Product Testing

The Photox 500 incorporates two different technologies, each having strong anti-microbial capabilities: 1) germicidal ultraviolet light (UVC); and 2) photocatalytic oxidation (PCO).

Product Testing is divided into three sections: 1) Proof of Photox Photocatalytic Oxidation (PCO) Technology; 2) Photox 500 Biological Efficacy Testing; and 3) Photox 500 Environmental Testing.

Section I. Proof of Photox PCO Technology

These experiments were designed to assess the value to air purification of the photocatalytic oxidation (PCO) technology described in U.S. Patent Numbers 5,766,455, “Fibrous matte Support for the Photopromoted Catalyzed Degradation of Compounds in a fluid stream” and 5,834,069, “In situ Method for Metalizing a semiconductor catalyst.”

We hypothesized that the potential benefits of PCO to air treatment would be greatly enhanced if a catalyst optimized for adsorption of a broad range of contaminants could be permanently bonded to a support structure that would allow air to pass through it (like an air filter) rather than just past it. In order to be destroyed by a catalytic reaction, a contaminant must first be adsorbed to the surface of the catalyst. A catalyst applied to the surface of an air duct could adsorb contaminants that physically come in contact with it. If an ultraviolet light were then to illuminate the catalyst, the adsorbed contaminant would be destroyed by photocatalytic oxidation. However, most of the air travel travelling through a duct does not actually touch the ductwork, leaving most of the airborne contaminants unaffected by the PCO process. Photox PCO technology consists of inserting, across the airflow, a platinum-infused titanium dioxide catalyst bonded to a glass fiber mat through which all air must pass. This configuration provides a tortuous path for any airborne contaminants, making it difficult for them to avoid being adsorbed. The addition of an ultraviolet light source that uniformly illuminates the entire surface of the catalyst containing the adsorbed contaminants would substantially reduce the concentration of contaminants in the processed air.

To prove how effective photocatalytic oxidation could be in purifying air, a method of testing had to be devised such that results could not be attributed to another technology. In the lab experiments discussed in this section, we used our proprietary catalyst-coated fibrous mat in the configuration described above, but used a non-germicidal wavelength of light (UVA) to excite the catalyst. The use of UVA light isolated the photocatalytic oxidation component of our device and allowed us to assess its potential in helping to reduce airborne contaminants as either a stand-alone technology or in concert with other technologies.

The effectiveness of the Photox PCO process is dependent on several factors, including the energy imparted to the catalyst via protons in the UV light source and the contaminant adsorption efficiency. The lower the wavelength of light, the higher the energy of the associated protons. The protons of lower wavelength UVC light have roughly 50% more energy to impart to the catalyst than do UVA protons, so the results achieved by the PCO process evaluated in this section would be expected to have been substantially better had UVC light been used instead of UVA, but if UVC light had been used, the PCO contribution to the antimicrobial results could not have been ascertained.

The adsorption efficiency of the Photox CRM is dependent on the speed of the air passing through the CRM and the area of the CRM through which the air must pass. The speed to area ratio is a good indicator of relative adsorption efficiency, with lower ratios being more efficient. The following matrix shows the adsorption efficiency rating of the two test units used in the proof of technology experiments and that of the Photox 500 for comparison. It also shows the UV light source used in the units and lists how the test units may have been referred to by the researchers in the various lab reports. As illustrated, the Photox 500 has a better adsorption efficiency rating than either test unit as well as the higher energy and germicidal wavelength associated with UVC light. The Adsorption Efficiency Rating (AER) for each experiment is indicated in the Test Matrix.

Process Efficiency Matrix

Adsorption Efficiency Rating (AER)	Fan Speed (cfm)	CRM Area (ft^2)	UV Band	How test units may be referred to in lab reports
Test Units				
59.5	100	1.68	UVA	LeVOCC 100, LeVOCC NP 100, Photox 100, Photox NP 100
21.3	100	4.69	UVA	LeVOCC 200, Photox 200, Photox NP 200
Subject Device - Photox 500				
13.9	500	36	UVC	Photox 500

Photox PCO Proof of Technology Test Matrix

Name of Test	Test Objective	Pre-Determined Pass / Fail Criteria	Result
EMSL Analytical, Inc. - (AER 59.5)			
Ozone	Demonstrate non-production of ozone	Remain at or below control levels of ozone (which were below the 25 ppb limit of detection)	Pass. Air samples remained below the limit of detection of throughout the testing process
Ammonia	Test ability to reduce the concentration of ammonia	Exceed the natural depletion rate	Pass. The accelerated reduction of ammonia was evident after two minutes of operation
Formaldehyde	Test ability to reduce the concentration of formaldehyde	Exceed the natural depletion rate	Pass. Elimination of formaldehyde in the test chamber was reduced from 90 minutes to 35 minutes.
Bacillus sp (spore producing bacteria)	Test ability to reduce the viable bacteria count	Decrease the viable to total bacteria count	Pass. The viable to total bacteria began to noticeably drop after 2 hours of operation and continued until less than half the bacteria were viable after 24 hours
Botrytis cinerea (Grey Mold)	Test ability to reduce the viable mold spore count	Decrease the viable to total mold spore count	Pass. The viable to total mold spore count began to noticeably drop after sixty minutes of operation until only about one third of the spores were viable after 24 hours.
Stachybotrys (Black Mold)	Test ability to reduce the viable mold spore count	Decrease the viable to total mold spore count	Pass. The viable to total mold spore count began to noticeably drop after sixty minutes of operation until less than half the spores were viable after 24 hours.
Rochester Midland Corporation - (AER 59.5)			
B.cereus (spore producing bacteria)	Test ability to reduce the viable bacteria count on inoculated catalyst	Decrease the viable bacteria count	Pass. A 2.92 Log reduction of viable *B.cereus* occurred on the catalyst over the span of 60 minutes.

Name of Test	Test Objective	Pre-Determined Pass / Fail Criteria	Result
Public Health Agency of Canada - Volatile Organic Compound Testing			
BTEX 1	Assess system effectiveness in destroying airborne BTEX contaminants with a used CRM (AER=59.5) in closed system	Meet NIOSH 8-hour TWA for Benzene of 0.1 ppm	Pass. Destroyed all BTEX gasses (from 2.6 ppm to less than detection limit) in 19 minutes
Isobutylene	Assess system effectiveness in destroying Isobutylene with a used CRM (AER=59.5) in a closed system	Substantial reduction (No NIOSH exposure limits for isobutylene)	Pass. Reduced concentration from 6.7 ppm to 0.7 ppm in 90 minutes
Carbon Monoxide	Assess system effectiveness in destroying Carbon Monoxide with a used CRM (AER=59.5) in a closed system	Meet NIOSH 8-hour TWA for Carbon Monoxide of 35 ppm	Pass. Reduced concentration from 18 ppm to 11 ppm in one hour and from 2.0 ppm to 0.0 ppm in 50 minutes
Toluene	Assess system effectiveness in destroying Toluene with a new CRM (AER=59.5) in a closed system	Meet Health Canada proposed guidelines for residential indoor air quality for toluene of 0.6 ppm for long term exposure and 4.0 ppm for short term exposure.	Pass. Reduced concentration from 8.3 ppm to 1.6 ppm in 4.5 hours and to 0.0 ppm within 24 hours.
BTEX 2	Assess system effectiveness in destroying airborne BTEX contaminants with a new CRM (AER=21.3) in a closed system	Meet NIOSH 8-hour TWA for Benzene of 0.1 ppm	Pass. Destroyed all BTEX gasses (from 5.1 ppm to less than detection limit) in 30 minutes
Formaldehyde	Assess system effectiveness in destroying Formaldehyde with a new CRM (AER=21.3) in a closed system	Meet NIOSH 8-hour TWA for Formaldehyde of 0.016 ppm	Pass. Reduced concentration from 3.6 ppm to 0.0.

BTEX = Benzene, Toluene, Ethylbenzene, Xylene
NIOSH = National Institute for Occupational Safety and Health
TWA = Time Weighted Average

Name of Test	Test Objective	Pre-Determined Pass / Fail Criteria	Result
Public Health Agency of Canada - Biological Efficacy Testing (AER 59.5)			
Proof of Concept	Evaluate functional ability to remove and inactivate a virus (H1N1)	Reduce airborne concentration	Pass. After running the air purifier for 30 minutes no virus was detectable in the air. Testing of the filter demonstrated the presence of no organism or any genetic material of the test organism.
Photox CRM Testing	Test efficacy of unit to reduce *Aspergillus niger* (Black Mold), *Bacillus atropheaus,* Methicillin-resistant *Staphylococcus aureus* (MRSA), Influenza A virus (H1N1 Puerto Rico 8 strain), and *Mycobacterium vaccae*	Reduce airborne concentrations of microorganisms in a closed test chamber	Pass. The system removed and inactivated biological material and was effective against all test organisms, spores, vegetative bacteria mycobacterium and negative stranded viruses

Proof of Photox PCO Technology - Test Summaries

<u>EMSL Analytical, Inc. Laboratory Testing</u>

Ozone Production

A 640 cubic foot containment was tested for background ozone by a Draeger CMS analyzer. The chamber ozone level was found to be less than the limit of detection (LOD) of 25 ppb. The Photox unit was placed in the containment and run for six hours during which the Photox unit and the chamber were analyzed for ozone accumulation. During the course of the procedure no ozone was detected above the LOD. In addition, ozone badges confirmed that no ozone was produced by the Photox unit during the six hour operation time. (See attached EMSL Photox Ozone Production Report.)

Ammonia Reduction

Phase 1: A 640 cubic foot containment was cleaned and tested for contaminants by Polarized Light Microscopy (PLM) and a Draeger CMS analyzer. No chemical contaminants were identified. The chamber was loaded with the Photox unit, two fans for circulation and a chemical aeration bath. The aeration bath subjects the chemical to heat and aeration to facilitate the release of gas into the airstream. The chamber was subjected to ammonia fumes until it reached a maximum saturation near 60 ppm. The aeration bath was turned off and the

concentration of ammonia was analyzed at specified intervals to determine the natural chemical depletion of the chamber.

Phase 2: The chamber was again saturated with ammonia as in Phase I. The Photox unit was turned on and the ammonia concentration was monitored with a Draeger CMS chemical analyzer. The results obtained during analysis were standardized vs. the results obtained in Phase I. The accelerated reduction in ammonia concentration with the Photox unit running became evident after two minutes of turning on the air purifier. (See attached EMSL Ammonia Report.)

Formaldehyde Reduction

A 640 cubic foot containment was cleaned and tested for contaminants by Polarized Light Microscopy (PLM) and a Draeger CMS analyzer. No chemical contaminants were identified. The chamber was loaded with the Photox unit, two fans for circulation and a chemical aeration bath. The aeration bath subjects the chemical to heat and aeration to facilitate the release of gas into the airstream.

Phase 1: The chamber was subjected to formaldehyde fumes until it reached a maximum saturation near 5ppm. The aeration bath was turned off and the concentration of formaldehyde was analyzed at specified intervals to determine the natural chemical depletion of the chamber.

Phase 2: The chamber was saturated with formaldehyde as in Phase I. The Photox unit was turned on and the formaldehyde concentration was monitored with a Draeger CMS chemical analyzer. The results obtained during analysis were compared to the results obtained in Phase I to determine the effect of the Photox unit.

The amount of time for the concentration of formaldehyde in the chamber to reach zero ppm was reduced from about 90 minutes to 35 minutes with the use of the Photox device. (See attached EMSL Formaldehyde report.)

EMSL Microbial Testing

In order to test the efficiency of the Photox unit in reducing airborne concentrations of bacteria and fungi, a 288 cubic foot containment was built from Plexiglas. The containment was cleaned and tested for contaminants by Polarized Light Microscopy (PLM) and Scanning Electron Microscopy (SEM) before each test. When no biological contaminants were identified the testing proceeded. The chamber was loaded with the Photox unit, two fans for circulation and an ozone generator. The chamber was exposed to ozone to further sterilize the containment and tested for bacterial and fungal contaminants before being deemed ready for each analysis.

The chamber was tested using both Air-O-Cell cassettes and an Anderson sampler to determine the total and the viable bacterial or spore counts. The viable count, reported in colony forming units (CFU), representing the “living” organisms and the total count representing the summation of both viable and non-viable, or “dead” organisms were calculated over time and compared to controls to determine the overall effect of the Photox unit.

Bacillus sp Reduction

An aqueous solution containing *Bacillus sp* was sprayed into the test chamber. This test was performed on a combination of *bacillus* species; these are members of the same genus as the

species which causes anthrax*, bacillus anthracis*. The fans dispersed the bacteria and the maximum reliable quantitative limit of ~125 structures per liter was maintained for twenty-four hours.

The viable to total bacteria counts began to noticeably drop after 2 hours of operation and continued until less than half the bacteria were viable after 24 hours. (See attached EMSL Bacillus Report.)

Botrytis cinerea (Grey Mold) Reduction

Petri dishes with mature Botrytis cinerea were placed into the sterilized test chamber and opened. The fans dispersed the spores and the maximum reliable quantitative limit of ~100 structures per liter was maintained for twenty-four hours.

The viable to total mold spore count began to noticeably drop after sixty minutes of operation until only about one third of the spores were viable after 24 hours. (See attached EMSL Boytrytis Report.)

Stachybotrys sp (Black Mold) Reduction

Petri dishes with mature Stachybotrys sp. were placed into the test chamber and opened. The fans dispersed the spores and the maximum reliable quantitative limit of ~80 structures per liter was maintained for twenty-four hours.

The viable to total bacteria counts began to noticeably drop after 60 minutes of operation and continued until less than half the bacteria were viable after 24 hours. (See attached EMSL Stachybotrys Report.)

<u>Rochester Midland Corporation</u>

The Photox system had previously been tested to determine the efficacy of removing microorganisms from the air, but the question remained, what occurred to these organisms once they were in the unit. Were the organisms just settling and remaining viable inside the unit, or were they being reduced to inert material. From this concern came the idea to inoculate a hardy organism (*B.cereus*) directly onto the photo-catalytic oxidizing filter surface and determine the levels of the viable bacteria over time. The results from this testing indicate from a 4.91 Log CFU/ 2 cm^2 concentration a 2.92 Log CFU/ 2 cm^2 reduction of viable *B.cereus* occurred over the span of 60 minutes. (See attached LeVOCC [Photox] Efficacy against *B. cereus* Report.)

<u>Public Health Agency of Canada (PHAC)</u>

PHAC Volatile Organic Compound Testing

System Trials were conducted by Eco Site Assessors, Inc., Brighton, Ontario for the Chief, Applied Biosafety Research Program, Public Health Agency of Canada to assess the effectiveness of the Photox air purification system in destroying selected contaminants of concern (COCs).

Air monitoring and analysis was conducted using a Photox air purification system with either a flat, single layer (AER 59.5) catalyst-coated filter or a pleated (AER 21.3) catalyst-coated filter. The system was equipped with an 18W UVA light bulb to activate the catalyst medium.

The trials were carried out by introducing a known gas or vapor into a vapor chamber, and through the use of ball valves and regulators, controlling the gas or vapor entering into an enclosed stainless steel system fabricated to hold a Photox unit inside.

Air samples were collected during the trials and analyzed using a Photo Ionization Detector (PID) that analyzed concentrations of volatile organic compounds (VOCs), present in the ambient air. The test apparatus consisted of a stainless steel tube with two sample ports connected to a sealed stainless steel enclosure which holds a Photox air purifier. The air purifier was sealed at the bottom and at the top to ensure that all recirculated gas mixture flowed through the unit. Gases or vapors were introduced via a vapor box with a valve to control gas or vapor release to a 380 litre stainless steel tank for air mixing prior to being drawn into an enclosure holding the Photox unit.

Once the desired gas or vapor concentrations were reached, the system was closed and allowed to re-circulate. An additional switch was installed in the Photox unit allowing switching the UVA light off while leaving the fan running bringing the gases or vapors to the desired concentration. Once the desired concentration was achieved, the system was allowed to run for five (5) minutes or until gas or vapor concentrations levels were confirmed to be stable. The UVA light was then switched on and the concentrations were recorded at proper time intervals. During experiments volumetric flow rate through the system was maintained at approximately 182 litres/min (6.43 ft^3/min).

BTEX 1

Forty-eight (48) litres of a certified Scott Brand Benzene, Toluene, Ethylbenzene, Xylene (BTEX) gas mixture, containing 10 ppm of each of the BTEX component gases, with a balance of nitrogen was introduced to the testing system. The BTEX gas was mixed with air bringing the initial VOC concentration to 2.6 parts per million (ppm).

The BTEX concentration was reduced from 2.6 ppm to below the limit of detection 19 minutes after activation of the UVA lamp.

BTEX 2

One hundred forty six (146) litres of a certified Scott Brand Benzene, Toluene, Ethylbenzene, Xylene (BTEX) gas mixture, containing 10 ppm of each of the BTEX component gases, with a balance of nitrogen was introduced to the test system. The BTEX gas was mixed with air bringing the initial VOC concentration to 5.1 ppm. The readings were measured for five minutes and once stable, the UVA light was turned on.

The BTEX concentration was reduced from 5.1 ppm to below the limit of detection 30 minutes after activation of the UVA lamp.

Isobutylene

One-hundred and two (102) liters of a certified NorLAB Isobutylene gas mixture, containing 100 ppm Isobutylene, with a balance of air was introduced to the test system. The Isobutylene gas

was mixed with air bringing the starting VOC concentration to 6.7 ppm. The readings were measured for five minutes and once stable, the UVA light was turned on.

The isobutylene concentration was reduced from 6.7 ppm to 0.7 ppm by the conclusion of the 90 minute test.

Formaldehyde

Five (5) ml of 37% liquid formaldehyde was introduced to the test system. The formaldehyde was introduced into the stainless steel tank using a plastic syringe through a sampling port. Vapor mixture was allowed to circulate in the system until concentration stabilized at 3.6 ppm as measured using the PID meter. Once the PID readings were stable the UVA lamp was turned on.

The formaldehyde concentration was reduced from 3.6 ppm to 2.3 ppm in 4 hrs 18 min, and further reduced to 0.0 ppm after an interval of less than 68 hours.

Carbon Monoxide

A quantity of a certified 300 ppm carbon monoxide (CO) in air gas mixture was introduced to the test system and mixed with air bringing the CO concentration to about 18 ppm. After stabilizing, the system was allowed to circulate for an additional 5 minutes before activating the UVA light.

The CO concentration was reduced from 18 ppm to 11 ppm in one hour, after which no further reduction occurred for nearly 19½ hours. A second experiment was then conducted by reducing the CO concentration to a starting point of 2 ppm and again activating the UVA lamp. The CO concentration was then reduced from 2 ppm to 0.0 ppm in 50 minutes.

Toluene

Five (5) ml of liquid toluene (Toluol) was added to the pre-mixing chamber and introduced to the test system. The resultant toluene vapors were mixed with air bringing the starting VOC concentration to 8.3 ppm within the test system. Once readings were stable, the system was allowed to circulate for additional five (5) minutes and before UV light was turned on.

The toluene concentration was reduced from 8.3 ppm to 1.6 ppm in 5½ hours and from 1.6 ppm to 0.0 ppm in less than 16½ hours.

Discussion

Results for the sampling experiment for BTEX gases, isobutylene, formaldehyde, and toluene vapors show that the Photox unit in a closed system environment can readily destroy these chemicals of concern. The Photox test unit is effective at treating CO, but seems to be better suited to completely destroying CO at lower concentrations (<3 ppm).

As most of these chemicals exist along the floor space of a home, and Photox units, bring gases into the system marginally above the floor level, it is safe to presume that a Photox unit would destroy all or most of moderate to low concentrations of the above listed chemicals of concern from the normal breathing space of a home or room.

Conclusion

The Photox air purifier is very capable of destroying BTEX gases, toluene vapors, formaldehyde vapors, carbon monoxide and isobutylene gases within a closed environment. (See attached LeVOCC-RMC Compound Testing Trials report for complete study including system diagrams, charts and graphs.)

PHAC Biological Efficacy Testing

Introduction

A Photox air purifer was tested to determine its efficacy in reducing microorganisms in closed areas. In testing other air purification units, the Photox process showed the best testable results. The Photox process uses photocatalytic oxidation technology to oxidize particles in the air. This technology has a core surface covered with titanium and platinum nanoparticles, which are activated by UV light, creating a powerful oxidizer. The purpose of this experimentation was to define the ability of the Photox process to inactivate microbial organisms. The biological experiments were carried out in two stages: 1) to define the efficacy of the Photox process in removing and inactivating bacterial, viral, and fungal species when challenged; and 2) to determine the ability of the Photox process to inactivate viral, bacterial, and fungal species from enclosed areas.

Test Chamber

An aerosolization testing chamber was designed and built internally. The chamber was equipped with an aerosolization port and a pressure release port fitted with a HEPA filter. Test organisms were aerosolized using a 6 Jet Collision Nebulizer. Air samples were taken using MAS-100 Microbial Air samplers (EMD Chemicals Inc.). Petri plates containing culturing media were placed in the air samplers, to catch any settled test organisms.

Proof of concept

To evaluate the functional ability of the Photox process an experiment was conducted to determine its ability to remove and inactivate a viral strain (HINI). To test its virucidal ability, the air purifier was first plugged in and allowed to warm up for l hour to ensure the reaction module was activated. After the air purifier was activated, it was placed in the testing box along with the air samplers. The virus was aerosolized and the air purifier was turned on and allowed to run for 30 minutes. After this time the air purifier was turned off and air samples were taken.

Half of each sample was used to determine the amount of viral particles present. The remaining half of each sample was processed for real time polymerase chain reaction (PCR) to determine the amount of RNA (viral genomic material) present.

After aerosolization, sampling methods were able to detect approximately 2 logs less than the originally calculated viral titer. This indicates that aerosolization and sampling methods were successful, but some loss of virus was seen on the surface due to settling. After running the unit for 30 minutes no virus or genetic material was detectable in the air. Likewise, testing of the Photox CRM revealed the presence of no organism or any genetic material of the test organism.

CRM Testing

A Photox Catalytic Reaction Module (CRM) (with an AER of 59.5) was evaluated for its efficacy in removing test organisms from the test chamber. Test organisms were aerosolized within the test chamber and an evaluation of residual organisms was tested. Starting concentrations of 10^6 CFU flooded the system to evaluate the ability of the Photox technology to neutralize the test organism. These experiments were broken up into three parts: 1) determining test organism in the air; 2) determining test organism which has settled on the surface of the test chamber; and 3) determining the reduction of test organism in the air by the Photox test unit.

Test Strains

Strains were chosen to represent a wide range of microorganisms. The following test organisms were evaluated: MRSA as a vegetative bacteria; *Bacillus atropheaus* as a spore former; *Aspirgillus Niger* as a fungal strain; HlNl as a viral strain; and *Mycobacterium vaccae* as a tuberculosis surrogate:

Bacillus atropheaus: A surrogate of *Bacillus anthracis, B. atropheaus* is a Gram positive catalase positive bacterium, carries a rod shape and has the ability to form a tough protective endospore allowing the bacterium to tolerate extreme environmental conditions.

Methicillin-resistant *Staphylococcus aureus* (MRSA). This is a designation for any *Staphylococcus aureus* that has developed resistance to beta-lactam antibiotics. *S. aureus* is a facultative anaerobic Gram-positive coccal bacterium. This organism is a common nosocomial transmitted bacteria.

Influenza A virus (HlNl Puerto Rico 8 strain) is a subtype of influenza virus, which causes the common cold. Influenza A viruses are negative-sense, single stranded, segmented RNA viruses.

Aspirgillus Nigar is a fugal strain that causes a disease called black mold. Commonly found in both indoor and outdoor environments, aspirgillus strains have been shown to cause respiratory problems in humans.

Mycobacterium vaccae is a non-pathogenic species from the Mycobacteriaceae family used as a surrogate for mycobacterium tuberculosis.

Analysis of Air Samples

For bacterial testing, TSA plates were incubated at 35°C to examine the residual bacterial counts, viral testing was carried out on VERO E6 cells. Tissue culture plates were incubated at 37°C with 5% CO_2. Air sampling was carried out over 15 minute intervals with the Photox unit running for 15 minutes, followed by sampling of air and surface areas.

Surface Sampling and Analysis

Surface samples were identified and labelled breaking the test chamber into three areas of testing: 1) right side of test unit; 2) left side of test unit; and 3) under the unit after testing was completed. Each area was sampled only once with sponge wipes being place in sterile bags and mixed with PBS. Serial dilutions were prepared and filtered through 0.2 µm filters and

grown on TSA or tissue culture plates. The test organisms were counted to determine the amount of residual organism.

Discussion

Three repetitions were conducted for each test organism. On average the CRM was able to remove two to three logs of test organism during experimentation with settling and natural death making up the remainder of the initial 6 log biological concentration. In each series of tests for each organism at least one repetition ended with no test organism remaining in the air. In other words, 100% of the airborne challenge had been removed by a combination of Photox PCO, settling and natural death, and no test organism was able to survive in the air.

Results

The proprietary Photox Catalytic Reaction Module demonstrated its ability to reduce all types of airborne microorganisms, spores, vegetative bacteria, mycobacterium and negative stranded viruses tested in the laboratory test chamber.

Section II. Photox 500 Biological Efficacy Testing

Introduction

Although the Photox 500 uses the same PCO technology as that used in the proof of technology experiments, it incorporates several performance enhancing features. The first is the replacement of the one 18 watt UVA lamp with four 36 watt UVC lamps. Simply by using UVC light instead of UVA light to stimulate the catalyst, the energy imparted to the catalyst increases by about 50%, which vastly improves PCO performance (UVA photon energy at 380 nm = 3.26 eV; UVC photon energy at 253 nm = 4.9 eV).

The second performance enhancing feature is the replacement of the fan with one able to draw five times as many cubic feet of air per minute. This required a corresponding increase in the area of the catalytic mat (CRM) to maintain performance. The cfm/ft^2 ratio is important in that it affects contact time with the catalyst and the attendant contaminant adsorption rate. The Photox 500 has an improved adsorption efficiency ratio (AER 13.9) over that used in the proof of technology experiments.

Replacement of the UVA light used in the lab with germicidal UVC light not only increased the efficacy of the PCO process by increasing the amount of energy stimulating the catalyst, but also introduced an entirely different mechanism for inactivating microorganisms. UVC light is well-understood and accepted in the medical community as being an exceptionally effective anti-microbial technology, used primarily in surface sanitation protocols. The purpose of this experimentation was to determine if the antimicrobial results obtained in the proof of technology testing in a test chamber would be replicated by the Photox 500 in a full-sized room (12x12 foot decontamination room).

Photox 500 Biological Efficacy Test Matrix

Name of Test	Test Objective	Pre-Determined Pass / Fail Criteria	Result
Public Health Agency of Canada - All tests conducted with the Photox 500 (AER 13.9)			
Photox 500 Biological Efficacy Testing	Test efficacy of unit to reduce *Aspergillus niger* (Black Mold), *Bacillus atropheaus,* Methicillin-resistant *Staphylococcus aureus* (MRSA), Influenza A virus (H1N1 Puerto Rico 8 strain), and *Mycobacterium vaccae*	Reduce airborne concentrations of microorganisms in an enclosed 12'x12' room	Pass. The system removed and inactivated biological material and was effective against all test organisms, spores, vegetative bacteria mycobacterium and negative stranded viruses

Photox 500 Biological Efficacy Test Summary

The protocols and test strains used to evaluate the Photox 500 in the decontamination room were the same as those used by Health Canada in the proof of technology experiments.

Results

The average 2-3 log reduction of airborne microorganisms achieved in the proof of technology experiments was replicated in the Photox 500 tests, with a substantial reduction in airborne microorganisms prevalent in every case and no airborne microorganisms remaining at the end of the timed tests in at least one of three experiment repetitions in 5 of the 6 organisms tested. The integration of our PCO technology with germicidal UVC light resulted in the successful reduction of airborne microorganisms in the contained 12 x 12 foot decontamination room and demonstrated the effectiveness of the device in treating ambient air. These results prompted the engagement of Wake Forest School of Medicine to develop a protocol for an environmental study to see if these results could be effective in treating air in an open area such as a hospital Emergency Department.

Section III: Photox 500 Environmental Testing

The following environmental study was conducted to determine the ability of the Photox 500 device to reduce airborne microorganisms in open areas such as a hospital Emergency Department with patients and hospital staff present. The ability to continually reduce airborne contaminants in occupied rooms could prove to be a useful tool in reducing the probability of airborne transmission of disease in healthcare environments.

Photox 500 Environmental Study Matrix

Name of Test	Test Objective	Pre-Determined Pass / Fail Criteria	Result
Wake Forest School of Medicine Environmental Study			
Airborne bacteria	Assess system effectiveness in reducing the concentration of airborne bacteria in an occupied open area clinical setting (hospital emergency department)	Achieve statistically significant (p-value ≤ 0.05) 20% reduction in ambient bacterial load.	Pass. Reduced airborne bacterial concentration by a low of 26.7% at the room exit and a high of 54.2% near the patient's head with an overall p-value of ≤ 0.001.

Photox 500 Environmental Study Summary

Introduction

Airborne transmission of pathogens, including flu virus, can result in the rapid spread of disease. For example, influenza has been responsible for three pandemics in the last century alone, with an overall death toll reaching tens of millions, and continues to cause annual epidemics of varying severity worldwide.[1] The current understanding of aerosol transmission assumes that a number of human pathogens are spread by respiratory secretions and/or infect by way of the respiratory tract.[2]

However, data on how to protect against the spread of these pathogens is sparse.[3, 4] Masks, respirators, and HEPA filtration systems are commonly used barrier and decontamination methods for preventing and/or reducing airborne transmission. This study was designed to assess the ability of the Photox 500 air purification system to serve as a broad pathogen decontamination system. Current air decontamination systems tend to revolve around HEPA filtration systems which require frequent costly filter replacements resulting in increased biohazard waste and decreased efficiency over time if not properly maintained. There are even some discussions regarding the HEPA filters ability to grow mold if they are not treated with an antimicrobial preservative, again adding to the biohazard waste conundrum in the effort to reduce airborne pathogens.[5] Under the requirements of the ongoing healthcare reform, it is critical to reduce healthcare associated infections in order to create a safe environment for the care of patients.

Hospitals and medical clinics are continually looking for better ways of controlling airborne microbial loads leading to hospital-associated infections. This study provides data to determine the effectiveness of the Photox 500 device in broadly eliminating the amount of bacterial contaminants in the air. This improves our understanding of the effectiveness of the Photox air purification system in a clinical setting as it relates to bacteria.

The Photox 500 is an innovative photocatalytic oxidation (PCO) system that effectively cleans the air of volatile organic compounds (VOCs) and has ancillary evidence supporting elimination of broad classes of pathogens. It is different from many of the current PCO systems on the market because it maximizes the number of air treatment cycles in a room and optimizes the PCO reaction process through the use of novel catalyst reaction materials. Together this provides superior clearance of VOCs and is expected to reduce or eliminate a broad range of airborne pathogens. This project is innovative since it examines how effective the Photox device is in eliminating bacteria in a real-life, clinical (emergency department) setting rather than a controlled, closed lab environment.

Methods

Baseline Air Sampling

The samplings were performed in emergency department (ED) rooms with door access. Rooms were selected based on availability and likelihood of the patient being present in the room for 90 minutes or more. Three 6-stage Andersen Samplers were used to sample the air and placed at the head and foot of a patient's bed along with one sampler at the exit/entrance doorway. All samples were collected on blood agar plates. The air was sampled for 20 minutes with no restrictions on care activities for the patient. If the patient had to leave the room for any reason during the air samplings, the sample was excluded from analysis. To assess the baseline bacterial load in the room air sampling was performed before the use of the Photox device.

Treated Air Sampling

After completion of the baseline air sampling the Photox 500 was placed at the foot of the bed and run to allow the room air to circulate a total of eight times. This was adjusted by room size (wash-out phase). At the end of the wash-out phase, air sampling was performed for 20 minutes as described above while the Photox device was left running.

Colony Quantification

Once the air samples were completed, the plates were placed in a 37^{o} C incubator. After incubating for 48 hours, the number of colonies was counted on all plates and recorded and data analyzed.

Results

A total of 70 participants were consented and enrolled in the study. Out of the 70 participants, 20 participants were excluded due to leaving the ED room before completion of sampling (n =16) or withdrawing (n = 4). Samples of the remaining 50 participants were analyzed.

All sampling locations showed a highly significant reduction in CFU from baseline to Photox treatment phase. The greatest reduction was seen at the head of the bed followed by the foot of the bed and the exit. The room total (sum across all sampling locations) also shows a highly significant reduction in the bacterial count after treatment with the Photox 500 device. The percent reduction ranges from 26.7% to 54.2% based on the sampling location. The originally expected percent reduction of 20% was met at all locations and for the total room.

Discussion

The Photox 500 device significantly reduced the bacterial load under routine care in an ED setting. The foot of the bed and the exit locations showed overall smaller decreases probably affected by higher traffic/activity patterns in these areas as compared to the head of the bed.

Conclusion

Use of the Photox 500 air purifier in an ED setting leads to a significant reduction of the airborne bacterial load. Applications of this new technology promise to reduce the pathogen load, reduce exposure, and provide a safe environment for patient care. (See attached “Photox bacteria - Aim 1 Final Report” and Infectious Disease Conference poster presentation “Reduction of Bacterial Air Burden During Routine Patient Care”).

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