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LEARNING OBJECTIVES

1. *Identify risks and consequences associated with TASS.*
2. *List some controllable factors that have been associated with TASS.*
3. *Discuss industry standards, recommendations and guidelines for reprocessing ophthalmic instruments.*

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SELF-STUDY SERIES

Seeing clearly

Preventing the avoidable when reprocessing ophthalmic surgical instruments

by Delores O'Connell, Clinical Education Specialist, STERIS Corporation

Unlike "animals who gain most of their information about the environment through their sense of smell,"[1] humans are dependent on their eyes to take in data from their surrounding environment and send it to the brain for processing.

Through the eyes, humans identify danger and possible threats from the environment, identify specific individuals, learn, create memories, and appreciate color, art, and nature. In a 2008 survey, 71 percent of respondents said, "a loss of their eyesight would rate as a 10 on a scale of 1 to 10, meaning it would have the greatest impact on their day-to-day life."[2]

The Department of Defense's (DoD) Walter Reed National Military Medical Center values eyesight so highly they have a website, 'Vision Center of Excellence,' dedicated solely to the preservation and protection of eyesight.[3] Medical emergencies are defined as "the sudden and unexpected onset of a medical condition that is 1) threatening to life, limb or eyesight; 2) requires immediate medical treatment; or 3) manifests painful symptoms that requires an immediate response to alleviate suffering."[4]

Eyesight preservation and protection is so highly valued that the United States Department of Labor's Occupational Safety & Health Administration (OSHA) has regulated the workplace environment to include eye protection. Employers are required to provide appropriate eye protection (e.g., face shields, goggles) to shield employees' eyes and face from potential injury from bloodborne pathogens, flying particles, chemicals, gases or vapors, and light radiation, and employees are required to wear it.[5]

According to the 2016 National Health Interview Survey, 90 percent of eye accidents are preventable with the use of eye protection, and 80 percent of worldwide vision loss is preventable or treatable. Eye injuries from surgical procedures are included in the preventable category.

For example, 3.6 million cataract extractions, the most common procedure performed by ophthalmic surgeons, are performed annually, a growing number in ambulatory surgery centers.[7, 8] Cataract surgery restores vision and improves quality of life, which is exactly what people expect when they make the decision to proceed with surgery. Cataract patients entrust their eyes to healthcare and sterile processing professionals. They don't expect to develop a preventable condition (such as toxic anterior segment syndrome (TASS) or endophthalmitis) that could lead to permanent loss of their eyesight.

TASS is in not an infection. It's an acute inflammation of the anterior (front) segment of the eye caused by the introduction of various contaminants on instruments and other items used during the surgical procedure. Symptoms include corneal edema (fluid collection) and an accumulation of white cells in the anterior chamber of the eye that develop within 24 hours of surgery. Topical agents often treat TASS successfully, but the TASS inflammatory response can cause serious permanent damage to eye tissues that can result in vision loss, which is the exact opposite of the intended surgical result.

In 2006, a hospital in Maine had an outbreak of TASS in patients who had undergone cataract surgery. As part of the investigation several changes were made, from replacing medication and solutions used at the sterile field, to functional testing of the steam sterilizer performed by the manufacturer. Unfortunately, these measures did not resolve the problem. Surgeries were suspended, and the following actions were taken: New irrigation cannulas replaced used, reprocessed ones; a new lot of balanced salt solution was used; instruments processed in the ultrasonic cleaner were rinsed with sterile water instead of tap water; and the enzymatic cleaning chemistry in use at that time was discontinued. In addition, a rapid test for the presence of endotoxins was performed on the solution from the ultrasonic cleaning equipment, and it came back positive. This supported the recommendation to change the ultrasonic solution, and to clean and disinfect the ultrasonic washer

between uses. Although the actual source of the TASS outbreak was not identified, the changes made during the suspension period resulted in no additional TASS cases.[9]

TASS is rare and may be caused by conditions other than improperly reprocessed surgical instrumentation. But the fact is, it is preventable. As sterile processing professionals, we have a responsibility to ensure that the products we deliver for surgical use have been fully processed in compliance with industry standards, recommendations and guidelines, by trained, competent personnel.

Ambulatory surgery centers perform a high number of intraocular surgical procedures, which makes sense because the procedure is an outpatient surgical procedure. Therefore, they report a greater number of TASS outbreaks in comparison to other facilities. "According to the FDA, hundreds of surgical centers in North America reported outbreaks of TASS between 2000 and 2011. Most appeared to be related to instrument processing."[10] A number of factors have been associated with TASS, some of which are related to reprocessing and some not. Tables 1 and 2 below list these factors.

Table 1: Non-reprocessing Factors
Wearing sterile gloves with powder
Incorrect use of preoperative skin antiseptics
Adding antibiotics to balanced salt solution
Using epinephrine with preservatives

Table 2: Reprocessing Factors
Inadequately flushing phacoemulsification and irrigation/aspiration handpieces
Incomplete removal of debris and residues
Improper disinfection of ultrasonic cleaners
Failure to change ultrasonic fluids
Inadequate rinsing of instruments
Use of enzymatic cleaners
Incorrect dilution of cleaning chemistries
Use of glutaraldehyde
Steam impurities during steam sterilization
Reprocessing single-use devices
Insufficient drying of lumens
Failure to properly maintain instruments
Lack of education related to the use, maintenance and reprocessing of ophthalmic surgical instruments (for reprocessing ***and*** surgical personnel).[10, 11]

A lack of adherence to instrument manufacturers' written instructions for use (IFU) and to national professional and regulatory standards, recommendations, and guidelines indicates poor reprocessing practices and has been linked to outbreaks of TASS.[12,10,9,13] Numerous agencies and organizations have weighed in on this topic, including: the American National Standards Institute with the Association for the Advancement of Medical Instrumentation (ANSI/AAMI), Association of peri-Operative Registered Nurses, the Centers for Disease Control and Prevention, and the International Association of Healthcare Central Service Materiel Management.

In 2018, the Ophthalmic Instrument Cleaning and Sterilization Task Force, a panel of experts from the American Society of Cataract and Refractive Surgery, American Academy of Ophthalmology, and Ophthalmic Outpatient Surgery Society, published *Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments*. The purpose of the specialty-specific document is to guide "ambulatory surgery centers in their efforts to adopt appropriate practices for the cleaning and sterilization of intraocular surgical instruments." The guidelines outline minimum standards for intraocular instrument cleaning and sterilization based on the consensus of the expert panel.[14]

Eye instruments: What's the difference?

Eye instruments are among the smallest and most delicate surgical devices of any specialty. These instruments are not usually heavily soiled with bioburden during surgical procedures, but trace amounts of ophthalmic viscosurgical devices (a viscoelastic solution used in cataract surgery) can dry and harden on instrument surfaces, making complete removal difficult. Overzealous manual cleaning can damage the delicate structures of ophthalmic instruments and create microscopic scratches or crevices. These microscopic deformities are ideal hiding places for residual bacteria and cleaning chemistries, making complete removal difficult.

When there is insufficient instrument inventory to meet the typical high volume of ophthalmic surgical cases performed every day, rapid turnover becomes a necessity. A lack of sufficient inventory can and does lead to the omission of cleaning and decontamination steps, which is a significant contributor to poor processing practices.

Decontamination step by step

Proper decontamination of eye instruments begins at the point of use. Instruments should be kept as clean as possible during the surgical procedure, using sterile water and a lint-free sterile surgical sponge. Lumens should be flushed with the effluent discharged into a separate basin from the rinsing solution. As with all surgical instruments, eye instruments must be kept moist until decontamination and complete cleaning can be initiated in the decontamination area.

All manufacturers' IFUs should be followed, including instructions for the cleaning implements used on eye instruments. For example, brushes and syringes labeled as disposable or single-use should only be used once and then discarded. If the implement is labeled reusable, the manufacturer's IFU will provide instructions for cleaning and disinfecting the implement. ANSI/AAMI ST79 7.4.1 recommends reusable brushes be cleaned after each use and disinfected or sterilized at least once a day, and that worn brushes be discarded.[12]

Ophthalmic instrumentation should be cleaned separately from non-ophthalmic instruments. Recently issued manufacturers' IFU include the instruction to dedicate specific ultrasonic cleaning equipment for eye instruments only. And, as with other mechanical cleaning equipment, ultrasonic cleaners need to be tested daily, and cleaned and disinfected between uses.

Rinsing and drying; they matter!

Some enzymatic detergents may not rinse completely from small, complex eye instruments. This is problematic because even minute amounts of solution can cause irreversible damage to eye tissue. Studies have demonstrated that effective rinsing is possible for most major brands of enzymatics and detergents. Each area that reprocesses reusable medical devices should have in their possession a copy of the manufacturer's technical data monograph (TDM) for the detergent in use. The TDM, a key document needed when selecting a cleaning chemistry, provides detailed information about the rinsibility of a chemistry.

The importance of thorough rinsing and flushing cannot be overstated, and the quality of the rinse water is equally as important. Potable water (safe-for-drinking tap water) should not be used as a final rinse because it can deposit contaminants onto a clean device. Treated or critical water (sterile, distilled, reverse osmosis [RO] or deionized [DI]) should be used for final rinsing. Many IFUs call for the use of critical water for the final rinse.

Complete and thorough drying of lumened devices is a must. Residual moisture can lead to biofilm development inside

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

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the channels, and lumened eye instruments can develop biofilm when conditions are favorable. Always follow the instrument manufacturer's IFU for safe and effective rinsing and drying methods.

Automated cleaning

Discussions and opinions abound about the value of mechanical cleaning after manual cleaning. Many decisions are made based on opinion rather than scientific evidence. When determining whether to use an additional mechanical cleaning step for ophthalmic instruments, the decision should be driven by the device manufacturer's IFU and by relevant industry standards, recommendations and guidelines. Due to the delicacy of a particular eye instrument, its manufacturer may recommend manual cleaning rather than the use of an automated washer/disinfector. In all cases, the manufacturer's written IFU must be followed.

Soil marker testing following cleaning and disinfection will detect residual soil not visible to the naked eye or through magnification. There are several tests available; each one identifies different residues. A popular test is the adenosine triphosphate (ATP) test, which tests for the presence of ATP. Then there is the hemoglobin test, which tests for the presence of hemoglobin (blood). There is a less popular carbohydrate test for detecting carbohydrates, and there is also a protein detection test, which shows the presence of amino acids. Soil marker testing is a fast and easy method to ensure eye instruments are free of residual bioburden and are ready for packaging and sterilization.

Sterilization

Terminal sterilization is the recommended method for sterilizing ophthalmic instruments. However, because of the need for rapid turnover due to insufficient inventory, many have employed an immediate-use steam sterilization (IUSS) process. AORN and AAMI have both stated that IUSS should not be used for "purposes of convenience or as a substitute for sufficient instrumentation. Instrument inventories should be sufficient to meet anticipated surgical volume and to ensure there is enough time to complete all critical elements of reprocessing… it should be used only in urgent clinical situations."[10,12]

In the past, IUSS has been confused with short cycle sterilization. The Centers for Medicare & Medicaid Services has clarified that short-cycle sterilization (sterilization cycle with a shortened dry time) is an acceptable terminal cycle for facilities performing eye surgeries. Devices that are sterilized in a short cycle are wrapped or containerized, and as with all cleaning and decontamination equipment and accessories, all manufacturers' IFUs must be followed for the packaging material, device, and sterilizer.

Low-temperature sterilization methods should not be used unless instructed by the ophthalmic instrument manufacturer and the sterilizer manufacturer. Manufacturers' instructed methods for low-temperature sterilization should be "validated for the specific instrument(s) with respect to efficacy of sterilization, potential ocular toxicity (e.g., from oxidation of metals), and instrument functionality."[14] Glutaraldehyde is not recommended due to the toxicity of residues resulting from inadequate rinsing or contamination during post-sterilization handling (OICS Task Force, 2018).

Let's prevent avoidable eye injuries

There is always risk when undergoing a surgical procedure, and the desired outcome may not be achieved due to uncontrollable conditions. Clinicians must inform patients about these risks before every procedure. *But improperly processed surgical instruments are an avoidable, controllable condition that should be prevented.*

First and foremost, reusing single-use devices may appear to reduce costs, but this off-label use puts patients at risk for post-surgical complications like TASS, which can lead to additional treatment costs. 'Single-use' means use it once and discard it.

Following all IFUs and guidance means not skipping steps, but it doesn't mean that your process must require a lot of extra time and cost. Processes can be streamlined by applying LEAN methodology to identify redundant steps and create opportunities for cost savings in workflow, purchasing, and energy and utility consumption.

Reprocessing policies and procedures should include optimized, measurable processes for pre-cleaning instruments at the point of use, transporting them to the decontamination area, performing effective manual cleaning and decontamination, not reprocessing single-use devices, cleaning and disinfecting tools and equipment used for instrument cleaning, maintaining equipment, and acquiring sufficient inventory to eliminate IUSS. Thoughtful scheduling of cases by the surgical department can help prevent the need for rapid instrument turnover and shortcuts, and a training program for both surgical and reprocessing staff can improve ophthalmic instrument handling, pre-cleaning and decontamination.

Facility leaders must also support this commitment. They should require and support robust training and observed competency evaluation programs for all staff members who use and/or reprocess ophthalmic surgical instruments. They should ensure that staff has easy access to the most current industry standards, recommendations, and guidelines. Leadership and staff should jointly develop policies, processes and procedures. These combined resources will help promote correct and adequate instrument reprocessing.

People have stated they would rather lose an arm or leg than their vision, and the Department of Defense and Occupational Safety and Health Administration are both dedicated to the preservation of eyesight. If it's a priority for us as individuals and for national regulatory agencies, shouldn't it also be a priority for professionals who use and reprocess ophthalmic surgical instruments? When you realize that any one of us, or one of our loved ones, could end up undergoing ophthalmic surgery at any time, the answer is an obvious "Yes." HPN

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CONTINUING EDUCATION TEST • NOVEMBER 2018

Seeing clearly

Preventing the avoidable when reprocessing ophthalmic surgical instruments

Circle the one correct answer:

1. **OSHA requires employers to provide eye pro-tection for employees who may be exposed to hazards such as bloodborne pathogens, flying particles, chemicals, gases or vapors and light radiation. Prescription eyeglasses are appropri-ate eye protection.**
   A. True B. False

2. **Which federal agency has a website dedicated to the preservation of eyesight?**
   A. CDC B. FDA
   C. DoD E. OSHA

3. **Which of the following professional organiza-tions comprise the panel of experts known as the Ophthalmic Instrument Cleaning and Sterilization Task Force:**
   A. Ambulatory Surgery Center Association
   B. American Society of Ophthalmic Registered Nurses
   C. American Academy of Audiology
   D. None of the above

4. **Ophthalmic viscosurgical devices are viscoelastic solutions used in the eye during intraocular surgery.**
   A. True B. False

5. **Enzymatic detergents are known to not rinse completely from ophthal-mic surgical instru-ments. The product-specific document that pro-vides information about effective rinsing for an enzymatic detergent is a/an _____.**
   A. Technical Data Monograph B. Manufacturer Instructions for Use
   C. ANSI/AAMI ST79 D. All the above

6. **Reprocessing single-use devices is an acceptable practice if the imple-ment is disinfected or steril-ized at least _____**
   A. Once a week B. Once a month
   C. Once a day D. None of the above

7. **You are the only sterile processing professional scheduled to work in the decontamination area until 09:00 am on Wednesday, the day with the highest volume of cataract surgery. You start your shift at 07:00 am. You head over to the ultrasonic washer to get it ready for the first case of the day. You see it has been filled with water and detergent and appears to be ready to go. What do you do?**
   A. Move to the next area that needs set-up for the day ahead
   B. De-gas the ultrasonic washer
   C. Empty the ultrasonic, clean and disinfect the basin and refill it with water and detergent per the manufacturer's IFU
   D. Put the instruments left from the day before in the ultrasonic washer to get them out of the way before things get busy.

8. **Low-temperature sterilization is not an approved alternative method of sterilization for ophthal-mic instruments.**
   A. True B. False

9. **Unlike IUSS, a short cycle (sterilization cycle with a shortened dry time) is a terminal sterilization cycle. Devices that are sterilized in a short cycle are wrapped or containerized.**
   A. True B. False

10. **Policies and procedures should include:**
    A. Optimized, measurable processes
    B. Steps for reprocessing single-use devices
    C. Scheduling cases and staff to minimize the need for rapid instrument turnover
    D. A and C

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