Major Article

Influence of a visible-light continuous environmental disinfection system on microbial contamination and surgical site infections in an orthopedic operating room

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Background: A growing body of research has demonstrated that manual cleaning and disinfection of the operating room (OR) is suboptimal. Residual environmental contamination may pose an infection risk to the surgical wound. This study evaluates the impact of a visible-light continuous environmental disinfection (CED) system on microbial surface contamination and surgical site infections (SSI) in an OR.
Methods: Samples from 25 surfaces within 2 contiguous ORs sharing an air supply were obtained after manual cleaning on multiple days before and after a visible-light CED system installation in 1 of the ORs. Samples were incubated and enumerated as total colony-forming units. SSIs in both ORs, and a distant OR, were tracked for 1 year prior to and 1 year after the visible-light CED system installation.
Results: There was an 81% (P = .017) and 49% (P = .015) reduction in total colony-forming units after the visible-light CED system installation in the OR in which the system was installed, and in the contiguous OR, respectively. In the OR with the visible-light CED system, SSIs decreased from 1.4% in the year prior to installation to 0.4% following installation (P = .029).
Conclusions: A visible-light CED system, used in conjunction with manual cleaning, resulted in significant reductions in both microbial surface contamination and SSIs in the OR.

Surgical site infections (SSI) continue to place a substantial burden on the US health care system.[1] They are among the most common health care−associated infections, accounting for a major source of perioperative morbidity, prolonged hospitalizations, and health care expenditures.[1-3] This is particularly true for SSIs involving an implant, such as periprosthetic joint infections (PJI), which have been associated with a cost of $389,307-$474,004 per infection, a mortality rate of 2%-7%, and a 5-year survival rate— that is worse than many cancers.[4-6]

Traditional stratification of SSI risk begins with the patient's own microbiome, followed by perioperative practice variables including surgical technique, attire and instrument sterility, and operating room (OR) environment.[7] The latter, however, is

increasingly recognized as a potentially significant reservoir for pathogens. Multiple studies have demonstrated the presence of organisms commonly associated with SSIs in the air and on surfaces within the OR, despite regular manual cleaning,[8-11] underscoring the idea that many traditional manual disinfection and decontamination protocols are suboptimal in achieving a truly "clean" OR environment.[11-15] Residual contamination can pose an infection risk via the complex interplay of surface and air dynamics in an occupied OR. Staff and equipment movement can disturb residual organisms and particulates on surfaces leading to their aerosolization and potential settling onto high-touch surfaces, sterile equipment, and into the surgical wound.[15-19]

The present study was a 2-pronged investigation to assess the efficacy of a visible-light continuous environmental disinfection (CED) system in (1) reducing bacterial contamination on surfaces within an orthopedic OR, and (2) impacting SSI rates for procedures performed

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therein. Throughout the study, a visible-light CED system was used as an adjunct to the normal OR manual cleaning and disinfection protocol.

METHODS

Background

This study was performed between October 2015 and October 2017 at Maury Regional Health Center, a 255-bed regional hospital in Columbia, Tennessee. The hospital has 12 ORs, 3 of which are dedicated to orthopedic surgery and were the ORs of interest in this study. The most common procedures performed in all 3 ORs are primary joint arthroplasties (total knee, total hip, shoulder, and ankle). The use of a visible-light CED system was designed to be an additional disinfection strategy complementary to the hospital's standard OR cleaning and disinfection protocol and preexisting SSI bundle. The study proposal was submitted to the institutional review board as a process improvement related to the overall surgical bundle and its goal of reducing SSIs. However, as part of this effort, some nonhuman research related to the effectiveness of the technology was required. This research included the analysis required to effectively dose the room and demonstrate bacterial reduction. The institutional review board approved the proposal as a process improvement and declared it exempt from full review.

A visible-light CED system (Indigo-Clean, Kenall, Kenosha, WI) was installed by the institution in one OR, hereafter referred to as OR2, on October 15, 2016. OR2 is adjacent to another OR (OR1) with which it shares a heating, ventilation, and air conditioning system. A third OR (OR3), included in the data analysis for SSIs, was across the hall from OR1 and OR2 and had a separate heating, ventilation, and air conditioning system. In all 3 ORs, airflow is via an engineered laminar system with a high-efficiency particulate air filtration system, such that the air passes through the system via returns designed to pull air away from the surgical site and back table with 30 air changes per hour. All 3 ORs are humidity-controlled and maintained between 66°F to 68°F.

The hospital's standard manual cleaning protocol for all ORs involves the use of a combined cleaner and disinfectant (Oxycide, Ecolab, St Paul, MN) used in conjunction with microfiber cloths. Each OR is cleaned between procedures and terminally at the end of the day, and the environmental services team is required to complete a checklist with each cleaning to ensure thoroughness.

The hospital's SSI bundle, which was implemented and fully in effect at the start of the study (October 1, 2015), included patient-related components (eg, methicillin-resistant *Staphylococcus aureus* screening and decolonization of positive patients, home chlorhexidine gluconate bathing), preoperative components (eg, chlorhexidine gluconate skin prep with appropriate dry time, weight-based, local antibiogram-based antimicrobial prophylaxis), intraoperative components (eg, restriction of door openings once case began, appropriate facility-laundered attire including caps and hoods), and postoperative components (eg, silver-impregnated dressings, education on sterile technique for dressing changes to caregiver). Aside from implementation of a visible-light CED system in one OR, no additional changes to the SSI bundle or infection prevention strategies were implemented throughout the study period.

Design, installation, and operation of a visible-light CED system in the OR

As far as we know, this is the first reported deployment of a visible-light CED system in an OR setting, and it is important to note that it's deployment and usage is very different from portable, ultraviolet (UV) systems.

As it is integrated into the overhead lighting, it requires additional considerations related to the center wavelength (per photon efficacy), irradiance (disinfecting power at a point in space), and number of fixtures and layout (disinfecting power throughout the room) to ensure the proper end result. This implies that just as with UV systems, no 2 products in this category will be identical highlighting the importance of clinical evidence in evaluating their true benefits based on the manufacturer's recommended usage. These recommendations should include the total average dose to the room, the quantity of fixtures needed, the required operation time, and clinical evidence demonstrating the performance using these recommendations.

The manufacturer provided technical assistance before and during installation to ensure that proper illumination and disinfecting dose was achieved across the entire OR. Each unit is a ceiling-mounted lighting system measuring 2 ft × 4 ft. Eight units were installed in the ceiling of OR2, which measured 450 square ft[2] with 9-foot ceilings. The antimicrobial light in the unit is generated from a matrix of light-emitting diodes, which emit low-irradiance violet-blue light with a narrow spectral profile centered within 405 nm-410 nm (indigo). This light conforms to international safety guidelines for clinical use in occupied rooms.[20-21] To provide optimal illumination for surgery, each unit operates in a "white mode" that combines indigo light and white light when the room is occupied. When the room is unoccupied, the units switch to "Indigo mode," which provides indigo light only, at approximately 4-times the dose of the white mode—and therefore, a greater degree of disinfection. An occupancy sensor switches between modes automatically but can be overridden with an emergency switch, if needed.

Bacterial bioburden in the OR

The effect of the visible-light CED system on bacterial levels on a variety of surfaces throughout OR1 and OR2 was studied prior to (period 1, October 4-14, 2016) and after (period 2, October 19 to November 4, 2016) installation of the visible-light CED system in OR2. To establish a baseline, surface samples were collected on 5 separate occasions during period 1 in both ORs (scheduling of light installation limited sampling times during period 1), and the same surfaces in both ORs were then sampled on 8 different occasions during period 2. The 50 surfaces sampled were the same in both ORs, and in both periods, and included the tops and bottoms of the door handle on the inside of the main door to the OR, the door handle to the blanket storage cabinet, the computer mouse and keyboard, the inside of the phone handle, the door handle to the glove storage cabinet, the boom light control, the right and left arms of the anesthesia chair, and the right and left edges of the anesthesia cart. Additionally, surfaces were sampled above and below the top of the intravenous warmer, the lower right and left front corners of the anesthesia machine, the handle of the fluid collection machine and on the left and right sides of the laundry bin lid, the top of the OR chair, the computer keyboard and top of the computer, the front of the anesthesia screen, the top of the syringe bin, the front of the bovie machine, the top of the fluid collection machine, the anesthesia monitor, and the blood pressure button.

The director of infection prevention and control collected all samples in both ORs and periods between 5 AM and 6 AM, prior to the first room entry and after the room had been terminally cleaned the previous evening. Samples were collected using 15 mm × 65 mm Baird-Parker agar (BPA) with egg yolk tellurite contact plates (Hardy Diagnostics, Santa Maria, CA). Nonflat surfaces were sampled using the roll plate technique and flat surfaces were sampled by directly pressing plates against the surface. Each sample was taken directly to the laboratory for a 48-hour incubation period at 35°C. Following incubation, enumeration of total colony-forming units (CFU) from each plate was made by a blinded microbiology technician and results were tallied to create a total CFU count for each OR on the date of collection.

In addition to culture counts, period, and OR, two more variables were collected in the bacterial bioburden analysis: number of cases (the number of surgical cases performed since the prior data collection occasion) and the total case duration (the total duration in minutes of all surgical cases performed since the prior data collection occasion). All data were collected and tracked by the department of infection prevention and control, which also reviewed OR terminal cleaning logs during this period to confirm each OR was cleaned per protocol.

SSIs

The effect of the visible-light CED system on SSI rates following procedures performed in the OR was the second outcome of interest. These data were collected in 3 ORs. OR1 and OR2 are the same ORs referred to in the bacterial bioburden evaluation. Additionally, a third distant OR (OR3) was added for comparison of data between OR1 and OR2, and an OR that was not neighboring or sharing an air supply system (control). SSI case data from each OR were collected between October 2015 and October 2017, to provide 1 year worth of data (period 1) prior to the installation of the visible-light CED system in OR2, and 1 year worth of data (period 2) after installation. All SSIs were identified by an orthopedic surgeon using the National Healthcare Safety Network definition for SSI and confirmed by an infectious disease physician. Three additional variables were collected for the SSI analysis: total operation time (total minutes between incision and closure), elapsed room time (total minutes OR was occupied for a procedure), and procedure severity (minor vs major procedure including number of staff needed for the case, ie, major 2, major 3). A major procedure is defined as any surgical procedure that penetrates and exposes a body cavity or any intervention that has the potential for encouraging permanent anatomic or physiological impairment, or any procedure related to orthopedics or extensive tissue dissection or transection. A minor procedure is defined as any procedure that neither penetrates a body cavity, nor encourages permanent impairment of any bodily functions. Data mining and collection from the hospital's electronic medical records was performed by a data analyst from the department of infection prevention and control at the hospital.

Statistical analysis

All statistical analysis was performed using R statistical software version 3.4.4 (R Foundation for Statistical Computing, Vienna, Austria). For the bacterial bioburden analysis, summary statistics were calculated for each variable (culture counts, OR, period, number of cases, and total case duration). Analysis of variance (ANOVA) was performed on continuous independent variables (number of cases, total case duration). ANOVA and pairwise comparisons were performed for the dependent variable (culture counts) including t tests and the Mann-Whitney U (Wilcoxon) tests. Linear regression analysis was then performed to determine what factors were predictive of culture counts. Any factor with a P value <.20 in simple linear regression was subsequently considered for continued inclusion in multiple regression analysis.

In addition to total culture count results for each sampling date, individual sampling site counts were analyzed at the 15 CFU per plate threshold. Previous research has suggested that counts ≥15 CFU may represent an infectious threshold for contamination.[15,22-23] Therefore, the individual plate count from each sampling site on each sampling date, with those sites having 2 facets sampled, averaged for 1 count (eg, top and bottom of door handle averaged for a "door handle" count) and were analyzed to determine what percentage of samples fell above the 15 CFU threshold during each period. Fischer exact test was used to determine whether the difference in percentages between periods were significant.

For the SSI data, summary statistics were calculated for all variables, as well as ANOVA and post hoc t tests performed for continuous independent variables (total operation time, elapsed room time). The Fisher exact test and the χ^2 test (when possible) were performed for both independent and dependent categorical variables (procedure severity, SSI). Fischer exact test results are reported in all cases because of small cell frequencies. Logistic regression analysis was then performed to determine what factors were predictive of culture counts using a forward stepwise procedure with a significance level of P <.20 as criteria to enter the model and P ≥.20 to be removed from the model.

RESULTS

Impact of a visible-light CED system on bacterial levels in the OR

The results, as shown in Table 1, indicate that a visible-light CED system was effective in reducing total surface bacterial counts in both OR1 and OR2. In OR2 alone, there was an 81% mean reduction in CFU counts (P = .017) and 85% median bacterial reduction (P = .002) between periods 1 and 2. The reduction in mean total BPA plate count was 185.2 CFU. There was additionally a statistically significant 49% mean and median reduction in bacterial counts in the neighboring OR1 that did not have a visible-light CED system (P = .015; P = .006), likely attributable to the contiguous location and shared air supply with OR2. The reduction in mean total BPA plate count in OR1 was 124.8 CFU.

Analysis of the other 2 variables collected in the bacterial reduction study—number of cases (number of procedures performed since the prior data collection date) and total case duration (total duration in minutes of all surgical cases performed since the prior data collection date)—revealed that OR2 had a statistically significant difference in total case duration compared to OR1. OR2 had a higher mean total case duration (P = .039) with a difference in mean duration of 382.7 minutes during period 1 and 237.7 minutes during period 2. It is widely acknowledged that there is a direct correlation between SSI risk and duration of surgery, with SSI rates increasing with longer duration of surgery.[24] The longer the case, the greater the opportunity for microbial shedding and disbursement in the OR.

Table 1
Bacterial reduction in OR1 and OR2. Daily total culture counts (CFUs) in period 1 (prior to OR2 light installation) compared with counts in period 2 (post OR2 light installation)

Location	Value	Period 1	Period 2	Mean bacterial reduction	Median bacterial reduction
OR1	Number of sampling dates	6	8	≥49%	≥49%
	Range	171-344	24-216		
	Median	258	130.5	t test	MWW test
	Mean (SD)	252.6 (74.4)	127.8 (57.8)	P = .015*	P = .006*
OR2	Number of sampling dates	6	8	≥81%	≥85%
	Range	105-392	13-79		
	Median	229	34	t test	MWW test
	Mean (SD)	226.6 (106.6)	41.4 (24.4)	P = .017*	P = .002*

CFUs, colony-forming units; *MWW*, Mann-Whitney U Wilcoxon; *OR*, operating room; *SD*, standard deviation.
*P < .05.

Table 2
Summary of final model resulting from multiple linear regression analysis, including significant predictors of culture counts

Factor	Coefficient [Standard Error]	P value
(Intercept)	271.18 [24.63]	<.001
Period 2	−155.04 [26.68]	<.001*
OR2	−63.15 [25.96]	.023*

NOTE. Model: F-value = 19.84 on 2 and 23 degrees of freedom, $P < .001$.
OR, operating room.

Total case duration was shorter in period 2 for both ORs, which might have mitigated bacterial shedding and potential environmental contamination compared to period 1. However, this difference in duration between periods did not achieve statistical significance ($P = .761$) nor was it a significant predictor of culture counts in the linear regression analysis. There was no significant difference in number of cases between ORs or periods.

Linear regression analysis was performed to determine which variables (period, OR, total case duration, and number of cases) were predictive of culture counts. All variables achieving a P value of <.20 in simple linear regression were included in multiple linear regression analysis. This resulted in only 2 variables—period 2 and OR2. Table 2 demonstrates that both variables, period 2 ($P < .001$) and OR2 ($P = .023$), were significantly predictive of culture counts in the final model. Thus, period 2, during which the visible-light CED system was in operation, and OR2, both before and after a visible-light CED system installation, appear to be factors predictive of lower culture counts. Although the effect of period and, thus, a visible-light CED system operation is greater (a reduction of 155.04 CFU, $P < .001$), there is an added reduction effect seen from OR2 alone.

Analysis of individual samples with CFU ≥ the 15 CFU threshold revealed that there was a significant reduction in percentage of samples with CFU counts above that threshold between periods in both OR1 (11.2%-1.5%, $P < .001$) and OR2 (8.8%-0.5%, $P < .001$).

Impact of a visible-light CED system on SSI in the OR

A total of 2,201 surgical cases were performed in period 1 of the SSI analysis, and 2,317 cases were performed during period 2. Table 3 demonstrates that there was a statistically significant reduction in SSIs in OR2 following installation of the visible-light CED system. The SSI rate in OR2 decreased from 1.4% during period 1 to 0.4% in period 2. The Fisher exact test was used for statistical analysis because it has been shown to be more accurate when some of the values are very small; however, analysis with both the Fisher exact test and the

χ^2 test showed this reduction to be statistically significant ($P = .029|.043$). Based on the infection rate from period 1 in OR2, a total of 12 infections would have been anticipated in period 2. However, only 3 infections occurred, suggesting that a potential 9 infections were prevented by augmenting disinfection with the visible-light CED system.

There was also a trend toward reduction in the SSI rate in OR1 from 1.2%-0.3% between period 1 and period 2, but there was not enough power to show a statistically significant difference ($P = .108|.114$). As expected, there was no significant difference in SSI rates in OR3 between periods.

When considering data from each period separately, there was no statistically in any OR comparisons. Although it would have been expected that the difference in SSI rates between OR2 and at least OR3, if not OR1, would be statistically significant in period 2 because of the visible-light CED system, this was not the case. However, to achieve statistical significance between 0.4% and 0.9%, a sample size of approximately 2,500 in each OR would be required and the actual number of cases in both ORs totaled only 1,657 in period 2.

Simple logistic regression analysis was performed to identify which variables were independently predictive of SSI occurrence. To avoid oversaturation of the model, some variables were simplified. Procedure severity was consolidated from 7 variables into 3 and OR was consolidated from 3 separate ORs down to 2 groups: OR1 or OR2 and OR3. This initial simple analysis revealed period 2 ($P = .022$), total operation time ($P = .020$), and elapsed room time ($P = .003$) to be significant predictors of SSI with a P value <.20, thus to be included in multiple logistic regression. Because elapsed room time is a natural extension of total operation time, and was the more significant of the 2 predictors, total operation time was not taken into multiple logistic regression analysis to avoid multicollinearity and redundancy in the model.

Table 4 shows the final model resulting from multiple logistic regression analysis. Elapsed room time (odds ratio: 1.009; 95% confidence interval [CI]: 1.003-1.014; $P = .003$) and the interaction effect between period 2 and OR1 or OR2 (odds ratio: 0.22; 95% CI: 0.05-0.90; $P = .039$) were the significant predictors of SSI occurrence. For each additional minute of elapsed room time, the odds of SSI occurrence increased. In period 2, the odds of SSI occurrence in OR1 or OR2 were 0.22 times the odds of SSI occurrence in OR3.

Although elapsed room time in OR2 was significantly longer in period 1 than in period 2, this analysis shows that even when accounting for this confounding effect and its contribution to the odds of SSI occurrence, the effectiveness of the visible-light CED system is still highly evident in the model. This is shown in the statistically significant interaction effect of period 2 and OR1 or OR2 and its contribution to the reduced odds of SSI occurrence.

Table 3
Frequencies and proportions for surgical site infections provided by period and OR

		Period 1		Period 2		
OR1	N	662		660		Fisher exact test, $P = .108$
	Yes	8	1.2%	2	0.3%	
	No	654	98.8%	658	99.7%	
OR2	N	788		850		Fisher exact test, $P = .029*$
	Yes	11	1.4%	3	0.4%	
	No	777	98.6%	847	99.6%	
OR3	N	751		807		Fisher exact test, $P = 1$
	Yes	6	0.8%	7	0.9%	
	No	745	99.2%	800	99.1%	
Fisher exact test		OR1-OR2: $P = .864$		OR1-OR2: $P = 1$		
		OR1-OR3: $P = .592$		OR1-OR3: $P = .198$		
		OR2-OR3: $P = .332$		OR2-OR3: $P = .215$		

OR, operating room.

Table 4
Summary of final model including significant predictors of surgical site infection resulting from multiple logistic regression analysis

Factor	Coefficient [95% CI]	P value	Odds Ratio [95% CI]
(Intercept)	−6.168 [−7.480, −4.958]	<.001	-
Elapsed room time	0.009 [0.003, 0.014]	.003*	1.009 [1.003, 1.014]
Period 2	0.216 [−0.856, 1.316]	.690	1.24 [0.42, 3.73]
OR1 or OR2	0.856 [−0.046, 1.882]	.063	2.35 [0.96, 6.57]
Period 2*OR1 or OR2	−1.504 [−2.989, −0.108]	.039*	0.22 [0.05, 0.90]

NOTE. Model: Likelihood ratio test = 17.85 on 4 degrees of freedom, P = .001, n = 4518.
CI, confidence interval, *OR*, operating room.

DISCUSSION

Establishing a direct link between environmental contamination and SSIs has been challenging, but there is a growing body of evidence supporting the relationship[8,25-31] and, subsequently, a surge in novel disinfection technologies aimed at enhancing OR disinfection. These technologies include a variety of episodic disinfection systems, such as no-touch UV systems or hydrogen peroxide vapor systems, used to augment manual cleaning. These systems have proven effective at further reducing environmental contamination[32-35] but are inherently limited by the episodic nature of their operation and, in some cases, compliance with manual application. It has been repeatedly demonstrated that active shedding by OR staff represents a potential source of contamination in the OR[36-43] and this shedding during a case cannot be addressed real-time by episodic disinfection. This is of particular concern in surgical procedures involving an implant as research has shown the microbial inoculum associated with infection is far smaller in the presence of a foreign body than in other clean surgical wounds.[7,44-45]

More recently, there have been several studies evaluating a visible-light CED system that provides continuous environmental disinfection in an occupied setting.[46-48] The visible-light CED system inactivates a wide range of bacterial pathogens in the air and on surfaces using a narrow bandwidth of high-intensity visible light with peak output at 405 ± 5 nm. Visible light in this spectrum has been shown to incite bacterial cell death via photo-excitation of porphyrins within the bacteria.[46,49-55] Clinical and laboratory studies have shown significant reductions in bacterial contamination of various health care settings including isolation rooms, a burn unit, and an intensive care unit, with use of the visible-light CED system.[46-48] Although light in this wavelength range is less germicidal than UV light, these systems have the notable benefit of being safe for use in occupied spaces, while providing the necessary illumination required for surgery. Additionally, because they can be used continuously, they can provide disinfection throughout the day, actively addressing organisms shed in the air and on surfaces by OR staff during cases and between manual cleanings.

The results of this study demonstrate that use of the visible-light CED system was effective in not only reducing residual bacterial contamination of surfaces in the OR but also in reducing the number of SSIs that occurred following procedures performed therein. The culture count arm of the study demonstrated several important findings. The impact on residual contamination extended beyond the OR in which the visible-light CED system was installed and into the contiguous OR, presumably by the shared circulation of air disinfected by the visible-light CED system. This has significant clinical, not to mention financial, implications as infection prevention measures taken in the OR alone do not wholly address all potential sources of perioperative environmental contamination. Both the preoperative and postanesthesia areas represent opportunities for environmental contamination, but these areas could, in theory, see a benefit from the system if they too shared an air supply and were in close proximity. The authors believe that this unanticipated finding could

potentially have wide-ranging impact based on common, connected airflow within an OR department. However, as this study focused on surface contamination, the authors recommend additional study focused specifically on airborne contamination to better quantify this effect.

The culture count results also demonstrated that the majority of surfaces in both ORs in this study were positive for CFUs prior to the visible-light CED system installation in OR2, despite regular manual cleaning. These results align with previous studies demonstrating the inadequacy of manual cleaning alone as a means of thorough disinfection.[11-15] Furthermore, 11.2% and 8.8% of sampled surfaces in OR1 and OR2, respectively, had counts that exceeded what several researchers have identified as a significant infectious threshold of contamination.[15,22-23] The fact that disinfection provided by a visible-light CED system resulted not only in statistically significant reductions in total culture counts but also reductions in the percentage of samples which reached this threshold underscores the added value of a disinfection strategy that supplements manual cleaning.

In this study, that value also translated into fewer infections, which is the ultimate goal of any environmental disinfection strategy. There were fewer SSIs for procedures performed in both the OR with the visible-light CED system and the contiguous OR, although the latter did not achieve statistical significance. Although the numbers were small to begin with, the reduction seen in OR2 following a visible-light CED system installation was statistically significant. Furthermore, that significant reduction was achieved despite an increase in use of the OR (greater elapsed room time of that OR) during period 2 as compared to period 1. Nine PJIs—from 1 OR in 1 year—were potentially avoided, which, using an average additional cost per SSI of $100,000, would have saved $900,000.[56] Other researchers have suggested that when personal liabilities such as lost productivity are factored in, the cost associated with a single PJI is closer to the $389,307-$474,004 range, which, at the lower end, would translate into a savings of roughly $3,500,000.[4] Although a cost-benefit analysis of this visible-light CED system technology could form a much larger discussion, it can be simply noted that the technology uses light-emitting diodes and is automated. Therefore, its cost represents a 1-time capital purchase of approximately $15,000-$25,000, eliminating the ongoing operational costs for labor, training, supplies, and maintenance typically associated with other technologies. Additionally, the fact that this technology uses visible light means that it can be used continuously throughout the day without disrupting room turnover—a substantial benefit given the financial value of OR time to the institution. A simple, conservative financial analysis would note that preventing a single SSI at an average cost of $20,781[57] over the 10-year lifespan of the product would approximately cover the cost of deploying and operating the technology in a single room. The return on investment would obviously be significantly greater if this analysis were performed using the average cost for a PJI. A more comprehensive financial cost-benefit analysis will be the subject of a future publication.

Current infection prevention guidelines do not include the use of no-touch disinfection technologies, largely because there are so few

studies demonstrating that reductions in environmental contamination translate into fewer SSIs. The Association for PeriOperative Nurses guidelines does state that these technologies should be considered as an adjunct to manual cleaning but do not differentiate between available technologies.[58] There is robust evidence that many of these technologies are a very effective means of augmenting manual cleaning and disinfection. Hydrogen peroxide vapors and UV light systems have been shown to significantly reduce environmental contamination in the OR and in other health care settings.[15,23,59-60] These technologies, however, are necessarily episodic strategies because of safety issues posed to exposed individuals and, thus, cannot address in real-time environmental contamination and disbursement that occurs during a procedure from sources like microbial shedding or door openings. Additionally, ultraviolet-C (UV-C) light's disinfection capability has been shown to be dependent on distance from and orientation to the targeted surfaces, with surfaces remote from the UV-C source or shadowed by neighboring objects often sub-optimally disinfected.[15,61] Mercury-based UV-C light sources can also cause degradation and discoloration to some surface materials with prolonged exposure.[15,62] This could pose a risk in the OR environment in which the integrity of surgical equipment is paramount.

By contrast, the design and placement of the visible-light CED system obviates these obstacles. The safety of the narrow spectrum visible light allows for both their continuous use (augmented by a higher dose of indigo light when the room is unoccupied) and the preserved integrity of environmental surface materials.[20-21] The design and placement of the ceiling units, combined with their continuous use, avoids the restrictive distance and orientation issues seen with mobile UV-C systems, and allows for more uniform disinfection of both air and surfaces. Furthermore, recent study has shown that sub-lethally damaged bacteria have increased susceptibility to 405 nm light inactivation, suggesting that a visible-light CED system may have enhanced efficacy in disinfecting residual contaminants that were "sub-lethally stressed by desiccation and disinfectants" during manual cleaning.[63] Finally, the impact of the automated nature of this technology cannot be understated. Manual operation adds cost, creates logistical challenges, and raises potential compliance issues. These issues can diminish the benefits of adding such an adjunct technology.

Although the use of adjunctive strategies for hard surface decontamination and disinfection has become a mainstream component of infection prevention efforts over the past decade, the same has not been true for air disinfection. As of this writing, there are no air quality standards in the United States for ORs. This stands in stark contrast to the stringent standards applied to compounding pharmacies and computer chip manufacturing facilities.[64] Experts have advocated that this represents a major gap in perioperative infection prevention practice, pointing to the rigorous standards recommended by the World Health Organization and adopted by the European Union in which the air contamination limit for orthopedic ORs is <10 CFU per cm.[3,7,65] The mounting evidence demonstrating the degree to which OR air can be contaminated despite standard dilution, filtration, and pressurization processes warrants the evaluation and adoption of innovative, evidence-based risk reduction strategies that address both air and surfaces.

Limitations

This study had several limitations. First, the cultures obtained were not speciated to confirm whether isolates were true pathogens often associated with SSI. We hoped to mitigate this by using BPA plates, a partially selective medium frequently used to identify staphylococci, one of the most common causative organisms in SSI globally and in our facility.[66-67] We did not sample floors in the OR, which are undoubtedly sources for environmental contamination. We did not perform air sampling to demonstrate the direct impact on air contamination and quality. However, the positive impact on bacterial surface contaminations and SSIs seen in the OR that shared an air supply with the visible-light CED system suggests a shared benefit from the recirculated disinfected air. Finally, there are a multitude of perioperative factors that can influence SSI risk. Although we accounted for 4 of these (total operation time, elapsed room time, procedure severity, and number of personnel in the OR), there are others, such as the number of door openings that occurred during each procedure, a factor known to influence air contamination,[68-69] and individual surgeon usage of each OR, which we did not track and which may have influenced results.

Conclusions

A visible-light CED system is a relatively novel disinfection technology that addresses some of the limitations posed by other supplemental no-touch environmental disinfection strategies in the OR, namely episodic disinfection, staffing, and lack of uniform disinfection. This study demonstrates that a visible-light CED system provides enhanced environmental disinfection beyond standard manual cleaning and that this optimized disinfection resulted in a significant reduction in SSIs for procedures performed in the visible-light CED system OR.

References

1. Centers for Disease Control and Prevention. Surgical site infection event. 2018. Available from: https://www.cdc.gov/nhsn/pdfs/pscmanual/9pscssicurrent.pdf. Accessed September 4, 2018.
2. Umscheid CA, Mitchell MD, Doshi JA, Agarwal R, Williams K, Brennan PJ. Estimating the proportion of healthcare-associated infections that are reasonably preventable and the related mortality and costs. Infect Control Hosp Epidemiol 2011; 32:101-14.
3. Magill SS, Edwards JR, Bamberg W, Beldavs ZG, Dumyati G, Kainer MA, et al. Multistate point-prevalence survey of healthcare-associated infections. N Engl J Med 2014;370:1198-208.
4. Parisi TK, Konopka JF, Bedair HS. What is the long-term economic societal effect of periprosthetic infections after THA? A Markov analysis. Clin Orthop Relat Res 2017;475:1891-900.
5. Tande AJ, Patel R. Prosthetic joint infection. Clin Microbiol Rev 2014;27:302-45.
6. Lange J, Troelsen A, Seballe K. Chronic periprosthetic hip joint infection: a retrospective, observational study on the treatment strategy and prognosis in 130 nonselected patients. PLoS One 2016;11:e0163457.
7. Parvizi J, Barnes S, Shohat N, Edmiston Jr CE. Environment of care: is it time to reassess microbial contamination of the operating room air as a risk factor for surgical site infection in total joint arthroplasty? Am J Infect Control 2017;45: 1267-72.
8. Loftus RW, Brown JR, Patel HM, Koff MD, Jensen JT, Reddy S, et al. Transmission dynamics of gram-negative bacterial pathogens in the anesthesia work area. Anesth Analg 2015;120:819-26.
9. Otter JA, Yezli S, Salkeid JA, French GL. Evidence that contaminated surfaces contribute to the transmission of hospital pathogens and an overview of strategies to address contaminated surfaces in hospital settings. Am J Infect Control 2013;41 (5 Suppl):6-11.
10. Yezli S, Barbut F, Otter JA. Surface contamination in operating rooms: a risk for transmission of pathogens? Surg Infect 2014;15:694-9.
11. Munoz-Price LS, Birnbach DJ, Lubarsky DA, Arheart KL. Decreasing operating room environmental pathogen contamination through improved cleaning practice. Infect Control Hosp Epidemiol 2012;33:897-904.
12. Jefferson J, Whelan R, Dick B, Carling P. A novel technique for identifying opportunities to improve environmental hygiene in the operating room. AORN J 2011; 93:358-64.
13. Frabetti A, Vandini A, Balboni P, Triolo F, Mazzacane S, Ferrara I. Experimental evaluation of the efficacy of sanitation procedures in operating rooms. Am J Infect Control 2009;37:658-64.
14. Carling PC, Briggs JL, Perkins J, Highlander D. Improved cleaning of patient rooms using a new targeting method. Clin Infect Dis 2006;42:385-8.
15. Simmons S, Dale Jr C, Holt J, Passey DG, Stibich M. Environmental effectiveness of pulsed-xenon light in the operating room. Am J Infect Control 2018;46:1003-8.
16. Chow TT, Wang J. Dynamic stimulation on impact of surgeon bending movement on bacteria-carrying particles distribution in operating theatre. Build Env 2012;57:68-80.

17. Anderson AE, Bergh I, Karlsson J, Eriksson BI, Nilsson K. Traffic flow in the operating room: an explorative and descriptive study on air quality during orthopedic trauma implant surgery. Am J Infect Control 2012;40:750-5.

18. Shaw LF, Chen IH, Chen CS, Wu HH, Lai LS, Chen YY, et al. Factors influencing microbial colonies in the air of operating rooms. BMC Infect Dis 2018;18:4.

19. Dalstrom DJ, Venkatarayappa I, Manternach AL, Palcic MS, Heyse BA, Prayson MJ. Time-dependent contamination of opened sterile operating-room trays. J Bone Joint Surg Am 2008;90:1022-5.

20. International Commission on Non-Ionizing Radiation Protection (ICNIRP). ICNIRP guidelines on limits of exposure to incoherent visible and infrared radiation. Health Phys 2013;105:74-96.

21. International Electrotechnical Commission. Application of IEC 62471 for the assessment of blue light hazard to light sources and luminaires. 2014. Available from: https://webstore.iec.ch/publication/7427. Accessed September 12, 2018.

22. Esposito S, Bassetti M, Bonnet E, Bouza E, Chan M, De Simone G, et al. Hot topics in the diagnosis and management of skin and soft-tissue infections. Int J Antimicrob Agents 2016;48:19-26.

23. Otter JA, Yezil S, French GL. The role played by contaminated surfaces in the transmission of nosocomial pathogens. Infect Control Hosp Epidemiol 2011;32:687-99.

24. International Consensus Meeting on Periprosthetic Joint Infection. Proceedings of the international consensus meeting on periprosthetic joint infection. 2013. Available from: https://www.efort.org/wp-content/uploads/2013/10/philadelphia_consensus.pdf. Accessed September 2, 2018.

25. Stocks CW, Self SD, Thompson D, Adame XA, O'Connor DP. Predicting bacterial populations based on airborne particulates: a study performed in nonlaminar flow operating rooms during joint arthroplasty surgery. Am J Infect Control 2010;38:199-204.

26. Sommerstein R, Ruegg C, Kohler P, Bloemberg G, Kuster SP, Sax H. Transmission of mycobacterium chimaera from heater-cooler units during cardiac surgery despite an ultraclean air ventilation system. Emerg Infect Dis 2016;22:1008-13.

27. Fornwalt L, Ennis D, Stibich M. Influence of a total joint infection control bundle on surgical site infection rates. Am J Infect Control 2016;44:239-41.

28. Catalanotti A, Abbe D, Simmons S, Stibich M. Influence of pulsed-xenon ultraviolet light-based environmental disinfection on surgical site infections. Am J Infect Control 2016;44:e99-101.

29. Darouiche RO, Green DM, Harrington MA, Ehni BL. Association of airborne microorganisms in the operating room with implant infections: a randomized controlled trial. Infect Control Hosp Epidemiol 2017;38:3-10.

30. Knobben BAS, Engelsma Y, Neut D, van der Mei HC, Busscher HJ, van Horn JR. Intraoperative contamination influences wound discharge and periprosthetic infection. Clin Orhtop 2006;452:236-41.

31. Byrne AM, Morris S, McCarthy T, Quinlan W, O'Byrne JM. Outcome following deep wound contamination in cemented arthroplasty. Inf Orthop 2007;31:27-31.

32. El Haddad L, Ghantoji SS, Stibich M, Fleming JB, Segal C, Ware KM, et al. Evaluation of a pulsed xenon ultraviolet disinfection system to decrease bacterial contamination in operating rooms. BMC Infect Dis 2017;17:672.

33. Stibich M, Stachowiak J, Tanner B, Berkeiser M, Moore L, Raad L, et al. Evaluation of a pulsed-xenon ultraviolet room disinfection device for impact on hospital operations and microbial reduction. Infect Control Hosp Epidemiol 2011;32:286-8.

34. Jinadatha C, Quezada R, Huber TW, Williams JB, Zeber JE, Copeland LA. Evaluation of a pulsed-xenon ultraviolet room disinfection device for impact on contamination levels of methicillin-resistant *Staphylococcus aureus*. BMC Infect Dis 2014;14:187.

35. Stibich M, Stachowiak J. The microbiological impact of pulsed xenon ultraviolet disinfection on resistant bacteria, bacterial spore and fungi and viruses. S Afr J Infect Dis 2016;31:12-5.

36. Edmiston CE, Seabrook GR, Cambria RA, Brown KR, Lewis BD, Sommers JR, et al. Molecular epidemiology of microbial contamination in the operating room environment: is there a risk for infection? Surgery 2005;138:572-88.

37. Daines BK, Dennis DA, Amann S. Infection prevention in total knee arthroplasty. J Am Acad Orthop Surg 2015;23:356-64.

38. Edmiston CE, Sinski S, Seabrook GR, Simons D, Goheen MP. Airborne particulates in the OR environment. AORN J 1999;69:1169-83.

39. Scaltriti S, Cencetti S, Rovesti S, Marchesi L, Bargellini A, Borella P. Risk factors for particulate and microbial contamination of air in operating theatres. J Hosp Infect 2007;66:320-6.

40. Clark RP, de Calcina-Goff ML. Some aspects of the airborne transmission of infection. J R Soc Interface 2009;6(Suppl 6):767-82.

41. Cristina ML, Spagnolo AM, Sartini M, Panatto D, Gasparini R, Orlando P, et al. Can particulate air sampling predict microbial load in operating theatres for arthroplasty? PLoS One 2012;7:e52809.

42. Mora M, Mahnert A, Koskinen K, Pausan MR, Oberauner-Wappis L, Krause R, et al. Microorganisms in confined habitats: microbial monitoring and control of intensive care units, operating rooms, cleanrooms, and the international space station. Front Microbiol 2016;7:1573.

43. American College of Surgeons. Minimizing operating room traffic may improve patient safety by lowering rates of surgical site infections. Available from: https:// www.facs.org/media/press-releases/2016/nsqip-ssi-071816. Accessed September 9, 2018.

44. Edmiston CE. Prosthetic device infections in surgery. In: Nichols RL, Nyhus LM, eds. Update surgical sepsis, Philadelphia(PA): JB Lippincott; 1993:196-222.

45. Zimmerli W, Trampus A, Ochsner PE. Prosthetic-joint infections. N Engl J Med 2004;35:1645-54.

46. Maclean M, McKenzie K, Anderson JG, Gettinby G, MacGregor SJ. 405 nm light technology for the inactivation of pathogens and its potential role for environmental disinfection and infection control. J Hosp Infect 2014;88:1-11.

47. Maclean M, MacGregor SJ, Anderson JG, Woolsey GA, Coia JE, Hamilton K, et al. Environmental decontamination of a hospital isolation room using high-intensity narrow-spectrum light. J Hosp Infect 2010;76:247-51.

48. Bache SE, Maclean M, MacGregor SJ, Anderson JG, Gettinby G, Coia JE, et al. Clinical studies of the HINS-light environmental decontamination system for continuous disinfection in the burn unit inpatient and outpatient settings. Burns 2012;38:69-76.

49. Hamblin MR, Viveiros J, Yang C, Ahmadi A, Ganz RA, Tolkoff MJ. *Helicobacter pylori* accumulates photoactive porphyrins and is killed by visible light. Antimicrob Agents Chemother 2005;49:2822-7.

50. Goldoni A. Porphyrins: fascinating molecules with biological significance. ELETTRA Laboratory, research highlights 2001-2002: atomic, molecular and supramolecular studies; 2002:64-5.

51. Ashkenazi H, Malik Z, Harth Y, Nitzan Y. Eradication of *Propionibacterium acnes* by its endogenic porphyrins after illumination with high intensity blue light. FEMS Immunol Med Microbiol 2003;35:17-24.

52. Feuerstein O, Ginsberg I, Dayan E, Veler D, Weiss EI. Mechanism of visible light phototoxicity on *Porphyromonas gingivalis* and *Fusobacterium nucleatum*. J Photochem Photobiol 2005;81:1186-9.

53. Maclean M, MacGregor SJ, Anderson JG, Woolsey GA. The role of oxygen in the visible-light inactivation of *Staphylococcus aureus*. J Photochem Photobiol 2008;92:180-4.

54. Lipovsky A, Nitzan Y, Friedmann H, Lubart R. Sensitivity of *Staphylococcus aureus* strains to broadband visible light. J Photochem Photobiol 2009;85:255-60.

55. Dai T, Gupta A, Murray CK, Vrahas MS, Tegos GP, Hamblin MR. Blue light for infectious diseases: *Propionibacterium acnes, Helicobacter pylori*, and beyond? Drug Resist Update 2012;15:223-36.

56. Kurtz SM, Lau E, Watson H, Schmier JK, Parvizi J. Economic burden of periprosthetic joint infection in the United States. J Arthroplasty 2012;27(8 Suppl), 61-5.e1.

57. Zimlichman E, Henderson D, Tamir O, Franz C, Song P, Yamin C, et al. Healthcare-associated infections: a meta-analysis of costs and financial impact on the US healthcare system. JAMA Intern Med 2013;173:2039-46.

58. Burlingame B, Davidson J, Denholm B, Fearon MC, Giarrizzo-Wilson S, Link T, et al. Guideline for a safe environment of care, part 1. In: Conner R, ed. Guidelines for perioperative practice, vol. 1, Denver(CO): AORN Inc; 2017.

59. Boyce JM. Modern technologies for improving cleaning and disinfection of environmental surfaces in hospitals. Antimicrob Resist Infect Control 2016;5:10.

60. Lemmen S, Scheithauer S, Hafner H, Yezli S, Mohr M, Otter JA. Evaluation of hydrogen peroxide vapor for the inactivation of nosocomial pathogens on porous and nonporous surfaces. Am J Infect Control 2015;43:82-5.

61. Simmons S, Dale C, Holt J, Velasquez K, Stibich M. Role of ultraviolet disinfection in the prevention of surgical site infections. In: Ahmad SI, ed. Ultraviolet light in human health, diseases and environment, New York(NY): Springer; 2017:255-66.

62. Dancer SJ. Controlling hospital-acquired infection: focus on the role of the environment and new technologies for decontamination. Clin Microbiol Rev 2014;27:665-90.

63. McKenzie K, Maclean M, Timoshkin IV, MacGregor SJ, Anderson JG. Enhanced inactivation of *Escherichia coli* and *Listeria monocytogenes* by exposure to 405nm light under sub-lethal temperature, salt and acid stress conditions. Int J Food Microbiol 2014;170:91-8.

64. United States Pharmacopeial Convention. Pharmaceutical compounding sterile preparations (general information chapter 797). In: United States pharmacopeia. 27th rev. and the national formulary. 22nd ed Rockville(MD): United States Pharmacopeial Convention; 2004. p. 2350-70.

65. Charkowska A. Ensuring cleanliness in operating theatres. Int J Occup Saf Ergon 2008;14:447-53.

66. Dickinson Becton. BD Baird-Parker Agar. 2011. Available from: http://www.bd.com/resource.aspx?IDX=25497. Accessed September 15, 2018.

67. Owens CD, Stoessel K. Surgical site infections: epidemiology, microbiology and prevention. J Hosp Infect 2008;70(Suppl 3):3-10.

68. Teter J, Guajardo I, Al-Rammah T, Rosson G, Perl TM, Manahan M. Assessment of operating room airflow using air particle counts and direct observation of door openings. Am J Infect Control 2017;45:477-82.

69. Rezapoor M, Alvand A, Jacek E, Paziuk T, Maltenfort MG, Parvizi J. Operating room traffic increases aerosolized particles and compromises the air quality: a simulated study. J Arthroplasty 2018;33:851-5.