FROM THE EDITOR

Guidelines for the cleaning and sterilization of intraocular surgical instruments

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"The [pirate's] code is more what you'd call guidelines, than actual rules."
—Hector Barbossa, *Pirates of the Caribbean*

Evidence-based specialty-specific guidelines for the cleaning and sterilization of intraocular instruments have been issued as the result of a 3-year collaborative effort by the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force and is published in this issue of the journal (pages 765–773). This task force was co-chaired by the two of us and was comprised of representatives from the American Society of Cataract and Refractive Surgery (ASCRS), the Ophthalmic Outpatient Surgery Society (OOSS), and the American Academy of Ophthalmology (AAO). This document makes evidence-based recommendations regarding issues specific to the cleaning and sterilization of intraocular surgical instruments.

It has been more than a decade since the publication of the initial recommended practices for cleaning and sterilizing intraocular surgical instruments.[1] A large outbreak of toxic anterior segment syndrome (TASS) in 2006 lead to the formation of the ASCRS TASS Task Force and was the impetus behind the guidelines. Since that time, ambulatory surgical centers (ASC) and hospitals have come under increased scrutiny by regulatory surveyors. Despite remarkably low endophthalmitis rates following cataract surgery, several longstanding practices for processing eye instruments have been cited by Joint Commission surveyors as deficiencies that could warrant licensure or coverage loss of ASCs.

In 2008, the Joint Commission began requiring a full terminal wrapped and dry cycle for all eye instruments, including those to be used immediately on consecutive cases. Because of the high volume and rapid operating room turnover in cataract surgery, these new regulations requiring a full 1-hour, wrapped, terminal sterilization cycle for ophthalmic instruments would have had dire practical and economic consequences for many ophthalmic surgery centers. A combined effort by the ASCRS and the AAO convinced the Joint Commission to modify this requirement on the basis that broad general surgical guidelines were not necessarily appropriate for the cleaning and sterilization of ophthalmic surgical instruments.

However, an additional challenge came in the form of a Centers for Medicare & Medicaid Services (CMS) 2014 ruling that immediate-use steam sterilization (IUSS) could not be performed routinely for any type of surgery. In fact, some CMS surveyors considered the typical short-cycle steam sterilization used for cataract instruments to be IUSS, which created an immediate problem for surgical centers performing anterior segment surgery. This led to the establishment of the OICS Task Force to address this issue. It became clear to the task force that there was a need for updated specialty-specific guidelines for the cleaning and sterilization of ophthalmic surgical instruments.

One of the first projects taken on by the task force was a survey of OOSS member-ASCs. What the survey showed is that approximately half of the 182 responding ASCs use short-cycle steam sterilization between sequential cases. Furthermore, there was no difference in the self-reported rates of endophthalmitis between the facilities using short and long sterilization cycles for sequential cataract cases performed on the same day. A series of discussions took place between CMS and the OICS Task Force. As a result of these discussions, allowances were made for continuation of short-cycle sterilization for sequential same-day ophthalmic surgery. However, there was still some ambiguity with respect to published CMS guidelines, especially over whether a full dry cycle had to be used. This led the OICS Task Force to design a series of studies of short-cycle steam sterilization using the 2 most commonly used sterilizers identified from the ASC survey. The study evaluated short-cycle sterilization of phacoemulsification handpieces from the 3 major ophthalmic manufacturers, which were inoculated with relevant bacteria. The study results were then compared to controls where instruments went through a full dry cycle. This study found that unwrapped short-cycle sterilization following the manufacturer's

0886-3350/$ - see frontmatter
https://doi.org/10.1016/j.jcrs.2018.06.002

instructions for use (IFU) for the machines effectively sterilize the instruments for same-day use. A complete dry cycle is not necessary when the instruments are kept within the covered sterilizer containment device for prompt use on a sequential case. This study firmly established the safety and acceptability of short-cycle ophthalmic instrument processing for sequential same-day surgery, even when the dry cycle is interrupted, if allowed by the IFU for the sterilizer.[2]

Another concern regarding the cleaning and sterilization of ophthalmic instruments is TASS. Analyses of recent TASS outbreaks found that one of the most common issues involved in the cleaning and sterilization of ophthalmic instruments was the use of enzymatic detergents.[3] These findings prompted several studies performed at the Moran Eye Center (Salt Lake City, Utah, USA) to look specifically at the incidence of enzymatic detergent residues left on surgical instruments even after rinsing according to the manufacturer's IFU. A study by Tsaousis et al.[4] evaluated 2 types of reusable phacoemulsification needles, following multiple sterilization cycles with and without the use of enzymatic detergents, followed by thorough rinsing with sterile water following the manufacturer's IFU. The phaco tips were then analyzed with scanning electron microscopy and energy-dispersive X-ray microscopy to assess the presence of any enzyme residue. Thorough rinsing reduced but did not eliminate enzymatic residue on the phaco tips.[4] Furthermore, research in the rabbit model showed that enzymatic detergents of differing dilutions caused anterior segment inflammation consistent with TASS.[5] Based on the findings in these studies, the new guidelines state that if intraocular surgical instruments are thoroughly rinsed with critical water (ie, sterile distilled, reverse osmosis, or deionized) promptly after each use, the routine use of enzymatic detergents is unnecessary and should not be required for routine decontamination of intraocular instruments.

While the publication of the guidelines for the cleaning and sterilization of intraocular surgical instruments is a major first step, the OICS Task Force is continuing to work with the ophthalmic surgical instrument industry to update the cleaning and sterilization IFU, specifically regarding the use of enzymatic detergents. The task force is asking manufacturers to validate intraocular instrument cleaning methods that do not require the routine use of enzymatic detergents.

These OICS guidelines are intended to educate and assist ASC staff in implementing appropriate practices for the cleaning and sterilization of intraocular surgical instruments.

Thanks to several new studies, the task force is able to provide ophthalmic-specific, evidence-based recommendations that may allow our members to adopt or defend certain longstanding practices that have come under increasing regulatory scrutiny.

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