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

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Where Are We Now?

As more orthopaedic procedures are performed in outpatient settings, and as we seek further efficiencies and cost reductions for the healthcare system, there has been an emphasis on reducing instrumentation and the overall expense of manufacturing. Disposable, single-use instruments have been suggested as a possible solution to avoid the consequences and concern over sterilization of equipment.

But until those become the norm, we are left with conventional instrument-sterilization approaches. The current study by Rashidifard and colleagues [2] calls into question our ability to detect holes in the sterilization packaging currently used for wrapping instrument trays. There is very little information available on this subject, but a recent study did find that sterilized wrapped trays demonstrate considerable protection against contamination of airborne bacteria compared to rigid containers [3]. However, there appears to be difficulty detecting holes in sterile wrappings that are less than 2 mm in size. Waked and colleagues [4] found that defects with a diameter of 6.7 mm were missed 18% of the time and puncture holes as small as 1.1 mm could transmit contaminants through the wrapping material. Considering the emphasis on improving other elements of patient care before surgery, it is perplexing that there is so little addressing the sterilization processes to reduce the risk of surgical-site infection. Intuitively, it would seem incredibly important to assure our instruments are sterile prior to surgery and that we can adequately detect when surgical wrappings have been compromised.

Where Do We Need To Go?

Put in this context, we need to consider potential options to assure that our instrumentation wrapped during the sterilization process is not compromised. Further, it is imperative to assess and determine the level of contamination that could be expected through small holes that are generally invisible to the human eye. Webster and colleagues [5] reported in 2005 that double-wrapping sterile instrument packs increased costs, and did not reduce the risk for tray contamination. While increasing the number of layers may not be the answer, other potential approaches to fill this gap in our knowledge include: (1) Improved training for detecting compromised wrapping of surgical trays, (2) modified surgical wrappings to make perforations more easily detected, (3) alternative options for sterilization, (4) implementation and adoption of single-use instruments, and (5) determining the clinical implications of various degrees of wrapping perforations.

In part because of the move towards outpatient surgery (but also because of more-general imperatives urging efficiency), there is pressure to improve turnover time and limit the instrumentation used for each case. As this occurs, sterile packaging and instrument containers will need to be updated and enhanced to adapt to our modern needs. Ultimately, the goal is to minimize flashing of instruments
while, maintaining a high level of sterility and avoiding potential complications for our patients [1].

**How Do We Get There?**

Future projects assessing the clinical impact of nonvisual holes in sterile packaging should include approaches for developing pathways and protocols to assure adequate sterility of the wrapped instruments used for surgery. Potential research studies that may help bridge the aforementioned gaps in knowledge include: (1) Randomized clinical trials to evaluate specialized training to detect holes in sterile wrapping utilizing enhanced visualization such as surgical loupes and glasses compared to standard operating room routine; (2) basic science studies that assess wrapping enhancement that would be expressed on perforation or that would stain the wrapping (pH or color change) with subsequent visual detection by eye or with a specialized light source; (3) contamination studies comparing a rigid container with sterile wrapped trays using modern containers that are commercially available; (4) a randomized-multicenter clinical trial, which will need large numbers of enrollment, examining the efficacy and cost-effectiveness of single-use instruments in reducing infection rates and costs of sterilizing wrapped instrument trays; (5) measuring the clinical implications of hole perforation size on tray contamination, which could be assessed by perforating the wrappings with specific size holes and then culturing the area on the tray correlating to the hole. To take this further, a surgical simulation in an animal model could be performed and bacterial contamination assessed on the field, which could help us determine infection rates.

The paucity of literature found on this topic compared to the medical and patient optimization studies in the last decade is surprising. But there is potential, by improving sterilization techniques and contamination detection, to prevent more infections, which could have an impact on orthopaedic surgery or any surgical/procedural aspect of medicine.

**References**

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