Recommendations Regarding Use of Enzyme Detergent For Cleaning Intraocular Surgical Instruments

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Toxic anterior segment syndrome (TASS) and postoperative infectious endophthalmitis are rare but potentially sight threatening complications of cataract and other intraocular surgeries. Particularly because of the high frequency of cataract surgery, improper instrument cleaning practices pose a significant risk to patients. Because of conflicting guidelines, one practice that is controversial and of concern to regulatory agencies is the use of enzymatic detergents for decontaminating intraocular surgical instruments.

The manufacturer's instructions for use (IFU) that accompanies ophthalmic instruments and ultrasound cleaning baths often calls for the use of enzymatic cleaners. However, the necessity of enzymatic detergents for cleaning contaminated intraocular instruments has not been established. **Contrary to some manufacturer's IFUs, it is our position that enzymatic detergents should not be required for intraocular instruments for several reasons.** These detergents typically contain exotoxins subtilisin or alpha amylase, neither of which are denatured by autoclave sterilization. Corneal endothelial toxicity from enzymatic detergents has been documented in both animal and human studies[1,2]. Inappropriate use or incomplete rinsing of enzymatic detergents have been associated with outbreaks of TASS[3-5].

The purpose of enzymatic detergent is to remove bulk biomaterial from surgical instruments. However, intraocular instruments acquire minimal bioburden during surgery and the material they do collect is usually completely removed with prompt manual rinsing and cleaning. Even minute enzyme residue left on intraocular instruments can cause TASS, and the small diameter lumens and fragile nature of intraocular instruments makes complete removal of all traces of detergent difficult. Therefore, enzymatic detergents may elevate the risk for TASS without providing any significant benefit to the patient.

Recent publications reported that the most commonly identified risk factors for TASS are related to improper instrument cleaning. The ASCRS TASS Task Force analyzed and compared causes of TASS during two periods: 2007-2009 and 2009-2012[4, 5]. Data from 130 questionnaires and 71 site visits to affected ASCs was 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 of handpieces, use of enzyme detergents, and use of ultrasound baths[5]. Based on the published ASCRS TASS Task Force findings, we conclude that if intraocular surgical instruments are thoroughly rinsed with sterile distilled or deionized water promptly after each use, then the use of enzyme detergents is unnecessary.

If enzyme detergents are used, instructions for proper dilution and disposal of cleaning solutions should be followed. The instruments should be thoroughly rinsed to ensure removal of all detergent. Because tap water may contain heat-stable endotoxin from gram negative bacteria found in the municipal water supply, sterile distilled or sterile deionized water should be used for the final instrument rinse.

Avoiding enzyme detergent for intraocular instruments is a common practice among ASCs. In 2014, a survey developed by ASCRS, AAO, and OOSS was sent to OOSS member ophthalmic single specialty ASCs regarding cleaning and sterilization of intraocular instruments. Complete responses were received from 182 ASCs. A majority (55.5%) did not use enzyme for intraocular instrument decontamination, compared with 44.5% who did. The average self-reported rate of endophthalmitis was 0.021% for non-enzyme-using facilities compared to 0.027% for enzyme-using facilities. We are not aware of a study demonstrating that enzyme detergent for intraocular instruments reduces the rate of endophthalmitis.

Based on the documented risk of TASS associated with enzyme detergent use, without proven benefit for endophthalmitis prevention, enzymatic detergent should not be required for routine decontamination of ophthalmic intraocular instruments.

References:

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