Toxic anterior segment syndrome (TASS) is an acute inflammation of the anterior chamber, or segment, of the eye following cataract surgery. A variety of substances have been implicated as causes of TASS. These substances can be divided into extraocular substances that inadvertently enter the anterior chamber during or after surgery (topical anti-septic agents, talc from surgical gloves, topical ophthalmic ointment), products that are introduced into the anterior chamber as a part of the surgical procedure (anesthetic agents, preservatives, inappropriately reconstituted intraocular preparations, mitomycin-C, intraocular lens), and irritants on the surfaces of intraocular surgical instruments that have accumulated as a consequence of inadequate or inappropriate instrument cleaning (denatured ophthalmic viscosurgical devices [OVDs], heat stable endotoxin from overgrowth of gram-negative bacilli in water baths of ultrasonic cleaners, degradation of brass-containing surgical instruments from plasma gas sterilization, and impurities of autoclave steam).

Whereas opportunities exist to prevent TASS resulting from extraocularly or intraocularly applied products by product withdrawals, product communications and compounding alerts, preventing TASS by appropriate management of intraocular surgical instruments is a challenge that must be repeated with each cycle of cleaning and sterilization of cataract surgical instruments at every cataract surgical facility. In fact, this challenge is not always satisfactorily addressed, resulting in single-facility outbreaks of TASS when the cleaning and sterilization steps are improved (N. Mamalis, MD, H. Edelhauser, PhD, personal communication, September 2006). Careful review of a number of facilities reporting cases of TASS to the Intermountain Ocular Research Center at the University of Utah in the spring of 2006 identified many opportunities to lower the risk for TASS through improving the steps of the cleaning process and sterilization.

The goal of these recommended practices for cleaning and sterilizing intraocular surgical instruments is to prevent single-facility outbreaks of TASS related to contaminated or degraded instruments. It is also hoped that the availability of recommended practices could facilitate the identification of causes of TASS and resolution of single-facility outbreaks of TASS when they occur. The recommendations have been written to be generic enough to enable appropriate application at all facilities performing cataract surgery, recognizing that differences in procedures and activities exist between surgical facilities.

The recommended practices are derived largely from existing, evidence-based general recommendations for cleaning and sterilizing all surgical instruments, from evidence derived from published reports of single-facility outbreaks of TASS, and from directions for management of equipment provided by manufacturers. The challenge of preventing TASS is multifaceted. Relevant factors include the minute amounts of irritants needed to cause clinically significant postoperative inflammation of the anterior chamber, the frequency with which cataract surgery is performed on a daily basis across the country, the variety of instruments used, and the...
various requirements for cleaning different types of instru-
ments. Consequently, these recommendations for cleaning
and sterilization were developed by representatives of pro-
fessional societies for cataract surgeons, ophthalmic and
operating room nurses, and infection control, in collabora-
tion with manufacturers of intraocular cataract surgical
instruments. Guidance was also provided by the Centers for
Disease Control and Prevention and the U.S. Food and Drug
Administration.

These recommended practices are not intended to address
all requirements for sterilization and quality assurance of the
sterilization process. They should be used in conjunction
with current consensus guidelines from the Association for
the Advancement of Medical Instrumentation, the American
Society of Ophthalmic Registered Nurses, and the
Association of periOperative Registered Nurses.22-24 The
recommendations are believed to be relevant for instruments
used in all intraocular surgical procedures, most of which
are cataract surgical procedures; therefore, to expedite con-
sistent and optimal instrument management, the recommen-
dations are intended to apply to all intraocular surgical
instruments. When recommendations for instrument man-
agement include cleaning without disinfection prior to steril-
ization, unsterilized instruments should be considered con-
taminated and therefore unsafe for handling unless appropri-
ate barriers and precautions are used (eg, gloves and separa-
tion from environments in which disinfected items are han-
dled).

The recommendations are divided into 2 sections. The first
establishes general principles of cleaning and sterilization
that must be addressed to prevent TASS. The second pro-
vides specific recommendations for cleaning and sterilizing
intraocular surgical instruments.

**General Principles of Cleaning and Sterilizing Intraocular Surgical Instruments**

The instruments should be kept moist until the cleaning
process begins to avoid drying of debris and OVD.23,25,26

All debris inclusive of OVD should be removed.15,25,27

Quality and volume of water should be used as specified by
manufacturer's directions for use (DFU) for suspension of
detergents and for cleaning and rinsing instruments.22,23,28 The
DFU for many intraocular instruments require or recom-
mand sterile distilled or sterile deionized water for most
cleaning steps. Sterile distilled or sterile deionized water is
required for final rinsing.25

Follow detergent and instrument manufacturers' DFU to
ensure proper use of the detergent and to ensure compatabil-
ity with the instruments.22,23,28

Rinsing should remove all cleaning agents as well as all
debris loosened during the cleaning process.25,26,29

The method of sterilization applied to instruments should be
approved by both the manufacturer of the sterilizer and the
manufacturer of the surgical instruments. Sterilizers should
be maintained in accordance with the manufacturer's recom-
mendations.22-24

Procedures for instrument cleaning and sterilization should
be developed and written for each healthcare facility.22,23

Adequate time should be provided to allow completion of
all steps of cleaning and sterilization.22,23

Staff training, competency validation, and periodic perform-
ance review should be implemented for each healthcare
facility.22,23,30

**Recommendations for Cleaning and Sterilizing Intraocular Surgical Instruments**

1. Adequate time for thorough cleaning and sterilization of
instrumentation should be established.
   a. Rigorous adherence to recommended procedures for
      cleaning and sterilizing surgical instruments should
      never be circumvented to save time or money.30,31
   b. Inventory of instruments should be sufficient to meet
      surgical volumes and to provide adequate time for
      completion of cleaning and sterilization.22,23
   c. Flash sterilization is designed to manage unanticipat-
      ed, urgent needs for instruments. Flash sterilization
      should not be used to save time or as a substitute for
      sufficient instrument inventory.22

2. For each piece of equipment, the manufacturer's
   DFU pertaining to cleaning and sterilization should be
   followed.22-24

3. Ophthalmic viscosurgical device solution, which can dry
   and harden within minutes, should not be allowed to dry
   on the instruments.25
   a. Instruments should be wiped with a dampened lint-
      free cloth and flushed and/or immersed in sterile
      water in the operating room (OR) immediately fol-
      lowing use, in strict accordance with manufacturer's
      DFU for each instrument.23,24 Sterile water baths used
      for cleaning or soaking soiled instruments should be
      kept in areas removed from the operative field and
      removed from sites that maintain instruments needed
      to complete the surgical procedure.
   b. The DFU for some reused cannulated instrument
      specify the solution, volumes, and frequency for
      flushing of each lumen. Flushing should be complet-
      ed as specified in the OR or in the decontamination
      area.23,24
4. Whether they are used, instruments opened for a procedure should be transported from the OR in a closed container to the decontamination area, where cleaning should be completed immediately.23,24

5. Disposable cannulas and tubing should be used whenever possible, and they should be discarded after each use. These devices are sold without a DFU for cleaning, and thorough cleaning is difficult to achieve and validate.25

6. Devices labeled for single use only should not be reused; single-use devices do not include instructions for reuse or reprocessing. The FDA actively regulates third-party and hospital reprocessors of single-use devices according to FDA guidance.32

7. To avoid contamination with bioburden and cleaning chemicals, intraocular instruments should be cleaned separately from nonophthalmologic surgical instruments.

8. The importance of enzymatic detergents for cleaning soiled intraocular instruments has not been established. Inappropriate use and incomplete rinsing of enzymatic detergents have been associated with outbreaks of TASS.16 If the DFU does not prohibit the use of a detergent and if a detergent is used
   a. Care should be taken to ensure instructions for proper dilution, outdate, and disposal are followed. The cleaning solution should be mixed with measured amounts of water and detergent (ie, not mixed with estimated volumes), according to the detergent’s DFU.23,24,28
   b. Following cleaning with detergents, with or without the use of an ultrasonic cleaner, instruments should be thoroughly rinsed with copious volumes of water to ensure removal of all detergent. If rinse volumes are specified by the detergent manufacturer's DFU or by the equipment manufacturer's DFU, they should be considered minimum volumes. Use of tap water for rinsing and for removal of detergent should be compatible with the manufacturer's DFU for the detergent and for the equipment. The final rinse should be with sterile distilled or sterile ionized water.25,29,30

9. If an ultrasonic cleaner is used
   a. Ensure that gross soil has been removed prior to placement in the ultrasonic cleaner.
   b. Check the manufacturer’s DFU of instruments to identify instruments that should not be subjected to ultrasonic cleaning.
   c. An ultrasonic unit designated for cleaning medical instruments should be used.24
   d. Validation of functioning, degassing, and preventive maintenance should be performed as recommended in the ultrasonic cleaner's DFU.23,24
   e. Ultrasonic machines must be emptied, cleaned, disinfected, rinsed, and dried at least daily and preferably after each use.17,18,33 Unless specified otherwise by the manufacturer, cleaning should be performed with an EPA-registered, facility-approved disinfectant and followed by sterile or tap water rinse sufficient to fully remove the cleaning agent. If not contraindicated by the ultrasonic cleaner's manufacturer, final rinse with 70% to 90% ethyl or isopropyl alcohol is recommended when feasible and unassociated with risk for fire. The machine should be dried completely with a lint-free cloth.34-36
   f. Refilling should occur immediately prior to use.

10. Manual cleaning processes
   a. Brushes should be designed for cleaning medical instruments.24
   b. Cleaning tools such as syringes and brushes should be discarded after each use. If brushes are reused, they should be designed for reuse and they should be cleaned and high-level disinfected or sterilized, preferably after each use, or at least once daily.24,34
   c. Cleaning solutions should be discarded after each use.24
   d. When flushing is used as part of a cleaning technique, the effluent should be discharged into a sink or separate basin so the fluid is not reused. Discharge of the effluent should be completed to minimize splash and aerosolization.

11. Rinsing
   a. Follow the manufacturer's DFU for selecting the appropriate type of rinse water for equipment.
   b. Unless otherwise specified by the manufacturer's DFU, sterile distilled or sterile deionized water should be used for the final rinse of instruments.25
   c. Rinsing should provide flow of water through and/or over instruments, with effluent discarded as it is used so only debris-free water is used for rinsing.
   d. Agitation in a basin of water should not be used as a final rinse.

12. Following thorough rinsing, instruments with lumens should be dried with forced or compressed air.
   a. Compressed air should be filtered and free of oil and water.
   b. Instruments with lumens should be fully dried.23

13. Specific instruments: phacoemulsifier handpiece, irrigator/aspirator, irrigator/aspirator tips, and inserters
   a. Flush phacoemulsifier handpiece with balanced saline solution prior to removing from the operative field.
   b. Wipe each instrument with a lint-free cloth and place immediately in a bath of sterile water. Remove from the operative field and remove from sites that maintain instruments needed for completion of the
surgical procedure, in strict accordance with the manufacturer's DFU for each piece of equipment. To avoid introduction of water or reintroduction of gross soil to the operative field, the sterile water bath should be clearly separated from the operative field.23

c. Clean and flush each item in accordance with the manufacturer's DFU and verify removal of all debris inclusive of OVD.23

d. Inspect irrigator/aspirator tips, preferably under magnification, before sterilization.23,24

14. If reusable woven materials are used for draping the sterile field, to absorb condensate in steam-sterilized instrument trays or to wipe instruments, they should be laundered and rinsed thoroughly between each use to eliminate surgical compounds, debris, and cleaning agents.

a. Inadequate rinsing of high pH detergents used in institutional laundering can leave chemical residues that could be transferred to intraocular instruments.20

b. A sufficient number of instrument sets, phacoemulsifier handpieces, irrigator/aspirators, and inserters should be purchased to allow adequate time for sterilization intraocular surgical instruments should be written, reviewed periodically (at least annually), and kept readily available within the practice setting.22,23

c. Personnel involved in handling and cleaning and/or sterilizing intraocular surgical instruments should

i. Be educated about TASS and its causes at hire and updated regularly thereafter.25

ii. Receive initial education, training, and validation of competency in the cleaning, inspection, packaging, sterilization, storage, and distribution of all intraocular surgical instruments.

iii. Be educated and trained in cleaning and sterilization procedures as well as related tasks (eg, equipment operation, preventive maintenance) via a formal, standardized training program administered by qualified personnel.22,23

iv. Undergo competency validations by direct observation of performance, using a competency checklist to ensure uniform evaluation of all personnel.22,23

d. Records of instrument use, of medication use, and of sterilization should be maintained in accordance with facility policy.22,24,25 Complete and detailed records will aid in the investigation of any occurrence of TASS.

e. A surveillance system for detecting TASS should be implemented. Cases of TASS should prompt re-evaluation of cleaning and sterilization procedures.21

17. Administrative controls should be implemented.

a. Policies and procedures regarding cleaning and sterilizing intraocular surgical instruments should be written, reviewed periodically (at least annually), and kept readily available within the practice setting.22,23

b. A sufficient number of instrument sets, phacoemulsifier handpieces, irrigator/aspirators, and inserters should be purchased to allow adequate time for cleaning and sterilizing between procedures.

c. Personnel involved in handling and cleaning and/or sterilizing intraocular surgical instruments should

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15. Cleanliness and integrity of instruments should be verified.23,24

a. Instruments should be visually inspected for debris and damage, preferably under magnification, immediately after cleaning and before packaging for sterilization to ensure removal of visible debris.24,25,30,37

b. Additional or repeated cleaning and rinsing steps may be required on a case-by-case basis to ensure removal of all debris and OVD.

c. Surgeons should examine instruments under the microscope prior to each use and reject any instrument that shows signs of residual debris or defects.28

16. Sterilization

a. The method for sterilizing intraocular surgical instruments should be in accordance with the DFU of the instruments and with the DFU of the sterilizer manufacturer.22,24

b. Steam sterilization should be completed in accordance with published guidelines.22,24

c. Glutaraldehyde is not recommended for sterilizing intraocular instruments because of the toxicity of glutaraldehyde residues resulting from inadequate rinsing or contamination during post-sterilization handling. Other low temperature methods of sterilization should not be used unless the ophthalmic instrument manufacturer and the sterilizer manufacturer have validated the method for the specific instruments with respect to efficacy of sterilization, potential ocular toxicity (eg, from oxidation of metals) and instrument functionality.19

d. Verification of sterilizer function should be completed at least weekly, preferably daily, in accordance with the sterilizer manufacturer's instructions for use and with published guidelines, and documented in the facility log.22,24

e. Measures should be taken to ensure that preventive maintenance, cleaning, and inspection of sterilizers are performed on a scheduled basis, according to the sterilizer manufacturer's written instructions.22,24 All preventive maintenance should be documented.

f. Maintenance of boilers, of the water filtration systems, and of the quality of water supplying the steam-sterilizing system should be verified at least yearly. Healthcare organizations may find consultation with companies specializing in boiler maintenance and water quality helpful.20,23,24
REFERENCES


28. AORN. Recommended practices for the evaluation and selection of products and medical devices used in perioperative practice setting. AORN J 1998; 67:270-272


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