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LEARNING OBJECTIVES

1. *Discuss the evolution of robot-assisted surgeries*
2. *Identify reprocessing challenges unique to robotic instrumentation*
3. *List practices and quality control methods to help address reprocessing challenges*

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SELF-STUDY SERIES

Managing the reprocessing challenges of robotic instruments

by Tamara Behm and Chasity Seymour

At the conclusion of the 1980 movie "Star Wars: The Empire Strikes Back," the hero, Luke Skywalker, gets a new hand courtesy of a robotic surgeon. Moviegoers were awed at the thought that someday, in the distant future, a robot would be able to surgically attach a robotic arm to a human being. Amazingly, just five years after the movie was released, the first surgical robots were assisting surgeons in performing biopsies! As we know, this was only the beginning of what robots are helping surgeons do today. Although robotic surgical tools seem like space-age technologies, they are prone to very down-to-earth processing challenges in our sterile processing departments.

The evolution of robot-assisted surgery

When developing advances in surgical technique, innovators have typically set two major clinical goals: to reduce invasiveness (which decreases pain) and to reduce length of stay for patients. Robot-assisted procedures have offered opportunities to provide both these benefits. Patients undergo less invasive procedures that result in less blood loss, and they are discharged sooner than with traditional versions of their surgeries. This is the very definition of surgical advancement.

The first robot-assisted procedure, performed in 1985, was a brain biopsy using the Programmable Universal Manipulation Arm (PUMA) 560 robot. Robot-assisted transurethral resection of the prostate and hip replacement surgeries soon followed, but robotic surgery did not yet enjoy widespread acceptance. In 1995, Intuitive Surgical launched an entirely new type of surgical robot that provided the added benefits of much greater precision and ergonomic support for surgeons.

With success comes competition. In 2006, TransEnterix Surgical launched their robotic solution for colorectal, gynecological, gallbladder and hernia procedures. Stryker followed in 2013 with a robotic solution for total and partial knee replacement surgeries. In 2018, robot-assisted surgery advanced again with the introduction of a hand-held robot from Human Xtensions and the first flexible endoscopic robot from Medrobotics. Most recently, CMR Surgical obtained FDA clearance for the Versius mobile surgical robot. The number of available robotic systems is expected to continue to grow exponentially.

Today, robots with specially designed instruments can assist in a variety of laparoscopic procedures. Due to their advanced precision, some procedures that were previously unsuitable for laparoscopic methods can be performed with less invasive robot-assisted versions.

The following types of robot-assisted procedures are currently performed around the world:

- Cardiac
- Colorectal
- Gynecological
- Orthopedic
- Thoracic
- Urologic

As with traditional laparoscopic procedures, patients receive the benefits of minimal tissue damage and blood loss from robot-assisted surgeries and diagnostic procedures. In addition, the robotic devices enable a greater degree of surgical accuracy for delicate tasks. In the future, a greater number of traditional laparoscopic and endoscopic procedures are expected to be replaced by robotic versions.

The many advantages of robot-assisted surgery come at a price. The main robotic system itself is about a $2-million investment, and the surgical arms, staplers and other accessories are limited-use consumables that must be purchased repeatedly. Unlike traditional laparoscopic instrumentation, robotic instruments are designed for a maximum number of uses based on the number of times the instruments have been energized on the robot. Each robotic instrument can cost between $600 and $4,000. These expensive devices must be handled thoughtfully in the surgical suite and in the sterile processing department in order to protect the facility's investment and maximize the number of procedures per instrument.

Processing challenges of robotic instruments

As with other surgical instrumentation, the goal of reprocessing is to remove all debris and bioburden from the instruments so that sterilization of all surfaces can occur. Any failure to sterilize can lead to potential cross-contamination and infections. Removing all bioburden and soils is also important because residual soils can lead to instrument damage and malfunctions, which can cause patient injuries and/or surgical delays.

Robotic instruments, which have complex designs and mechanics, pose unique cleaning challenges that may increase the risk of residual soil. For example, many devices have multiple articulation points controlled by various wires and pully systems that become contaminated during a procedure. Technicians are challenged to clean around the wires and within the channels in which they lie. Not only is it difficult to reach these points, but technicians are unable to see all areas clearly.

Another unique robotic challenge is char. Char occurs when bioburden on the instrument is exposed to a cauterization arc that burns the bioburden onto the instrument surface and creates a baked-on soil that is especially hard to clean.

Failure to remove bioburden or char in these tight, complex segments of a robotic tool can block sterilant from reaching these areas and impede sterilization. It can also lead to the formation of biofilm, an aggregate of bacteria and soils in a sticky matrix that adheres to surfaces and becomes very difficult to remove.

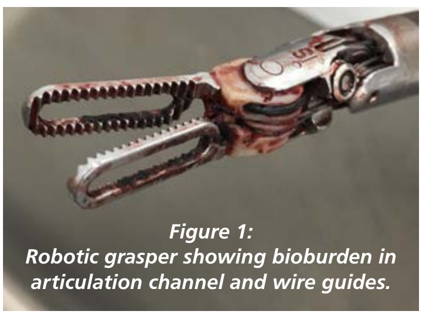

Figure 1: Robotic grasper showing bioburden in articulation channel and wire guides.

In the OR

To assure thorough cleaning of robotic instruments, every step of their instructions for use must be followed, starting with point-of-use treatment. Operating room staff must remove debris on these instruments between uses and ensure that the device is ready for reuse during the procedure. This can be challenging when robotic instruments remain secured to the robot arms instead of being placed on a surgical stand between uses.

Post-procedure point-of-use processes typically include some disassembly and treatment to maintain moisture on the devices. However, unlike traditional surgical instrumentation, robotic instruments require the priming of channels and other additional steps. Remembering which devices require these extra steps can be challenging for OR staff. Missing a step can be detrimental because bioburden can dry on surfaces and become hard to remove.

In decontamination

The special instructions continue as the instruments move to the decontamination area. Cleaning involves multiple steps and equipment. For example, the Da Vinci Endowrist instruments from Intuitive Surgical require 15 steps for decontamination alone. Reprocessing a single set of robotic instruments according to their instructions can take three hours or more to complete. Decontamination technicians may be tempted to skip steps or shorten soak times as the pressure to turn robotic sets increases. Unfortunately, shortcuts can potentially create opportunities for residual soils and biofilm formation.

Challenges of usage counts

The most restrictive challenge of these instruments is their limited reuse. Each instrument has a defined number of times that it can be used and sterilized. Continued reuse beyond the prescribed processing limits may lead to instrument failure or the formation of biofilm, both of which have the potential to injure patients.

Robotic instruments typically have a manual means to track uses. Technicians manually advance the sterilization count during processing typically by marking the instrument. However, misunderstandings about who does the advancing and when it should occur can lead to problems. Missing a count leads to inadvertent overprocessing and overuse. On the other hand, extra counts lead to premature device disposal and increased cost to the facility.

Addressing the challenges

Robotic instrument reprocessing challenges are not going away, but they can be managed. For example, point-of-use treatment has a big impact on the success of cleaning, so OR staff should be trained and tested on all the required steps and competencies to ensure consistency among all staff members who handle the robotic devices. Consider using placards or cue cards in the OR to remind staff of the proper steps to follow for each instrument.

It's also helpful to include all necessary materials and equipment for point-of-use treatment on each case cart. This may include flushing solution, syringes, adapters and point-of-use treatment products, for example. It can be especially helpful to use tubes that contain cleaning detergents or enzymes on instrument tips. These products perform two functions; they keep the soiled instruments moist, and they begin to loosen bioburden and char from the device.

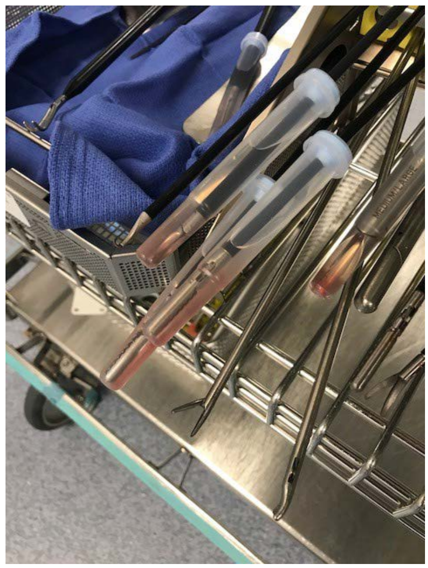

Figure 2: Enzymatic cleaner within tip tubes begin to breakdown bioburden as shown by the red color in the solution

Precleaning is especially important in the case of robotic instruments since each is limited to a specific number of reprocessing cycles. If residual soil is found after a sterilization cycle, one reuse is wasted because the soiled instrument must now undergo an extra cleaning/sterilization cycle.

As with OR staff, training must be provided for decontamination technicians,

Self-Study Test Answers: 1. B, 2. A, 3. C, 4. C, 5. B, 6. C, 7. A, 8. C, 9. B, 10. A

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and their ability to properly perform all tasks should be verified. Using competency checklists and spot audits confirms technician performance and captures process changes, both intended and unintended, before they become problems.

Technicians also need easy access to the tools they need to do the job. For example, lighted magnification at the sink allows technicians to see residual soil that may otherwise be missed. Having the correct brushes, syringes and attachment accessories to scrub and flow fluids through robotic channels helps assure thorough cleaning and avoid internal damage.

In addition, ultrasonic cleaners must meet the validated parameters described in each robotic device's instructions for reprocessing. Since robotic instrument channels are too small to be brushed, it's critical that cleaning solution be flushed through them during ultrasonication to remove bioburden. Technicians should be trained on the use of the ultrasonic cleaners and the correct attachments to ensure effective flow.

Thermal disinfection is the last step before the instruments are sent to assembly. When an ultrasonic cleaner is not capable of thermal disinfection, departments use automated washer disinfectors for thermal disinfection. Unfortunately, most of these systems are not designed for use with robotic instruments. Although placing robotic devices loosely in a basket during the automated washer disinfector cycle may seem like a good idea, it can pose serious risks. Cleaning chemistry can become trapped in the channels during the cleaning cycle. Without a flow mechanism, there is no guarantee that the channel is flushed free of chemistry. The instrument may be thermally treated, but it could harbor residual cleaning chemistries that may harm patients or interfere with sterilization. Only washer disinfectors with racks designed and validated for thermal disinfection of robotic instruments should be used for these devices.

It's important to note that even washer disinfectors that have been designed for robotic instruments may not fully replace required manual cleaning and ultrasonication steps. A thorough reading of the washer's instructions for use will help determine which, if any, of the manual cleaning and ultrasonication steps described in the robotic instrument's reprocessing instructions can be replaced by the washer disinfector's cycle. In addition, the correct cleaning chemistry must be used.

Assuring quality control

Quality control is an important function that helps to assure that robotic instrument sets are delivered to the OR on time and ready for use. Consistent cleanliness is one of the deliverables needed for every robotic set to be made ready, and quality checks can help capture failures to meet this deliverable before the set gets to the OR.

Proper training and tools contribute to better cleaning quality. For example, both the decontamination technicians performing the cleaning and the assembly technicians preparing sets for sterilization must be aware of the difficult spots to clean and must watch for evidence of physical part failure (fracture lines, cracks, plastic chips, etc.). Both teams should have lighted magnification to perform these intricate jobs. Furthermore, all staff members, including operating room and sterile processing staff, must be trained for their robotics-handling functions and demonstrate competency. Reevaluation of competency should be set per the facility policies and account for any deficiencies found during audits or inspections.

Various types of cleaning tests also help departments manage quality. For example, protein detection tests help detect residual soil on cleaned instruments. Cleaning indicator tests for automated equipment should be conducted daily to assure cycle effectiveness. And all tests should be documented to provide a traceable record of the data.

For robotic tools, accurate sterilization counts are essential for controlling costs and preventing overprocessing. Policies and procedures should identify who is responsible for tracking the instrument sterilization counts and when this will occur. Facilities can also consider using an instrument tracking software to automate the tracking process. If they do, a policy should be in place to resolve discrepancies between the robotic use counter and the tracking system's sterilization counter.

Even if sterilization counts are accurate, premature disposal can still occur. Any time a set is opened to retrieve just one instrument, the remaining instruments must be processed again before the set can be used. Right-sizing the robotic sets can reduce the chances of breaking up a set and wasting a sterilization cycle. Collaborating with surgeons and OR personnel can help determine the minimum requirements for each set. It can also help to use peel pouches for instruments or staplers that may be needed as procedure replacements or for specific cases. This will not only optimize sterilization processes but will offer versatility when picking case carts.

The future is here

Robot-assisted surgeries are here to stay. They will continue to evolve and advance therapeutic techniques to help improve patient outcomes. With proper planning, training, and quality control measures in place, sterile processing departments will be better able to reduce risk and support the unique processing needs of robotic instruments, staplers, and all the new accessories to come. **HPN**

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CONTINUING EDUCATION TEST • NOVEMBER 2020

Managing the reprocessing challenges of robotic instruments

Circle the one correct answer:

1. **Which specialties offer robot-assisted surgical procedures today?**
   A. Dental
   B. Cardiac
   C. Ophthalmology
2. **Which is an advantage of using robot-assisted surgery?**
   A. Patients have less blood loss and shorter length of stay
   B. Patients recover in the hospital
   C. The hospital must invest $2 million
3. **Which is true about the design of robotic instruments?**
   A. Instrument char is easy to remove
   B. All wires and pullies are sealed away from bioburden
   C. Bioburden can be trapped at the articulation points
4. **What can happen if residual soils or char remain on the instruments after cleaning?**
   A. Nothing
   B. Sterilization can be easier
   C. Biofilms can form
5. **What is a unique requirement for robotic instruments during point-of-use treatment?**
   A. Instruments are kept moist for transport
   B. Channels are primed
   C. Instruments are disassembled per the instructions for use
6. **How long does the typical decontamination process take for a robotic instrument?**
   A. 30 minutes
   B. 1 hour
   C. 3 hours or more
7. **Which helps remove soil during transport?**
   A. Tip tubes containing cleaning detergents or enzymes
   B. Priming the channels
   C. Point-of-use moisture retention product
8. **How does lighted magnification help decontamination technicians at the sink?**
   A. Makes it easier to see inside the channel
   B. Checks for protein
   C. Makes seeing residual soil easier
9. **When can a washer/disinfector be used to clean and thermally disinfect robotic instruments?**
   A. When the ultrasonic cleaner does not have a thermal disinfection cycle
   B. When the washer-disinfector is validated for these instruments
   C. Instruments cannot be put in the washer/disinfector
10. **Pouching individual robotic instruments for reprocessing can help facilities optimize the number of uses.**
   A. True
   B. False

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