Evaluation of an air cleaner device in an operating room

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Objectives: To test the hypothesis that the use of a portable stand-alone air cleaner in an operating room environment is effective in reducing airborne bioburden in the environment.
Design: Single centre, one location within the centre, two sampling conditions (control and test), two samping time periods (pre- and post-operation), with a total of 60 control and 60 test samples, collected over three different dates, non-randomized trial.
Setting: One healthcare facility, one environment within the facility: operating room.
Intervention: Use of one Novaerus/Wellair Defend NV400 air cleaner set to process air at an airflow rate of 210 CFM (356 m^3/h) at the named location within the healthcare setting.
Main outcome measure(s): Measure of airborne bioburden as bacterial colony forming units (CFU/m^3) from air samples collected during control and test conditions, pre- and post-operation times, and identification of most prominent species found in air samples.
Results: Post-operation total colony counts saw a reduction of 56.7% between control and test samples (p-value 0.003432). Identification of 1 bacterial pathogen and 19 bacterial opportunistic pathogens.
Conclusions: The use of a portable stand-alone air cleaner in an operating room has shown substantial reduction in airborne bacterial bioburden overall.

Keywords: Air cleaner, airborne bioburden, air sampling, operating room, field testing

I. INTRODUCTION

Recent Public Health Emergency of International concern announcements have highlighted a need for better methods of cleaning, sanitation and infection control (WHO 2022). This concern extends to indoor air quality and its potential as a mode of transmission of infections and diseases. It is quite clear to state that exposure to potentially harmful microorganisms particularly during operations may have serious effects on patients. This effect can be influenced by the type of microorganism, such as human pathogens, be it a virus, bacteria or fungi species. It may also depend on exposure time, the concentration/numbers, virulence and toxicity of that microorganism.

Here we report the use of a portable air cleaner in an operating room in a healthcare setting. The aim of the present study is to measure airbone bioburden and to evaluate the effectiveness of a portable air cleaner in reducing the bioburden levels. In general, it is expected that lower airborne bioburden shall result in lower number of infections occurring on-site.

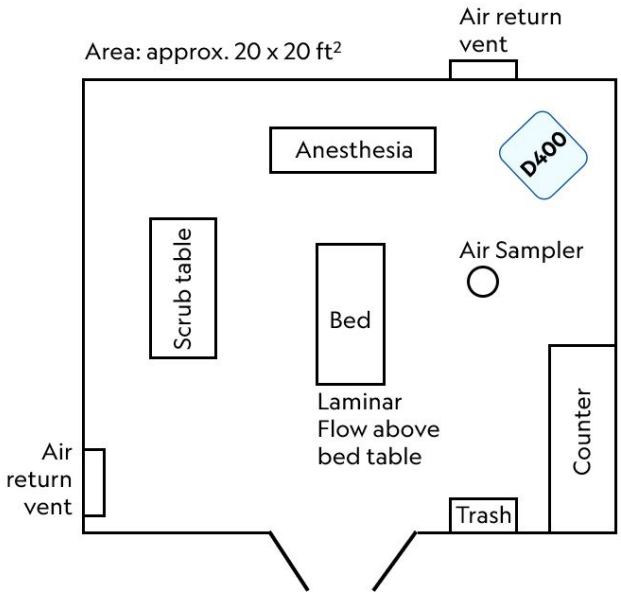

FIG. 1 Layout diagram of the operating room. The stand-alone air cleaner is tagges as *D400*.

II. MATERIALS AND METHODS

II.A. Study design

This study evaluates the levels of airborne bioburden were measured in an operating room located in Glen Echo, Maryland, Washington DC, with and without an air cleaner device. The operating room is dedicated to female related surgeries including: sling operation for stress incontinence, repair of blepharoptosis, hysteroscopy, mastectomy, laparoscopy, cystourethroscopy, vulvectomy, and colposcopy.

The floor area of the breakroom environment is approximately 400 ft^2 (37 m^2). Figure 1 shows a diagram of the operating room layout including the location of the air cleaning device, tagged as *D400*, and the location of the impaction air sampler.

The difference in bacterial bioburden levels where no air treatment device is in place (*control* or *baseline*) versus when an air cleaner is implemented (*test* or *intervention*) were compared and analysed. The airborne levels of micro-organisms were monitored using an air sampler in the opeating room

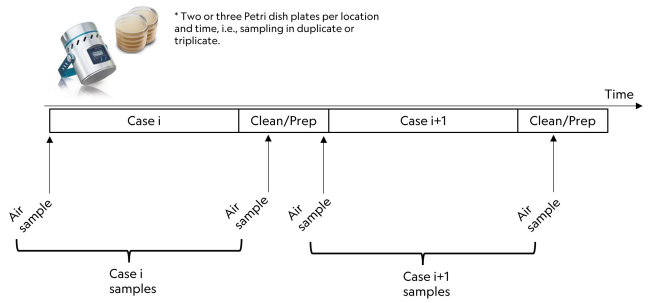

FIG. 2 Diagram of the air sampling sampling sequence.

within the facility.

Test and control samples were collected before and after operations. Figure 2 illustrate the pre- and post-sampling plan sequence followed in this study. The first pre-operation samples were taken before the operation as there was no cleaning prior to the first operation of the day. The rest of pre-operation samples where taken at the end of cleaning and preparation of the operation room. Post-operation sampling was taken right after the patient is rolled out of the operating room, when the operating room cleaning process was started. Most air samples were taken in duplicate, while some samples were taken in triplicate.

The testing was performed over 6 days in December 2021, March 2022 and April 2022. There were 3 days for testing and 3 days for control sampling; with one day each on each month listed. There were 25 cases in total; 13 cases were recorded on control days while there were 12 cases recorded on the test days. The air cleaner device was operated continually for the duration of the test sampling days. The air cleaner device was turned off during the control sampling days.

II.B. Equipment used

An air cleaning device, model NV400 – also commercialized as model Defend 400 – (WellAir, 290 Harbor Drive, 2nd Floor, Stamford, Connecticut 06902, US), was set in the operating room. The device is a portable stand-alone air cleaner. Figure 1 show the location of the air cleaner within the environment.

The device was set at speed 5 (maximum speed), 210 CFM (356 m^3/h) and was switched on for the duration of the test sampling periods. The device was turned off for the duration of the control sampling periods.

A range of portable air cleaners designed to inactivate microorganisms are available from WellAir. These devices use an atmospheric plasma discharge, called NanoStrike^{TM} Technology as their core technology. Two of the WellAir portable devices have been cleared by the Food and Drug Administration (FDA): the NV1050 and the Defend 400. The plasma technology is complemented with high-efficiency particulate arrestance (HEPA) filters in these two devices. These devices have also been challenge tested at independent laboratories against various microorganisms to show their efficacy in inactivating and removal[1].

II.C. Sample collection and laboratory analysis

An impaction air sampler, MAS-100 Eco Microbiological Air Sampler (MBV AG, Industriestrasse 9, CH-8712 Staefa, Switzerland), was used to obtain each sample. The air sampler was calibrated by Lennox Labs, Ireland on the 10th of June 2021.

Tryptone Soy Agar (TSA) was used as the media for growing and identification. This agar is a general-purpose media which can support a broad range of micro-organisms therefore ideal for this type of analysis. 9 mm pre-poured agar plates were obtained from EMSL and used with the MAS-100 Eco air sampler during sampling. The air sampler was set to collect air at a rate of 100 L/min. Each sample was collected for 1 minute, therefore sampling a 100 litre of air. Most air samples were taken in duplicate and some in triplicate, one after the other.

After sampling was complete, the agar plates were delivered to an external accredited laboratory, EMSL Analytical, Inc. (200 Route, 130 North, Cinnaminson, NJ 08077, U.S.), where they were incubated and analysed, under their code *M010 Bacterial ID (3MPT)*, following their own internal method, *MICRO-SOP-132*, with a turnaround time of two weeks. The bacterial counts were expressed as both colony count and Colony forming units per unit volume (CFU/m^3). The three most prominent bacteria present were also identified.

A total of 120 air samples were collected: 60 during control sampling, and 60 during test sampling.

II.D. Data analysis

The data analysis comprised (1) collating the identification of most abundant species in air samples, (2) ranking the species identified by their pathogenicity (pathogens, opportunistic pathogens, non-pathogenic and unknown), and (3) enumeration of colony counts per species, per date, and overall counts.

Statistical analysis of pre-operation, post-operation, and differences between pre- and post-operation for all colony counts and colony counts of pathogenic species were performed. A non-parametric statistical test was used for these: the Wilcoxon Rank Sum test. The alternative hypothesis (H_a) was that the test data set was lower than the the control data set. A standard cut-off probability or significance level of $\alpha = 0.05$ (5%) was used[2]. The null hypothesis is rejected if the p-value is less than the significance level; i.e., if p-value$< \alpha$ then it is highly improbable to observe a difference between the control and test data by mere chance and therefore there must be a factor affecting the air samples. In the case of the present study, the factor is the amount of additional air cleaning provided by the use of a portable stand-alone air cleaning device during the test phase.

The data was organised using a Microsoft Excel spreadsheet and processed with the R software for statistical computing and graphics with built in functions for the Wilcoxon test[3].

TABLE I List of all bacterial species identified during control and test sampling.

Pathogenicity	Bacterial strain	Control	Test
Pathogen	*Bacillus licheniformis*		T
Opportunistic pathogen	*Bacillus circulans*	C	T
	Bacillus pumilus	C	
	Brevundimonas vesicularis	C	T
	Corynebacterium afermentans	C	T
	Corynebacterium minutissimum		T
	Corynebacterium riegelii	C	
	Dermabacter hominis	C	
	Kocuria palustris	C	T
	Kocuria rosea	C	
	Micrococcus luteus	C	T
	Micrococcus lylae	C	T
	Staphylococcus epidermidis	C	T
	Staphylococcus haemolyticus	C	T
	Staphylococcus hominis	C	T
	Staphylococcus pasteuri		T
	Staphylococcus pettenkoferi		T
	Staphylococcus warneri		T
	Stenotrophomonas maltophilia	C	
	Pseudomonas mosselii		T
Non-Pathogen	*Bacillus sp.*	C	T
	Gram negative rod	C	T
	Gram positive cocci	C	T
	Gram positive rod		T
	Staphylococcus sp.	C	
	Kocuria rhizophila	C	T
	Rhodococcus erythropolis	C	
	Staphylococcus auricularis	C	
	Acinetobacter radioresistens		T
	Bacillus clausii		T
	Corynebacterium amycolatum		T
	Corynebacterium sp.	C	
	Dermacoccus nishinomiyaensis		T
	Microbacterium paraoxydans	C	
	Nocardia farcinica	C	
	Paenibacillus pabuli	C	
	Pseudomonas aeruginosa	C	
	Staphylococcus capitis	C	T
	Staphylococcus cohnii		T
	Bacillus simplex	C	
	Corynebacterium auris	C	

TABLE II Averaged air sample data collected in the operating room during control and test sampling, pre- and post-operation, and difference between pre- and post-operation counts.

		Colony Counts (CFU/m^3)					
		Control			Test		
Date	Case No.	Pre	Post	Difference	Pre	Post	Difference
Dec-21	1	5.0	10.0	5.0	15.0	15.0	0.0
	2	25.0	25.0	0.0	30.0	10.0	-20.0
	3	15.0	35.0	20.0	20.0	15.0	-5.0
	4	0.0	20.0	20.0	30.0	15.0	-15.0
Mar-22	5	5.0	30.0	25.0	20.0	35.0	15.0
	6	25.0	25.0	0.0	30.0	10.0	-20.0
	7	140.0	25.0	-115.0	135.0	35.0	-100.0
	8	25.0	20.0	-5.0	N/A	N/A	N/A
Apr-22	9	36.7	83.3	46.7	23.3	13.3	-10.0
	10	40.0	36.7	-3.3	6.7	20.0	13.3
	11	50.0	33.3	-16.7	13.3	23.3	10.0
	12	16.7	96.7	80.0	23.3	13.3	-10.0
	13	23.3	90.0	66.7	16.7	6.7	-10.0

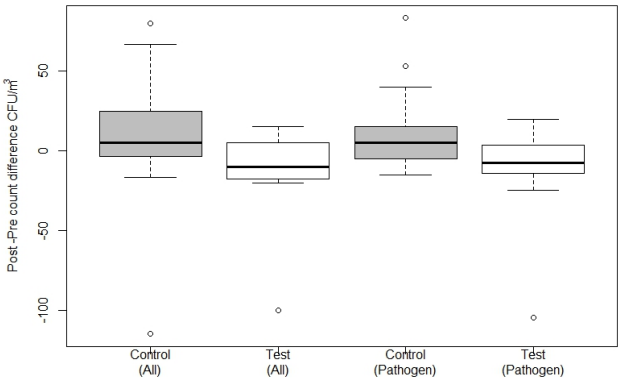

FIG. 3 Box-Whisker plot of colony count differences between pre- and post-operation samples for all microorganisms and all pathogenic organisms.

III. RESULTS

III.A. Bacterial species identification

A total of 41 different bacterial species were identified in the agar plates analysis that were collected throughout the trial in total which are listed in table I. 29 bacterial species were identified in the control samples and a total of 26 species were identified in test samples. There were 14 common bacterial species identified among the control and test samples. No samples were taken to detect and/or identify for fungi or virus species.

The bacterial species identified were ranked by pathogenicity and summarized in table I. The first species in this table is a pathogen, while the next 19 species are opportunistic pathogens. Opportunistic pathogen made up the abundance of retrieved bacteria. All other remaining species identified are deemed non-pathogenic, generalised or of unknown status.

III.B. Colony counts

Air samples were taken in duplicate for operation case numbers 1–8 (for both, control and test), and in triplicate for operation case numbers 9–13. The average of every colony count collected is summarized in table II.

For the purpose of analysis, the data is grouped in two ways: colony counts from all species identified (*All*), and colony counts from only those species identified as pathogens or opportunistic pathogens (*Pathogen*), referred from hereon simply as pathogens.

III.B.1. Difference in colony counts between pre- and post-operation

Analysis using non-parametric Wilcoxon hypothesis testing (H_a is test $<$ control). Data is processed in pairs as the difference of post- and pre-operation colony counts. The test indicates a reduction for all microorganisms data (p-value = 0.01922), and for pathogens (p-value = 0.04821). Figure 3 shows a Box-whisker plot of all differences in colony counts for control and test samples, including all the microorganisms and only those identified as pathogens.

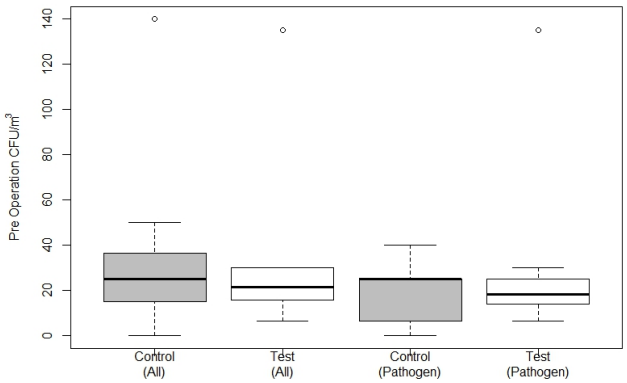

FIG. 4 Box-Whisker plot of colony counts from pre-operation samples for all microorganisms and all pathogenic organisms.

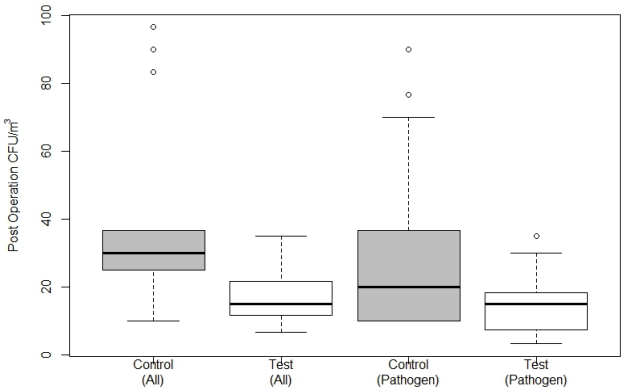

FIG. 5 Box-Whisker plot of colony counts from post-operation samples for all microorganisms and all pathogenic organisms.

III.B.2. Pre-operation colony counts

Analysis using non-parametric Wilcoxon hypothesis testing (H_a is test $<$ control). Data processed is pre-operation colony counts only. The test indicates no statistically significant difference for all microorganisms data (p-value = 0.4243), or for pathogens (p-value = 0.4781). Figure 4 shows a Box-whisker plot of all differences in colony counts for control and test samples, including all the microorganisms and only those identified as pathogens. These results indicate that before the start of the operation the bioburden in the operating room is comparable in control and test days. Effectively, the airborne bioburden in the operating room starts at about the same level in both (test and control) days.

III.B.3. Post-operation colony counts

Analysis using non-parametric Wilcoxon hypothesis testing (H_a is test $<$ control). Data processed is post-operation colony counts only. The test indicates a statistically significant difference for all microorganisms data (p-value = 0.003432), and for pathogens (p-value = 0.04432). Figure 5 shows a Box-whisker plot of all differences in colony counts for control and test samples, including all the microorganisms and only those identified as pathogens. These results indicate that after the operation there is a measurabe difference (reduction) in the airborne bioburden in the operating room. Effectively, the airborne bioburden in the operating room ends up being lower during tests than during control sampling.

The difference in post-operation average colony counts between control and test, and for all microorganisms and pathogens only is shown in the bar plot of figure 6. The corresponding average colony count reduction, comparing control and test, in percentage for (a) all microorganisms is 56.7%, and (b) only pathogens is 54.0%. This is, the use of the standalone air cleaner delivers an average of more than 50% reduction in airborne bioburden in the operating room.

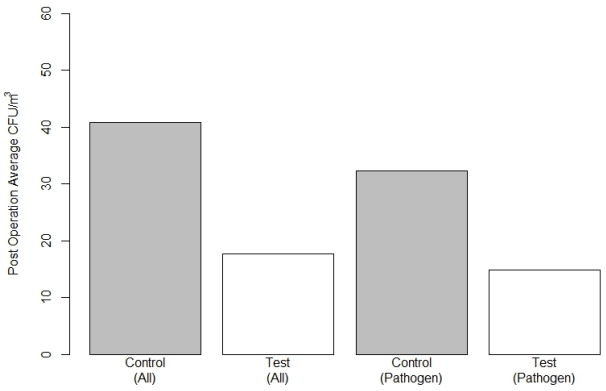

FIG. 6 Bar plot of average colony counts from post-operation sampling for all microorganisms and all pathogenic organisms.

IV. DISCUSSION AND CONCLUSION

The summary of bacteria colony count concentrations reported in the literature can be found in table III. When comparing the results obtained from this study to those identified in published literature[4–12], the counts reported here are comparable as well as lower with the air cleaner in place.

Previous earlier studies conducted in operating rooms have been found to contain a range of microorganism levels over the years. In earlier separate studies from 1962 and 1968 it was documented that the tested operating rooms had a bacterial range of 25–847 CFU/m^3 with a mean count of 370 CFU/m^3 and a microbial range of 35–6,356 CFU/m^3 respectively[4,5], these results would be particularly high counts in comparison with the results obtained from this study. However, in more recent times these levels have decreased significantly. Average microbial counts of 79, 107 and 93 CFU/m^3 were retrieved in a government run hospital while the same study reported an average of 34, 25 and 29 CFU/m^3 in a private hospital operating room[10]. Both sets of results seem similar to what was retrieved from this study. However, the results from the intervention tests where the air cleaner was in use were notably lower, see table II.

Further comparisons can be made with other areas within the hospital settings such as neonatal wards in a private

hospital, which were reported with averaged of 33, 46 and 27 CFU/m^3[10]. In this study post procedure results during the test phase saw all lower results than this upper result. Intensive care units (ICUs) were also reported in previous literature to have higher microbial concentrations in comparison to the pre-sample in the operating room within this study[10].

As expected, *Micrococcus species* and *Staphylococcus species*, both common derma flora, were found to be the most dominant species identified from both control and test phases of the study. In addition to these, *Bacillus*, *Brevundimonas*, *Corynebacterium* and *Kocuria species* were also found during both control and test sampling phases (table I).

The most abundant type of bacteria were found to be opportunistic pathogens, which commonly would not cause infection or illness unless it colonizes a patient who is immunocompromised. Non-pathogenic bacteria were also found, these were identified as normal dermal flora, soil or water bacteria or bacteria that inhabit plants. Finally, some pathogenic bacteria were found but in small numbers. This is not surprising as clothing and people can be transmitters of pathogens in hospitals and healthcare settings.

In conclusion, reduction in colony counts between control and test sampling measurements in the operating room are reported here. The post-operation reductions are statistically significant. The data collected and reported in this study suggests that the use of a portable stand-alone air cleaning device may reduce the airborne bacterial bioburden in an operating room in a healthcare setting. Further testing in similar settings is recommended to evaluate the performance of air cleaning in more depth.

ACKNOWLEDGMENTS

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TABLE III Airborne sample colony counts (CFU/m^3) as reported in the literature.

Area	Range (CFU/m^3)	Mean (CFU/m^3)	Reference
Clinical outpatient rooms		1,000	Pastuszka et al. (2005)[7]
Hospital rooms	4–1,293	124	Ortiz et al. (2008)[9]
Hospitals in Poland	100–1,000		Pastuszka et al. (2005)[7]
Patient rooms (gov. hospital)		198, 254, 185	Qudiesat et al. (2009)[10]
Patient rooms (private hospital)		145, 163, 137	Qudiesat et al. (2009)[10]
Ward	42–325		Obbard & Fang (2003)[6]
Maternity wards	14–224	67	Ortiz et al. (2008)[9]
Neonatal ward (gov. hospital)		95, 82, 69	Qudiesat et al. (2009)[10]
Neonatal ward (private hospital)		33, 46, 27	Qudiesat et al. (2009)[10]
Pneumonological dept.	257–436		Augustowska & Dutkiewicz (2006)[8]
ICU (gov. hospital)		109, 107, 121	Qudiesat et al. (2009)[10]
ICU (private hospital)		149, 197, 147	Qudiesat et al. (2009)[10]
Operating room	25–847	370	Greene et al. (1962)[4]
Operating room (gov. hospital)		79, 107, 93	Qudiesat et al. (2009)[10]
Operating room (private hospital)		34, 25, 29	Qudiesat et al. (2009)[10]
Operating rooms	35–6,356		Favero et al. (1968)[5]
Operating theatres	1–157		Ortiz et al. (2008)[9]
Overall hospital areas	353–2,472		Greene et al. (1962)[4]
Lobbies		720	Park et al. (2013)[11]
Lobby	445–890		Obbard & Fang (2003)[6]
Main enterance (gov. hospital)		174, 229, 163	Qudiesat et al. (2009)[10]
Main enterance (private hospital)		120, 115, 87	Qudiesat et al. (2009)[10]
Pharmacy	201– 827		Obbard & Fang (2003)[6]
Personal (cleaners)	103– 1,710	351	Lu et al. (2020)[12]
Waste storage		6,709	Greene et al. (1962)[4]
Industrial clean rooms	35–353		Favero et al. (1968)[5]