiological emission rates between space suits and standard surgical clothing as a potential mechanism to explain the increased rates of infection recently reported.

1.5 Hypothesis and Aim

This study aimed to assess the emissions of space suits and standard surgical clothing in a laboratory based setting by creating a simulated surgical environment. The null hypothesis tested was that there is no difference in particle or microbiological emission rates between space suits and standard surgical clothing.

Chapter 2: Materials and Methods

2.1 The simulated surgical environment

This study was conducted in a laboratory-based setting at the Prince Charles Hospital, Chermside, Australia and Queensland University of Technology, Brisbane, Australia between September 2011 and January 2015. Data was collected prospectively in a simulated surgical environment, designed to replicate actual operating theatre conditions and custom-built for the investigation of particle sources during five separate experiments.

The simulated surgical environment consisted of an airtight spirometry chamber with dimensions measuring 2.1 x 0.9 x 0.85 m. The internal volume of the chamber measured 1.6 $m³$. A circular inlet measuring 17 cm in diameter was cut in the roof of the chamber (Figure 2). The inlet was connected to a high efficiency particulate air (HEPA) filtered air supply from a large filter bank and fan unit via aluminium tubing measuring 15cm in diameter (Figure 3). HEPA filtered clean air was thus introduced into the chamber constantly to ensure there was no confounding influences from ambient room air, and that activities in the chamber were the only source of particles and bacteria. The quality of the air was verified by checking that there was a zero particle count prior to each experiment using two optical particle counters (Chapter 2.2). The chamber operated at a slightly higher air pressure than the surrounding room to prevent ingress of room air. This was verified using tracer smoke. A circular outlet measuring 16cm in diameter was cut at a low point on the front wall of the chamber 10cm above the floor (Figure 4). Electrically conductive rubber tubing measuring 4mm in diameter was attached at this outlet, and attached to a T-shaped bifurcation that channelled air towards two separate particle counters. A steel hook was also attached to the underside of the roof of the chamber to allow suspension of clothing for unequipped clothing testing.

Figure 2 – Spirometry chamber and inlet.

Figure 3 – HEPA filtered clean air supply.

Figure 4 – Spirometry chamber and outlet

2.2 Measurement Devices

Particle counting was performed with two instruments, the Lasair II 110 optical particle counter (OPC) (Lasair, Korskildelund, Greve, Denmark) and the TSI 3312A ultraviolet aerodynamic particle sizer (UVAPS) (TSI, Shoreview, MN, USA) (Figures 5 & 6). The use of both these counters has been reported in other similar studies analysing air quality^{40-42, 45}. The instruments were used together to ensure the widest possible range of particle sizes was captured. The OPC analysed particles between 0.1µm and 5.0µm with channel sizes (lower boundary) of 0.1μ m, 0.2μ m, 0.3μ m, 0.5μ m, 1.0μ m and 5.0μ m. The UVAPS analysed particles between 0.5µm and 20 µm. Due to the high levels of noise and low detection efficiency of channel sizes below 0.523µm and channel sizes above 15µm, these measurements were excluded. This left channel sizes of 0.542µm, 0.583µm, 0.626µm, 0.673µm, 0.723µm, 0.777µm, 0.835µm, 0.898µm, 0.965µm, 1.037µm, 1.114µm, 1.197µm, 1.286µm, 1.382µm, 1.486µm, 1.596µm, 1.715µm, 1.843µm, 1.981µm, 2.129µm, 2.288µm, 2.458µm, 2.642µm, 2.839µm, 3.051µm, 3.278µm, 3.523µm, 3.786µm, 4.068µm, 4.371µm, 4.698µm, 5.048µm, 5.425µm, 5.829µm, 6.264µm, 6.732µm, 7.234µm, 7.774µm, 8.354µm, 8.977µm, 9.647µm, 10.37µm, 11.14µm, 11.97µm, 12.86µm, 13.82µm and 14.86µm for the UVAPS. Measurements were made by both particle counters at 10 second intervals.

Figure 5 – OPC particle counter

Figure 6 – UVAPS particle counter

Microbiological analysis was performed in addition to particle counting as differences in microbiological counts are far more likely to derive from the individual within the surgical clothing rather than from the sterile surgical clothing itself. To sample air for microbiological analysis, a Thermo Scientific six-stage viable Andersen cascade impactor (Waltham, MA, USA) was also placed at the spirometry chamber outlet. The lower cut-point of the six size channel was 0.6μ m, 1.1μ m, 2.1μ m, 3.3μ m, 4.7μ m and 7.0μ m. A pump drew 28.3 L/min of air through the impactor. Air was sampled onto Tryptone soya agar plates on each size stage (Biomerieux*,* Marcy*-*l*'*Étoile, Lyon, France) which have previously been used in similar experiments^{40, 42}. Plates were sent immediately for microbiological analysis on the day of the experiment and incubated for 48 hours at 37°C in air. Colony counts were performed at 24 and 48 hours, except for the first experiment where counts were only performed at 24 hours. Bacterial subtyping was also done but only for the first experiment. Aspiration (eg sampling) efficiency calculations were performed for all channel sizes on both the particle counters and the air sampler (Appendix). These calculations showed lower efficiencies with the larger particle sizes.

Figure 7 – Andersen cascade impactor and pump

A hot-wire anemometer (TSI model 9535, Shoreview, MN, USA) was used to measure the air velocity at the spirometry chamber outlet where the particle and microbiological samples were collected. This allowed the volume flow of air during each test to be calculated in order to determine the mean emission rate of particles and bacteria.

2.3 Experiment Protocol

Five experiments were conducted in total over five separate days. Each experiment involved twelve 40-minute cycles conducted sequentially. This in turn consisted of four separate cycle conditions that were tested three times each in a computer randomised order on the day of testing. The four separate cycles tested were identical apart from the type of surgical head gear used and whether or not a surgeon was present inside the suit. For every experiment, the surgeon wore the same pair of cotton surgical scrub trousers/shirts with Work Bistro Vent Clog shoes (Crocs, Niwot, CO, USA) along with for each cycle new sets of:

1) Kimberley-Clark large standard surgical gowns (Kimberley-Clark, Roswell, GA, USA).

2) Ansell Gammex PF surgical gloves (Ansell, Richmond, Victoria, Australia).

3) Sentry Medical shoes covers (Sentry Medical, Eastern Creek, NSW, Aus).

4) Sentry Medical surgical caps (Sentry Medical, Eastern Creek, NSW, Aus).

The two different types of surgical head gear used were either:

1) The combination of a Kimberley Clark Balaclava Hood and Kimberley Clark Fluid-Shield surgical mask (Kimberley-Clark, Roswell, GA, USA).

2) The Stryker T3 Sterishield Helmet and Stryker T3 Sterishield Hood Cover (Stryker Instruments, Kalamazoo, MI, USA).

A plastic stool was always present in the chamber. A steel frame was used to suspend the clothing and was used when the surgeon was not present in the chamber. The purpose of this was to obtain baseline particle shedding data from each type of clothing when it was not being worn, and therefore enabling this to be accounted for in the tests when it was worn. The four cycles and exact items entering the spirometry chamber for each experiment were:

1) Space suit equipped - surgeon, scrub trousers, scrub shirt, shoes, surgical gown, surgical gloves, shoe covers, surgical caps, space suit helmet, space suit hood cover (Figure 8).

3) Space quite unequipped - steel frame, scrub trousers, scrub shirt, shoes, surgical gown, surgical gloves, shoe covers, surgical caps, space suit helmet, space suit hood cover (Figure 9).

2) Standard surgical gown equipped – surgeon, scrub trousers, scrub shirt, shoes, surgical gown, surgical gloves, shoe covers, surgical caps, balaclava hood, surgical mask (Figure 10).

4) Standard surgical gown unequipped – steel frame, scrub trousers, scrub shirt, shoes, surgical gown, surgical gloves, shoe covers, surgical caps, balaclava hood, surgical mask (Figure 11).

Figures 8 – Space suit clothing equipped Figure 9 – Space suit clothing unequipped

Figures 10 – Standard surgical clothing equipped Figures 11 – Standard surgical clothing unequipped

In order to best simulate operating theatre conditions, the same set of scrubs and shoes were used during each experiment, but all other items of clothing were changed for each cycle. Thus, twelve sets of gowns/gloves/shoe covers/surgical caps, six masks/balaclavas and six hood covers were used for each individual experiment. The same space suit helmet was used for all cycles/experiments and was cleaned with 70% ethanol after every cycle.

On each separate day prior to commencement of the cycles, the HEPA filter fan unit was allowed to initially run for a total of two hours to flush the spirometry chamber and ensure a steady flow rate. Each cycle involved the surgeon entering the spirometry chamber fully clothed with a particular type of surgical clothing or suspension of a particular type of surgical clothing within the chamber. The chamber was then sealed with the surgeon/clothing inside and a total of twenty minutes was allowed to elapse before sampling was commenced to allow particle counts to return to baseline and all external air that had entered from opening of the door to be washed out, as confirmed by the real-time OPC and UVAPS data. Prior to each cycle, the chamber was wiped clean with 70% ethanol and also vacuumed. Sampling periods in total lasted twenty concurrent minutes for both particle counters and the impactor.

During each twenty minute sampling period, at one minute intervals for a total of thirty seconds, the surgeon would perform a standardised set of upper body movements to simulate an actual surgeon's movements. These consisted of five sets of movements performed for thirty seconds each in fixed consecutive sequence with a break of 30 seconds in between movements. The surgeon's hands were otherwise always held at chest height and apart at shoulder length. The movements performed were:

1) Sagittal plane movements (front to back) of the hands for a distance of 30cm, with movements once every second.

2) Coronal plane movements (side to side) of the hands for a distance of 30cm, with movements once every second.

3) Axial plane movements (up and down) of the hands for a distance of 30cm, with movements once every second.

4) Clockwise movements of the hands around a diameter of 30cm, with movements once every second.

5) Clockwise movements of the hands around a diameter of 30cm, with movements once every second.

The unequipped space suits and standard surgical gowns were not manipulated in any way and allowed to sit still while suspended from the hook in the ceiling of the chamber.

2.4 Emission rate analysis

The mean emission rate (ER) of particles and bacteria numbers was determined for each experiment and condition via the formula:

$$
ER = C_{mean} V/t
$$

where ER is the mean particle number (particles/sec), or microbiological (bacterial CFU/sec) emission rate, C_{mean} is the arithmetic mean particle number (particles/m³) or bacterial $(CFU/m³)$ concentration during the measurement, V is air volume that flowed past the sample point during the measurement (m^3) , and t is the duration of the measurement (sec). This formula has been used for similar experiments previously⁴⁵.

Statistical analysis of data was performed for each experiment using descriptive analysis and a univariate general linear model in the Statistical Package for the Social Sciences Version 22 (SPSS, IBM, Armonk, NY, USA). The primary comparisons made were between equipped space suits versus equipped standard surgical clothing and unequipped space suits versus unequipped standard surgical clothing. In addition to standard analysis of overall results from both particle counters, a separate analysis of the larger channel sizes (0.5 µm, 1.0 µm and 5.0µm) for the OPC was done, as this size range includes particles that have been associated with the ability to carry and seed bacteria²³. Results were analysed separately for each experiment as subtle variations in flow velocities and surgeon particle counts on each experimental day made a combined analysis invalid.

Chapter 3: Results

3.1 Particle Emission Rates

The results of this study show statistically significant increases in particle emission rates (PER) when space suits are used compared with standard surgical clothing. This finding was independent of whether the type of clothing was being worn or not, although the increase in particle count was found to be more profound when the clothing was worn. This was a constant finding in all experiments, except in experiment one, which showed inconsistent findings trending towards an increase in PER with space suits. Tables 2-6 below show the mean, standard deviation, minimum and maximum PER for each particle counter during each experiment. Statistical comparisons of PERs between 1) equipped space suits versus equipped standard surgical clothing and 2) unequipped space suits versus unequipped standard surgical clothing for each particle counter in all the experiments is then shown in Tables 7-12. Figures 12-17 provide graphs of this combined information.

3.1.1 Experiment results

Table 2 – Particle emission rates for experiment 1

Table 3 – Particle emission rates for experiment 2

Table 4 – Particle emission rates for experiment 3

Table 5 – Particle emission rates for experiment 4

Table 6 – Particle emission rates for experiment 5

3.1.2 Statistical Comparison

UVAPS:

Table 7 – UVAPS particle emission rates equipped Table 8 – UVAPS particle emission rates space space suit vs standard unequipped suit vs standard

OPC (All Particle Sizes):

OPC (Large Particle Sizes):

Table 11 – OPC Large particle emission rates equipped Table 12 – OPC Large particle emission rates space suit vs standard unequipped space suit vs standard

3.1.3 Combined Graphs

UVAPS:

Figure 12 – Mean of UVAPS particle emission rates equipped space suit vs standard

Figure 13 – Mean of UVAPS particle emission rates unequipped space suit vs standard

OPC (All Particles):

Figure 14 – Mean of OPC All particle emission rates equipped space suit vs standard

Figure 15 – Mean of OPC All particle emission rates unequipped space suit vs standard

OPC (Large Particles):

Figure 16 – Mean of OPC Large particle emission rates equipped space suit vs standard

Figure 17 – Mean of OPC Large particle emission rates unequipped space suit vs standard

3.2 Microbiological emission rates

The results of this study show statistically significant increases in microbiological emission rates (MER) when equipped space suits are used compared with standard surgical clothing. Low/absent microbiological counts made statistically significant comparisons of unequipped surgical clothing type impossible. This was a constant finding in all experiments, except experiment one, which also showed low microbiological counts preventing a statistically significant analysis of results even when surgical clothing was equipped, although the trend was towards increases in microbiological emission rates when equipped space suits were used compared to equipped standard surgical clothing. These microbiological findings are consistent with the particle counts results. The 8 bacterial colonies cultured and subtyped in the first experiment consisted of four coagulase negative staphylococcus species, one gram positive micrococcus species, one gram negative bacillus

species and one gram positive corynebacterium species. Tables 13-17 below show the mean, standard deviation, minimum and maximum MER for each experiment at 24 and 48 hours. Statistical comparisons of MER between equipped space suits versus equipped standard surgical clothing at 24 and 48 hours in all the experiments is then shown in Tables 18 and 19. Figures 18 and 19 provide graphs of this combined information.

3.2.1 Experiment Results

Table 13 – Microbiological emission rates for experiment 1

Table 14 – Microbiological emission rates for experiment 2

Table 15 – Microbiological emission rates for experiment 3

Table 16 – Microbiological emission rates for experiment 4

		Clothing			
		Spacesuit		Standard	
		Equipped	Unequipped	Equipped	Unequipped
Micro Emission Rate	Mean	2.64×10^{-5}	$\bf{0}$	8.22×10^{-6}	$\bf{0}$
(24 hours) (CFU/sec) Micro Emission Rate (48 hours) (CFU/sec)	Std Dev	$1.88 \ge 10^{-6}$	$\mathbf{0}$	3.23×10^{-6}	$\mathbf{0}$
	Minimum	2.48×10^{-5}	$\mathbf{0}$	5.44×10^{-6}	$\mathbf{0}$
	Maximum	2.85×10^{-5}	$\boldsymbol{0}$	1.18×10^{-5}	$\mathbf{0}$
	Mean	$1.68 \ge 10^{-5}$	$\bf{0}$	6.23×10^{-6}	$\bf{0}$
	Std Dev	2.55×10^{-6}	$\mathbf{0}$	2.69×10^{-6}	$\mathbf{0}$
	Minimum	1.42×10^{-5}	$\mathbf{0}$	4.23×10^{-6}	$\boldsymbol{0}$
	Maximum	1.93×10^{-5}	$\mathbf{0}$	9.28×10^{-6}	$\mathbf{0}$

Table 17 – Microbiological emission rates for experiment 5

3.2.2 Statistical Comparison

Table 18 – Microbiological emission rates at 24 hours

Table 19 – Microbiological emission rates at 48 hours

3.2.3 Combined graphs

Microbiological Emission Rates Graphs:

Figure 18 – Mean of microbiological emission rates at 24 hours

Figure 19 – Mean of microbiological emission rates at 48 hours (Experiment 1 not read at 48 hours)

Chapter 4: Discussion

4.1 Increased emission rates

This study is the first to examine particle and microbiological emission rates of space suits and standard surgical clothing. Overall, the results show a statistically significant increase in particle and microbiological emission rates when space suits are used compared to standard surgical clothing, especially when the space suits are worn during simulated operating procedures.

There are a number of explanations for the increased emission rates seen with the use of space suits. The first has previously been discussed in the literature and relates to the positive pressure environment created by the space suit²⁵. Space suit systems have an intake valve on the helmet itself, which draws air in from outside using the hood material as a filter. The air is then blown down across the surgeon's face, neck and body, creating a positive pressure environment inside the surgeon's gown, continually expelling particles that are generated within the suit, such as desquamated skin cells, externally into the operating environment and potentially the surgical field²⁵.

The predecessor of the space suit, the body exhaust suit, was designed with outlet tubing connected to the suit designed to extract air from within the gown and away from the surgical field, thus creating a negative pressure environment. Overall, the literature has shown results in favour of these negative pressure body exhaust suits, with a significant reduction in infection rates, particle counts and bacterial counts at the surgical site and within the operating environment when compared to standard surgical clothing^{21, 22, 29-32, 37}. This is in contrast to the literature assessing the use of space suits, which has shown either no significant reduction in particle and bacteria counts when space suits are used compared to standard surgical clothing and at times even increased infection and particle contamination rates, which the findings of this current study would support 25, 26, 34, 36-38, 44.

Another explanation for the increased emission rates may relate to the increased amount of clothing material involved when space suits are used. The hoods on the Stryker T3 hoods (Stryker Instruments, Kalamazoo, MI, USA) measure more than 50 x 70cm. This creates a separate interface generating particles within the surgical gown that could be responsible for additional particles being emitted. That is, there is a greater surface area of the wearer's body in contact with the suit, and a greater surface area in contact between the surgical gown material and the space suit hood, thus leading to increased particle shedding. However, this mechanism alone could not have been entirely responsible for the results of this study, as the magnitude of difference in emission rates between space suits and standard surgical clothing was consistently greater when the suits were worn compared to when they were not, suggesting other causes were also responsible

The lack of face and head coverage provided by space suits may also have contributed to increased emission rates. Standard surgical headgear used during joint arthroplasty surgery involves a balaclava similar to the one used in this study that covers most of the surgeon's forehead, ears and eyebrows. Space suit helmets and hoods do not routinely cover these areas unless additional headgear is worn. Studies have shown that there are a significant amount of potentially harmful bacteria and squames present on a surgeon's foreheads, eyebrows, and ears particularly⁴⁶. The lack of coverage provided by space suits in combination with the positive pressure environment that is created may thus be responsible for the increased emission rates.

A final possible explanation for the increased emission rates relates to spatial awareness issues that arise when space suits are used. Although meticulous attention was paid to the simulated surgeon's surroundings within the spirometry chamber, contact of the surgeons hands with the hood or the sides of the chamber may due to decreased spatial awareness may have resulted in additional particles being generated. This concern has been raised by surgeons surveyed previously 44 .

The clinical significance of the emissions observed in this study is unclear, but the literature suggests that they are likely to be of importance. Studies have shown that theatre staff and their emissions are thought to be the primary source of microbial contamination in up to 98 % of cases $46, 47$. It has also been shown that space suit emissions specifically are not merely expelled randomly into the operating theatre environment but do in fact reach the surgical site^{25, 26}. There is also a clear correlation between air quality and infection rates²¹⁻²⁴.

4.2 Limitations of study

There are a number of limitations to this study. Firstly, large variations exist between particle emission rates of the experiments. This variation is up to tenfold when comparing

certain experiments (one and five for example). It is difficult to explain this variation. Causes include varying levels of surgeon skin contamination on the day of each experiment, varying levels of surgical scrub particle content and contamination used for each experiment and varying levels of chamber contamination during each experimental day. Surgeon skin contamination could have been controlled more accurately using a strict and consistent personal hygiene and grooming routine (such as showering/shaving) at the same time on day of the experiment; this was not done. Similarly, varying levels of surgical scrub particle content and contamination could have been standardised by following a regimented laundry regime, which was again not performed. Finally, attempts were made to control levels of chamber contamination during each experimental day with a structured cleaning routine of the chamber, but it is plausible that minor variations in chamber cleaning could have contributed to the varying rates between experiments. However, regardless of these influences because each space suit and standard clothing test was done on the same day, the relative differences between the two should be retained. This is bolstered by the observation of a relatively consistent trend showing increased emission rates of space suits compared with standard surgical clothing in all the experiments.

Another limitation of this study is its laboratory-based nature. Clinical studies conducted during actual total hip and knee replacements are the current gold standard for investigating factors associated with prosthetic joint infection. The feasibility in performing such studies is limited though due to the current low rates of infection and the large number of participants that would be required for a clinical trial. The correlation between the importance of air quality and infection rates has been proven previously on multiple occasions, and laboratory based studies such as the current study using air particle and bacterial counts as surrogate markers for actual prosthetic joint infection rates still have relevance²¹⁻²⁴. Moreover, this study was able to account for the confounding influence of

non-clothing particle/bacteria sources by using HEPA filtered supply air. This would be exceedingly difficult under real world operating conditions.

The results of the first experiment were not consistent with the other four experiments. There was no consistent statistically significant relationship between type of clothing and the particle/microbiological emission rate (with particle emission rates at times even showing an opposite effect). The cause of this is unclear, but it may be attributed to the large variations in velocity found in the first experiment and the high overall velocity, which may have diluted the concentration of particles and bacteria that was able to be detected (Appendix 1). This is also reflected by the fact that overall particle counts were much lower in the first experiment compared with the other four experiments. The experience of the first experiment allowed the velocity to be adjusted in prior experiments.

Microbiological speciation was only performed for one experiment. This raises a question regarding the significance of the total CFU counts, as only organisms capable of causing prosthetic joint infection are likely to be relevant. The organisms grown during the solitary experiment all showed some degree of virulence and have previously been reported as causative organisms for prosthetic joint infection, thus proving that the CFU data and bacterial emissions may be a good proxy for pathogenic bacteria¹¹. However, an analysis of microbiological growth performed for all the experiments would have undoubtedly added to the power of this study.

The low aspiration efficiency of both the particle counters, particularly with larger particles may also be considered a weakness of this study (Appendix 1). Measures were taken to overcome this such as using tubing that was as short as possible and employing lower and more consistent velocities from the HEPA filter/fan source. The result of the low aspiration efficiency of these higher particle sizes may have resulted in the effect of space suit use on

large particles being underestimated by this study. This is of clinical significance, as it is these larger particles that have been associated with particle attached or stand-alone b acteria²³. The findings here may thus be underestimates of true bacteria emissions, which adds additional weight to the significance.

4.3 The future of space suits

Advocates of space suits describe two main reasons for their use, prosthetic joint infection prevention and personal protection. This study and the majority of studies in the literature support either an equivalent or detrimental effect of space suits with regards to

infection prevention. The use of space suits for personal protection has more merit, with studies showing a high rate of surgeon and clothing contamination with the surgical site as the primary source during total knee and hip arthroplasty^{48, 49}. The recent literature on space suits and their role in the surgical setting has suggested that space suits should be used primarily as a form of self-protection and not as an infection prevention tool⁴⁴.

Based on the findings of this study and the potential explanations, surgeons who choose to use space suits as a form of self-protection can implement a number of steps to potentially reduce the potential for causing infection. Firstly, all gown interfaces which could serve as an external conduit for emissions, particularly those coming into close contact with the surgical field such as the surgeon's hands (gown/glove interface) should be sealed air tight, and exhaust air routed through a single pathway which is either filtered or discharged such that it cannot contaminate the surgical field. This has been highlighted in the literature recently, with measures such as sealant tape having been recommended^{25, 26}. Further headgear should be used to cover as much as the surgeon's face as possible including ears and eyebrows, such as the balaclava used with standard surgical clothing. Surgeons using space suits should also pay meticulous attention to their surroundings and have a heightened sense of spatial awareness. Unnecessary movements generating excess particles should also be avoided.

Modification to current space suit instrumentation and other operating room equipment may also potentially help reduce emission rates. Bulky space suit helmets and hoods should be modified, and excessive hood material should be avoided. A translucent hood material may help with a surgeon's spatial awareness. Negative pressure suits with outlet tubing are no longer commercially available but modifications to existing suits such as the implementation of an exhaust fan within the gown that expels emissions towards a specific location away from the surgical field may also be useful.

The use of laminar flow systems and similar devices which blow clean air onto and away from the surgical field may also be of benefit. Large clinical studies dating back to Lidwell's trial in the 1970s showed lower infection rates (1.5% vs 0.56%) when laminar flow was used in conjunction with modified surgical clothing (body exhaust suits)^{21, 22}. Recent nationwide registry data has also shown a slight but clinically significant reduction in infection rates when space suits are used in laminar flow theatres compared to conventionally ventilated theatres. A combination of these measures should be employed to limit the effect of the potentially harmful emissions of space suits when they are used.

The potential exists for a number of different areas to be researched based on the findings of this study. A study assessing the flow of bioaerosols emitted by surgeons and surgical clothing has yet to be performed. The clinical significance of bioaerosols and their impact on prosthetic joint infection rates also requires further research. Finally, a comparison between positive and negative pressure clothing systems (ie body exhaust suits and space suits) would be of value, as this is an important mechanism contributing to the results of this study.

4.4 Conclusion

Orthopaedic prosthetic joint infection rates may be affected by the emissions of orthopaedic surgical clothing. This study compared the emission rates of space suits to standard surgical clothing, via laboratory based methods of particle and microbiological counting, in a simulated surgical environment. The results of this study consistently showed statistically significant increases in particle and microbiological emission rates when space suits are used compared with standard surgical clothing. These findings can be used to inform the choices made by surgeons about their clothing. Surgeons should proceed with caution when using space suits during surgery, particularly total joint arthroplasty.

Chapter 5: References

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Chapter 6: Appendix

Aspiration efficiency calculations were performed for all channel sizes on both the particle counters and the air sampler based on standard methods for calculating aerosol transport in sampling lines and inlets⁵⁰.

Velocities:

 $Vi = Air$ velocity in the inlet

 $Vw = Velocity range through the chamber exit where the sampling head was placed for all$ experiments combined:

Velocity mean/range per experiment:

1) 0.775 m/s (0.40-.0.92 m/s)

2) 0.464 m/s (0.43-0.48 m/s)

3) 0.416 m/s (0.40-0.44 m/s)

4) 0.431 m/s (0.42-0.45 m/s)

5) 0.409 m/s (0.40-0.43 m/s)

Thus range (Vw) = $0.409 - 0.775$ m/s

Tube Lengths:

Common sample tube - 237mm

OPC tube - 448mm

UVAPS tube - 417mm

UVAPS/OPC Measurements:

Flow rate UVAPS – 5 litres/min

Flow rate OPC – 28.3 litres/min

Flow rate combined -33.3 litres/min

Inlet Diameter – 0.004m

Air velocity in the inlet (Vi) - 44.20970641441095007627071495526 metres/sec

Andersen Measurements:

Flow Rate -28.3

Inlet Diameter – 0.025

Air velocity in the inlet (Vi) - 0.96087144309346943912388539301682 metres/sec

Vw/Vi - 0.425655277 to 0.80655951

Aspiration Efficiencies:

OPC:

0.1µm - 0.999382448% to 0.999371663%

0.2µm - 0.998394334% to 0.998366335%

0.3µm - 0.996991085% to 0.996938731%

0.5µm - 0.992918997% to 0.99279656%

1.0µm - 0.975669038% to 0.975259554%

5.0µm - 0.645265672% to 0.642400684%

UVAPS:

- 0.542µm 0.99185229% to 0.991711641%
- 0.583µm 0.990741324% to 0.990581773%
- 0.626µm 0.989502842% to 0.989322296%
- 0.673µm 0.988064051% to 0.987859217%
- 0.723µm 0.98643681% to 0.986204642%

0.777µm - 0.984568763% to 0.984305388% 0.835µm - 0.98243597% to 0.982137196% 0.898µm - 0.979973117% to 0.979633766% 0.965µm - 0.977189524% to 0.976804703% 1.037µm - 0.97401279% to 0.973576582% 1.114µm - 0.970407324% to 0.969913447% 1.197µm - 0.96628576% to 0.965726809% 1.286µm - 0.961602624% to 0.960970834% 1.382µm - 0.956254985% to 0.95554145% 1.486µm - 0.950127578% to 0.949322255% 1.596µm - 0.943284553% to 0.942379086% 1.715µm - 0.935483037% to 0.934466443% 1.843µm - 0.926655369% to 0.92551694% 1.981µm - 0.916665386% to 0.91539408% 2.129µm - 0.905448926% to 0.904034751% 2.288µm - 0.892872292% to 0.891305872% 2.458µm - 0.878887406% to 0.877161548% 2.642µm - 0.863204774% to 0.861312453% 2.839µm - 0.845882646% to 0.843821592% 3.051µm - 0.826744956% to 0.824515928% 3.278µm - 0.805820108% to 0.803429546% 3.523µm - 0.782894245% to 0.780353191% 3.786µm - 0.758072302% to 0.755399484% 4.068µm - 0.731416689% to 0.728638393% 4.371µm - 0.702949063% to 0.700099229% 4.698µm - 0.672659913% to 0.669780483%

5.048µm - 0.640972475% to 0.638113293%

Andersen:

- 0.85µm 0.999913961% to 0.999955991%
- 1.6µm 0.99971859% to 0.999856083%
- 2.7µm 0.999229974% to 0.99960637%
- 4.0µm 0.998344319% to 0.999154307%
- 5.85µm 0.996514432% to 0.998222567%
- 7.0µm 0.995044745% to 0.997476454%