Annex N
(informative)

Toxic anterior segment syndrome (TASS) and the processing of intraocular surgical instruments

N.1 Introduction

Special considerations are associated with the processing of instruments used for intraocular surgery, both because of the nature of the instruments themselves and because of the sensitive nature of the eye. Many of the intraocular instruments currently in use are complex and delicate and cannot be processed by automated methods; therefore, they must be cleaned manually. Because manual cleaning methods might be less controlled than automated cleaning methods, additional care must be taken during processing to ensure effective cleaning. The situation is further compounded by the sensitivity of ocular tissue to the introduction of foreign material into the anterior chamber of the eye, which could result in an acute inflammatory response known as toxic anterior segment syndrome (TASS). This inflammatory response could lead to severe visual impairment if it is not recognized and treated in a timely manner.

Although the induction of TASS might be associated with specific products such as contaminated balanced salt solution, which is used with ophthalmic instruments during surgery (Holland, et al., 2007), detergent residues, endotoxin, denatured ophthalmic viscoelastic devices (OVDs), preservatives, foreign matter, and residues from sterilization processing can all induce TASS and cause severe damage to ocular tissue (Mamalis, et al., 2006). Therefore, particular care must be taken in the processing of intraocular surgical instruments to ensure that foreign substances or materials associated with the instruments will not be introduced into the anterior chamber of the eye during surgery.

Outbreaks of TASS have often been linked to the failure to follow the processing procedures recommended by the instrument manufacturer and by organizations such as AAMI (ANSI/AAMI ST79), the Association of periOperative Registered Nurses (AORN, 2010a), the Centers for Disease Control and Prevention (CDC, 2003b), and the International Association of Healthcare Central Service Material Management (IAHCSMM, 2007). Specific instrument cleaning and sterilization recommendations intended to diminish the risk of TASS associated with intraocular surgical instruments have been compiled by a multidisciplinary panel and published by the American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Registered Nurses (ASORN). See this document (ASCRS and ASORN, 2007) for additional details.

The purpose of this Annex is to highlight existing recommendations for reducing the risk of TASS and to provide additional guidance in the overall context of surgical instrument processing in health care facilities.

N.2 Processing recommendations

N.2.1 General considerations

Because health care facilities must process a wide range of surgical instrumentation, it is often difficult to implement specific cleaning procedures for a particular class of surgical instruments. However, in view of the sensitivity of ocular tissue to the presence of foreign substances or material, it is critical that the cleaning and sterilization procedures recommended both by the manufacturer of the intraocular surgical instruments and by professional societies such as ASCRS and ASORN be closely followed. In addition, ongoing education, training, and verification of competency in the cleaning and sterilization of intraocular surgical instruments are essential.

N.2.2 Important elements of a processing program for intraocular surgical instruments

N.2.2.1 Instrument inventory

An adequate inventory of the necessary intraocular surgical instruments should be maintained to allow for the timely processing of instruments between cases. Adequate time must be allowed for processing instruments according to the manufacturer's written IFU; otherwise, the cleaning and sterilization of the instruments will be ineffective.

N.2.2.2 Designated cleaning area and equipment

A designated cleaning area and equipment dedicated to the cleaning of intraocular surgical instruments should be identified. Intraocular surgical instruments should be processed separately from general surgical instruments and equipment to reduce the potential for cross-contamination by material or residue from general surgical instruments. The recommendations provided in ANSI/AAMI ST79 for work area design, work flow, physical facilities, housekeeping, and personnel should be followed, because the same considerations apply to the processing of intraocular surgical instruments.

N.2.2.3 Manufacturer's instructions

The manufacturer's written IFU for the cleaning and sterilization of a particular intraocular surgical instrument should be read, understood, and followed by those responsible for processing the instrument; personnel training in the cleaning and sterilization procedure should be documented. All written IFU should be readily accessible and periodically reviewed to ensure that they reflect the manufacturer's current recommendations. (Manufacturers frequently update their instructions to incorporate new information or to list newly approved cleaning products or procedures.) The cleaning process should be audited to ensure that the procedures being used comply with the manufacturer's written IFU and that the personnel performing cleaning procedures have received documented training and have demonstrated competency in the cleaning process.

N.2.2.4 Precleaning

Instruments should be precleaned immediately following use. Gross debris should be removed, and instrument lumens should be flushed with sterile distilled water or another suitable agent as recommended by the manufacturer. The instruments should be maintained in a moist state before cleaning in order to prevent the drying of surgical debris onto or within them. In particular, OVDs can dry onto instruments very quickly following use and resist removal during subsequent cleaning.

N.2.2.5 Transport of instruments to the decontamination area

During transport of instruments from the point of use to the decontamination area, appropriate precautions (e.g., use of a closed transport container) should be taken to avoid personnel exposure to blood-borne pathogens, contamination of the work environment, and further contamination of the instruments. The time between using instruments and cleaning them should be kept to a minimum.

N.2.2.6 Personal protective equipment

Personnel who clean and process instruments should wear appropriate personal protective equipment (PPE) and avoid generating aerosols during the cleaning procedure. Aerosols can contaminate processing equipment and the work area and expose personnel to blood-borne pathogens.

N.2.2.7 Cleaning agents

Intraocular surgical instruments should be cleaned with the appropriate cleaning agent and with water of the appropriate quality, as specified in the instrument manufacturer's written IFU. Only cleaning agents that have been recommended by the manufacturer should be used. Particular attention should be directed toward ensuring that the specified concentration of cleaning agent and water of the recommended water quality are used. Final rinsing of the instrument should be performed with the volume of sterile, distilled, or deionized water recommended by the manufacturer. The water used to clean or rinse instruments should be discarded after each use. If an ultrasonic cleaner is used to process the instruments, it should be emptied, cleaned, rinsed, and dried at least daily or, preferably, after each use. Brushes and other cleaning implements should be cleaned and decontaminated as recommended by the manufacturer at least daily or, preferably, after each use. Whenever possible, single-use brushes and other cleaning implements should be used and then disposed of afterwards.

N.2.2.8 Sterilization

Intraocular surgical instruments should be sterilized using the methods and conditions recommended in the instrument manufacturer's written IFU. If there are discrepancies between the sterilizer manufacturer's written IFU, the user's sterilization processing conditions or equipment, and the instrument manufacturer's written IFU, the instrument manufacturer should be consulted before the items are processed. The sterilization process should be effective, monitored, and documented. ANSI/AAMI ST79 provides detailed recommendations for sterilization processing, including quality control and restrictions regarding the use of immediate-use steam sterilization (formerly known as flash sterilization).

N.2.2.9 Maintenance of processing equipment

Cleaning and sterilization equipment, boilers, and water filtration systems should be properly maintained. Otherwise, foreign materials such as endotoxin, heavy metals, or chemical contaminants or impurities could be deposited onto the instruments during processing and induce TASS. Maintenance requirements vary, depending on the complexity of the equipment. The operator's manual provided by the equipment manufacturer should be consulted for the required frequency and type of maintenance activities. All maintenance and repair activities should be performed by qualified personnel and documented.

N.3 Resources and training

Facility-specific written policies and procedures that are both general and instrument-specific should clearly outline the important steps in instrument cleaning and sterilization. Processing personnel should not only follow the appropriate processing procedures, but also maintain knowledge of those factors and practices that could have an impact on the efficacy of cleaning and sterilization. At each surgical center or other health care facility, at least one individual should be responsible for remaining current with recommendations for processing intraocular surgical instruments. Responsibility should also be designated for monitoring the continued competency of those who clean and sterilize surgical instruments. Useful sources of information on the processing of surgical instruments and the implementation of training programs include

a) Recommended practices, guidelines, procedures, and notifications published by government agencies and professional associations, e.g.:

   - American Society for Cataract Refractive Surgery (http://www.ascrs.org)
   - American Society of Ophthalmic Registered Nurses (http://webeye.ophth.uiowa.edu/ASORN)
   - Association for the Advancement of Medical Instrumentation (http://www.aami.org)
   - Association of periOperative Registered Nurses (http://www.aorn.org)
   - Centers for Disease Control and Prevention (http://www.cdc.gov)
   - Food and Drug Administration (http://www.fda.gov)
   - International Association of Healthcare Central Service Materiel Management (http://iahcsmm.org)

b) Scientific publications and trade journals

c) Manufacturers of surgical instruments and processing equipment

d) Discussions with professional peers and associates

Training programs should include the means of verifying the efficacy of training and continued competency in instrument processing procedures; written examinations specific to intraocular surgical instrument processing procedures might be useful for documentation purposes. Periodic observation of cleaning and sterilization practices by training personnel and periodic audits of the cleanliness of processed instruments are essential. Section 10 and Annex D include information on quality control and user verification of the cleaning process.

N.4 Summary

Because many different materials can elicit a TASS response if they are inadvertently introduced into the anterior chamber of the eye, the importance of following the proper intraocular surgical instrument processing procedures cannot be overemphasized.