Looking for Holes in Sterile Wrapping: How Accurate Are We?

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Abstract

**Background** Defects in sterile surgical wrapping are identified by the presence of holes through which light can be seen. However, it is unknown how reliably the human eye can detect these defects.

**Questions/purposes** The purpose of this study was to determine (1) how often holes in sterile packaging of various sizes could be detected; and (2) whether differences in lighting, experience level of the observer, or time spent inspecting the packaging were associated with improved likelihood of detection of holes in sterile packaging.

**Methods** Thirty participants (10 surgical technicians, 13 operating room nurses, seven orthopaedic surgery residents) inspected sterile sheets for perforations under ambient operating room (OR) lighting and then again with a standard powered OR lamp in addition to ambient lighting. There were no additional criteria for eligibility other than willingness to participate. Each sheet contained one of nine defect sizes with four sheets allocated to each defect size. Ten wraps were controls with no defects. Participants were allowed as much time as necessary for inspection.

**Results** Holes $\geq 2.5$ mm were detected more often than holes $\leq 2$ mm (87% [832 of 960] versus 7% [82 of 1200]; odds ratio, 88.6 [95% confidence interval, 66.2-118.6]; $p < 0.001$). There was no difference in detection accuracy between OR lamp and ambient lighting nor experience level. There was no correlation between inspection time and detection accuracy.

**Conclusions** Defects $\leq 2$ mm were not reliably detected with respect to lighting, time, or level of experience. Future research is warranted to determine defect sizes that are clinically meaningful.

**Level of Evidence** Level II, diagnostic study.

Introduction

Sterile wrapping in the operating room (OR) is essential to preserving the sterility of equipment in surgical cases. A considerable number of orthopaedic sets is either sterilized in metal trays or wrapped in double-layered sterile wraps [4]. As part of routine preoperative practice in the United States, surgical staff lift sterile wraps upward toward the
ambient light in the operative suite to look for imperfections. Even small holes in sterile wrapping potentially allow for contamination of materials [1, 6]. With 33% of surgical site infections (SSIs) resulting from orthopaedic cases [2, 3], visual inspection for defects in sterile wraps is essential to the prevention of SSIs.

There has been no scarcity of attention in research dedicated to patient optimization and preoperative prevention to prevent SSIs, but with the considerable burden SSIs place on both patients and the healthcare system [2, 3], more consideration for sterilization techniques, particularly visual inspection for imperfections in sterile wrapping, is warranted. To date, little research has been conducted that examines detection accuracy of defects of varying sizes. Likewise, the detection accuracy among (1) variations in light source; (2) observers of varying experience levels; and (3) time to detection has not been explored. Furthermore, the Centers for Disease Control and Prevention has provided a 158-page guideline for disinfection and sterilization in healthcare facilities with only a four-line recommendation dedicated to inspecting sterile wrapping as a suggestion for implementation [1, 4, 5, 7]. By identifying shortcomings in the abilities of surgical staff to identify defects in sterile wrapping, more focused sterility training can be provided to surgical staff, thereby lessening the risk of equipment contamination and resulting SSIs.

We therefore sought to determine (1) how often holes in sterile packaging of various sizes could be detected; and (2) whether differences in lighting, experience level of the observer, or time spent inspecting the packaging were associated with improved likelihood of detection of holes in sterile packaging.

**Materials and Methods**

Our study included 30 surgical personnel from two different hospitals within the same healthcare network and was comprised of 10 surgical technicians, 13 operating room nurses, and seven orthopaedic surgery residents. Each group had 15 ± 9, 20 ± 11, and 2.6 ± 1.5 years of OR experience, respectively. A sample size calculation yielded a minimum of 25 participants and was based on the assumption that participants would reach the same conclusion approximately 50% of the time when inspecting sterile wrapping for defects. Participants were included based solely on willingness to participate; no participants were excluded on the basis of eyesight, corrective eyewear, age, or any other characteristic. No time or corrective eyewear restrictions were placed on the participant when examining the wrapping. Each participant was provided a brief demographic survey to capture both the participant’s role and years of experience in the OR before beginning the inspection trials.

In this study we used KimGuard® One-Step® KC400 48-inch x 48-inch sterile wraps (Kimberly-Clark Corporation, Roswell, GA, USA), similar to the standard sterile wrapping used at our institutions. We created nine different defect sizes (0.86 mm, 1.0 mm, 1.25 mm, 1.6 mm, 2 mm, 2.5 mm, 3 mm, 4.5 mm, and 5 mm) using Kirschner wires, Steinmann pins, and nails that were pierced completely through both layers of the two-ply wraps. Each perforation was placed in the middle third vertically and horizontally of each wrap. Four wraps were designated to each of the nine defect sizes for a total of 36 defective wraps. The remaining 10 sterile wraps had no defects and served as controls.

Each participant completed the sterile wrap inspection in compliance with the standard technique for our institution. This technique entails unwrapping the sterile dressing, lifting it to a light source in the OR, and identifying any perforations that may compromise sterility.

All study participants examined 46 sterile wraps twice: once using ambient OR lighting alone and once using a standard powered OR lamp in addition to ambient lighting (Fig. 1). Participants were randomized to the order of the lighting environments. Each participant received one wrap at a time. The order in which the participant received each wrap was also randomized. On receipt of a sterile wrap, the participant would report if there was a defect, and the research coordinator (AB) would record the result on a scoring document. A false-positive was defined as detecting a hole in a nonperforated sheet and also contributed to the participant’s detection accuracy score. All sheets with alleged false-positives were examined to confirm that there was no defect present.

The participants were instructed to use as much time as needed to reliably inspect each wrap. The coordinator timed each 46-wrap session from the time the first sheet was touched until the final sheet was placed down. The time spent inspecting each sheet individually from the time it was first touched until the time it was placed down was also recorded. After the first 46-wrap assessment, participants would complete the second assessment in the lighting environment he or she had not yet experienced per his or her randomization assignment.

All participants correctly executed the trial methodology as dictated by original randomization assignments.

**Statistical Analysis**

The level of statistical significance was determined a priori at 0.05. On inspection of the data, it was apparent that detection accuracy was markedly higher for defects ≥ 2.5 mm. Therefore, we performed our primary statistical
analysis using a two-tailed, two-sample test for proportions to compare the percentage of correctly identified defects between holes ≤ 2 mm and holes ≥ 2.5 mm.

Secondary statistical analyses included a two-tailed, two-sample test for proportions to compare the percentage of correctly identified defects between the OR lamp and the ambient lighting groups. The mean detection accuracy was compared between each of the varying levels of experience using an analysis of variance test and Fisher’s least significant difference test. The levels of experience compared for the purposes of this analysis were categorized into 1 to 9 years, 10 to 20 years, and > 21 years of experience and contained 11, 10, and nine participants, respectively. The aforementioned experience categorizations were chosen after data collection and were chosen based on the distribution of years of experience in the collected data. Each experience category attempted to capture the detection accuracy among novice, moderately experienced, and veteran participants. Finally, a multivariate correlation was performed to evaluate the correlation between time spent inspecting the sterile wrapping and the percentage of correctly identified defects. The data were collected using Microsoft Excel® (Redmond, WA, USA). Statistical analyses were performed using SAS JMP Version 13 software (Cary, NC, USA).

Results

Defects ≤ 2 mm were not reliably detected; holes ≥ 2.5 mm were detected more often than those ≤ 2 mm (87% [832 of 960] versus 7% [82 of 1200]; odds ratio, 88.6 [95% confidence interval {CI}, 66.2-118.6]; p < 0.001). As a rule, smaller holes were much less likely to be detected than larger ones (Table 1; Fig. 2). The secondary analyses revealed no difference in detection accuracy between differences in lighting or experience level of the participant. The percentage of imperfections that were correctly identified in each light source was 55% (753 of 1380) and 54% (747 of 1380) for the OR lamp and ambient lighting, respectively (odds ratio, 0.98 [95% CI, 0.85-1.14]; p = 0.82). Additionally, there was no difference in the detection accuracy among participants of varying levels of OR experience. The mean percentages of correctly detected defects were 56% (563 of 1012), 53% (492 of 920), and 54% (445 of 828) for 1 to 9, 10 to 20, or > 21 years of OR experience, respectively (p = 0.47). There was no correlation between years of experience and ability to detect defects. Participants with ≤ 9 years of experience were 1.1 times as likely to detect imperfections when compared with participants with both 10 to 20 years of experience (95% CI, 0.9-1.3; p = 0.34) and ≥ 21 years of experience (95% CI, 0.9-1.3; p = 0.42), respectively. Participants having between 10 and 20 years of experience were 1.0 times as likely to detect imperfections as participants with at least 21 years of experience (95% CI, 0.8-1.2; p = 0.91). Finally, there was no strong correlation between the time spent inspecting each wrap and the detection accuracy (r = 0.1950 [95% CI, -0.067 to 0.4316]; p = 0.14).

Discussion

As part of preoperative practice, surgical staff members lift sterile wraps up to ambient light in the operative suite to assess for holes, tears, or abrasions. Imperfections in sterile wrapping provide opportunities for contamination, thereby increasing the risk of SSI. To our knowledge, there is no research to date that examines the ability of surgical staff to identify imperfections in sterile wrapping under varying conditions such as defect size, experience level, light source, and inspection time. The results of our study indicate that holes ≤ 2 mm were detected less often than those that were ≥ 2.5 mm. Furthermore, there was no difference in detection ability between varying levels of OR experience, light source, or inspection time.

This study has several limitations. This was a simulation; as such, the tears we evaluated may not replicate everyday handling of the instrument trays that may cause more abrasions or linear tears as opposed to circular tears.
However, including circular tears of various sizes may help simulate a similar difficulty level to detecting linear tears or abrasions. Likewise, preparation of the sterile wraps to include imperfections only in the middle third of the sheets may have allowed for participant learning and improvement. The undamaged sterile wraps served as controls to rectify this limitation. Furthermore, because participants were aware that this exercise was simulated, real-life performance during similar preoperative inspections may differ. However, we did not feel as though we would obtain enough data to provide a reliable estimate of the ability to detect imperfections in a true preoperative setting.

We did not measure actual contamination resulting from holes in the sterile wrap nor did we account for other means of contamination that may occur in a true operative setting. Our objective by performing this study served not to test the contamination resulting from punctured sterile wrapping, but to assess the ability of surgical staff to identify

### Table 1. Correctly detected defects with respect to defect size

| Defect size (mm) | Defects correctly detected (%) | Number of defects identified | Total number of sterile wraps |
|------------------|-------------------------------|-----------------------------|------------------------------|
| 0.86             | 5                             | 11                          | 240                          |
| 1.0              | 3                             | 7                           | 240                          |
| 1.25             | 18                            | 43                          | 240                          |
| 1.6              | 3                             | 7                           | 240                          |
| 2                | 7                             | 17                          | 240                          |
| 2.5              | 76                            | 182                         | 240                          |
| 3                | 95                            | 229                         | 240                          |
| 4.5              | 93                            | 223                         | 240                          |
| 5.0              | 83                            | 198                         | 240                          |

![Fig. 2](image-url) The graph shows the detection percentage rates for each hole size (mm), false-positives (FP) in both light source groups, and total overall detection. The error bars indicate 95% CIs of the total detection rates.
defects that could potentially lead to equipment contamination. Therefore, this study provides an opportunity for future research to determine hole sizes that are clinically meaningful.

We had several nondifferent statistical findings. Specifically, we found no difference in the ability to detect imperfections with respect to variations in lighting, inspection time, or level of experience. Our sample size calculation was conservative, assuming that participants would successfully detect the same defects 50% of the time. In reality, this percentage may be either higher or lower than 50%. Therefore, future findings may differ from the results of our study because assumptions regarding the proportion of successful defect detection (and consequently sample size) are manipulated.

Finally, orthopaedic residents are typically not the staff members responsible for visually inspecting the integrity of sterile wrapping. However, orthopaedic residents were an accessible participant population. Future research can repeat this exercise utilizing only staff who are responsible for performing preoperative sterility inspections.

We found that imperfections < 2.5 mm were not detected reliably. Our results were consistent with those of Waked et al., which demonstrated similar findings for 2.5-mm imperfections [8]. Our study not only validates, but expands on these results by evaluating detection reliability under an expanded set of conditions and with a larger sample size. However, because we did not test for contamination during this study, we were unable to determine which imperfection sizes are clinically meaningful nor the resulting contamination frequency and type. Future research should address these uncertainties.

In addition, we found no difference in the proportion of correctly identified defects between the two lighting scenarios nor levels of experience. Furthermore, there was no association between the inspection time and proportion of correctly identified defects. To our knowledge, there is no existing literature to support the detection of sterile wrapping imperfections under these conditions. Goals for future research should repeat these assessments with a larger sample size using only surgical staff members who are responsible for inspecting sterile wrapping preoperatively. These future assessments will become increasingly important after determining (1) the smallest defect that can be visually detected; and (2) how often defects in sterile wrapping lead to contamination of equipment.

Ultimately, holes < 2 mm in diameter were not reliably detected. Other factors including light source, level of experience, and inspection time were seemingly unrelated to the successful detection of imperfections. Further research is warranted to determine the size of imperfections that contribute to equipment contamination. If imperfections of smaller sizes are not contributing to equipment contamination and SSIs, then more thorough training for inspection of sterile wrapping as performed in this study may not be necessary. Future studies should focus on contamination frequency and type by defect size. Overall, the reliability of sterile instrumentation must be determined to rectify all potential factors contributing to SSIs in orthopaedic surgery patients.

Acknowledgments We thank research coordinator, Adrienne Brandon CCRP, for her assistance with randomization and preparation of study materials. We also thank the Emig Research Center of WellSpan Health for their input in our sample size calculation. Finally, we thank all surgical staff who participated in this study.

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