Evaluation of outpatient surgery center air bacterial and particulate levels

Case Study:
David Kirschman, M.D.
Chief Scientific Officer
Aerobiotix, Inc.
350 Fame Road
West Carrollton, Ohio
USA
Phone +1 888-978-7087
e-mail: dk@aerobiotix.com

Study Sponsor
Confidential Outpatient Aesthetic Surgery Center
Southern, CA

Evaluation start date: July 8, 2014
Evaluation completion date: July 9, 2014

Study acceptance

David Kirschman, M.D.
Date: September 1, 2014
This study was designed to evaluate the effectiveness of the Aerobiotix HEPA/Ultraviolet air recirculation system to reduce airborne particle levels and culturable bacterial levels in operating room air at an outpatient aesthetic surgery center in southern California.

Air quality was monitored before and after use of the Aerobiotix system by using a continuous air particle measurement system, with readings taken every 2 minutes for the test period.

- Control measurement of the operating room before use of Aerobiotix system
- Experimental measurement of the operating room during use of Aerobiotix system

Additionally, bacterial air samples were taken using vacuum impactors and agar plates to obtain the number of airborne colony forming units (CFU) in each test modality using the USP 797 standard. Sample plates were placed in various locations within the operating suite during aesthetic procedures. Twenty-four samples were utilized in the analysis. The agar plates were incubated by an independent microbiological laboratory.

**Background**

Airborne pathogen levels in healthcare settings are a significant, yet under-appreciated cause of hospital acquired infections and surgical site infections. Infections acquired at hospitals are the number four cause of death in the United States, exceeding the combined mortality of breast cancer, AIDS and traffic accidents at an annual cost estimated at $40 billion (McCaughey, 2008; Mitka 2008). Increasingly, the microorganisms causing these infections have mutated into antibiotic resistant strains, making the resulting morbidity/mortality of a healthcare associated infection greater than ever. Surprisingly, there is no minimum U.S. standard for the number of bacteria, viruses, or fungi in hospital air, including critical areas of surgery suites, immunocompromised patient areas, or intensive care units.

The Aerobiotix in-room decontamination-recirculation unit (Figs. 1 and 2) utilizes a hybrid of biological and physical systems to remove bacteria, fungi and viruses from the air. Its key biocidal technology is a solid-state germicidal irradiation system which provides simultaneous physical filtration and irradiation of high-volume air flow. The system utilizes C-band ultraviolet light (UVC) at a 254 nm wavelength diffused into a solid media which is gas and radiation permeable. While organisms are slowed or trapped in the solid media, they are inactivated by the internal UVC dosage. This has the effect of increasing the inactivation efficiency over prior UV technologies.
Evaluation of operating room air contamination levels

Methods

Using a continuous air quality monitor (IC Sentinel, Oberon Technologies) the indoor air quality assessment consisted of the measurement of the following particulate levels:

- 0.5 µM/m³
- 2.5 µM/m³
- 5.0 µM/m³

During the control period, levels of air contamination were obtained for all particulate sizes using automated particle air sampling on a per 2 minute basis. For the Aerobiotix test period, the particle measurements were taken along with an Aerobiotix T1 unit running at a 450 CFM air treatment rate. Again, levels of air contamination were obtained for all particulate sizes using automated air sampling on a per-2 minute basis.

Measurements were taken in a fully occupied general operating room, while a mixture of plastic and reconstructive procedures were performed using standard techniques and protocols.
A. Particulate Studies

### Outpatient surgery Baseline vs T1 OR Graphs

<table>
<thead>
<tr>
<th>Particles per m³</th>
<th>Ch1 Data 0.5μ</th>
<th>Ch2 Data 2.5μ</th>
<th>Ch3 Data 5.0μ</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTROL</td>
<td>6889035.086</td>
<td>548518.4095</td>
<td>41886.59048</td>
</tr>
<tr>
<td>ABX T1</td>
<td>2209157.383</td>
<td>151508.6411</td>
<td>14183.33971</td>
</tr>
<tr>
<td>% reduction</td>
<td>68.08</td>
<td>72.51</td>
<td>66.30</td>
</tr>
</tbody>
</table>
B. Microbial Studies

### AIRBORNE BACTERIAL LEVELS – OUTPATIENT SURGERY

<table>
<thead>
<tr>
<th>Sample</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>MEAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTROL</td>
<td>63</td>
<td>34</td>
<td>10</td>
<td>22</td>
<td>27</td>
<td>15</td>
<td>16</td>
<td>8</td>
<td>22</td>
<td>14</td>
<td>33</td>
<td>22</td>
<td>23.8</td>
</tr>
<tr>
<td>ABX T1</td>
<td>11</td>
<td>13</td>
<td>4</td>
<td>14</td>
<td>7</td>
<td>8</td>
<td>11</td>
<td>17</td>
<td>8</td>
<td>11</td>
<td>8</td>
<td>21</td>
<td>11.1</td>
</tr>
</tbody>
</table>

**Discussion and Conclusion**

The collected data demonstrate a marked reduction in air contamination for the particle sizes measured using the T1 device. Reductions ranged from 66.3% to 72.5%, with comparable reductions across all measured particle sizes. In this study, we concentrated on airborne particles in the 0.5 to 5.0 µm size. This particle size range has been most closely identified with pathogenic airborne bacterial populations (Kowalski, 2012). It is important to note that for any given environmental air sample, there will be orders of magnitude higher amounts of particles than culturable bacterial colony forming units. Particles include a broad population of inorganic matter, non-viable organic particles, and prokaryotic and eukaryotic cells.
There are no regulated standards for airborne particulate levels in most health care settings in the United States. However, international literature recommends the benchmarking of ISO 14644-1 cleanroom standards, with ISO 8 and ISO 7 levels published as operating room reference levels, depending on procedural requirements. (Scaltriti 2007, Wan 2011, Charkoska 2008). The ISO 8 level has been promulgated under ISO 14644-1 to describe the minimal standard for cleanroom air, with air exchange and enclosure requirements.

For the standardized particle sizes measured, the ABX unit improved mean airborne particulate levels from ISO 9 (red box above), to ISO 8 (blue box above) based upon reductions in 0.5 and 5.0 µM particles.

For the cultured samples obtained, there was a 67.7% reduction in CFU count in twelve paired samples. This reduction is statistically significant (p=.0163) using a paired T-test.

In conclusion, the ABX technology successfully reduced airborne contamination and bacterial colony forming units under the test parameters and environment described. The addition of ABX supplemental air decontamination to this facility should be considered, as part of a comprehensive environmental management plan.

**References**


