Time-Dependent Contamination of Opened Sterile Operating-Room Trays

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Investigation performed at Miami Valley Hospital, Dayton, Ohio

Background: There are no clear guidelines for how long a sterile operating-room tray can be exposed to the open environment before the contamination risk becomes unacceptable. The purpose of this study was to determine the time until first contamination and the rate of time-dependent contamination of sterile trays that had been opened in a controlled operating-room environment. We also examined the effect of operating-room traffic on the contamination rate.

Methods: Forty-five sterile trays were opened in a positive-air-flow operating room. The trays were randomly assigned to three groups. All trays were opened with use of sterile technique and were exposed for four hours. Culture specimens were obtained immediately after opening and every thirty minutes thereafter during the study period. Group 1 consisted of fifteen trays that were opened and left uncovered in a locked operating room (i.e., one with no traffic). Group 2 was identical to Group 1 with the addition of single-person traffic flowing in and out of the operating room from a nonsterile corridor every ten minutes. Group 3 included fifteen trays that were opened, immediately covered with a sterile surgical towel, and then left uncovered in a locked operating room (i.e., one with no traffic).

Results: Three of the thirty uncovered trays (one left in the operating room with traffic and two left in the room with no traffic) were found to be contaminated immediately after opening. After those three trays were eliminated, the contamination rates recorded for the twenty-seven uncovered trays were 4% (one tray) at thirty minutes, 15% (four) at one hour, 22% (six) at two hours, 26% (seven) at three hours, and 30% (eight) at four hours. There was no difference in survival time ($p = 0.47$) or contamination rate ($p = 0.69$) between the uncovered trays in the room with traffic and those in the room without traffic. The covered trays were not contaminated during the testing period. The survival time for those trays was significantly longer ($p = 0.03$) and the contamination rate was significantly lower ($p = 0.02$) than those for the uncovered trays.

Conclusions: Culture positivity correlated directly with the duration of open exposure of the uncovered operating-room trays. Light traffic in the operating room appeared to have no impact on the contamination risk. Coverage of surgical trays with a sterile towel significantly reduced the contamination risk.

Clinical Relevance: Sterile trays should not be opened until they are specifically needed during the procedure. Coverage of opened trays with a sterile towel is recommended to minimize their exposure to environmental contaminants.

The prevention of surgical site infection remains an important focus in the practice of orthopaedic surgery. As there are many potential host and environmental factors that contribute to surgical bacterial contamination, a multimodal approach to minimize this complication has been developed. Host factors such as nutritional status, immune-system health, medical comorbidities, age, and residence in a nursing home facility have been shown to affect surgical infection rates. Likewise, multiple interventions have been developed to promote sterility both at the surgical site and within the surgical suite. The advent of modern surgical preparation and draping strategies, laminar flow operating rooms, implant

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sterilization techniques, and preoperative administration of antibiotics have significantly reduced the frequency of perioperative infections.

While we often take great care in addressing factors that are perceived as readily modifiable, other factors may perhaps be overlooked, be thought to be uncontrollable, or be taken for granted as already being ideal. Specifically, the absolute sterility of surgical trays and the instruments that they contain is often assumed. Additionally, the contribution of operating-room air quality to surgical infection rates is generally considered to be minimal or perhaps even inconsequential given the routine use of positive or laminar air-flow systems.

The purposes of this study were (1) to determine the time to first contamination and the rate of time-dependent contamination of opened sterile trays in a controlled operating-room environment, (2) to examine the effect of a simple model for operating-room traffic on this rate of contamination, and (3) to assess the results of a relatively simple intervention on the sterility of opened sterile trays. Our hypothesis was that bacterial contamination of opened sterile trays increases in a time-dependent manner. Additionally, we expected that traffic in the operating room would further increase the contamination rate compared with the baseline exposure, whereas covering the trays with a sterile towel would decrease the rate of contamination.

**Materials and Methods**

Forty-five sterile trays were opened in a positive-air-flow operating room. The study was performed during routine daytime operating hours on two consecutive weekdays. The trays were randomly assigned to one of three groups. All trays were opened with use of sterile technique and were exposed for four hours. Culture specimens were obtained from the trays immediately after opening and every thirty minutes thereafter for the four-hour study period.

Group 1 consisted of fifteen trays that were opened and left uncovered in a locked operating room, with the doors remaining closed for the entire study period. Group 2 was identical to Group 1 with the addition of single-person traffic flowing in and out of the operating room every ten minutes from a nonsterile corridor. The individual would enter the room, walk briskly next to the trays, and then leave. Group 3 consisted of fifteen trays that were opened, covered immediately with a sterile surgical towel, and then left in a locked operating room without traffic. The culture specimens from

<table>
<thead>
<tr>
<th>Contaminated</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>Group 1: no traffic, uncovered</td>
<td>4*</td>
<td>9</td>
</tr>
<tr>
<td>Group 2: traffic, uncovered</td>
<td>4†</td>
<td>10</td>
</tr>
<tr>
<td>Group 3: covered</td>
<td>0</td>
<td>15</td>
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</tbody>
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*Two trays were eliminated because they were found to be contaminated immediately after they were opened. †One tray was eliminated because it was found to be contaminated immediately after it was opened.

![Survival Curves for the Three Groups](image)

Fig. 1

Kaplan-Meier survival plot for covered (Group-1 and 2) and uncovered (Group-3) trays. In Group 1, the 95% confidence interval was 1.8 to 3.2 hours, and the point estimate of mean survival was 2.50 hours. In Group 2, the 95% confidence interval was 1.9 to 2.9 hours, and the point estimate of mean survival was 2.37 hours. No confidence interval or point estimate could be calculated for Group 3 because no contamination occurred over the four-hour testing period. All that can be said of Group-3 trays is that the point estimate of the mean time to contamination was greater than four hours.
the Group-3 trays were obtained at the designated time intervals by lifting one corner of the sterile towel and replacing it after the specimen was taken from the tray. Bacterial and fungal plates were used to assess air-quality control. At least two study participants were involved with the testing of each tray. All of the trays were analyzed in a controlled operating-room setting in which no patient was present and no surgery was being performed.

**Results**

Specimens taken immediately after the opening of three of the thirty uncovered trays (two in Group 1 and one in Group 2) were positive on culture. After eliminating those three trays, the contamination rates for the twenty-seven uncovered trays were 4% (one tray) at thirty minutes, 15% (four) at one hour, 22% (six) at two hours, 26% (seven) at three hours, and 30% (eight) at four hours (Table I). Of the positive cultures, 44% showed coagulase-negative Staphylococcus; 22%, Corynebacterium; 11%, alpha Streptococcus; 11%, Bacillus species; 6%, Micrococcus; and 6%, Moraxella species. Only one of the eight contaminated trays had polymicrobial contamination. With the numbers studied, there was no difference in survival time (p = 0.47) or contamination rate (p = 0.69) between the uncovered trays in the operating room with traffic and those in the room without traffic.

None of the fifteen covered trays were contaminated during the four-hour testing period. The survival time in this group was significantly longer (p = 0.03) and the contamination rate was significantly lower (p = 0.02) than those of the uncovered trays, in the rooms with and without traffic (Fig. 1). In all three groups, the air-quality bacterial plates were positive and the air-quality fungal plates were negative.

**Discussion**

In evaluating ways to prevent surgical infection, many investigators have examined various potential sources of contamination in the operating room. Baird et al. reported a 74% rate of positive cultures, by the time of case completion, in an analysis of contamination of surgical splash basins used in orthopaedic surgery. Similarly, Andersson et al. found that 62% of irrigation solutions become contaminated during procedures lasting at least one hour.

Additional investigations have focused on the use of “sterile” operating-room equipment. Strange-Vognsen and Klareskov found 55% of suction tips used in total hip arthroplasty to be culture-positive. Greenough found similar results after total hip arthroplasty and correlated the contamination rate with the duration of use. Charnley and Eftekhar investigated the penetration of organisms from the surgeon’s body through the surgical gown. Exhaust suit systems were developed on the basis of their findings. Hamilton et al. compared three types of conventional gowns with exhaust suits and reported findings that favored the latter. More recently, following an investigation of the passage of bacteria through surgical drapes, Blom et al. recommended nonwoven disposable drapes after comparing seven different types of surgical drapes.

Regarding the operating-room environment itself as a source of contamination, Ritter et al. found bacterial counts in an empty operating room to increase significantly after the doors were left open and to increase even further when five or more people were added to the room. The use of surgical face masks had no apparent effect on the bacterial counts. Ritter et al. concluded that people appear to be the major source of environmental contamination in the operating-room environment. In a later study, Ritter reported his experience with, and practices for, reducing infections following joint replacement. While people remain as the source of bacteria in the operating setting, individuals vary in their bacterial shedding capacity, which ranges from 1000 to 10,000 viable bacteria per minute.

The current study confirms that common skin flora appear to be the predominant source of contamination of exposed trays and instruments in the operating room. These findings similarly implicate people as the most likely source of intraoperative contamination of trays. In contrast to the results reported by Ritter et al., our model for generating light traffic in the operating room did not appear to influence the rate of contamination of opened sterile instrument trays.

We recognize that this investigation had several limitations. First, a direct causal relationship between tray contamination and surgical wound infection cannot be established. While coagulase-negative Staphylococcus is a common source of infections following orthopaedic procedures, the other contaminating bacteria found in this study are not.

Second, the two study participants were not the same for the tests of all forty-five trays. Despite a preestablished protocol, slight alterations in sterile technique could have influenced the study findings. In addition, the trays were tested on two different days because of time constraints, and this possibly could have impacted the results in an unknown way.

Third, our model of traffic was simple. Two study participants remained in the room. A third entered from a non-sterile corridor, briskly walked by the exposed trays, and immediately left the room. Such a scenario by no means reproduces a true surgical setting, where more people are involved and the traffic flow is heavier and less regimented.

Fourth, it is possible that some of the positive culture results were due to contamination during the handling or preparation process. We have no way to determine to what extent this possible artifact may have occurred, if at all. However, the culture specimens were obtained with sterile technique, and the
containers in which they were placed were immediately sealed. They were personally transported to the hospital’s laboratory by laboratory personnel, and the laboratory personnel were notified prior to their arrival. All cultures were processed by experienced laboratory personnel in a timely fashion, and all standard steps were taken to minimize the chance of contamination by means not introduced by the experiment itself.

Lastly, the three trays that were found to be contaminated immediately after they were opened presented a dilemma. We chose to eliminate them from the analysis as it could not be determined whether the contamination had occurred secondary to improper sterilization, during the culture handling and processing, or within seconds after exposure to the environment.

In conclusion, during surgery there are situations (such as a delay before the start of the operation or multiple procedures performed in the same operative setting) where sterile trays are opened but not immediately used. There are no clear guidelines for how long a sterile tray can be exposed to the open environment before the contamination risk becomes unacceptable. We found that the sterilization process may not necessarily produce absolute sterility, even when parameters confirming sterilization have been reached. Culture positivity correlated directly with the duration of open exposure of the uncovered trays, with culture-positive rates of 22% and 30% at two and four hours, respectively. Light traffic through the operating room did not appear to affect the contamination risk. The simple, practical step of covering the surgical tray with a sterile towel significantly reduced the contamination risk. To decrease the potential for contamination, every effort should be made to reduce the exposure of sterile trays prior to use. Sterile trays should not be opened until they are specifically needed during the procedure. However, if a tray is opened but not immediately used, it should be covered with a sterile towel to minimize exposure to environmental contaminants.

References


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