Toxic anterior segment syndrome (TASS) is an acute sterile postoperative inflammation secondary to toxic substances introduced intraocularly during anterior segment surgery. The American Society of Cataract and Refractive Surgery (ASCRS) TASS Task Force has been evaluating outbreaks of TASS for more than a decade. The most recent analyses of the causes of TASS took place over 2 periods of time—from 2007 to 2009 and 2009 to 2012.1,2 Data from 130 questionnaires submitted to the task force as well as 71 site visits to affected surgery centers and hospitals resulted in 1454 reported cases of TASS out of approximately 69,000 concomitant cataract surgeries. Both surveys found that the most commonly found risk factors for TASS involved instrument cleaning and sterilization. Specifically, inadequate flushing of handpieces, use of enzymatic detergents, and use of ultrasound (US) baths were found to be the most common factors involved in TASS.

The use of enzymatic detergents in the cleaning of intraocular surgical instruments is problematic. Previous studies in both animals and humans3,4 have shown that enzymatic detergents are toxic to the corneal endothelium. The purpose of enzymatic detergents is to remove bulk biomaterial from surgical instruments. However, instruments used in anterior segment ophthalmic surgery acquire little bioburden during surgery and the materials that are left on the instruments can be completely removed with prompt rinsing and manual cleaning. If enzymatic detergents are not completely rinsed from ophthalmic instruments before sterilization, the residue of this material can be a source of TASS. Enzymes contain endotoxins, subtilisin, or α-amylase, which are substances that are not deactivated by autoclave sterilization.

There have been issues with the use of enzymatic detergents because the directions for use (DFU) that accompany ophthalmic instruments often call for the use of enzymatic detergents. Hospitals and ambulatory surgery centers are required by the Centers for Medicare & Medicaid Services (CMS) to strictly adhere to the ophthalmic instrument DFU during the cleaning process. Surveyors in the United States are now citing facilities for failure to use enzymatic detergents if the DFUs recommend them.

Because of these issues, a joint task force on Ophthalmic Instrument Cleaning and Sterilization (OICS) with representatives from the ASCRS, American Academy of Ophthalmology, Outpatient Ophthalmic Surgery Society, and American Society of Ophthalmic Registered Nurses has been formed to evaluate the issues relating to the cleaning and sterilization of ophthalmic instruments. Specifically, this task force has looked into the problems requiring surgery centers and hospitals to use enzymatic detergents to decontaminate their instruments. In December 2015, these societies released a joint advisory statement to their members warning about the potential for enzymatic detergent residues to cause TASS.A

Because of the issues involved in enzymatic detergents and TASS as well as the DFUs regarding TASS, several studies have been performed to assess the existence of enzymatic detergent residues on phacoemulsification tip surfaces after cleaning and autoclave sterilization. An article in this month’s journal by Tsaoosis et al. (pages 1353–1360) reports a study performed at the Intermountain Ocular Research Center at the University of Utah’s Moran Eye Center that evaluated the presence of enzymatic detergents on the areas of US tips using scanning electron microscopy and electron dispersive spectroscopy to assess morphologic changes and surface deposits. One group of tips underwent cycles of autoclave sterilization with the use of detergents followed by thorough rinsing with sterile water between cycles following the instrument manufacturer’s DFUs. Another set of tips underwent the same procedures but without rinsing. Analysis of the tips found that those that underwent autoclave sterilization without flushing and rinsing of the instruments had extensive areas of residual enzymatic material on the tips. However, even tips that underwent sterilization after the use of enzymes and thorough rinsing were found to have small amounts of enzymatic residue on the tips. This study concluded that enzymatic detergent residues could be detected on phaco tip surfaces even after thorough rinsing with sterile water.

Additional studies at the Intermountain Ocular Research Center in a rabbit model evaluated whether
enzymatic detergents used in the cleaning of surgical instruments can cause TASS-like responses. Various dilutions of enzymatic detergents were injected into the anterior chamber of the rabbit eye, and the animals were evaluated for signs of anterior segment inflammation postoperatively. A dose-related response was found in anterior chamber fibrin formation and iris vasculature over the first 72 hours after the injections. Furthermore, corneal endothelial cell loss was evaluated; once again, a dose-response curve was found, with the highest concentration of enzymatic detergents causing the most amount of damage. Toxicity of the enzymatic detergent to the corneal endothelium was also found with corneal vital staining, once again showing a dose-response curve to the various doses of enzymatic detergents.

Enzymatic detergents appeared to elevate the risk for TASS without providing any additional offsetting benefits. It was the conclusion of the OICS Task Force that enzymatic detergents should not be used for routine decontamination of anterior segment ophthalmic instruments. Because of the issues with the need to comply with manufacturer’s DFUs that require enzymatic detergents for the cleaning of instruments, the OICS Task Force has been working with the CMS as well as the U.S. Food and Drug Administration (FDA) and the Association for the Advancement of Medical Instrumentation on ways to solve the problem of requiring surgery centers and hospitals to use enzymatic detergents to decontaminate ophthalmic instruments. The OICS Task Force, in conjunction with the FDA, concluded that the best way to eliminate the potential risk for TASS with the use of enzymatic detergents is to have ophthalmic instrument manufacturer’s develop validated alternative methods of decontamination that do not require enzymatic detergents. This group has put out a formal recommendation to the ophthalmic instrument manufacturers to help devise and validate methods to clean and decontaminate ophthalmic surgical instruments without the use of enzymatic detergents. This request has been sent to all ophthalmic instrument manufacturers to help implement these changes to decrease the potential risk for TASS in anterior segment surgery.

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REFERENCES

OTHER CITED MATERIAL