PEER-REVIEW PAPER

Reducing Airborne Microbes in the Surgical Operating Theater and Other Clinical Settings

A Study Utilizing a Unique Photocatalytic Reactor Biocide Unit

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The authors provide a research study examining the airborne microbial killing efficiency of a unique photocatalytic reactor (PCR) to eliminate fungal and bacterial pathogens. The study examines baseline bacterial and fungal cultures, commonly known as pathogens, collected at specific clinical sites. The cultures were incubated, and separate culture counts (colony-formed units, or CFUs) for specific microbes were recorded for the given clinical area. The samples are identified by gram stain and special growth media and samples of unique clinical interest such as methicillin-resistant Staphylococcus aureus (MRSA) are studied in depth, identifying genus and species in varying culture media. Samples and cultures are collected at specific times for a 24-hour period after the installation and use of the PCR biocide unit, revealing up to a 300% reduction of airborne microbes.

Clinical engineers and biomedical technicians play a vital role in bioterror preparedness because of their extensive expertise regarding new technology assessment. This article details a new technology for maintaining healthy indoor air quality in the event of a bioterror attack.

The study examines 2 outcomes: (1) examination of a reduction of airborne microbial counts in specific clinical areas as a result of implementing the PCR unit in the clinical areas sampled (as identified in Tables 1-7) and (2) statistical evidence related to the cost-related savings due to lessened risk factors of lower microbial counts involving nosocomial and cross-infections. Healthcare economics and patient comfort will be impacted as a result, if lower airborne microbial colonies result from the implementation of the PCR biocide unit. A scientific explanation of the photocatalytic oxidation (PCO) process and the distinct uniqueness of the PCO and ultraviolet (UV) combination process (PCO) utilized by the PCR biocide unit will be examined in depth.

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Air Quality Standards

Several state and national organizations and agencies, as well as the Joint Commission on Accreditation of Healthcare Organizations, regulate and recommend standards for hazard control in the healthcare setting. Air quality is accessed based on the lack of hazardous materials contained in a specific area, department, or facility and the air surrounding that environment. Given this assessment process, there is no specific designation for a medical grade of air contained in the surgical operating theater or the healthcare environment in general. The Occupational Safety and Health Administration states defined clean air as "air of such a purity that it will not cause harm or discomfort to an individual if it is inhaled for extended periods of time."[1] There is a designation and standard for medical compressed gases, which is governed by the Compressed Gas Association and the National Fire Protection Agency

Table 1. CFU Counts in Active Stage Versus Time (ENT Day Surgery Data)				
Volume of air	1423.8 ft^3	Baseline sample	228 CFUs per m^3	June 21, 2003
FPM in: duct 1	80 average	Total no. active sample: off after 4 h	572 CFUs per m^3	June 20, 2003
FPM out: duct 2	140 average	Total active sample: on after 24 h	179 CFUs per m^3	June 5, 2003
Exchanges per hour	5.8	Percent decrease in CFUs per m^3 vs. active off	68.7%	—

Section 50.[2,3] There is also no uniform method of testing the air in the surgical operating theater for microbes or hazardous gases.

Bioterrorist threats, conceivably exposing the environment to airborne toxic gases and microbes, as well as the annual trend of increasing nosocomial infections in the healthcare setting, create an acute necessity for uniform standards of testing, monitoring, and containing hazardous air through active implementation of biocide devices, especially in the surgical operating theater and other clinical areas.

Statistical Verification

The study is statistically a binomial experiment, with probabilities given that the expected value (E) of surviving microbial colonies will be less than the total colonies sampled (S) during a surgical/clinical procedure. Since this is a Bernoulli random variable with only 2 outcomes, the Bernoulli variable is $m = P$. The binomial probability distribution is supported by actual colony counts (CFUs) after the PCR biocide unit was installed during a surgical procedure, compared with the baseline sample, which was taken prior to its installation (see Tables 1-7). The killing efficiency hypothesis will be a demonstration of lowered airborne microbial counts after clinical procedures with the unit off versus those with the unit on. The sampling procedures followed a strict protocol. The full protocol is listed in attachment A, B, and C. The lowered nosocomial rate hypothesis will be verified by a demonstration of Hypothesis 1 and empirical extrapolation of data and existing scenarios.

Sampling Population

Select diverse clinical areas were sampled using the air sampling method of a "slit" sampler. The "slit" sampler has an attached vacuum compressor that samples the air within 5 m^3 every minute. The air sampling method is far superior to surface sampling, where swabs are cultured from the surfaces of equipment and structures. To verify a uniform mechanism of action for the PCR biocide unit in a variety of environments, 4 distinct clinical areas were sampled: (1) ear, nose, and throat (ENT) day surgery, (2) pulmonary spirometry, (3) surgical operating theater (OR), and (4) surgical instrument sterile preparation. The unit is a PCR capable of eradicating fungi, molds, bacteria, viruses, and volatile organic chemicals. Volatile organic chemicals may introduce offensive odors or toxic chemicals, which intensify the problem of indoor air quality.

To maintain a statistically normal population in relation to the area sampled, back-to-back sampling of 4 consecutive days was preformed. This method eliminates variables of cleaning and maintenance regimens as well as the variation in clinical procedures performed.

This is known as a "2 + 2 method" of sampling. The first 2 days gather a baseline with the PCR biocide unit turned off, while days 3 and 4 are run during a typical clinical setting with the PCR biocide unit turned on. The samples were delivered to the testing laboratory at the Microbiology and Immunology Testing Laboratories, College of Medicine, Texas A&M University (College Station, Tex) without any representative plate sample markings of the area being sampled, to avoid any bias in the CFU count(s) or microbial expectation. A single blind study was therefore achieved, which promoted preservation, theoretically and statically of the clinical normality of the population and reduced variance in the samples tested.

Science of Photocatalytic Oxidation

Organic Molecular Bond Theory

To fully understand UV and photocatalytic processes, it is necessary to first understand the concept of organic molecular bonding. Organic material is carbon based, as opposed to inorganic material, which contain no hydrocarbons (C-Hx). A definitive academic definition of *organic*

Table 2. Surgical Operating Theater: OR 1				
Volume of air	6710 ft^3	Baseline sample	7 CFUs per m^3	June 10, 2003 to June 11, 2003
FPM in: 8 ducts	2250 ft^3	Active sample: off	17 CFUs per m^3	July 28, 2003 to July 25, 2003
FPM out: 3 ducts	2603 ft^3	Active sample: on after 24 h	12 CFUs per m^3	July 29, 2003
Exchanges per hour	20.7 ft^3	Percent decrease in CFUs from active off	29%	
OR standard specifications usually call for 14 to 20 air turns per hour. The Texas Department of Health requires a minimum of 20 air exchanges per hour (Hospital Licensing Standards, Texas Department of Health, amended through May 1994, p 77T). The small sample size relates to a smaller percent decrease in CFUs, however, the restive microbes eradicated were significant (see Table 5).				

Table 3. Pulmonary Test Area				
Volume of air	1222 ft^3	Baseline sample	5 CFUs per m^3	June 17, 2003 to June 18, 2003
FPM in: duct 1	50 average	Active sample: off after 2 h	80 CFUs per m^3	June 26, 2003 to June 27, 2003
FPM out: duct 2	110 average	Active sample: on after 24 h	103 CFUs per m^3	July 1, 2003
Exchanges per hour	5.04	Percent decrease in CFUs below baseline	NA	—
Variation in number of patients tested resulted in CFU sample anomalies.				

material is "those containing carbon and one or more other elements, most often hydrogen, oxygen, nitrogen, . . .(and) sulfur."[5] Organic compounds may be connected in a ringlike configuration, such as the hexagon benzene ring or in short or long single-stranded structures. Organic material consists of commonly identified substances, such as plastics, sugar, and pharmaceuticals. Bacteria, viruses, molds, yeasts, and fungi are also organic compounds.

Chemical bonds are forces that connect each atom to the next, sometimes in complex spatial arrangements. There are 3 types of chemical bonds: (1) ionic, (2) covalent, and (3) metallic. Carbon-based materials (organic materials) are confined to covalent bonding. Organic carbon most commonly exists as a 4-bonded molecule. Covalent bonds are the weakest bond forces of the 3 molecular bonds.[5]

Van der Waals forces are also an important atomic bonding force at the atomic and molecular level, which measures the attractive force between molecules and atoms and is especially important in hydroxyl groups.

The ability to break or weaken these covalent bonds results in the destruction or denaturizing of organic materials. All living substances have a form or self-preservation or defense mechanism to prevent the bond forces from weakening. Bacteria and viruses mutate and share gene information, which has caused several antibiotics to become ineffective. Some researchers, including these authors, believe that this antibiotic resistance of microbes could lead to eventual epidemic problematic areas. As discussed earlier, nosocomial infections due to drug resistance could determine a positive or negative clinical outcome or even life itself. Nosocomial infections resulting from microbial resistance are also costly for both the patient and the healthcare facility and they require extended lengths of stay in the hospital. The consequences of nosocomial infections will be discussed in detail in a separate topic in this article.

The pharmaceutical industry continues to make advances in antibiotic research and tissue engineering, and gene therapy could also provide a reduction in resistant strains of microbes. Each of these solutions involves individual one-on-one patient intervention, which is not an efficient epidemiological approach to a mass contamination scenario. A device or system that is active on a larger environmental scale is a more practical means of preventing epidemics. This type of large-scale, broad-spectrum biocide device will be critical for public safety and Homeland Security if future SARS, TB, West Nile Virus, or bioterrorist microbial or toxic gas threats endanger whole metropolitan areas or communities.

Photocatalytic Oxidation Versus Ultraviolet

Not all organic material contains the same elements and the same spatial relationships, and there is actually a wavelength spectrum (range of wavelengths) in the UV range where some organic compounds (microbes, fungi, yeasts, and molds) are more susceptible than others. The sun is the primary source of UV rays. It kills a plethora of viruses, bacteria, and fungi in outdoor exposed areas. It will also cause decay of human cells in the process of the popular youthful tradition of tanning. Certain Microcidal UV bond-breaking energy, in a certain range or spectrum, makes the protein contained in microbes susceptible to protein denaturizing (a means of changing the chemical structure of ribonucleic acid or deoxyribonucleic acid) and ultimately cellular death of the microbe. Spores are more resilient to UV irradiation and may remain on surfaces for months.[6]

The Greek physician Hippocrates (the father of medicine and the originator of the Hippocratic Oath taken by all physicians) was the first to realize that sunlight, which contains UV rays, contributed to his patient's health. He regularly had his patients positioned in outdoor recliners to gain full access to sunlight.

Table 4. Sterile Preparation Testing Area				
Volume of air	5760 ft^3	Baseline sample	32 CFUs per m^3	July 18, 2003
FPM in: duct 1	5 FPM	Active sample: off after 2 h	207 CFUs per m^3	July 21, 2003
FPM out: duct 2	3 FPM	Active sample: on after 12 h	11 CFUs per m^3	July 22, 2003
FPM out: duct 3	3 FPM	—	—	—
Exchanges per hour	<0.5	Percent decrease in CFUs from active off	95%	—

Table 5. *Summary of Organisms Cultured Versus Clinical Area*

Organism	ENT day surgery*	ENT day surgery: active*	Operating room*,†	Operating room active†,‡
Gram-negative rods	Yes: baseline 242 CFUs	None after biocide unit on 24 h	Yes: baseline 5 CFUs	None after biocide unit on 24 h
Gram-positive rods	Yes: baseline 232 CFUs	None after biocide on 24 h	Yes: baseline 8 CFUs	5 after biocide on 24 h
Gram-positive cocci	Yes: baseline 269 CFUs	297 CFUs after biocide on 24 h	Yes: baseline 3 CFUs	2 after biocide on 24 h
Gram-negative cocci	Yes: baseline 9 CFUs	None	None	None
Yeast	Yes: Baseline 1 CFU	None	None	None
Fungus	Yes: Baseline 5 CFUs	None	None	None
MRSA	None	None	3 CFUs	None

*Numbers in Tables 1-4 are the average over 2 days and may differ numerically from those presented in Table 6 as the total count over 2 days. This table is intended to show all organisms present in a normal population.
†Some plates (2-3) showed signs of drying on June 13 and new baseline was sampled.
‡Arthroscopic procedure, with very little blood aspiration into sterile field (3 operations); total surgery time 4.25 h.

In clinical applications, there are several variables that hinder the bond-breaking ability of UV. These include (1) temperature, (2) humidity, (3) room air mixing, (4) maintenance and cleaning schedules, (5) employee carriers, (6) unsterile surgical instruments, (7) healthcare processes that encourage microbial growth (eg, kitchen procedures that allow meat to be uncooked to kill inherent microbes, delivery schedules that expose sterile areas to contamination, etc), (8) dust or other inorganic matter, (9) cross-contamination during surgical procedures, (10) improper hand washing and scrub and sterile techniques for all healthcare personnel, (11) mechanical duct damage, (12) heating, ventilation, and air conditioning (HVAC) damage, (13) control factors of visitors especially in the newborn intensive care unit, (14) improper personal protective measures and garments, and (15) a closed environment of persons in waiting rooms with high transmission capabilities.[7]

The research and study of UV germicidal irradiation is by no means new scientific landscape. Productive and reliable research studies dating back to the early 1930s are well documented for sterilization of microbes.[11] However, this energy is significantly higher than that required by the PCO process.

This light spectrum of UV is below visible light and therefore cannot be seen by the naked eye. Organic material of all types, including the human dermis (skin) and eyes, are also damaged by this average wavelength of light produced by the sun. In humans, tanning and/or burning of the skin and eyes result. Prolonged UV radiation from the sun irradiates organic compounds, such as microbes. This is the

Table 6. *Summary of Organisms Cultured Versus Clinical Area—Active Unit On*

Organism	Pulmonary testing*	Pulmonary testing active*	Sterile prep testing*	Sterile prep testing active*
Gram-negative rods	None	29 CFUs some in chains after biocide on 24 h	None	None
Gram-positive rods	Yes: baseline 39 CFUs	5 CFUs some with spores after biocide on 24 h	Yes: baseline 15 CFUs: some in chains	8 CFUs
Gram-positive cocci	Yes: baseline 37 CFUs	6 CFUs after biocide on 24 h	Yes: baseline 61 CFUs	11 CFUs
Gram-negative cocci	None	None	None	None
Yeast	None	None	None	None
Fungus	Yes: baseline 5 CFUs	None	None	None

*Numbers in Tables 1-4 are the average over 2 days and may differ numerically from those presented in Table 6 as a total count over 2 days. This table is intended to show all organisms present in a normal population. There were some anomalies and conditions that require explanations. In Table 6, the number of CFUs for gram-positive rods in the pulmonary testing area after the unit was running for 24 hours indicates that there were more CFUs present with the unit on than when the unit was off. This area is used on inconsistent days and with varying patient loads. Although every attempt was made to normalize the patient population, in the pulmonary testing area, the sampling was not consistent with a normal population. After investigating the anomaly, the authors discovered that the spirometry tests had not been conducted for the prior 3 days. It was also noted that on the active testing days for the pulmonary area, there were 8 patient tests during the "unit off" samples and 17 patient tests during the "unit on" samples. In addition, the door to the test area was found open when the 24-hour final samples were taken. Still, there was evidence of a reduction of gram-positive microbes and fungi, which further confirms that the biocide unit was effective. The timetables of a physician's practice and that of the research team rarely coincide. This anomaly is not considered unusual, and again the authors emphasize the attempt to normalize a population in a single research study, from a given regional area is difficult.

Table 7. *Technical Data for Clinical Areas Sampled*

Technical component	Sterile prep testing area	ENT day surgery	Surgical operating theater: OR 1	Pulmonary testing area
HVAC duct system	Shared common duct	Shared duct common hall	Separate duct	Shared duct common hall
Filter location	Central hallway	Central hallway	In-room per each vent (8)	In-room per each vent (2)
Filter type/rating	HEPA 99%	HEPA 99%	HEPA 99%	Fiber: 0.5 in 50% to 60%
Room temperature	79.4 F	79.8 F	59.3 F	78.2 F
Humidity	80%	72%	52%	65%
Duct size: in	16 in × 16 in	16 in × 16 in	24 in × 48 in (6)	14 in × 14 in
Duct size: out	16 in × 16 in (2)	16 in × 16 in	12 in × 14 in (3)	14 in × 14 in
HVAC management	Honeywell	Honeywell	Honeywell	Trane
HVAC age	2 y	2 y	2 y	9 y
PM change out	Quarterly	Quarterly	Quarterly	Quarterly

main reason that outdoor air has less microbial counts than indoor air.[12] Excessive amounts of toxins and microbial growth inside buildings can result in what is known as the "sick building syndrome." This became a public phenomenon with the outbreak of Legionnaire disease, caused by Legionnaire bacilli.[13]

UV systems must also be louvered (placed in containers with vents pointing downward), so as not to directly expose patients and personnel to the UV rays. Prolonged exposure to UV can create carcinogenic conditions, such as skin cancer. The louvered requirement of UV systems decreases their microbial killing efficiency and also has a negative effect on air mixing. Air mixing is a very important aspect of microbial kill rates and will be discussed in detail in a future section of the article.

Photocatalytic Oxidation and Ultraviolet Catalytic Process

A newer biocide process, which uses a catalyst such as titanium dioxide, is known as PCO. The PCR biocide unit tested efficiently eliminated not only the airborne microbes in the ENT surgical area, but actually reduced the 24-hour CFU count below the baseline count (see Table 1). This would imply that the PCR biocide unit was actively eradicating microbes not only on the ENT surgical area, but also along the entire clinical corridor in 4 proximal offices. There is no other explanation for the lower 24-hour CFU count versus the original CFU baseline count.

The PCR biocide unit tested in this research article is of the PCO with UV catalytic variety. A catalyst is a substance that accelerates or enhances a chemical reaction, or in this case, a photoreaction, without loss of original mass. Titanium is a heavy metal with strong metallic bonding characteristics. In a natural state, titanium always exists as titanium dioxide due to the affinity of oxygen atoms to the titanium atoms. If the surface of titanium is scratched and the oxide coat is removed, it is almost instantly replaced with a new oxide coat when exposed to air or water, due to its natural metallic bonding characteristics. This explains the highly anticorrosive nature of titanium, which protects it from the oxidative process common to other metals commonly known as "rust." Titanium dioxide (TiO_2), when irradiated, produces a high refraction ratio and catalytic reaction, which lowers the intensity field required for UV bulb wattage required to produce the energy needed to break organic covalent bonds. Hydroxyl radicals are produced as the UV strikes the titanium oxide coating. The hydroxyl radicals (negative OH free radicals) attract molecular organic titanium dioxide (TiO_2) constitutes a semiconductor, which can be modeled mathematically with similar electronic semiconductor properties found in common electronic components, such as diodes, transistors, and operational amplifiers. In electronics, the energy required to cause "conduction" of electrons must exceed the "barrier potential." In the case of a simple light emitting diode, when a 0.7 DC voltage potential is exceeded, the light will glow constantly.[8] The end product of the TiO_2 catalyst is a chemical oxidative reaction rather than an electron transfer on a circuit board. The same laws of physics dictate that "energy" is required to free an electron from its atomic orbital shell, whether it is electronic or chemical in nature. Irradiation of TiO_2 with UV lowers the required "band gap energy" to enable an electron to free itself from its orbital shell and partake in chemical reactions. The "band energy gap" of TiO_2 is 3.2 eV. The result of this irradiation is the production of hydroxyl radicals (OH− and H+) and superoxide ions (O_2 + e−) from the dioxide coating surrounding the titanium. The strong metallic bonding properties of titanium, which attracts oxygen atoms and water vapor, allow an almost inexhaustible source of free electrons from the dioxide coating when it is irradiated by UV light.

Free electrons from the hydroxyl molecule and the superoxide ions are extremely potent oxidizing agents. An oxidizing agent is a substance that removes electrons from other atoms or molecules. In the case of carbon-based

microbes, removing electrons causes an oxidation-reduction reaction. This oxidizing potential reacts with airborne organic compounds and creates a chemical oxidative reaction, producing water vapor and carbon dioxide. Carbon is the basic compound in all organic matter. Therefore, the weak covalent bonds of the carbon atom attach to the superoxide ions forming carbon dioxide and the hydroxyl radicals seek out oxygen, which is abundant in the air, to form water vapor.[9,10]

Bioaerosols (the type found in organic aerosol odors) are also subject to an oxidation reaction in which the hydroxyl radicals seek out any local compounds to bind with to neutralize their free electrons. Vinyl wallpaper contains polyvinyl chloride, which over time releases chemical vapors that contain the poison dioxin and chlorine gas. These carbon-based volatile substances also bind with the titanium dioxide catalyst. The binding process produces an oxidation reaction with byproducts of water and carbon dioxide. This process is superior to the standard single UV process, which produces ozone as a byproduct. This catalytic oxidation process eliminates microbes, molds, fungi, and yeast as well as organic odors without producing ozone, which causes respiratory irritation and has been linked in some studies as a carcinogenic enhancing molecule.[6,7]

Significance of the Clinical Areas Sampled

This research study examined 4 clinically disparate areas utilizing uniform testing standards and protocols: (1) ENT day surgery, (2) surgical operating theater (OR), (3) pulmonary testing laboratory, and (4) OR sterile preparation area. In addition, 2 separate clinical facilities were involved in the test samples. Each area had a distinct airflow volume, which will be discussed in the summary and is available for inspection in Tables 1-7. The amount, type, and placement of medical equipment varied in each location. The number and type of medical personnel varied in each location. The physical environment of temperature, humidity, personnel, and equipment traffic varied in each location. Viewing the research parameters and variables from a mathematical modeling, the correlation is staggering. Although the results varied, the research outcomes of lowered CFU counts with the baseline were achieved in all 4 clinical areas. A review of the clinical data in Tables 1-4 and the technical data presented in Table 5 establishes the versatility of the PCR biocide unit and the general PCO concept for aerobic microbial and fungus eradication within a certain "kill block" parameter.[14] The higher and lower "kill block efficiencies" will be discussed in the microbial and fungus summary in Table 6 ("kill block efficiencies" refer to the spectrum of microbes a device/drug is able to eradicate).

There was a single PCR biocide unit in the ENT surgical area during this 24-hour period displayed in Figure 1. Essentially, the air-mixing component of the building HVAC system was nonexistent. The bulk of air mixing was due to the PCR biocide unit. Note also from Table 1 that the HVAC system used a common corridor exposing the ENT surgical area to all microbes in clinical suites along the entire corridor.

The PCR biocide unit efficiently eliminated not only the airborne microbes in the ENT surgical area, but actually reduced the 24-hour CFU count below the baseline count (see Table 1). This would imply that the PCR biocide unit was actively eradicated microbes not only on the ENT surgical area, but also along the entire clinical corridor in 4 proximal offices. There is no other explanation for the lower 24-hour CFU count versus the original CFU baseline count.

These research data from Figure 1 indicate the importance of air mixing as a criterion in factoring the ability of a system to eradicate microbes and fungi. Without the air-mixing factor, the PCR biocide unit was actively killing microbes during and after the procedure. This is an especially important concept when considering situations where back-to-back surgical procedures are preformed. Without the PCR biocide unit, there is no protection from microbes released airborne during the previous case. The PCR biocide unit efficiently eliminated not only the airborne microbes in the ENT surgical area, but actually reduced the 24-hour CFU count below the baseline count (see Table 1).

The PCR biocide unit has its advantages, which are not possible with the best HVAC high-efficiency filter systems. Spores will germinate within the ductworks and collect on refrigerator compressor coils. This is a common source of *Aspergillus* and *Penicillium* fungi. These are often

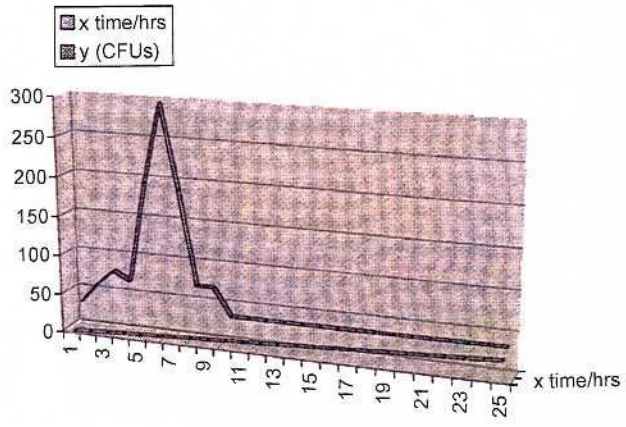

Figure 1. *Total CFU count versus time (in hours). This provides an interesting profile of the action of the PCO process (note the spike at the 7-hour time sample). This graph entices researchers and gives rise to an interest in developing other sampling techniques to better understand the PCO process. Note in Table 1 that the room air exchange is very low relative to most clinical areas.*

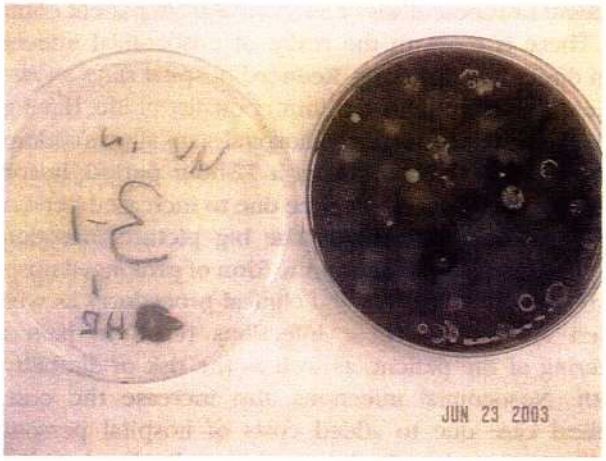

Figure 2. *Photos of culture plate from ENT Day surgery suite after biocide air treatment.*

released in the ductwork into clinical and waiting areas of hospitals accounting for 80 percent of indoor fungi spores.

Verification of Hypothesis

The research hypothesis was validated with a decrease in CFUs in the "active sample-on" stages of clinical procedures with a similar sampling environment with the unit off. The samples in the pulmonary test area, "active test" day 2, were considered an outlier. The statistical test method was a binomial Bernoulli method with 2 possible outcomes[15]: (a) outcome true: with the biocide unit turned on, it would reduce the number of CFUs in an active clinical setting compared with the number of CFUs with the biocide unit turned off; (b) outcome false: with the unit turned on, it would not reduce the number of CFUs in an active clinical setting compared with the number of CFUs with the unit turned off.

Verifying a Normal Population

Our binomial random variable X is the number of CFUs counted among 16 trials. The trials are identified as success or failure (true or false). The trials were independent and the probability of success is constant dependant on the uniformity of the PCR biocide unit. The same units were not used in all samples. We assume that the quality of PCO in all units is equal. The clinical areas vary considerably. Therefore, a separate binomial probability is required for each area. Since we have a Bernoulli random variable, without a pool of data for the binomial outcome, we will satisfy our experimental outcomes without a binomial probability exercise. After several samples are compared with our research, a true binomial probability can be calculated. In this research we must assume $X(s) = x$, as associated with our sample population. Microbial air sampling is in the neonate stage. To make any statement as to the probability of CFUs as an expected value would be premature. In addition, in a clinical setting, the variables are considerable. A modeling of airflow and an examination of several CFU counts would be more valuable than a binomial probability distribution and linear regression curve at this time.

Research Commentary on the Photocatalytic Reactor Biocide Unit

Clearly, the clinical environment presents challenges not seen in the clinical laboratory. We counted 15 variables that contribute to the possibility of creating a nosocomial infection or cross-infection in the healthcare arena. The PCR biocide unit is normally mounted on the ceiling. Due to time constraints, logistics, and the need to reuse some units in other clinical areas, the units were mounted on stainless steel carts, 36 in above the floor. They were positioned in areas around the patient-care setting to place them in the airflow path. The effect of not mounting the units on the ceiling certainly decreased their efficiency. To what extent the "kill block" was decreased cannot be determined. It is significant that even in this nonoptimal position, the units had a significant effect in decreasing the CFU counts. The addition of personnel or equipment to an area creates air turbulence. Air turbulence is defined as chaotic, nonlinear motion of a fluid. A swirling effect is created in turbulent air. As a result, the direction and force of the air are changed from its original path. Filtering systems depend on a consistent airway path. Certain pathogens (disease-causing microorganisms) are carried by air currents (those pathogens sampled in this study). If the air pathway changes or turbulence occurs, it reduces the efficiency of the filtering system. The number(s) of personnel and equipment were required information on the data sheet for this reason. Each additional nurse,

Figure 3. *Photos of culture plate from ENT Day surgery suite before biocide air treatment.*

physician, or piece of equipment and its placement presents the possibility of creating turbulence. The correlation of this factor may help explain anomalies and provide a modeling base for further research of this system.

Significance of Nosocomial Infections and Airborne Pathogens

Indoor air quality is significant in hospitals due to the continuous exposure of bacteria, viruses, and fungi they are confronted with everyday. Antibiotics used to treat these organisms have become ineffective in recent years due to the adaptation of the organisms' survival instincts. This has resulted in microbial mutations known as "super bugs." Since hospitals serve as a receptacle of microbial and fungi from the patients being treated for diseases caused by these organisms, hospitals are a central source of resistant organisms. Visitors enter the hospital virtually uncensored for pathogens on their clothing or exposed surfaces of their body. The authors conclude that an entryway system for the public, such as the PCR biocide unit tested, would result in a reduction of pathogens and have a major impact on nosocomial infections. Decreasing opportunities for cross contamination is a major factor in the vector of nosocomial infections in patient rooms.

Simmelweis, a Hungarian physician practicing in Vienna during 1847 to 1849, was the first healthcare practitioner to identify the correlation vector of illness caused by healthcare providers. He found that when he washed his hands after visits to the anatomy laboratory and before obstetrical delivery of infants, his patients did not contract postpartum infections (puerperal fever) as did his fellow physicians'.

Although he was initially ostracized by a small group of Vienna academics, due to his initially unexplainable superb clinical outcomes, his sterile technique changed the accepted practice standards of medicine. Dr Simmelweis introduced the medical world to the first concept of cause and effect related to sterile technique. Surgeons began to not only wash their hands, but also dip them into caustic carbolic acid prior to surgical cases. This practice also lead to a decrease in postsurgical infections. Louis Pasteur would later expand this concept in the 1880s and introduce the science of microbiology as a part of medical practice. This was the first scientific recognition that bacteria caused infections.

Today, the challenge of reducing microbial infections in the healthcare arena is still a major source of scientific and clinical study. Hospital acquired infections are known as "nosocomial" infections. *Nosocomial infections* are defined as "an infection not present or incubating prior to (the patient's) admittance to the hospital, but generally occurring 72 hours after admittance."[17] The term is usually used in reference to "patient" disease, but hospital personnel may also acquire nosocomial infection, such as the autoimmune deficiency syndrome's HIV virus, hepatitis, etc, from a self-inflicted needle stick while drawing blood from a patient or tuberculosis or SARS virus from patient contact.

There is more to the realm of nosocomial infections than direct hospital costs. Reduced hospital stays allow the patient to return to his/her former quality of life. Having an available bed due to reduced hospital stays allows additional patients to receive care. After a 72-hour period, hospitals begin to have reduced revenue due to increased personnel and equipment charges. In the big picture, nosocomial infections impact patients in the form of prolonged hospital stays, added medication, and clinical procedures as well as added discomfort. These infections result in pain and suffering of the patient, as well as the risk of disability or death. Nosocomial infections also increase the cost of medical care due to added costs of hospital personnel, medications, and medical device usage. Regional studies in the authors area attribute costs for an average nosocomial infection to be in the range of $12,000 to $50,000 per case.[18] National data on the costs of nosocomial infections reveal fiscal expenditures for hospital care alone above $100,000. Therefore, hospitals and hospital personnel expend enormous time, energy, and resources for educational training in the area of universal precautions, protective equipment (gloves, gowns, masks, etc), and aggressive decontamination and sterilization techniques to eliminate and/or reduce them.

Airborne infections, such as Legionnaire disease and tuberculosis, are difficult to control due to their aerosolized spreading or epidemiological method. These microbes and fungi may remain in the air for days waiting for a host that passes into the infected environment. They may settle in wounds, inhaled, or settle on surfaces, which spread the infection by touch and continue the cycle of spreading from hands that touch other surfaces. These airborne microbes and fungi may also enter the HVAC systems of hospitals, homes, and offices. These are the pathogens that this article addresses.

Summary and Conclusion

The authors' research is an attempt to better understand how a PCO device could impact decreased nosocomial infections in a variety of clinical settings. As noted on the "Verification of Hypothesis" section, the tested unit was effective in reducing the number of airborne microbes and fungi in all sampled clinical environments. This verifies the first objective of this research study and confirms the original hypothesis as true.

Tables 5 and 6 provide dramatic research evidence that airborne microbes are reduced by nearly 300% or greater with the implementation of the PCR biocide unit. Empirical correlation of these research data would suggest that a reduction in nosocomial infections would follow an exponential decrease in nosocomial rates. The authors base this statement on the research evidence in Table 5, where MRSA is cultured during an arthroscopic procedure (a surgical procedure that causes very little aspirated fluid and is minimally invasive). After the unit was activated during

a similar arthroscopic procedure 45 minutes later, no MRSA CFUs were cultured after sampling. Also, gram-positive rods (a microorganism, which is highly resilient to antibiotics) were also dramatically reduced with the unit in the active stage. These facts verify the second objective of the research study, which correlates reduction of airborne microbes to an augmentation and enhancement of risk management in cases of nosocomial infection rates.

Tables 5 and 6 summarize the microbial and fungi eradication ability of PCR more explicitly than any commentary. There are a variety of microbes sampled. PCR was able to reduce the CFU count in each category. This study provides encouraging data of a medical device that provides reduction of microbes and fungi of multiple varieties in multiple clinical settings. The authors can conclude that the PCO process is a viable and practical means of reducing biohazards.

Three surgical cases were sampled in the OR study, all of which were arthroscopic in nature. An arthroscopic surgery causes very little aspiration of blood or body fluids. A 1- or 2-cm cut is made in the indicated joint area and a probe is inserted to remove damaged ligaments and cartilage. This was also a factor in the low CFU counts during the active stage of sampling. During the active phase of sampling in the surgical operating field, an average of 6 personnel entrances and exits occurred. The CFU counts remained low despite this disruption of the airflow. Airflow, duct size, and placement are very critical when examining airborne diseases. Further study of this aspect of nosocomial and cross-infections revealed that the air-mixing process of the tested PCR unit contributes to and enhances the existing HVAC system of the facility. In the areas sampled, the authors found satisfactory maintenance of the HVAC systems. This is also a sizeable factor when considering the normality of the samples taken. The design and flow dynamics of the operating room sampled were superb. This factor further indicates the importance of the air-mixing process, which is part of the tested system. Air mixing has been found to impact cross-infections, especially in prosthetic surgery. In the absence of air mixing, CFU counts are significantly higher.[18] The fact is evident in the low CFU counts from the OR area, where large CFU counts were cultured during the active stage of the arthroscopic procedure, and the CFU samples cultures were lower than the baseline CFU samples after the PCR unit was engaged during the following arthroscopic procedure. This comparison of similar surgical procedures in the same OR is an extremely relevant research comparison, which demonstrates a reenactment where the PCR biocide unit proved superior to HEPA HVAC surgical air systems alone. The HVAC system used in the OR tested was extremely well designed and less than 2 years old with a laminar airflow over the patient. The test unit augmented and enhanced this state-of-the-art HVAC-engineered OR system.

The authors conclude that a medical device that does not produce mutants (which have been documented by UV-only systems) or cross-resistance is the most effective means of eradicating or reducing nosocomial and environmental microbial contamination. The unit tested in this research both enhances and augments existing facility HVAC systems, resulting in lower risk factors for nosocomial infections. It should also be pointed out that the manufacturer recommends that the units be mounted on the ceiling or upper wall for maximum effectiveness. Due to logistics constraints, the authors were confined to placing the units on mobile carts 36 in above the floor. With the superb and startling results achieved in this research scenario, it can only be concluded that ceiling-mounted units would provide an even more dramatic effect. This would contribute to a more economical baseline for any facility considering the cost of nosocomial infections and lost opportunities for revenue due to a prolonged hospital stay. There is also the clinically superior aspect of positively impacting the risk management system of the facility.

In summary, the PCR biocide tested system has the following advantages:

1) an efficiently high destruction rate of pathogens,
2) no chemical additives,
3) no residual ozone,
4) efficient energy requirements,
5) the ability to oxidize and eliminate volatile organic chemicals and bioaerosols (odors),
6) low maintenance and long product life,
7) not effected by humid conditions,
8) does not affect the HVAC duct flow or pressure drop,
9) enhances air mixing with existing HVAC systems,
10) installation does not require any room renovations, and
11) size and placement will not obstruct normal clinical processes.

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