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Surgical Space Suits Increase Particle and Microbiological Emission Rates in a Simulated Surgical Environment. — Source link 🖸

Praveen Vijaysegaran, Luke D. Knibbs, Lidia Morawska, Ross Crawford

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Dr Praveen Vijaysegaran, MBBS/B Med Sci (Melb)/M App Sci (QUT), Dr Luke David Knibbs, BSc (Macq), MPH (Syd), PhD (Macq), Professor Lidia Morawska, MSc (Jagiellonian University), PhD (Jagiellonian University), Professor Ross William Crawford, MBBS (Qld), D Phil (Oxon), FRACS (Orth)



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Surgical space suits increase particle and microbiological emission rates in a simulated surgical environment

Dr Praveen Vijaysegaran, MBBS/B Med Sci (Melb)/M App Sci (QUT)¹

Dr Luke David Knibbs, BSc (Macq), MPH (Syd), PhD (Macq)²

Professor Lidia Morawska, MSc (Jagiellonian University), PhD (Jagiellonian University)^{3,4}

Professor Ross William Crawford, MBBS (Qld), D Phil (Oxon), FRACS (Orth)^{1,4}

1. Faculty of Built Environment and Engineering, School Of Engineering Systems, Queensland University of Technology, Brisbane, Australia.

2. Faculty of Medicine, School of Public Health, The University of Queensland, Brisbane, Australia.

3.International Laboratory for Air Quality and Health, Queensland University of Technology, Brisbane, Australia.

4. Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane, Australia.

Please address all correspondence to:

Professor Ross William Crawford Faculty of Built Environment and Engineering, School Of Engineering Systems, Queensland University of Technology, GPO Box 2434, Brisbane, Queensland 4001, Australia. Phone: 0731394481, Mob: 0417420759 Email: r.crawford@qut.edu.au

4	ABSTRACT				
3	SURGICAL ENVIRONMENT				
2	MICROBIOLOGICAL EMISSION RATES IN A SIMULATED				
1	SURGICAL SPACE SUITS INCREASE PARTICLE AND				

5	BACKGROUND: The role of space suits in the prevention of orthopaedic prosthetic joint				
6	infection remains unclear. Recent evidence suggests space suits may in fact contribute to				
7	increased infection rates, with bioaerosol emissions from space suits identified as a				
8	potential cause. This study aimed to compare the particle and microbiological emission				
9	rates of space suits and standard surgical clothing.				
10	METHODS: A comparison of emission rates between space suits and standard surgical				
11	clothing was performed in a simulated surgical environment during five separate				
12	experiments. Particle counts were analysed with two separate particle counters capable of				
13	detecting particles between 0.1 and 20 μ m. An Andersen Impactor was used to sample				
14	bacteria, with culture counts performed at 24 and 48 hours.				
15	RESULTS: Four experiments consistently showed statistically significant increases in				
16	both particle and microbiological emission rates when space suits are used compared with				
17	standard surgical clothing. One experiment showed inconsistent results, with a trend				
18	towards increases in both particle and microbiological emission rates when space suits				
19	are used compared with standard surgical clothing.				
20	CONCLUSION: Space suits cause increased particle and microbiological emission rates				
21	compared with standard surgical clothing. This finding provides mechanistic evidence to				
22	support the increased prosthetic joint infection rates observed in clinical studies.				
23	KEYWORDS: Orthopaedics; space suit; clean air; arthroplasty; prosthetic joint				
24	infection; emission rates				

INTRODUCTION 25

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26	Total joint arthroplasty is one of the most successful commonly performed				
27	orthopaedic procedures and an effective method of alleviating symptoms associated with				
28	hip and knee osteoarthritis [1-3]. Prosthetic joint infection is a concerning complication				
29	of total hip and knee replacement, with current rates estimated to be between 2.0% and				
30	2.4% over an eight year period in the USA [4]. This is a marked improvement compared				
31	to early arthroplasty series in the 1960s that described rates as high as 10% [5].				
32	This reduction has been attributed to a number of measures that were introduced				
33	at the time, including the formulation of the clean air hypothesis which suggested that the				
34	prosthetic joint might constitute a system uniquely sensitive to infection by a very small				
35	bacterial inoculums derived from airborne particles [5-7]. A multifaceted approach				
36	involving both improved room air ventilation systems incorporating laminar flow and				
37	modified surgical clothing consisting of body exhaust suits were introduced in an effort to				
38	reduce infection rates [5, 6].				
39	Multiple clinical and non-clinical studies supporting the use of body exhaust suits				
40	have since been published, leading to their widespread use [8-14]. These studies have				
41	used air and wound bacterial and particle counts as surrogate markers for infection, as the				
42	number of samples or participants required in a study of statistical significance with the				
43	current low prosthetic joint infection rates would be in the thousands and very difficult				

logistically [10-27]. Body exhaust suits were originally designed with both the air inlet and outlet tubing arranged to create negative pressure inside the gown, ensuring any shed 45 particles are extracted via the outlet tube and released in a controlled manner away from 46 the surgical field, preventing any contamination. However, such tubing is cumbersome, 47

48	which led to the development of more portable 'space suit' systems such as the T4 Steri-				
49	Shield (Stryker Instruments, Kalamazoo, MI, USA), the Provision Surgical Helmet				
50	(DePuy, Warsaw, IN, USA), and Stackhouse FreedomAire (Stackhouse Incorporated,				
51	Palm Springs, CA, USA). With the added benefit of being splash resistant and serving as				
52	a form of self-protection for the surgeon, space suits have now become the most common				
53	form of clean air clothing systems used [28].				
54	In contrast to the proven effectiveness of body exhaust suits, the impact of space				
55	suits on infection rates remains unclear. Recent reports have suggested that space suits				
56	appear to cause increased rates of wound contamination and deep infection compared				
57	with standard surgical clothing [29]. Various hypotheses have been put forward to				
58	explain these increased rates, including decreased spatial awareness, which makes it				
59	easier to contaminate oneself, and also the exhaust emissions of space suits.				
60	To date no studies have compared particle or microbiological emission rates				
61	between space suits and standard surgical clothing as a potential mechanism to explain				
62	the increased rates of infection recently reported.				
63	This study aimed to assess the emissions of space suits and standard surgical				
64	clothing in a laboratory based setting by creating a simulated surgical environment,				
65	providing a mechanistic rationale for the increased infection rates that have been				
66	observed in the literature.				
67	MATERIALS AND METHODS				

68 This study was conducted in a laboratory-based setting at our institution between69 September 2011 and June 2015. Data was collected prospectively in a novel simulated

70 surgical environment, designed to replicate actual operating theatre conditions and custom-built for the investigation of particle sources during five separate experiments. 71 The simulated surgical environment consisted of an airtight flow-through chamber 72 with dimensions measuring 2.1 x 0.9 x 0.85 m, with an internal volume of 1.6 m^3 . A 73 circular inlet measuring 17cm in diameter in the roof of the chamber was connected to a 74 high efficiency particulate air (HEPA) filtered air supply from a large filter bank and fan 75 unit via aluminium tubing. HEPA filtered clean air was thus introduced into the chamber 76 constantly to ensure there was no confounding influences from ambient room air, and that 77 activities in the chamber were the only source of particles and bacteria. The chamber 78 79 operated at a slightly higher air pressure than the surrounding room to prevent ingress of 80 room air. A circular outlet was located on the front wall of the chamber adjacent to the floor. With this configuration, the filtered air entered above and exited below the 81 simulated surgical field. No other air ingress or egress pathways were present in the 82 sealed chamber and therefore all emissions from the surgical clothing were captured, free 83 84 of contamination from other sources. An isokinetic sampling cone attached to electrically 85 conductive rubber tubing measuring 4mm in diameter was attached at the chamber air outlet, and in turn attached to a flow splitter that directed air towards two separate particle 86 87 counters.

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). The use of
both these counters has been reported in other similar studies analysing air quality [25-27,
30]. The instruments were used together to ensure the widest possible range of particle

sizes was captured. The OPC measured particles between 0.1µm and 5.0µm. The UVAPS
measured 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 for
the UVAPS, these measurements were excluded. Measurements were made by both
particle counters at 10 second intervals.

Microbiological sampling was performed in addition to particle counting because 98 particle concentrations alone do not indicate the presence of viable organisms. A Thermo 99 100 Scientific six-stage viable Andersen cascade impactor (Waltham, MA, USA) was also placed at the test chamber outlet., analysing particles between 0.6µm and 7.0 µm. Air was 101 102 sampled onto Tryptone soya agar plates on each size stage (Biomerieux, Marcy-l'Étoile, 103 Lyon, France) which have previously been used in similar experiments [25, 27]. Plates were sent immediately for microbiological analysis on the day of the experiment and 104 incubated for 48 hours at 37°C in air. Colony counts were performed at 24 and 48 hours, 105 except for the first experiment where counts were only performed at 24 hours. Bacterial 106 107 subtyping was also done but only for the first experiment.

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 rates of particles and bacteria.

Five experiments were conducted in total over five separate days. Each
experiment involved twelve 40-minute cycles conducted sequentially. This in turn
consisted of two separate cycle conditions that were tested three times each in a computer

116	randomised order on the day of testing. The two separate cycles tested were identical			
117	apart from the type of surgical head gear. For every experiment, the surgeon wore the			
118	same pair of cotton surgical scrub trousers/shirts with Work Bistro Vent Clog shoes			
119	(Crocs, Niwot, CO, USA) along with for each cycle new sets of:			
120	1) Kimberley-Clark large standard surgical gowns (Kimberley-Clark, Roswell,			
121	GA, USA).			
122	2) Ansell Gammex PF surgical gloves (Ansell, Richmond, Victoria, Australia).			
123	3) Sentry Medical shoes covers (Sentry Medical, Eastern Creek, NSW, Aus).			
124	4) Sentry Medical surgical caps (Sentry Medical, Eastern Creek, NSW, Aus).			
125	The two different types of surgical head gear used were either:			
126	1) The combination of a Kimberley Clark Balaclava Hood and Kimberley Clark			
127	Fluid-Shield surgical mask (Kimberley-Clark, Roswell, GA, USA) – "Standard			
128	Surgical Clothing"			
129	2) The Stryker T3 Sterishield Helmet and Stryker T3 Sterishield Hood Cover			
130	(Stryker Instruments, Kalamazoo, MI, USA) – "Space Suits"			
131	A plastic stool was always present in the chamber. In order to best simulate			
132	operating theatre conditions, the same set of scrubs and shoes were used during each			
133	experiment and cleaned afterwards. All other items of clothing were changed for each			
134	cycle. The same space suit helmet was used for all cycles/experiments and was cleaned			
135	afterwards.			
136	Prior to each cycle, the chamber was wiped clean with 70% ethanol and also			
137	vacuumed. On each separate day prior to commencement of the cycles, the HEPA filter			

138	fan unit was allowed to initially run for a total of two hours to flush the test chamber and				
139	ensure a steady flow rate. Each cycle involved the surgeon entering the spirometry				
140	chamber fully clothed with a particular type of surgical clothing. The chamber was then				
141	sealed with the surgeon inside and a total of twenty minutes was allowed to elapse before				
142	sampling was commenced to allow particle counts to return to baseline and all external				
143	air that had entered from opening of the door to be washed out, as confirmed by the real-				
144	time OPC and UVAPS data. Sampling periods lasted twenty concurrent minutes for both				
145	particle counters and the impactor. During each twenty minute sampling period, the				
146	surgeon would perform a standardised set of upper body movements at one minute				
147	intervals for a total of thirty seconds to simulate an actual surgeon's movements.				
148	The mean emission rate (ER) of particles and bacteria was determined for each				
149	experiment and condition via the formula:				
150	$\mathbf{ER} = \mathbf{C}_{\text{mean}} \mathbf{V} / \mathbf{t}$				
151	where ER is the mean particle number (particles/sec), or microbiological (bacterial				
152	CFU/sec) emission rate, C_{mean} is the arithmetic mean particle number (particles/m ³) or				
153	bacterial (CFU/m ³) concentration during the measurement, V is air volume that flowed				
154	past the sample point during the measurement (m ³), and t is the duration of the				
155	measurement (sec). This formula has been used for similar experiments previously [30].				
156	Statistical analysis of data was performed for each experiment using descriptive analysis				
157	and a univariate general linear model in the Statistical Package for the Social Sciences				
158	Version 22 (SPSS, IBM, Armonk, NY, USA). Comparisons were made between the				
159	space suits and standard surgical clothing. In addition to standard analysis of overall				
160	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 bacteria [31]. 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.
RESULTS

166 Particle Emission Rates

167 The results of this study show statistically significant increases in particle 168 emission rates (PER) when space suits are used compared with standard surgical clothing. 169 This was a consistent finding in all experiments, except in experiment one, which showed 170 inconsistent findings trending towards an increase in PER with space suits. Statistical 171 comparisons of PERs between space suits and standard surgical for each particle counter 172 in all the experiments are shown in Figures 1-3.

173 Microbiological emission rates

The results of this study show statistically significant increases in microbiological 174 emission rates (MER) when space suits are used compared with standard surgical 175 clothing. This was a consistent finding in all experiments, except experiment one, which 176 showed low microbiological counts preventing a statistically significant analysis of 177 results, although the trend was towards increases in microbiological emission rates when 178 space suits were used compared to standard surgical clothing. These microbiological 179 findings are consistent with the particle counts results. The 8 bacterial colonies cultured 180 and subtyped in the first experiment consisted of four coagulase negative staphylococcus 181 182 species, one gram positive micrococcus species, one gram negative bacillus species and

one gram positive corynebacterium species. Statistical comparisons of MER between
space suits and standard surgical clothing at 24 and 48 hours in all the experiments are
shown in Figures 4 and 5.

186 DISCUSSION

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 during simulated operating procedures. These findings support the results of previous studies and provide a mechanistic rationale for the increased rates of wound contamination and deep infection that have been observed [29].

There are a number of limitations to this study. Firstly, large variations exist 194 between particle emission rates of the experiments. This variation is up to tenfold when 195 196 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 197 experiment, varying levels of surgical scrub particle content and contamination used for 198 each experiment and varying levels of chamber contamination during each experimental 199 200 day. Surgeon skin contamination could have been controlled more accurately using a strict and consistent personal hygiene and grooming routine (such as showering/shaving) 201 202 at the same time on day of the experiment; this was not done. Similarly, varying levels of 203 surgical scrub particle content and contamination could have been standardised by following a regimented laundry regime, which was again not performed. Finally, attempts 204 were made to control levels of chamber contamination during each experimental day with 205

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 remain.
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.

213 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 214 215 investigating factors associated with prosthetic joint infection. The feasibility of 216 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 217 between the importance of air quality and infection rates has been proven previously on 218 multiple occasions, and laboratory based studies such as the current study using air 219 220 particle and bacterial counts as surrogate markers for actual prosthetic joint infection rates still have relevance [8, 9, 31, 32]. Moreover, this study was able to account for the 221 confounding influence of non-clothing particle/bacteria sources by using HEPA filtered 222 supply air. This would be exceedingly difficult under real world operating conditions. 223 The results of the first experiment were not consistent with the other four experiments. 224 225 There was no consistent statistically significant relationship between the type of clothing 226 and the particle/microbiological emission rate (with particle emission rates at times even 227 showing an opposite effect). The cause of this is unclear, but it may be attributed to the 228 large variations in air 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. 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.

There are a number of explanations for the increased emission rates seen with the use of space suits. The first relates to the positive pressure environment created by the space suit. Space suit systems have an intake valve on the helmet itself, which draws air in from outside using the disposable 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 into the operating environment and onto the surgical field [15].

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 for generating particles within the surgical gown that could be responsible for additional particles being emitted, thus leading to increased particle shedding.

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

surgeon's foreheads, eyebrows, and ears particularly [34]. The lack of coverage providedby 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 due to decreased spatial awareness may have resulted in additional particles being generated. This concern has been raised by surgeons surveyed previously [33].

Advocates of space suits describe two main reasons for their use, prosthetic joint 261 infection prevention and personal protection. This study and the majority of studies in the 262 263 literature support either an equivalent or detrimental effect of space suits with regards to 264 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 265 as the primary source during total knee and hip arthroplasty [34, 35]. The recent literature 266 on space suits and their role in the surgical setting has suggested that space suits should 267 be used primarily as a form of self-protection and not as an infection prevention tool [33]. 268

Based on the findings of this study and their potential implications, 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 [15, 16]. 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. 281 Modification to current space suit instrumentation and other operating room equipment 282 may also potentially help reduce emission rates. Bulky space suit helmets and hoods 283 284 should be modified, and excessive hood material should be avoided. A translucent hood 285 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 286 the implementation of an exhaust fan within the gown that expels emissions towards a 287 specific location away from the surgical field may also be useful. The use of laminar flow 288 systems and similar devices which blow clean air onto and away from the surgical field 289 290 may also be of benefit. Large clinical studies have shown lower infection rates (1.5% vs 0.56%) when laminar flow is used in conjunction with modified surgical clothing (body 291 292 exhaust suits) [8, 9]. Recent nationwide registry data has also shown a slight but 293 clinically significant reduction in infection rates when space suits are used in laminar flow theatres compared to conventionally ventilated theatres. A combination of these 294 295 measures should be employed to limit the effect of the potentially harmful emissions of 296 space suits when they are used.

297 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 particles and bacteria emitted by 298 surgeons and surgical clothing has yet to be performed. While particles derived from the 299 skin and clothing of surgeons have been shown to carry both aerobic and anaerobic skin 300 bacteria capable of causing infections[31], the clinical significance of different thresholds 301 of particle and microbiological emission rates and their impact on prosthetic joint 302 303 infection rates specifically also requires further research. Finally, a comparison between 304 positive and negative pressure clothing systems (i.e. body exhaust suits and space suits) would be of value, as this is an important mechanism contributing to the results of this 305 306 study.

307 CONCLUSION

308 Orthopaedic prosthetic joint infection rates may be affected by the emissions of 309 orthopaedic surgical clothing. This study compared the emission of space suits to standard surgical clothing, via laboratory based methods of particle and microbiological 310 counting, in a simulated surgical environment. The results of this study consistently 311 312 showed statistically significant increases in particle and microbiological emission rates when space suits are used compared with standard surgical clothing. These findings 313 provide mechanistic evidence to support the findings of large epidemiological studies 314 reporting higher infection rates, and can be used to inform the choices made by surgeons 315 316 about their clothing. Surgeons should proceed with caution when using space suits during surgery, particularly total joint arthroplasty. 317

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Figure Legends

- Figure 1: Mean of UVAPS particle emission rates space suit vs standard
- Figure 2: Mean of OPC All particle emission rates space suit vs standard
- Figure 3: Mean of OPC Large particle emission rates space suit vs standard
- Figure 4: Mean of microbiological emission rates at 24 hours
- Figure 5: Mean of microbiological emission rates at 48 hours (Experiment 1 not read at 48 hours)



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