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Major Article

Assessment of focused multivector ultraviolet disinfection with shadowless delivery using 5-point multisided sampling of patient care equipment without manual-chemical disinfection

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Background: The aim of this study was to evaluate the performance of a focused multivector ultraviolet (FMUV) system employing shadowless delivery with a 90-second disinfection cycle for patient care equipment inside and outside the operating room (OR) suite without manual-chemical disinfection.

Methods: A 5-point multisided sampling protocol was utilized to measure the microbial burden on objects inside and outside the OR environment in a 3-phase nonrandomized observational study. Surface sampling was performed pre- and postdisinfection in between cases (IBCs) to assess the performance of manual-chemical disinfection. FMUV system performance was separately assessed pre- and postdisinfection before the first case and IBCs. Additionally, visibly clean high-touch objects were sampled outside the OR, and the microbial burden reductions after FMUV disinfection were quantified without manual-chemical disinfection.

Results: Manual-chemical disinfection reduced the active microbial burden on sampled objects IBCs by 52.8%-90.9% ($P < .05$). FMUV reduced the active microbial burden by 92%-97.7% ($P < .0001$) before the first case and IBCs combined, and 96.3%-99.6% ($P < .0001$) on objects outside the OR without chemical disinfection.

Conclusions: Five-point multisided sampling proved effective for assessing disinfection performance on all exterior sides of equipment. FMUV produced significant overall reductions of the microbial burden on patient care equipment in all study phases and independent of manual cleaning and chemical disinfection.

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Health care-acquired infection (HAI) prevention efforts are challenging and have led to the current impasse where continued focus on chemical disinfection and manual cleaning protocols has brought diminishing returns.¹ Using current standards, surface contamination is minimized with cleaning followed by chemical disinfection.² However, accumulating evidence indicates that visibly clean hospital surfaces may have high levels of residual contamination owing

to varying degrees of compliance with protocols and human oversight.³⁻⁵ Disinfection efficacy is also impacted by staff training, frequency and thoroughness of cleaning, degree of adherence to the manufacturer's chemical preparation guidelines, disinfectant compatibility with cleaning wipes/mops, disinfectant contact time, and other factors.⁶ In response to these concerns, new technologies such as ultraviolet (UV) disinfection have gained increasing interest as an adjunct to manual cleaning with disinfectants.⁷⁻¹⁷

Recent UV disinfection applications in health care environments have primarily focused on patient rooms.^{7,10-14} Although largely effective at reducing surface contamination in these applications, some shortcomings have been noted, including a sharp drop-off in UV intensity with distance from the central lamp source, shadowing effects, and prolonged disinfection times.^{10,15-17} The new focused multivector ultraviolet (FMUV) shadowless delivery technology (PurpleSun Inc, New York, NY) was designed to address these issues.

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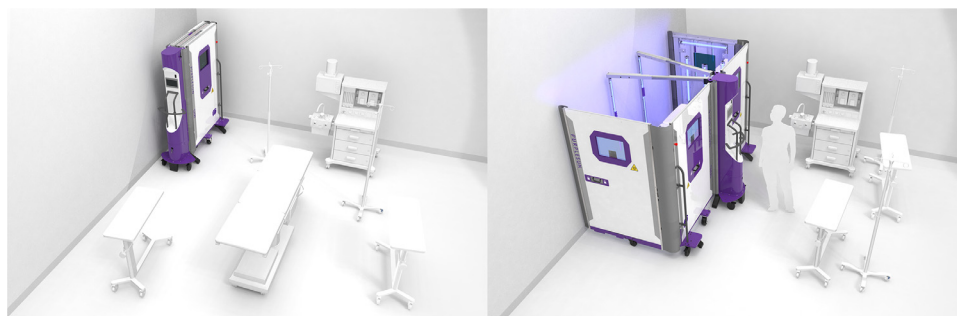


Fig 1. The focused multivector ultraviolet device collapsed for storage (left) and deployed (right) with extension arms against the wall to surround equipment on all sides with multivector ultraviolet light.

FMUV employs modular panels of lamps and reflectors that enclose a target zone in which UV rays converge on surfaces from multiple directions and shadowing is virtually eliminated. Inside the enclosed target zone, the UV intensity level remains high and homogenous, and objects placed within the target zone are disinfected rapidly and thoroughly on all sides (Fig 1). Since the modular panels block UV, personnel may continue to occupy the room and perform their activities during operation.

In comparison with typical wide area disinfection units where UV rays emanate from a central source (Fig 2), the FMUV system provides higher levels of UV intensity and a shorter disinfection cycle (90 seconds), which makes it more suitable for faster disinfection during turnovers. In operating rooms (ORs), surgical site infections (SSIs) are dependent on intrinsic patient factors, as well as extrinsic environmental factors, which include surfaces and equipment within the OR that may serve as sources of contamination.^{18–20} The critical nature of the cleaning requirements and the need for rapid turnover make the OR an ideal environment to investigate the performance of the automated FMUV system. To more accurately investigate the capabilities of the shadowless delivery mechanism, a unique test protocol was implemented that involved 5-point multisided surface sampling on patient care equipment.

METHODS

This nonrandomized observational study was conducted at a New York City area teaching hospital with 24 ORs and 524 beds, a second hospital with 23 ORs and 806 beds, and a community hospital with 7 ORs and 219 beds. A total of 3,420 microbiological samples were taken over a 1-week period from 104 surgical cases and from equipment outside the OR environment. The 3 phases of this study are described next.

Phase 1: Inside the OR with manual-chemical disinfection

Quantitative environmental sampling evaluated the active microbial burden in between cases (IBCs) before and after manual-chemical disinfection. Manual-chemical disinfection was performed IBCs according to Association of periOperative Registered Nurses recommended guidelines.² A total of 270 pre- and postsamples were collected from the operating room table (ORT), the back table (BACKT), and the Bovey machine (BOVEY), and the target objects were sampled before and after receiving manual-chemical disinfection. Total pre-sample colony-forming units (CFUs) were compared with postsamples to assess reductions.

Phase 2: Inside the OR with automated FMUV disinfection

A total of 1,350 samples were collected in the early morning from 45 ORs before the first case (BFC), and 1,500 samples were collected from 50 ORs IBCs before manual-chemical disinfection. Samples were taken before and after each FMUV disinfection cycle. Objects were placed in the target zone in arbitrary locations because distance from the lamps is not a factor. High-touch objects, such as the ORT, the BACKT, and the BOVEY, were chosen because in phase 1, higher levels of CFUs were observed on these 3 pieces of equipment in comparison to other OR surfaces, which included the wall, anesthesia machine, medication cart, ring stands, light boom, and workstation (data not shown).

BFC

Visibly clean ORTs, BACKTs, and BOVEYS were sampled before and after applying FMUV disinfection within select ORs. The sampling began between 5 AM and 7 AM each day BFC. ORs received standard manual terminal cleaning and disinfection during the overnight shift

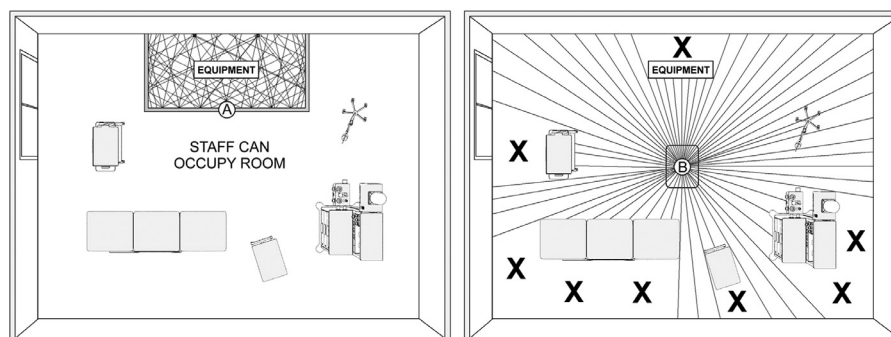


Fig 2. (A) Ray-tracing diagram illustrating how shadowless delivery of multivector light exposes all sides of the equipment, including from the wall where 2 extension arms with ultraviolet lamps are located. (B) Ray-tracing of a wide-area ultraviolet device; “X” illustrates shadowed regions.

as per Association of periOperative Registered Nurses² guidelines and were visibly clean and ready for use.

IBCs

Presamples were collected from the ORT, the BACKT, and the BOVEY immediately after each surgery case but before manual-chemical disinfection was performed. After the presamples were taken, the objects were disinfected by FMUV alone. This method was applied to isolate and evaluate performance of the FMUV system under nonideal conditions and to remove any variability that might be introduced from manual-chemical disinfectants that could impact results. Manual-chemical disinfection was performed after all sampling was complete, for phase 2 IBCs only.

Phase 3: Outside the OR with automated FMUV disinfection

Patient care equipment near the emergency department was also sampled. A total of 300 pre- and postsamples were taken from warming device, stretchers, electrocardiogram machines, intravenous pumps, and patient vital sign monitors. Equipment was visibly clean and considered ready for patient use, and no chemical disinfection had been performed before sampling.

Sample collection

Surface sampling was performed according to standard industry practice.^{11,21} Clean hospital scrubs, jackets, face masks, and gloves were donned within the change room. Gloves were replaced between each OR, and 70% alcohol-based hand sanitizer was applied to each hand before and after conducting sampling. Standard RODAC (Replicate Organism Detection and Counting) plates (Tryptic Soy Agar) without disinfectant neutralizer were used after surfaces were dry. A trained clinician collected 5 samples by pressing each RODAC plate for at least 3 seconds on 5 separate touchable sides of each piece of equipment pre- and post-disinfection (Fig 3). For example, stretchers were sampled on (1) push handles at the head of the bed, (2) the right side rail, (3) locking handles, (4) the left side rail, and (5) the top side of the mattress. The specific sampling locations were free of soilage and dry. In the event of gross soilage, samples were taken from the nearest adjacent location on the same side that was free of visible soiling. Samples were packaged each day and delivered to an independent third-party laboratory for incubation (37°C for 48 hours) and plate counting. If plates were too numerous to count, a limit of 250 CFUs was used for data calculation purposes.

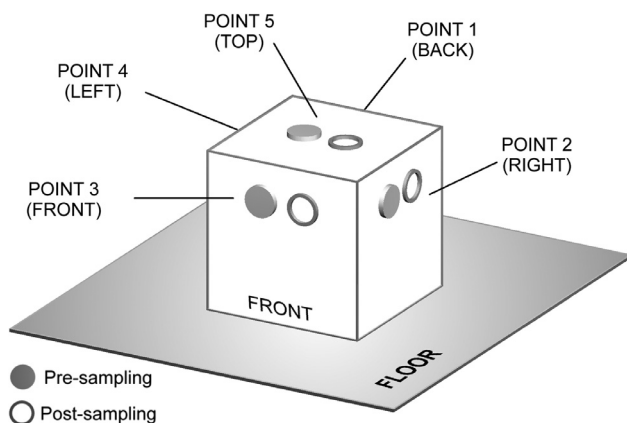


Fig 3. Diagram of 5-point multisided sampling showing all 5 sides of an object, each of which was sampled with a separate RODAC (Replicate Organism Detection and Counting) plate.

Deployment procedure

The FMUV system was deployed both inside and outside the OR environment and was transported from case to case depending on OR schedules. The system is compact for transport and was expanded from its portable configuration once inside the designated area or room. Protocols for system setup were predefined by the manufacturer and used consistently for all cases. The system was positioned in a rectangular configuration with 2 extension arms deployed against a wall containing UV sources to illuminate equipment from all sides. All equipment to be disinfected was moved inside of the target zone. The ORT was moved inside of the target zone for one 90-second disinfection cycle. The BACKT and the BOVEY were then moved inside and disinfected together with one 90-second cycle. To disinfect equipment outside the OR, the FMUV system was deployed in an area near the emergency department and equipment was moved into the device.

OR selection criteria

The FMUV system was only applied in an OR if all selected objects were present and the prior surgery exceeded 1 hour in duration. If FMUV disinfection and sampling had been previously conducted within a designated OR, then a second FMUV application could only be performed if there had been a minimum of 3 surgery cases or 1 case of at least 6 hours completed in the same room that day. This step was taken to prevent any possible cumulative UV disinfection effects from impacting presamples at later sampling times during the same day. Ten ORs were explicitly designated for BFC, and 10 ORs were explicitly designated for IBCs during phase 2.

Statistical analysis

The Wilcoxon signed-rank test was applied to the differences between the number of total CFUs per equipment before and after FMUV disinfection, as per similar studies.¹¹ Statistical significance was achieved when a 2-sided P value was $< .05$. No statistical comparison was performed between the phase 1 chemical cleaning results and the phase 2 FMUV results because phase 1 was observational and not intended to be a direct comparison of the methods.

RESULTS

Table 1 shows a complete overview of the results for phases 1-3, and the second column notes what equipment was visibly clean. CFUs are totaled per piece of equipment. In phase 1, manual-chemical disinfection achieved an overall CFU reduction of 79.4% ($P < .05$) on 27 objects, with a range of 52.8%-90.9%.

In phase 2 and phase 3, the 90-second FMUV disinfection cycle was initiated 220 times. In phase 2 BFC, the average total CFUs per object from pre- and post-FMUV samples were compared as shown in Figure 4. FMUV disinfection alone reduced surface contamination for all critical objects BFC by 97.2% ($P < .0001$) from 135 objects, with a range of 96.5%-97.7%. An overall average reduction of 94.8% ($P < .0001$) was achieved in phase 2 IBCs independent of manual cleaning and disinfection from 150 objects, with a range of 92.0%-96.7% (Fig 4).

In phase 3, a total of 300 samples were taken from 30 objects outside the operative environment pre- and post-FMUV disinfection. Consistently high CFU counts were found in the baseline condition before FMUV disinfection on all of the targeted objects that were visibly clean and ready for patient use. Although the active microbial burden of high-touch objects outside the OR was much greater than that of the targeted objects inside of the OR, FMUV demonstrated overall average reductions of 97.8% ($P < .0001$), with a range of 96.3%-99.6% without the use of chemical disinfection (Fig 4).

Table 1
Efficacy of manual-chemical disinfection and automated FMUV disinfection in phases 1, 2, and 3

Name of object	Visibly clean	No. of objects	Total CFUs		Reduction (%)	P value
			Pre-	Post-		
Phase 1: Chemical cleaning in OR						
ORT		9	739	141	80.9	.38
BACKT		9	362	33	90.9	.07
BOVEY		9	197	93	52.8	.41
IBC totals*		27	1,298	267	79.4	<.05
Phase 2: FMUV in OR						
ORT	✓	45	774	22	97.2	<.0001
BACKT	✓	45	375	13	96.5	<.0001
BOVEY	✓	45	575	13	97.7	<.0001
BFC totals†		135	1,724	48	97.2	<.0001
ORT		50	487	39	92.0	<.0001
BACKT		50	483	28	94.2	<.0001
BOVEY		50	824	27	96.7	<.0001
IBCs totals‡		150	1,794	94	94.8	<.0001
Phase 3: FMUV outside OR						
Warming device	✓	5	1,899	42	97.8	.06
Stretcher	✓	5	1,197	44	96.3	.06
Electrocardiogram	✓	13	1,858	36	98.1	0
Intravenous pump	✓	4	557	2	99.6	0.13
Patient monitor	✓	3	392	7	98.2	0.25
Equipment totals‡		30	5,903	131	97.8	<.0001

NOTE. P values were determined via the Wilcoxon signed-rank test.

✓, indicates visibly clean; BACKT, back table; BFC, before the first case; BOVEY, Bovey machine; CFUs, colony-forming units; FMUV, focused multivector ultraviolet; IBCs, in between cases; OR, operating room; ORT, operating room table.

*NOTE. Totals from 3 hospitals.

†Totals from 1 hospital.

Consistently significant total equipment CFU reductions were demonstrated in all cases and in all environments by the FMUV system with the 5-point multisided sampling protocol. Consistent efficacy of disinfection ($P < .0001$) was demonstrated in phase 2 and phase 3 in the absence of manual-chemical disinfection. No correlation could be observed between type of surgery and levels of active microbial burden.

DISCUSSION

The results of the 5-point multisided sampling method used in this study suggest that high performance of disinfection can be achieved by multivector UV light on unsoiled surfaces without the application of liquid disinfectants. The reductions in surface contamination achieved in phase 1 with manual-chemical disinfection are in

accordance with cleaning and disinfection practices as reported in other studies.¹⁹ In phase 2 and phase 3, the reductions in surface contamination shown in Table 1 were achieved with an FMUV disinfection cycle of 90 seconds, as compared with 5–55 minutes or more for other types of UV machines.^{3,8,9,14,15,22–25}

To our knowledge, our study is the first to use a 5-point multisided sampling protocol to assess full and complete disinfection of equipment from all sides. Some UV studies performed in ORs have demonstrated reductions in microbial burden, but the sampling protocols differ substantially from those used here. One study used UV cycle times of 1–8 minutes with samples taken only in direct line of sight on equipment after standard cleaning, achieving reductions of 46.7%–73.1%.²⁴ Another study used UV on high-touch equipment after cleaning with cycle times of 10 minutes twice, and surface sample growth decreased from 51% before to 33% after UV.²⁵ A third UV study reports

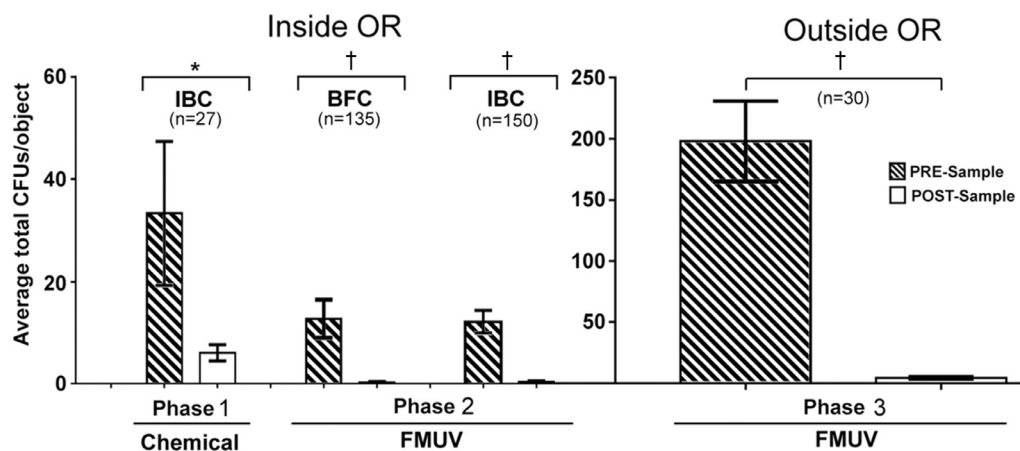


Fig 4. Pre- and postsampling results of active microbial burden inside the operating room (OR) for manual-chemical disinfection and focused multivector ultraviolet (FMUV) disinfection. Phase 1: 79.4% reduction (*, $P < .05$). Phase 2: 97.2% reduction before the first case (BFC) and 94.8% reduction in between cases (IBCs) (†, $P < .0001$). Phase 3: 97.8% reduction (†, $P < .0001$). Error bars indicate the mean ± SEM.

a 65.3% reduction in bacterial loading in the ORs.⁸ A fourth UV study reports 99% reduction from 1 side of the anesthesia cart using cycle times of 20–55 minutes.²² A fifth study used two 5–10 minute cycles after manual cleaning and obtained an 86% reduction in total CFUs.¹⁵ Comparison of the 5-point sampling data taken herein with any of these results may be of limited value because of differences in sampling protocols.

In phase 1, phase 2 BFC, and phase 3, residual contamination was found on visibly clean equipment after manual-chemical disinfection. Previous studies have shown that surfaces in the OR look clean after manual-chemical disinfection, but 47% of surfaces still harbor pathogens and only 25% of surfaces are cleaned according to policy.²⁰ Some residual contamination spikes that were too numerous to count were found during phase 2 BFC that are comparable to sampling results shown in other published OR studies.¹⁸ There are limited studies on the quantitative contamination levels of visibly clean high-touch surfaces in the OR, but residual contamination may represent a daily reality in the hospital environment in which many HAIs hail from unknown sources. The lack of thoroughness in cleaning of contaminated surfaces has been linked to an increased risk of infection to the next occupant in the room.⁶ Further research into the possible risks associated with such residual contamination of visibly clean surfaces may be warranted, but it is worth noting that effective delivery of UV can mitigate against flaws left over from the execution of manual-chemical cleaning and disinfection,¹⁴ as illustrated in Figure 4.

The fact that hospital staff can remain in the OR during operation of the FMUV system allowed for integration of the system into the workflow environment, and this introduces the possibility of conducting manual cleaning and disinfection procedures in parallel with the UV disinfection process. Verification of the absence of any impact on turnover time is the subject of a separate study that is currently under way by the authors.

Some of the limitations of this study include that (1) too few samples were taken in phase 1 and phase 3 to achieve statistical significance for individual pieces of equipment using the Wilcoxon signed-rank test, (2) no speciation of sampled microbes was performed, and (3) no direct statistical comparison was made between phase 1 and phase 2 results, as this was not the objective of the study. No conclusions can be drawn regarding the impact the measured reductions may have on SSI rates, but existing studies suggest that reduction of SSIs and HAIs may be possible with UV surface disinfection.^{8,9,16,17,25}

The hospital environment is a microbiologically dynamic system that can defeat the best efforts of manual cleaning with chemical disinfectants, and this underscores the growing importance of adjunct UV technologies. Two key barriers to the more widespread adoption of UV technology have been noted by other industry experts: (1) identification of rooms that would most benefit from the technology and (2) the time constraints that would allow staff to apply enhanced terminal disinfection.¹⁰ Further barriers to successful implementation of UV technology in hospitals include shadowing, sharp drop-offs in UV intensity with distance, and the issue of complete disinfection for all sides of patient care equipment. All of these barriers can be overcome by the shadowless delivery technology and performance of the FMUV system.

CONCLUSIONS

Current manual cleaning and chemical disinfection remain essential approaches to maintaining hospital environmental hygiene, but sole reliance on chemical disinfectants and manual cleaning protocols is being continuously challenged by the limited time, complexity, and quantity of equipment, the evolving nature of HAI pathogens, and the driving force of patient safety in the era of value-based health care. This evolution of UV technology is by design and in response to the needs of the health care industry, and the combined

improvements in speed, efficacy, and usability that it represents could alter the absolute dependence on the use of liquid chemical disinfectants on visibly clean surfaces. Improvements in the demonstrated performance of such technology may signal a paradigm shift away from the 1-step process of cleaning plus chemical disinfectants to a parallel process that includes cleaning plus UV disinfection.

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