OICS Task Force issues guidelines for cleaning and sterilization of ophthalmic instruments

by Liz Hillman EyeWorld Senior Staff Writer

Next step: Task force requests manufacturers change IFUs according to published research

Evidence-based specialty-specific guidelines for the cleaning and sterilization of intraocular instruments were developed and issued through a 3-year collaborative effort spearheaded by ASCRS. The guidelines were released on April 5, 2018, and announced in the April issue of *EyeWorld*.

Under the leadership of co-chairs and ASCRS Executive Committee members **David F. Chang, MD**, Los Altos, California, and **Nick Mamalis, MD**, Salt Lake City, the "Guidelines for Cleaning and Sterilization of Intraocular Surgical Instruments" were developed by the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force composed of representatives from ASCRS, the Ophthalmic Outpatient Surgery Society (OOSS), and the American Academy of Ophthalmology (AAO). These guidelines were created with evidence from scientific, published studies that address the use of enzymatic detergents for intraocular instruments, the safety and efficacy of short-cycle steam sterilization for sequential same-day ophthalmic procedures, and the carbon footprint of cataract surgery.

"The small size of our instruments and the unique susceptibility of the eye to microscopic contaminants differentiates optimum cleaning and sterilization procedures for cataract surgery from other types of general surgery," Dr. Chang said, explaining the need for ophthalmology to have specialty-specific cleaning and sterilization guidelines. "In our complex regulatory ecosystem, where the default is to apply general guidelines that are broad enough to cover all surgeries, it is important for ophthalmology to establish specialty-specific guidelines for cataract and intraocular surgery. The guideline document is intended to be educational for ophthalmologists, ASC staff, and the organizations charged with assuring ophthalmic patient safety.

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"We based many recommendations in these guidelines on new or recently published studies, many of which were initiated by task force members," Dr. Chang continued. "These included studies on reuse of titanium phaco tips, on failure to eliminate microscopic enzyme residues from intraocular instruments, and on short-cycle sterilization practices for sequential same-day cataract surgeries. We also reference recent studies from the Aravind Eye Hospital system that raise the possibility that many of our traditional ophthalmic OR protocols may increase cost, waste, and carbon footprint, without any actual safety benefit. Further study is warranted, but because our surgical endophthalmitis rate is already so low, we would caution against arbitrarily changing or adding more regulations for instrument processing without some scientific evidence of benefit."

Richard Hoffman, MD, Eugene, Oregon, a member of the OICS Task Force, said having guidelines agreed upon by ASCRS, AAO, and OOSS gives them "unprecedented validity" that "will hopefully go a long way for standardizing how we clean and sterilize our distinct instrumentation, in addition to allowing manufacturers the rational to change the current [instructions for use (IFU)] to be more in line with ophthalmic needs.

"Anyone working within an ASC should read this document and have it available for their employees and anyone wishing to defend their current clinical practices," Dr. Hoffman continued.

"We want to make sure that the instruments are in fact sterile; we want to make sure they are clean and they're not going to promote or cause infection," said **Francis Mah, MD**, La Jolla, California, a member of the OICS Task Force. "On the other hand, we don't want to create a scenario where the cleaning itself and the chemicals used cause problems in the eye."

Dr. Mah explained manufacturers often list what might have been validated and tested for safety and efficacy for cleaning and sterilization of instruments used in other surgical situations, creating broad instructions for use that might not be suitable for ophthalmic instruments. IFUs directing enzyme detergents and the residues that have been associated with toxic anterior segment syndrome (TASS) are an example, Dr. Mah said.

One of the first projects of the task force was surveying OOSS member ASCs. Dr. Chang said more than 200 centers responded and the average endophthalmitis rate, based on self-reported data, was 0.02%, which he called "very reassuring."

"For sequential, same-day cases, roughly half of respondent ASCs do not use enzyme to clean instruments and about half employ short-cycle sterilization," Dr. Chang noted. "There was no difference in the overall pooled infection rates compared to ASCs routinely using enzyme or routinely using full, terminal wrapped sterilization cycles for consecutive same-day cases."

Dr. Mamalis stated that analyses of recent TASS outbreaks found that issues with the cleaning and sterilization of ophthalmic instruments were the most common factors involved, with the use of enzymatic detergents frequently associated with TASS.[1] This prompted several studies, performed at the Moran Eye Center, to look specifically at enzyme residue that might be left on surgical instruments, even after rinsing according to the IFUs, and the effect that such residue might have.

Research by Tsaousis et al. studied two types of reusable phacoemulsification needles undergoing multiple sterilization cycles with and without the use of enzyme detergents, which was followed by

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Billing for corneal crosslinking update

Important development since the "Crosslinking reimbursement" article in the April issue of EyeWorld

Avedro (Waltham, Massachusetts) submitted a request for the reconsideration of a separate J code for Photrexa. On May 7, Healthcare Common Procedure Coding System (HCPCS) preliminary results were released in favor of a J code for Photrexa. The public meeting will take place on May 14, at which time meeting participants will hear presentations and have the opportunity to ask questions. It is important to note that the preliminary recommendations are not final or binding upon any payer and are subject to change. The final decision will be made in late November, which would then be effective on January 1, 2019. **EW**

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rinsing with sterile water.[2] Afterward, the researchers analyzed the phaco tips with scanning electron microscopy and energy-dispersive X-ray microscopy to assess any physical changes to the phaco tips and the presence of any enzyme residue. While Tsaousis et al. found that rinsing the phaco tips did reduce enzymatic residue, such residue was still present on the phaco tips despite rinsing.

Further, research on a rabbit model showed that enzymatic detergents of different dilutions (like those that would be considered residue even after rinsing) caused anterior segment inflammation that mimics a TASS reaction.[3]

With these recent studies in mind, the new OICS guidelines state, "if intraocular surgical instruments are thoroughly rinsed with critical water promptly after each use, the routine use of enzyme detergents is unnecessary and should not be required for routine decontamination of ophthalmic intraocular instruments."

Another recommendation that is evidence based, born out through scientific research, Dr. Mamalis noted, is the validation of short-cycle steam sterilization for cleaning instruments between cases. Chang et al. evaluated short-cycle sterilization (using two common steam sterilizers) of unwrapped phaco handpieces from three manufacturers that were inoculated with relevant bacteria. These were compared to controls that went through a full wrapped, dry cycle.[4] The research found that unwrapped, short-cycle sterilization, following the IFUs for the machines used, effectively sterilized the instruments for same-day use. "A full drying phase is not necessary when the instruments are kept within the covered sterilizer containment device for prompt use on a sequential case," Chang et al. wrote.

Task force members took on this research after, as described in the April 5 ASCRS member alert announcing the guidelines, "Separate challenges came from The Joint Commission, which originally required a full terminal wrapped and dry cycle for sequential same-day cases, and from a CMS ruling that immediate use steam sterilization (IUSS) could not be performed routinely for any type of surgery." Due to efforts by the task force, CMS clarified its acceptance of short-cycle sterilization for sequential same-day ophthalmic cases as long as the IFUs are followed.

Jeffrey Whitman, MD, Dallas, president of OOSS, said these studies give scientific evidence that supports cleaning and sterilization practices that have not changed since the early days of phacoemulsification.

"We now have published literature that says this is what works and we need to put that in action for the [instructions for use]. This is one of the largest effective changes for surgery center sterilization procedures since I've been an ophthalmologist, and I've been an ophthalmologist for 30 years," Dr. Whitman said.

The work does not stop here though. Dr. Whitman said he and other task force members are meeting with manufacturers, presenting them with this data in an effort to get them to formally change their IFUs.

"Some of these things have changed already, but what we need is the vendors and their published material, their [IFUs], to say this is the right thing to do. The surgery center in doing the right thing should not have to constantly defend themselves," Dr. Whitman said, noting that some inspectors will stick to what the IFU says, even when presented with published research that might show otherwise.

Dr. Hoffman explained that the manufacturer's IFUs, even despite these evidence-based recommendations, are the ultimate guideline that government auditors use to determine compliance. Thus, there is still work to be done to update these instructions.

"The guidelines were a huge first step, but it's not the end," Dr. Mamalis said. "We're going to continue meeting, and the next step is going to be working with industry to try to get them to update their directions for use, especially in instrument cleaning, sterilization, and more specifically in the use of enzymatic detergents." **EW**

References

1. Bodnar Z, et al. Toxic anterior segment syndrome: Update on the most common causes. *J Cataract Refract Surg.* 2012;38:1902–10.
2. Tsaousis KT, et al. Comparison of different types of phacoemulsification tips. II. Morphologic alterations induced by multiple steam sterilization cycles with and without use of enzyme detergents. *J Cataract Refract Surg.* 2016;42:1353–1360.
3. Mamalis N. Toxic anterior segment syndrome: Role of enzymatic detergents used in the cleaning of intraocular surgical instruments. *J Cataract Refract Surg.* 2016;42:1249–1250.
4. Chang DF, et al. Evaluation of ophthalmic surgical instrument sterility using short-cycle sterilization for sequential same-day use. *Ophthalmology.* 2018. Epub ahead of print.

Editors' note: The physicians have no financial interests related to their comments.

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