Contaminated Air and Surgical Infection Associated With Implant Procedures

Surgical Site Infection (SSI) Risk for Patients Who Have Implant Procedures

Patients undergoing surgical procedures which involve an implant such as prosthetic joint replacement, are at risk of post-operative infection caused by the very smallest bacterial inoculum.\(^1\) This is due to the surface of the implant on which biofilm can expediently develop, and also due to the patient’s immune system focusing initially on the implant versus any bacteria that might have adhered to its surface. Consequently, the number of organisms required to cause an infection when an implant is involved is reduced by a factor of 100,000.\(^2\)

The Impact of Implant-Associated SSI

A common implant procedure in the United States is total hip replacement, of which there are approximately 300,000 performed annually. The average SSI rate for these procedures is 2.18 percent.\(^3\) While this is a low rate it still represents 8,400 patients, each experiencing pain, suffering and for some lost wages and impact on family and quality of life.\(^4\) For each patient the range of cost for treatment of the infection is between $389,307 and $474,004, and is associated with a mortality rate of between 2 percent and 7 percent.\(^5,6\) In addition to prosthetic joint replacement, many other types of surgical procedures now involve implants including, breast, plastics, orthopedic, spine, general (hernia mesh), gynecology (pelvic floor mesh), cardiac (pacemaker, stent, valve, internal atrial defibrillator).

Air Contamination and SSI

The direct correlation of bacteria laden particulates in operating room air to surgical infection risk has been reported for decades in peer reviewed studies.\(^7-9\) These particulates can become transiently airborne during a case, settle in the open incision and adhere to the implant.\(^10\) These may originate from any one of several sources, including respiratory aerosols of the surgical team which can escape from the surgical mask, especially in the presence of an upper respiratory tract viral infection.\(^11,12\) Another potential source of transiently airborne pathogens in operating rooms is the skin of surgical team members and/or patient. Skin scales are constantly shed from the human body, to which bacteria are often attached.\(^13\) Illustrating this risk, is a documented outbreak involving eight SSI reported after modified radical mastectomy in a tertiary-care hospital, caused by Group A streptococci (GAS). The source was found to be a surgeon colonized (skin) with GAS.\(^14\)

A third potential source of transient airborne contamination in operating rooms is equipment which includes a water reservoir. The outbreak of *Mycobacterium chimaera* SSI after cardiac surgical procedures demonstrates this risk. In this outbreak, the water tanks on the heater-cooler devices used in open heart surgery were found to be the source for the airborne transmission of *M. chimaera* resulting in more than 100 SSI cases since 2013 in Europe and the U.S.\(^15,16\)

Current State of Air Quality in US Operating Rooms (OR) versus Compounding Pharmacies

In the OR, surgical procedures involve an incision (sterile space), which remains open to the OR air. In compounding pharmacies sterile solutions are prepared to be introduced into the sterile vascular system. Regulations governing these two spaces are not equivalently protective. On the one hand, U.S. compounding pharmacies must comply with International Standards Organization (ISO) class 5 standards for air quality.\(^17\) However, there is no requirement for air quality testing in US operating rooms, where it is assumed to be sufficient as a result of the engineering controls (positive air pressure, increased air changes, temp and humidity control and high efficiency particulate air filter or HEPA).\(^18\) However, it has been demonstrated that those controls can be defeated by door openings and room traffic during cases.\(^19-21\)

Adjunctive Air Decontamination Technology

Technologies designed to improve air quality in operating rooms fall into three primary categories — air filtration, air disinfection and combined filtration plus disinfection. This adjunctive technology is arguably most crucial in the outer area of the OR beyond the OR table, which is not protected with directional air flow and HEPA air filtration. In this outer area of the OR, there is typically less effective air flow, increased human activity, door openings and floor contamination. Consequently, the air in this surrounding area can potentially contaminate instrumentation, implants, gloves, surgical team members, surgical drapes, and tables which are in direct communication with the patient. Employing an adjunctive technology for the outer area of operating rooms, which provides air disinfection plus filtration of particulates, would seem prudent. Innovative portable devices which combine ultraviolet (UV) technology and HEPA filtration to eliminate particulates and microorganisms are in use in increasing numbers of ORs. These devices have been reported in peer reviewed studies to reduce transiently airborne bacteria in operating rooms by 50 percent to 60 percent and reduce overall rates of prosthetic joint infection (p<0.042).\(^22-29\)

Conclusions

Current standard methods for ensuring adequate OR air quality are limited to positive air pressure, 20 air changes per hour, surgical attire, traffic control (and HEPA filtration in some ORs). These methods alone have been proven insufficient to prevent contaminated air associated SSI as demonstrated by multiple outbreaks including the *M. chimera* outbreak in
What is in the OR air?

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REduced occurrences of pji

Periprosthetic Joint Infection (PJI) was reduced from 1.9% to 0% by the use of intraoperative air decontamination system.

**Table 1.** Patient demographic and comorbid risk factors of retrospective cohort analysis of patient undergoing total joint arthroplasty

<table>
<thead>
<tr>
<th>Procedure</th>
<th>OR A (^a)</th>
<th>OR B (^b)</th>
<th>p-value (^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td>98 (35.6)</td>
<td>78 (33.5)</td>
<td>0.09</td>
</tr>
<tr>
<td>Mean age</td>
<td>62.7</td>
<td>63.1</td>
<td>0.63</td>
</tr>
<tr>
<td>Mean BMI</td>
<td>33.4</td>
<td>33.2</td>
<td>0.70</td>
</tr>
<tr>
<td>Revision surgery</td>
<td>34 (12.8)</td>
<td>39 (16.8)</td>
<td>0.15</td>
</tr>
<tr>
<td>Diabetes dx</td>
<td>58 (21.1)</td>
<td>61 (26.2)</td>
<td>0.69</td>
</tr>
<tr>
<td>Smoker</td>
<td>48 (17.5)</td>
<td>36 (15.1)</td>
<td>0.32</td>
</tr>
<tr>
<td>Mean operative time (min)</td>
<td>63.5</td>
<td>60.4</td>
<td>0.11</td>
</tr>
</tbody>
</table>

\(^a\) Operating Room A = Standard HEPA-Filter HVAC

\(^b\) Operating Room B = Standard HEPA-Filter HVAC plus Supplemental UV-decontamination

\(^c\) Two-sample unpaired t-test

**Table 2.** Distribution of total joint arthroplasty procedures and periprosthetic joint infections (PJI)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary hip</td>
<td>65 (24.6)</td>
</tr>
<tr>
<td>Primary Knees</td>
<td>132 (49.9)</td>
</tr>
<tr>
<td>Primary shoulder</td>
<td>5 (1.8)</td>
</tr>
<tr>
<td>Revision hip</td>
<td>9 (3.4)</td>
</tr>
<tr>
<td>Revision knee</td>
<td>24 (9.1)</td>
</tr>
<tr>
<td>Revision shoulder</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Bilateral hip</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Bilateral knee</td>
<td>26 (9.8)</td>
</tr>
</tbody>
</table>

\(^a\) Operating Room A = Standard HEPA-Filter HVAC

\(^b\) Operating Room B = Standard HEPA-Filter HVAC plus Supplemental UV-decontamination

\(^c\) Fisher’s Exact test

**References:**


Cardiac surgery associated with heater cooler devices. Air decontamination technology (UV + HEPA) can serve as an adjunct to standard methods for ensuring safe air quality for ORs, especially where implant procedures are performed. 

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