REVIEW/UPDATE

Guidelines for the cleaning and sterilization of intraocular surgical instruments

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These Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments were written by the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force, comprised of representatives of the American Society of Cataract and Refractive Surgery, the American Academy of Ophthalmology, and the Outpatient Ophthalmic Surgery Society. These consensus subspecialty guidelines include evidence-based recommendations regarding issues that may be unique to the cleaning and sterilization of intraocular instrumentation. A newly published OICS Task Force study supports the safety of common short-cycle instrument processing practices for sequential same-day anterior segment surgery. Other studies substantiate the risk of toxic anterior segment syndrome from routine use of enzymatic detergent, whose microscopic residues are difficult to eliminate from intraocular instrumentation. Finally, based on published international outcomes and endophthalmitis rates, future studies should critically evaluate a variety of operating room protocols that may increase cost, waste, and carbon footprint, without any actual safety benefit.

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Postoperative infectious endophthalmitis and toxic anterior segment syndrome (TASS) are rare, but potentially sight-threatening, complications of cataract and other intraocular surgery. The small volume of the eye and its sensitivity to minute amounts of chemical or microbial contaminants means that improper instrument cleaning or sterilization practices might pose a significant risk to patients. The Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force is made up of representatives of the American Society of Cataract and Refractive Surgery (ASCRS), the American Academy of Ophthalmology (AAO), and the Outpatient Ophthalmic Surgery Society (OOSS). These professional societies represent ophthalmologists and the clinical staff of ophthalmic outpatient surgery centers, including surgeons, nurses, and technicians. The OICS Task Force includes experts on TASS and endophthalmitis and has written this document to provide specialty-specific, evidence-based guidelines for the cleaning and sterilization of intraocular surgical instruments. This document is an update of original recommended practices for cleaning and sterilizing intraocular surgical instruments published in 2007.[1]

Most of the recommended practices are derived from existing evidence-based recommendations for cleaning and sterilizing all surgical instruments in general,[2–4] from published analyses of TASS outbreaks,[5–12] and from manufacturers' instructions for use (IFU) for surgical instruments and equipment. In addition, task force members have collaborated in performing new research that supports certain recommendations, which is referenced in this document.

This specialty-specific document seeks to outline minimum standards for intraocular instrument cleaning and sterilization based on a consensus of experts representing the 3 sponsoring societies. Although developed specifically for cataract surgery, the recommendations in this document are also relevant for instruments used in other intraocular surgical procedures. It is not intended to be a comprehensive list of every requirement for sterilization and quality assurance of the sterilization process. Individual centers might elect to incorporate additional measures beyond what is outlined in this document.

Appropriate consideration should also be given to guidelines from other relevant organizations.[2–4,13]

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A full list of the Ophthalmic Instrument Cleaning and Sterilization Task Force members appears at the end of this article.

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However, many recommendations from these published guidelines are made with respect to all surgical procedures and are not specific to ophthalmic instrumentation and surgery. Therefore, those recommendations often do not take into account the unique conditions of intraocular surgery and special requirements for cleaning and sterilizing ophthalmic instrumentation. As a result, all-inclusive, broad guidelines attempting to cover surgery from head to toe could sometimes include inappropriate, or even risky, practices for ophthalmic cases. For example, cataract surgeries are shorter than many general surgical procedures and are often performed with higher daily volumes. Intraocular surgical instruments are among the smallest in size and generally do not become heavily soiled from tissue or bacterial contamination. On the other hand, minute amounts of detergent or chemical contaminants that would be well tolerated in other body cavities can cause severe intraocular inflammation (TASS) when introduced into the eye.[14,15] These characteristics might differentiate optimum cleaning and sterilization procedures for cataract surgery from those required for many other types of surgery.

TOXIC ANTERIOR SEGMENT SYNDROME

Toxic anterior segment syndrome is an acute severe inflammatory reaction to a toxic contaminant introduced into the anterior chamber during intraocular surgery. In addition to severe anterior chamber cell and flare, it might be associated with fibrin, hypopyon, diffuse limbus-to-limbus corneal edema, atonic pupil, secondary glaucoma, and in some cases, vitreous cells.[16] Because of these signs, TASS might be misdiagnosed and mistreated as infectious endophthalmitis. Even if TASS resolves with treatment and without permanent sequelae, the patient often suffers the emotional trauma of believing he or she might have a potentially blinding infection.

A large outbreak of TASS in 2006 led to the formation of the ASCRS TASS Task Force, whose surveys and site visits have consistently shown that improper instrument cleaning and sterilization is the most commonly identified cause of TASS.[17,18] The TASS Task Force separately analyzed and compared causes of TASS during 2 periods: 2007–2009 and 2009–2012.[17,18] Data from 130 questionnaires and 71 site visits to affected ambulatory surgery centers (ASCs) were incorporated into the final analysis of 1454 cases of TASS from approximately 69 000 concomitant cataract surgeries. The most common risk factors for TASS included inadequate flushing and rinsing of handpieces, use of enzyme detergents, and use of ultrasonic baths.[18]

2014 OPHTHALMIC AMBULATORY SURGERY CENTERS SURVEY OF STERILIZATION PRACTICE

In 2014, a survey developed by the OICS Task Force was sent to OOSS member–ASCs regarding cleaning and sterilization of intraocular instruments. The survey was completed by 232 respondent centers representing a variety of ambulatory surgical settings including single-specialty ophthalmology and multispecialty centers. Ownership models included 100% physician owned, corporate affiliated, hospital affiliated, and hospital outpatient departments (HOPD). For the purposes of analyzing cleaning and sterilization practices for ophthalmic surgery specifically, multispecialty ASCs, hospital-affiliated ASCs and HOPDs were excluded. In total, 182 complete responses were analyzed for this OICS guideline document. During the preceding 12 months, the responding single-specialty ASCs reported performing a total of 608 117 eye surgical procedures. The overall infection rate was 0.02%, with 116 facilities reporting zero cases and 66 facilities reporting 104 cases of endophthalmitis. The overall rate of TASS was 0.01%, with 161 facilities reporting zero cases and 21 facilities reporting a total of 50 cases. Most facilities (97.3%) had been inspected by a regulatory agency during the previous 3-year period. As a result of the inspection, 16.9% of the facilities reported being asked to change cleaning or sterilization protocols.

GENERAL ADMINISTRATIVE PRINCIPLES

All facilities should establish written protocols for instrument cleaning and sterilization. These "policies and procedures" should be based on industry standards and guidelines with input from the nursing and medical staff. They should be approved by the governing body of the facility and be available to operating room (OR) and instrument processing staff. In addition, these policies and procedures should be reviewed annually and on acquisition of new instrumentation or sterilizing equipment.[2,3] We acknowledge the wide diversity among ophthalmic surgical settings and in the surgical products and instrumentation used. Physician and nursing medical staff directors should be allowed some discretion in developing and reviewing their facility's written policies and procedures for instrument cleaning and sterilization based on the best available clinical evidence. These should then be approved by the facility governing body.

Personnel involved should be properly trained in handling, cleaning, and sterilizing intraocular surgical instruments and subject to periodic oversight.[2,3,13] In addition to the general principles of asepsis, this training should also include the cleaning, inspection, preparation, packaging, sterilization, storage, and distribution of intraocular surgical instruments. Appropriate staff should also be trained in related tasks, such as equipment operation and preventive maintenance. They should undergo competency validations by direct observation of performance.[2,3] Staff education, training, and the validation of competency should be updated and documented at least annually and coincident with introduction of new surgical equipment, medical devices, or packaging systems.[2,3]

Both infectious endophthalmitis and TASS are rare events, and their incidence should be monitored as a means of confirming the safety and efficacy of the facility's written protocols. The OR staff should be educated about the causes of both endophthalmitis and TASS. A surveillance system for reporting and documenting infectious endophthalmitis and TASS should be implemented. Any increase in the