TASS and Implications for Sterile Processing

Background:

The only effective treatment for cataracts is surgery to remove the clouded lens, which usually includes replacing the lens with a clear lens implant. Cataract surgery is successful in about 95 percent of all cases. In the past, people were advised to wait until their vision had deteriorated to about 20/200. Today, because techniques have improved and the risks from cataract surgery are much lower, it is generally recommended that surgery occur when cataracts begin to affect quality of life or interfere with a person’s ability to perform normal daily activities.¹

Toxic Anterior Segment Syndrome (TASS), also known as 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. Investigations have shown that TASS may be caused by toxins from improperly rinsed surgical instruments soaked in enzymatic detergents, improper use of ultrasonic cleaners, residue from instruments sterilized with plasma gas, abnormalities in the pH or ionic composition of irrigation solutions, ophthalmic viscoelastic devices (OVDs), intraocular medications, or even the finish of an intraocular lens (IOL).²

Frequently Asked Questions:

1. What are the symptoms of TASS and what is the prognosis for recovery?

TASS is characterized by a reduction in visual acuity due to corneal edema and accumulation of white cells in the anterior chamber of the eye that occurs within 12-24 hours after surgery. This early onset of symptoms helps to differentiate it from an infectious process that generally appears 48-72 hours after surgery. TASS is not bacterial and cultures will be negative. Patients with TASS may be pain-free or have only mild to moderate pain. Pupils are dilated and intraocular pressure may increase suddenly.³
Milder cases will resolve within a few days to 1-3 weeks, but after 5 weeks, more dire consequences are likely. Recovery prognosis ranges from good to very poor as the inflammatory response to the toxins has the potential to cause serious damage to intraocular tissues. Prompt and proper diagnosis and treatment are imperative. TASS often resolves quickly with anti-inflammatory treatment, but in severe cases it can lead to a torn or detached retina, a form of glaucoma, a permanently dilated pupil and vision loss.\textsuperscript{2,4}

2. How often does TASS occur?

Data on the incidence of TASS are lacking. Clusters ranging from a few cases to up to 20 cases occur several times each year in the US.\textsuperscript{3} 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.\textsuperscript{4}

The Association of periOperative Registered Nurses (AORN) 2008 Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment notes that “more than 300 cases of TASS associated with balanced salt solution contaminated with endotoxins were reported to the US Food and Drug Administration (FDA), leading to the contaminated product being recalled by the FDA.”\textsuperscript{5}

3. What substances have been implicated as toxins?

Three general categories of substances show up in the literature review of TASS cases. They include extraocular substances that inadvertently get into the anterior chamber during or after surgery, products introduced into the anterior chamber during the surgical procedure, and irritants on the surfaces of surgical instruments used for the procedure.\textsuperscript{3} Here are some examples of these categories of toxins:

a) Extraocular substances that inadvertently get into the anterior chamber during or after surgery may include: topical antiseptics, talc from surgical gloves, and ophthalmic ointments.\textsuperscript{3}

b) Products introduced into the anterior chamber during the surgical procedure may include: anesthetics, such as lidocaine 2%; preservatives, such as benzalkonium chloride; inappropriately reconstituted intraocular preparations; Mitomycin-C; intraocular lenses, including phakic IOL; and contaminated irrigating solutions.\textsuperscript{3}

c) Irritants on the surfaces or inside lumens of surgical instruments used for the procedure may include: denatured viscosurgical devices, enzymatic detergents, bacterial endotoxin residue from ultrasonic cleaners, impurities of autoclave steam, and oxidized metal deposits and residues.\textsuperscript{3}
4. Are there “recommended practices” for processing intraocular surgical instruments?

Recommended 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). Additionally, general decontamination and sterilization references from the American Society of Ophthalmic Registered Nurses (ASORN), Centers for Disease Control (CDC), Association for the Advancement of Medical Instrumentation (AAMI), Association for Professionals in Infection Control and Epidemiology, Inc. (APIC), and the FDA also provide valuable information that can be applied to reprocessing of intraocular instrumentation to prevent TASS.

5. Can I clean intraocular instruments with enzymatic detergents like other instruments?

It is important to note that inappropriate use and/or incomplete rinsing of enzymatic detergents has been associated with TASS outbreaks. Enzymatic detergents can contain subtilisin, an exotoxin, which is not inactivated by autoclaving and causes inflammation, edema, and potential corneal damage.² The manufacturer’s reprocessing instructions should be on file and used to develop procedures for cleaning every type of instrument. Detergents must be EPA-registered and approved by the facility as appropriate for cleaning instruments, not environmental surfaces.⁶ Instrument manufacturers should specify the appropriate cleaning products and, if a detergent is specified, its use must be in alignment with the detergent manufacturer’s recommended dilutions and use. Some ophthalmic instrument manufacturers may not recommend use of any detergent for cleaning their products, so be sure to check with them, and not just assume that the products you use for other instruments will be safe for ophthalmic instruments.⁵

6. What are the concerns with using an ultrasonic cleaner for intraocular instruments?

Bacterial endotoxin contamination of ultrasonic cleaners is a highly probable outcome of their use, especially if they are not properly emptied, cleaned, disinfected, rinsed, and dried at least daily and preferably after each use. Check the manufacturer’s reprocessing instructions before putting intraocular instruments into an ultrasonic cleaner. Intraocular instruments should always be cleaned separately from any other nonophthalmologic surgical instrumentation.⁵,⁶ Validation of proper functioning of the ultrasonic cleaner is required, if it is used.⁶
7. What are the responsibilities of surgery staff to prevent TASS?

Several references site the increased risk of TASS when instruments (including cannulas) are reused quickly between cases and the proper time is not available for thorough cleaning and rinsing prior to sterilization.\(^4,6,7,8\) Flash sterilization shouldn’t be used to save time or as a substitute for having sufficient inventory.\(^5,9\) Ophthalmic viscosurgical device solutions (OVDs), which can dry and harden within minutes, should not be allowed to dry on the instruments. Therefore, during the surgical procedure instruments should be wiped with a damp, lint-free cloth and flushed and/or immersed in sterile water immediately after use. Biofilm adheres to the surfaces of instruments and is very difficult to remove. Keeping the organic material moist prevents the formation of biofilm.\(^5,6\) Phacoemulsifier handpieces, irrigators and aspirators and their accessories must be flushed, cleaned, inspected and maintained in accordance with the manufacturer’s directions for use.\(^6\) Best practices also support the use of disposable cannulas and tubing whenever possible and no reuse of devices labeled “single use.”\(^5,6\) All materials used in intraocular surgery or instrument management must be lint-free.\(^5,6\) Only preservative-free epinephrine should be available and used during surgery.\(^5,6\) Materials placed in the eye during surgery such as anesthetics, OVDs, antibiotics, or other medications have been found to be related to TASS, and must be monitored.\(^8\) Furthermore, the ASCRS recommended practice states that all instruments “opened for the procedure should be transported from the OR in a closed container to the decontamination area where immediate cleaning (separate from other nonophthalmologic instruments)” must take place.\(^6\)

8. Are there any additional issues for those cleaning and sterilizing instruments to remember to help the OR to prevent TASS?

Single use syringes and brushes used to clean ophthalmic instruments and cleaning solutions should be discarded after each use; reusable ones must be sterilized following all recommended precautions. Cleaning tools such as brushes can harbor contaminants that may be reintroduced during cleaning of subsequent instruments.\(^5\)

Following cleaning, instruments must be thoroughly rinsed with copious volumes of water to ensure removal of all chemicals from all surfaces. Rinsing procedures should flow/flush the water over/through the instruments and discard it into a sink or separate basin so that the fluid is never reused during the rinsing process. A final rinse of sterile distilled or sterile deionized water is required.\(^5\)

After manual or ultrasonic cleaning, instruments should be wiped with alcohol before preparation for sterilization. Wiping with alcohol disinfects the instruments and renders them safe to handle.\(^5\)

After cleaning and disinfection, instruments contacting viscoelastic material should be inspected for residue under magnification. Viscoelastic material is difficult to remove during cleaning, and inspection with magnification can enhance detection of residual material.\(^5\)
Instruments that have “oxidized metal deposits and residues” have been implicated in TASS outbreaks. Inspection with magnification can assist in identifying any instruments that show signs of rust or corrosion; remove these from inventory as they cannot be safely sterilized or used in surgery.

AORN also 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 facilitate investigation of any suspected or confirmed cases of TASS.”

Glutaraldehyde is not recommended for sterilizing intraocular instruments because of the toxicity of its residues that can result from inadequate rinsing or contamination during post-sterilization handling. Other low temperature sterilization methods must be approved by the ophthalmic instrument manufacturer.

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. How difficult is it to prevent TASS and find the cause if an outbreak occurs?

Preventing TASS is a multifaceted challenge. The frequency of cataract surgery is expected to increase with an aging population and only minute amounts of irritants are needed to cause clinically significant inflammation of eye tissues. Due to the multiple causes and associations implicated, it is often time-consuming, expensive and difficult for a surgery center to isolate a particular cause directly after an outbreak.

Since many factors must be reviewed to determine the cause of an outbreak; here are some of the most important considerations to have in place in your continuous quality improvement program:

- There are a variety of instruments that require cleaning and implementation of the manufacturer’s recommendations for re-processing; make sure you have all of the updated written documentation needed.
- Flash sterilization, though not recommended by AORN, still occurs as a substitute for maintaining sufficient instrument inventories; budget for enough instrument sets so that flashing is not required for turnaround of eye cases.
- Facilities may also lack a surveillance system for detecting TASS; develop one if you don’t have it currently. Cases of TASS should prompt re-evaluation of the cleaning and sterilizing procedures.
- Employees’ general knowledge of TASS/prevention may be inadequate; improve awareness of the many issues involved.
• Staff training, competency assessment, and periodic performance reviews are required for those handling intraocular instrumentation, and should be documented.  

• Understand the specifics of instrument processing for intraocular instruments; have current written procedures available and review them annually.  

• Select appropriate cleaning and rinsing solutions per manufacturer’s written recommendations; use a final rinse of sterile distilled or sterile deionized water.  

• Maintain sterilizers, boilers and water filtration systems properly and on a scheduled basis.  

• Monitor steam quality; be aware of annual boiler maintenance (chemical treatment) so that steam lines can be properly flushed prior to re-using the sterilizers.  

• Review your quality assurance procedures for use of ultrasonic cleaners for intraocular instruments.  

• Use only lint-free, residue-free woven materials. Discuss the TASS issues with the laundry that provides any reusable textiles for surgery use.  

• Use compressed air to dry instrument lumens to eliminate moisture that can serve as a medium for microbial growth.  

• Use only preservative-free intraocular solutions.  

Summary:

Knowledge of the manufacturer’s recommendations for instrument re-processing continues to be an indispensable aid in determining best practices and must be followed for intraocular instrumentation. Everyone responsible for handling ophthalmic instrumentation must be aware of the issues related to TASS and take special care to isolate these instruments from other instruments during handling and cleaning. Thorough and meticulous rinsing of these instruments prevents toxins from accumulating and posing a threat to delicate eye structures. It is not enough for the surgeon and OR team to have information about TASS; all sterile processing personnel must become informed about this emerging issue. It is the responsibility of sterile processing areas to incorporate best practices into the policies and procedures for handling all types of instrumentation through all phases of reprocessing. Documented training, verification and annual competency review of skills in reprocessing intraocular instruments will assist in reinforcing the importance of each one’s role in preventing TASS outbreaks.
For more information, call the 3M Help Line: 1-800-228-3957

1. www.mayoclinic.com/health/cataracts/DS00050/DSECTION=treatments-and-drugs


