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Learning Objectives

1. Describe the causes of TASS.
2. Understand the issues related to safe reprocessing of intraocular instruments.
3. Update your procedures to incorporate TASS prevention recommendations.

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SELF-STUDY SERIES

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TASS awareness

Emerging issue impacts the sterile processing team

by Cynthia Hubbard, RN, BS

Toxic Anterior Segment Syndrome (TASS), a.k.a. toxic endothelial cell destruction, is a non-infectious inflammation after an uncomplicated and uneventful eye surgery. TASS is an early postoperative complication of anterior chamber surgery. The anterior segment is located between the lens and the cornea — the area targeted in cataract surgeries.¹

A cataract is a clouding of the eye's lens that affects vision. Cataracts are very common and most are related to aging. By age 80, more than half of all Americans either have a cataract or have had cataract surgery. A cataract can occur in either or both eyes, but it cannot spread from one eye to the other.² The only effective treatment for cataracts is surgery which removes the clouded lens and usually replaces it with a clear lens implant.³ The CDC reports that over 3.1 million cataract procedures were performed in the US during outpatient surgery in 2006.⁴ The frequency of cataract surgery is expected to increase as baby-boomers age and cataracts interfere with their ability to continue active lifestyles.³

Cataract surgery is successful in 90-95 percent of all cases. How often, then, does TASS occur? Data on the incidence of TASS are lacking, but databases are available to collect voluntary data in the US, Canada and other countries to track outbreaks that appear to be increasing since 2005. Over 100 North American clinics reported TASS over a 4-month period in 2006.⁵ In 2008 it was reported that clusters ranging from a few cases to up to 20 cases occur several times each year in the US.¹ Sometimes surgery centers must close until the cause(s) are identified and appropriate changes are made. This has happened in both the US and in Canada.^{6,7}

Investigations have shown that TASS may be caused by abnormalities in the pH or ionic composition of irrigation solutions, ophthalmic viscoelastic devices (OVDs), intraocular medications, powdered gloves, or even the finish of an intraocular lens (IOL). But, TASS has also been cited by many sources as occurring

from toxic residues on improperly rinsed surgical instruments; instruments soaked in enzymatic detergents; improper use of ultrasonic cleaners and residues from sterilization.^{1, 5, 8, 9, 10, 11}

Due to the multiple potential sources of toxins it is often time-consuming, expensive, frustrating and difficult to isolate a particular cause following an outbreak.^{1, 6, 7, 10} Preventing TASS is a more cost-effective approach, consistent with facility quality control goals. Since Sterile Processing Department (SPD) professionals are the most knowledgeable and experienced in instrument reprocessing they play an important role in TASS prevention from reprocessing-related causes. The key ways SPD can make a positive difference in preventing TASS include:

- developing a greater overall awareness of the TASS issue;
- reviewing current procedures for cleaning and sterilizing ophthalmic instruments;
- updating procedures based on recommended practices;
- educating staff and documenting competency;
- incorporating TASS awareness into continuous quality monitoring programs.

Awareness of TASS

Free-standing eye surgery centers, with onsite reprocessing, may be more familiar with TASS than hospital risk managers, SPD managers and technicians. But, educating everyone about this complex issue will increase awareness and updating to recommended practices may eliminate reprocessing errors implicated in prior TASS outbreaks.

Recommended practices

Best practices related to processing intraocular instruments have been published by AORN and the Ad Hoc Task Force on Cleaning and Sterilization of Intraocular Instruments of the American Society of Cataract and Refractive Surgery (ASCRS). The most recent revision to the Association for the Advancement of Medical Instrumentation's steam steril-

ization standard, AAMI ST79, includes an informative annex devoted to TASS. Additionally, general decontamination and sterilization references from the American Society of Ophthalmic Registered Nurses (ASORN); Centers for Disease Control and Prevention (CDC); AAMI; Association for Professionals in Infection Control and Epidemiology, Inc. (APIC); and the Food and Drug Association (FDA) also provide valuable information that can be applied to reprocessing of intraocular instrumentation to prevent TASS. The following summarizes the recommended practices of these groups for comparison with your current policies and procedures:

1. Segregation and transport of intraocular instruments:

- a) All instruments opened for ophthalmic procedures should be transported in dedicated closed containers to the decontamination area. Do not co-mingle these instruments with other types.⁹

2. Cleaning and rinsing recommendations: ANSI/AAMI ST79:2006/A1:2008 notes in Annex N that many of the reprocessing issues related to TASS outbreaks have occurred due to improper processing methods and procedures that are not in alignment with recommended practices. Intraocular instruments are complex, delicate, and many can not be processed by automated methods. This means that manual cleaning is the preferred processing method.¹⁶

- a) Always consult the instrument manufacturer for written cleaning procedures and acceptable cleaning products.⁹
- b) Several references cite the increased risk of TASS when instruments (including cannulas) are reused quickly between cases. Rigorous adherence to recommended practices for cleaning should never be circumvented to save time or money.^{7,9,11}
- c) Immediate cleaning, separate from other nonophthalmologic instruments, must take place so that viscoelastic solutions do not harden on or in the lumens of instruments.^{8,9}
- d) Single use syringes and brushes are recommended to clean ophthalmic instruments; they should be discarded after each use.⁹
- e) If you use reusable cleaning tools, understand that they may harbor various contaminants that can be reintro-

duced during cleaning of subsequent instruments. All reusable cleaning tools must, themselves, be cleaned and high-level disinfected or sterilized, preferably after each use or, at a minimum, daily.^{8,9}

- f) Some ophthalmic instrument manufacturers may not recommend use of any detergent for cleaning their products; do not just assume that the products you use for other instruments will be safe for ophthalmic instruments.^{8,11}
- g) Use enzymatic cleaners only in accordance with the instrument and chemical manufacturer's directions. Some enzymatic detergents contain subtilisin, an exotoxin that is not inactivated by autoclaving and causes inflammation, edema and potential corneal damage.¹⁰
- h) Following cleaning, instruments must be thoroughly rinsed with copious volumes of water to remove all chemicals from all surfaces. Consider any rinse volumes recommended by the detergent or instrument manufacturers to be *minimum rinse volumes*.⁹
- i) Rinsing procedures should flow/flush water over/through the instruments and discard it into a *sink or separate basin* so that the *fluid is never used during the rinsing process*.⁸
- j) If tap water is approved for rinsing by the detergent and instrument manufacturers always use sterile distilled or sterile deionized water for the final rinse.⁸ In 2008, a Spanish hospital implicated tap water final rinses as the cause of their five patient TASS outbreak.¹²
- k) Instruments with lumens should be fully dried with filtered forced or compressed air that is free of oil and water.^{8,9}
- l) AORN recommends that instruments should be wiped with alcohol after manual cleaning to disinfect and render them safe to handle.⁸

3. Using an ultrasonic cleaner: Concerns with using ultrasonic cleaners for intraocular instruments stem from the high probability of bacterial endotoxin contamination discovered in some TASS outbreaks.^{8,10} If you decide to continue to use an ultrasonic cleaner update to these best practices:

- a) Use only ultrasonic cleaners designated for cleaning medical instruments.⁹
- b) Properly empty, clean, disinfect, rinse, and dry the ultrasonic with a

lint-free cloth preferably after each use, or at least daily. If not contraindicated by the manufacturer, an alcohol rinse is also recommended.⁹

- c) Use only EPA-registered, facility-approved disinfectants, suitable for use in ultrasonic cleaners; their use must also be approved by the instrument manufacturer.⁹
- d) Check the manufacturer's reprocessing instructions before putting intraocular instruments into an ultrasonic cleaner, as some may not be compatible with the process.⁹
- e) Remove gross soil from instruments prior to using an ultrasonic cleaner.⁹
- f) Refill the ultrasonic just prior to use so that the water does not sit for long periods of time; do not put nonophthalmologic instruments into the ultrasonic at the same time it is used for ophthalmologic instruments.⁹
- g) Endotoxins, released by certain gram negative bacteria when these cells are destroyed, must be thoroughly removed by rinsing after the ultrasonic cleaning cycle.^{8,9}
- h) Instruments with lumens should be fully dried with filtered forced or compressed air that is free of oil and water.⁹
- i) AORN recommends that instruments should be wiped with alcohol after ultrasonic cleaning to disinfect and render them safe to reassemble.⁸
- j) Verification of the functioning, degassing and preventive maintenance of ultrasonic cleaners is required.⁹

4. Instrument inspection and assembly:

- a) Review use of water-soluble instrument lubrication as it may not be appropriate for intraocular instruments. Any "milk bath" residuals in the cannula lumens may be toxic when injected into the anterior chamber of the eye. Milk bath can grow gram-negative bacteria when left unchanged for an extended time. Upon sterilization the heat-stable endotoxins may cause TASS.¹³
- b) After cleaning and disinfection, instruments that have contacted viscoelastic material (which is difficult to remove during cleaning) should be inspected under good lighting and magnification.⁸
- c) Instruments that have "oxidized metal deposits and residues" have been implicated in TASS outbreaks.⁶ Inspection with magnifi-

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cation can assist in identifying instruments with rust or corrosion; remove them from inventory as they cannot be safely sterilized or used in this condition.

5. Sterilization concerns: Residues from sterilization processes have been implicated in TASS.^{1,14} When quick turnaround of low instrument inventories occurs frequently, inadequate time for proper cleaning and sterilization may result.¹¹

- a) Glutaraldehyde is not recommended for sterilizing intraocular instruments due to highly toxic residues that can result from inadequate rinsing.⁹ In 2006, a Turkish hospital reported a TASS outbreak related to cold sterilization with 2% glutaraldehyde in the OR. The affected corneas did not heal and subsequent surgical procedures were required for 6 patients.¹⁵
- b) Low temperature sterilization must be approved by the ophthalmic instrument manufacturer.^{9,16} In 2000, gas plasma sterilization degraded brass-containing instruments implicated in a TASS outbreak.⁹
- c) Verification of sterilizer function should be "completed at least weekly, preferably daily, in accordance with the sterilizer manufacturer's instructions and with published guidelines, and be appropriately documented."^{9,16}
- d) Flash sterilization is not recommended^{8,9} but still occurs as a substitute for maintaining sufficient inventories; budget for appropriate instruments so that flashing or 'short cycle' sterilization is not required for turnaround of eye cases.^{9,11}

6. Record Keeping: Documentation of policies/procedures related to surgical instrument reprocessing is already required by many agencies.^{8,15,17} Here are a few reminders of record keeping that helps prevent TASS:

- a) A variety of eye instruments require cleaning based on the manufacturer's reprocessing recommendations. Retain updated written documentation in work areas.^{8,9,15,17}
- b) Understand the specifics of instrument processing for intraocular instruments; maintain current written procedures and review them at least annually.⁹
- c) Document sterilizer monitoring in accordance with recommended

practices.^{8,9,15,17} A Korean hospital concluded that ineffective sterilization of eye instruments caused 15 patients to develop TASS in 2005.¹⁸

- d) Monitor steam quality; SPD must be aware of annual boiler maintenance (chemical treatment) so that steam lines can be properly flushed prior to re-using the sterilizers.⁹ A Florida hospital implicated steam impurities (sulfates, copper, zinc, nickel and silica) in their improperly maintained steam autoclaves in the outpatient surgical center as the cause of a TASS outbreak in 2002.¹⁴
- e) Facilities usually lack a surveillance system for detecting TASS. Cases of TASS should prompt re-evaluation of cleaning and sterilizing procedures.⁹
- f) AORN recommends that "records should be maintained of all cleaning methods, detergent solutions used, and lot numbers of cleaning solutions. These records can be used to help investigate any suspected or confirmed cases of TASS."⁸

Education

Education, competency validation and periodic performance reviews are required for anyone handling intraocular instruments; document this as you would for other training.^{9,16,17} When new devices/procedures are introduced, educate and document personnel competency. The ASCRS recommends that all staff involved with handling eye instrumentation be educated about TASS upon hiring and included in updates.⁹

Quality monitoring

A continuous quality monitoring program has long been recommended by AAMI.¹⁶ While the specifics are left up to individual facilities, all phases of instrument reprocessing must be monitored. The development of a TASS surveillance system could be a high-priority SPD goal this year once procedures are updated.

Summary

The experience gained by investigators in TASS outbreaks challenges some previously accepted cleaning practices. Identifying toxins as a cause for patient injury during cataract surgery brings new focus to the need for meticulous removal of cleaning products and other potential toxins. Obtain the manufacturer's latest recommendations for in-

traocular instrument re-processing, and then develop best practices. Everyone responsible for handling ophthalmic instruments must be aware of TASS-related issues. It is not enough for the surgeon and OR team to be informed about TASS; all SPD personnel must be aware of this emerging issue to help prevent it. It's SPD's responsibility to incorporate best practices into policies and procedures to handle all types of instrumentation through all phases of reprocessing. Documenting training and skills validation annually reinforces the importance of each person's role in preventing TASS outbreaks. **HPN**

Cynthia Hubbard, RN, BS is a consultant, author and presenter on topics related to quality control and best practices for sterile processing-related activities.

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TASS awareness

Emerging issue impacts the sterile processing team

Circle the one correct answer:

1. TASS is an early postoperative complication of cataract surgery caused by an infection.
A. True B. False
2. TASS may be caused by toxins from reprocessing, including improperly rinsed surgical instruments; use of enzymatic detergents; improper use of ultrasonic cleaners; and residues left on instruments following sterilization.
A. True B. False
3. Several references cite the increased risk of TASS when instruments are reused quickly between cases.
A. True B. False
4. Bacterial endotoxin contamination of ultrasonic cleaners is highly probable, especially if they are not properly emptied, cleaned, disinfected, rinsed, and dried at least daily and preferably after each use.
A. True B. False
5. If tap water is approved by the detergent and instrument manufacturers for rinsing always use sterile distilled or sterile deionized water for the final rinse.
A. True B. False
6. Low temperature sterilization methods are always appropriate for delicate ophthalmic instruments.
A. True B. False
7. Flash sterilization, though not recommended, still occurs as a substitute for maintaining sufficient instrument inventories.
A. True B. False
8. It is important to monitor steam quality and for SPD to be aware of annual boiler maintenance so that steam lines can be properly flushed prior to re-using the sterilizers.
A. True B. False
9. Cases of TASS should prompt re-evaluation of the cleaning and sterilizing procedures.
A. True B. False
10. Staff training, competency validation and periodic performance reviews are required for handling intraocular instrumentation in the OR, but do not apply to SPD.
A. True B. False

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