Toxic Anterior Segment Syndrome: Contributions to Prevention
Cynthia Spry, MS, MA, CNOR, CSIT

May 2012
Objectives

After completion of this self-study activity, the learner will be able to:

1. Define Toxic Anterior Segment Syndrome (TASS).
2. Identify possible causes of TASS.
3. Understand recommendations for processing ophthalmic instruments used in cataract surgery.
4. Discuss the FDA initiative relative to TASS surveillance.

Test Questions

1. Toxic Anterior Segment Syndrome (TASS) is most commonly associated with cataract surgery and typically occurs within 48 hours of surgery.
   A. True  
   B. False

2. Most cases of TASS are mild and resolve readily; however TASS can lead to permanent impaired vision.
   A. True  
   B. False

3. The FDA has developed a test that will determine the level of contaminates in a medical device that causes TASS.
   A. True  
   B. False

4. Occurrence of TASS has been associated with:
   A. Failure to follow manufacturer’s instructions for processing ophthalmic instruments
   B. Extended surgery time
   C. Patient age
   D. Endotoxins in ultrasonic baths
   E. A and C
   F. A and D
   G. All of the above

5. Viscodlastic devices used in cataract surgery:
   A. Are used to create a space within the eye during surgery
   B. Dry very quickly, may adhere to instruments and may resist removal
   C. A and B

6. Immediate-use steam sterilization (IUSS) is an acceptable practice when inventory is insufficient to meet demand of the surgery schedule.
   A. True  
   B. False

7. As a final rinse ophthalmic instruments should be placed in a basin of deionized or sterile water and agitated.
   A. True  
   B. False

8. After ophthalmic instruments have undergone sterilization the risk of injury from endotoxins is eliminated.
   A. True  
   B. False

9. Terminal sterilization of ophthalmic instruments is the preferred method of processing.
   A. True  
   B. False

10. To stem outbreaks of TASS the FDA has announced a surveillance program to monitor the medical devices used in cataract surgery.
    A. True  
    B. False
Toxic Anterior Segment Syndrome (TASS) is an acute postoperative intraocular inflammation caused by the introduction of a noninfectious toxic agent into the anterior chamber of the eye at the time of surgery. Cellular necrosis and damage to the endothelium cause a severe inflammation which can lead to permanent impaired vision and can result in a pupil that constricts and dilates poorly. It is a rare and serious complication most commonly associated with cataract surgery.

Introduction

Patients diagnosed with TASS have reported blurry vision and eye redness. If pain is present it is usually very mild. To be diagnosed as TASS serious anterior segment inflammation should occur within 48 hours after surgery. Fibrosis should be present and limbus to limbus corneal edema should be seen. The limbus is the border of the cornea and the sclera. The vitreous body should not be infected.

When the vitreous body is infected the diagnosis is more likely to be infectious endophthalmitis. Although symptoms can be similar, one significant difference is that TASS has an earlier onset than infectious endophthalmitis. Although the symptoms may be similar, a distinction between the two diagnoses is important because treatment is not the same for both conditions.

Mild cases of TASS usually resolve within a few weeks without treatment however some patients may develop serious complications that can lead to additional surgery and permanent vision loss. In rare cases the patient may need a corneal transplant or glaucoma surgery. Common treatment for TASS is topical administration of corticosteroids to decrease the inflammation.

Incidence

Actual incidence of TASS is unknown. In a 4 month period in 2006 over 100 clinics in North America reported cases of TASS and in 2011 the FDA reported that in the past 11 years hundreds of surgical centers in North America have reported outbreaks of TASS. In an effort to better understand the incidence of TASS and prevent outbreaks, the FDA recently announced a surveillance program to monitor medical devices used in cataract surgery and to aid in identification of a TASS outbreak. Tests developed by the FDA’s Center for Devices and Radiological Health have determined the level of contamination that leads to inflammation and may help identify the source of an outbreak. This information will be shared with medical device manufacturers so they may improve the safety of their devices.

“This program includes:
- collaboration between the FDA and the American Academy of Ophthalmology on a registry designed to collect information about the devices used in cataract surgery and patient outcomes following surgery
- standardized methods to test the levels of TASS-related contaminants in ophthalmic devices
- an agreement with the CDC to collect and transport samples from suspected TASS outbreaks to FDA’s laboratory for analysis”

When personnel become aware of an adverse event related to surgery it should be reported to risk management and a report should be filed with the MedWatch program. MedWatch is the FDA Safety and Adverse Event Reporting Program. This data can assist the FDA in its efforts to identify incidence and causes of TASS.
Causes

The cause of TASS is not always certain and a variety of substances have been implicated. These include talc from surgical gloves, topical ophthalmic ointments, antiseptic agents, preservatives in solutions, irritants that remain on surgical instruments after processing, impurities in the steam source for the sterilizers, and residues from polishing of lens implants.8 Endotoxin contamination of balanced salt solution and ophthalmic viscosurgical devices have been associated with development of TASS.8,9 In 2006 the FDA announced they had received 300 injury reports of patients who had been treated with balanced salt solutions found to contain dangerous levels of endotoxins.9 Balanced salt solutions are used to irrigate the eye during cataract surgery. In 2008 the FDA announced a recall of an ophthalmic viscosurgical device when 66 adverse events were associated with its use. Tests of a particular lot of this product revealed elevated levels of endotoxin, which has been associated with postoperative intraocular inflammation and TASS.10 Viscoelastic devices are used to maintain space within the eye during surgery.

Cleaning and sterilization of ophthalmic instruments appears to play a significant role in the development of TASS. Sterilizing agents and detergent residues have been implicated in TASS. Some enzymatic detergents contain subtilisin and α-amylase, endotoxins that can cause corneal edema if introduced into the eye. These substances are only inactivated when the steam sterilizer temperature is more than 140°C (284°F), a temperature that most steam sterilizers are not typically set for.11 Residues from these substances that remain on instruments after cleaning have been implicated in development of TASS.4 Endotoxins in the municipal water supply have been implicated in an outbreak of TASS at an ambulatory surgery facility.12 Ultrasonic water baths can also be a source of endotoxin residue.13

In an effort to identify the causes of TASS, the American Society of Cataract and Refractive Surgery (ASCRS) posted a questionnaire on ophthalmic instrument cleaning and reprocessing on its web site and a task force from the Society visited 54 surgical centers where cataract surgery is performed. Survey and site visits included the period of June 2007 to May 2009. Results from the survey identified common practices associated with TASS. These included inadequate flushing of the Phaco® handpieces, use of enzymatic cleaning agents, incorrect detergent concentration, ultrasonic bath, antibiotic agents, balanced salt solution, preserved epinephrine, powered gloves, reuse of single use products, and poor instrument maintenance.14 Proper processing of eye instruments is a critical component of any program intended to prevent TASS.

Advances in cataract surgery — impact on instrument processing

Developments in cataract surgery have been dramatic. Historically the procedure has evolved from extracapsular extraction of the lens to a technique in which the lens content is emulsified and the cataract aspirated and replaced with an intraocular lens, from surgery within the hospital with a hospital stay to an ambulatory procedure with no hospital stay, and from required extended immobility to rapid recovery. New techniques and instrumentation have also reduced the time it takes to perform a cataract surgery. It is not unusual for a surgeon to complete a dozen or so cataract procedures in a single morning. A problem this often presents is that the number of cataract surgeries performed in a facility in a day exceeds the number of cataract instrument sets. Because the procedure takes little time, e.g., less than 20 minutes, there is often insufficient time to send the instruments to Sterile Processing (SP) for them to be processed using a terminal process and then returned to the operating room (OR) for use in a subsequent procedure shortly after the first procedure. As a result, cataract trays may be processed in the OR using immediate-use steam sterilization (formerly known as “flash sterilization”). Processing procedures and resources in the OR may not match those in SP (e.g., mechanical washers, ultrasonics, cleaning tools, purified water source, steam sterilizer cycles) or those required by the medical device manufacturer’s instructions for use which may not even be available in the OR or may not be followed precisely if they are available.

OR and SP staff may also be under pressure to turn around sets quickly so as not to interrupt the surgical schedule. Time constraints may encourage immediate-use steam sterilization and short cuts in processing. Eye instruments however are complex and delicate and some of them contain tiny lumens all of which present significant processing challenges. Patient safety demands rigid adherence to instructions and allowance for the time it takes to “do it correctly.”
Practices that might have been established in the name of expediency time required to follow the IFU exactly eliminates estimates based on time that it currently takes to process a set. Calculating the not by the time it would take to follow the IFU exactly, but rather by the instructed and also to determine the actual time needed to carry them in. 

The Centers for Disease Control (CDC) in both its Guideline for Prevention of Surgical Site Infection and its Guideline for Sterilization and Disinfection in Healthcare Facilities state that flash sterilization should not be used for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time.15-16

An adequate inventory is absolutely necessary to allow for timely processing of instruments between cases. One possible method to increase inventory at minimal cost is to conduct a thorough review of all cataract trays to determine if the instruments on the tray reflect those that are actually used in each case. Oftentimes cataract trays expand as a request is made to include “one more instrument” in the set. Repetition of this process can result in cataract trays that started out with 10 or so instruments expanding so that sets now contain upward of 30 instruments, some of which are seldom used and some that are duplicates which could possibly be used to help create additional sets. A simple project would be to:

- Create a check off list on a piece of paper of every instrument that is contained in every cataract tray. Duplicate that list to match the number of cataract procedures performed in a time period that would capture utilization by the surgeons or staff who perform cataract procedures.
- For each cataract procedure use a check off list making a check alongside of the instrument that is used. This exercise would identify the instruments that are always, or almost always used, and that should be on every cataract tray. Many facilities report that in reality 10 instruments or less are used in most cataract procedures.
- Configure a cataract tray to include these instruments used most frequently. Call this the master tray.
- Determine if any of the excess instruments could be used to help create additional master trays.
- Identify those instruments that must be purchased in addition to the excess instruments to create additional master cataract trays. Facilities may find that they can in fact afford to purchase 10 instruments or less as opposed to the 30 or so that may constitute a current cataract tray.
- Package those instruments that are seldom used in peel pouches and store in a portable instrument bin that is well organized and that can be easily brought into the operating room before the start of surgery. This assures that instruments that may be occasionally called for will be readily available.

Although the actual implementation is fairly simple this is not something that should be attempted without significant preparation and without communication to and support from the surgeons who must have the instruments they need when they need them. The CDC and Joint Commission guidelines should be used to support such an initiative and support and involvement should be solicited from the managers of sterile processing, infection prevention, risk management and the operating room. This is not a total solution to inadequate inventory but it may serve as a starting point in an effort to comply with CDC guidelines and could help to reduce the sometimes intense pressure to turn sets around quickly.

Initiatives to prevent TASS

Facilities often claim that they do not have enough cataract sets to meet demand to provide every patient with a terminally sterilized cataract instrument. One argument is that facilities do not have the dollars to purchase additional cataract trays. This argument should not be used as an excuse to employ immediate-use steam sterilization.

Personnel, whether in the operating room or sterile processing, should be aware of the incidence of TASS and the possible complications that can result when eye instruments are not properly processed. It is the goal of all staff to contribute to a positive patient outcome and knowing how their efforts can contribute to this goal is important.

As always it is critical to follow the device manufacturer’s instructions for use (IFU) when determining how to process eye instruments. They should be used to determine the steps needed to process as instructed and also to determine the actual time needed to carry them out. Often the amount of personnel resource needed is determined, not by the time it would take to follow the IFU exactly, but rather by the amount of time that it currently takes to process a set. Calculating the time required to follow the IFU exactly eliminates estimates based on practices that might have been established in the name of expediency that include possible short cuts. The information gathered that determines actual time needed to precisely follow the IFU may serve as a justification for additional resources. Rigorous adherence to manufacturer’s instructions should never be circumvented.17

In addition to the device manufacturer’s IFU the Association of periOperative Registered Nurses (AORN), The Association for the Advancement of Medical Instrumentation (AAMI), and the Society of Cataract and Refractory Surgery (ASCRS) provide general as well as specific guidelines for processing ophthalmic instruments.12,17,18 The following recommendations can be found in guidelines from these organizations.

Cooperation, understanding, and acceptance of the responsibilities for care of ophthalmic instruments is critical. Care of ophthalmic instruments begins at the OR.
• OR staff should take steps to prevent viscoelastic and other possible debris from drying or hardening on instruments. Instruments should be wiped clean with sterile water and a lint-free sponge during the procedure. Viscoelastic devices dry quickly and can be difficult to remove during cleaning.
• Instruments should be immersed in sterile water immediately following use.
• Instruments should be kept moist prior to cleaning in order to prevent debris from drying on them and they should be cleaned as soon as possible after the surgery. When debris is allowed to dry on instruments it becomes more difficult to remove.
• Instruments should be cleaned in an area designated for cleaning/decontamination.
• Instruments should be transported to the designated decontamination area in a closed transport container.
• Ophthalmic instruments should be processed separately from general surgery instruments. This can reduce the possibility of cross contamination by material or residue from general surgery instruments.
• Devices without instructions for processing should be discarded after use. Single use devices should not be reprocessed.
• Single use cannulae and tubing should be used when possible. Tiny lumens associated with ophthalmic instruments are difficult to clean and assessing the validation of cleaning adequacy of these is all but impossible.
• When reusable cannulae are used they should be flushed with sterile water as soon as possible after the surgery. The IFU for reused cannulated instruments should be consulted to determine specified volume, solution and frequency for flushing each lumen.
• Irrigation and aspiration ports of phacoemulsification handpieces, tips and tubings should be flushed before the handpiece is disconnected from the unit. Occluded tips have been implicated in the occurrence of TASS.12

**Manual cleaning**

• Personnel performing cleaning should wear personal protective equipment.
• Only those cleaning agents recommended by the device manufacturer should be used. It is important to ensure that detergent concentration and quality of the water used to dilute the detergent reflect the IFU. Use of enzymatic detergents for cleaning has not been established and outbreaks of TASS have been associated with inappropriate use and incomplete rinsing.6 The IFU should be consulted to determine if use of enzymatic detergents is contraindicated.
• Unless otherwise recommended in the IFU, final rinsing of detergent should be accomplished with sterile or treated (distilled or mineral) water. Tap water can contain gram-negative bacteria which over time can produce endotoxins. Heat-stable endotoxins that can result in TASS will remain on instruments that have been sterilized.5 Endotoxins have been implicated in the occurrence of TASS.
• Rinse water should be used one time and discarded.
• Single use brushes are preferred for cleaning. If reusable cleaning brushes are used they should be cleaned daily, preferably after each use.

**Mechanical cleaning**

• Mechanical cleaning equipment should be used unless contraindicated in the device IFU.
• Gross soil should be removed from instruments before they are placed in an ultrasonic cleaner.
• The ultrasonic cleaner IFU should be followed with regard to selection of detergent, verification of function, and operation.
• Instruments with lumens should be completely submerged and filled with solution in order to remove air in the lumens which could impede contact with the solution.
• Ultrasonic cleaners used for ophthalmic instruments should be emptied, cleaned, disinfected and dried at least daily, preferably after each use. Ultrasonic cleaners can harbor gram negative bacteria that can produce endotoxins that may not be inactivated in a subsequent sterilization process.
• Unless contraindicated in the IFU the ultrasonic cleaner should be rinsed with either 70% or 90% ethyl or isopropyl alcohol.
• After ultrasonic cleaning, instruments should be rinsed with sterile or deionized water. Rinse water should be directed down the drain and not reused. Instruments should not be rinsed by agitation in a basin.
• Instruments should be dried with filtered, oil-free, forced air. Compressed air can facilitate removal of moisture from lumens. Moisture can be a medium for growth of microorganisms.
• Containment devices and their accessories should be cleaned after each use.

**Inspection**

• Instruments should be inspected for integrity and cleanliness prior to sterilization. Ophthalmic instruments are delicate and easily damaged. Viscoelastic devices dry rapidly and can resist cleaning. Inspection of instruments under magnification can aid in determining removal.

**Sterilization**

• Ophthalmic instruments should be packaged in a manner that protects them from damage and that permits sterilant contact.
• Only those methods and cycles validated by the device manufacturer should be used for sterilization.
• Quality monitoring of the sterilization process should include as a minimum:
  – Prior to sterilization an internal Class 5 integrating or a Class 6 emulating chemical indicator should be placed inside every tray. The Class 6 emulating indicator must be specific to the cycle that will be used.
Prior to sterilization an external chemical indicator (Class 1 process indicator) should be placed on the outside of every package.

Following sterilization the sterilizer printout (physical monitor) should be inspected to determine whether selected parameters have been achieved.

Following sterilization and prior to transport to the operating room the external indicator should be examined to determine that exposure to the sterilant has occurred.

Packages should be inspected for integrity or moisture. Where these are suspect the package should be considered contaminated and should not be used.

The internal chemical indicator should be examined before the instruments are placed on the back table to determine if the sterilant penetrated the packaging.

If the physical monitors, external or internal chemical indicators detect a problem the package should not be used. Running a biological indicator process challenge device in each load will provide additional assurance that the sterilizer has achieved parameters necessary for sterilization.

Solutions and medications used in surgery should be documented and traceable to the patient on whom they were used. Detergent solution lot numbers should also be documented. Outbreaks of TASS have been associated with preservatives used in ophthalmic solutions, with topical antibiotics and with detergent residues. In the event of an outbreak of TASS in a facility this documentation may aid in identification of the cause for the outbreak.5,12,8

Policies and procedures for processing ophthalmic instruments should be written and reviewed annually and whenever changes are indicated because of new information or new equipment. These policies must be readily available and accessible on all shifts. Personnel should receive initial education and training in care and handling of ophthalmic instruments and competency evaluated prior to processing these instruments. Additional training and education should be provided when new equipment or processes are introduced. Competency should be evaluated on an annual basis. To increase the probability that policies, procedures and competencies are reviewed annually, oversight responsibility should be assigned to a staff member.17,12,8

When an outbreak of TASS occurs a thorough investigation of possible causes should be undertaken. Investigation should include solutions, medications, detergents used, OR protocols, and adherence to IFU for processing instruments. The American Society of Cataract and Refractive Surgery has established a center to help facilities investigate incidences of post-operative ocular inflammation and has developed a Reprocessing and Product Questionnaire that can be helpful in identifying the cause of a TASS outbreak. The questionnaire is available on the ASCRS web site.18

Summary

More than 3 million cataract surgeries are performed annually in the United States and it is estimated that 1 in 6 people over the age of 40 have a cataract. Cataract surgery is most prevalent among those older than 65. According to Department of Health and Human Services Administration on Aging, those over 65 represented 12.5% of the population in 2000. That percentage is expected to grow to 19% by 2030.19 As the population ages the number of cataract surgeries will increase as will the number of patients at risk for developing TASS. Careful attention and adherence to the device, the ultrasonic cleaner, and the sterilizer manufacturers’ instructions for use cannot be overemphasized as a means of prevention of TASS.
References

### Answers

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>A</td>
</tr>
<tr>
<td>2.</td>
<td>A</td>
</tr>
<tr>
<td>3.</td>
<td>A</td>
</tr>
<tr>
<td>4.</td>
<td>F</td>
</tr>
<tr>
<td>5.</td>
<td>C</td>
</tr>
<tr>
<td>6.</td>
<td>B</td>
</tr>
<tr>
<td>7.</td>
<td>B</td>
</tr>
<tr>
<td>8.</td>
<td>B</td>
</tr>
<tr>
<td>9.</td>
<td>A</td>
</tr>
<tr>
<td>10.</td>
<td>A</td>
</tr>
</tbody>
</table>

### Cynthia Spry, MA, MS

Cynthia Spry, MA, MS in Education & Nursing is now an independent consultant. She retired from Advanced Sterilization Products after 12.5 years where she worked as an international consultant in sterilization and disinfection. Cynthia is a member of APIC, IAHCSMM and AORN where she was a past national president. She has authored over 75 publications and two nursing texts. She has presented seminars on many healthcare related topics across the world. Cynthia is also a member of several AAMI Working Groups writing and updating recommended practices, including co-chairing the committee responsible for the ST79 Steam Sterilization recommended practice.

**Ms. Spry is a consultant for 3M Health Care.**
Sterile Process and Distribution CE Information

CE Applicant Name: __________________________
Address: ___________________________________
City: ___________________________ State: ______ Zip Code: ______

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this inservice for 1.5 contact hours for a period of five (5) years from the date of publication. Successful completion of the lesson and post test must be documented by facility management and those records maintained by the individuals until re-certification is required. DO NOT SEND LESSON OR TEST TO CBSPD.

For additional information regarding Certification contact: CBSPD, Inc. 148 Main St., Lebanon, NJ, 08833 or call 908-236-0530 or 1-800-555-9765 or visit the website at www.sterileprocessing.org.

IAHCSMM has awarded 1.5 approved contact hours for completion of this continuing education lesson toward IAHCSMM recertification.

Nursing CE Application Form

This inservice is approved by the California Board of Registered Nurses, CEP 5770 for 1 contact hour. This form is valid up to five (5) years from the date of publication.

1. Make a photocopy of this form.
2. Print your name, address and daytime phone number and position/title.
3. Add the last 4 digits of your social security number or your nursing license number.
4. Date the application and sign.
5. Answer the true/false CE questions. Keep a copy for your records.
6. Submit this form and the answer sheet to: 3M Infection Prevention Attn: HC4160 RR Donnelly Fulfillment Services 585 Hale Avenue North Oakdale, MN 55128-9935
7. For questions please call the 3M Healthcare helpline: 1-800-228-3957.
8. Participants who score at least 70% will receive a certificate of completion within 30 days of RR Donnelly’s receipt of the application.

Application Please print clearly or type.

Name: ___________________________________
Mailing Address: __________________________
City: ___________________________ State: ______ Zip Code: ______
Country: __________________________
Social Security or Nursing License Number: __________________________
Daytime phone: (_________)
Position/Title: ___________________________________
Date application submitted: __________________________
Signature: __________________________

Offer expires May, 2017

Infection Prevention Division
3M Health Care
3M Center, Building 275-4E-01
St. Paul, MN 55144-1000
U.S.A.
1 800 228-3957
www.3M.com/infectionprevention

3M is a trademark of 3M.
© 3M 2012. All rights reserved.