CATARACT

Guidelines Issued on Short-Cycle Steam Sterilization

IF STERILIZER MANUFACTURERS' IN-structions for use are followed, surgical centers can safely employ short-cycle steam sterilization of unwrapped instruments for sequential same-day cataract surgeries, a multiorganizational task-force has concluded.[1] This comes with a significant caveat, however: The transit time to the operating room (OR) should be 3 minutes or less.

"We concluded that the common practice of transporting still wet but sterile instruments directly to the OR for prompt use was safe as long as the instruments were in a rigid, covered containment device and were then handled by sterile gloved personnel within the OR," said task force cochair David F. Chang, MD, who practices in Los Altos, California.

Impetus. In 2014, the Centers for Medicare & Medicaid Services issued a policy that addressed acceptable sterilization methods. However, some terminology used in that policy led to confusion among cataract surgeons. In response, the Academy, the American Society of Cataract and Refractive Surgery, and the Outpatient Ophthalmic Surgery Society convened the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force.

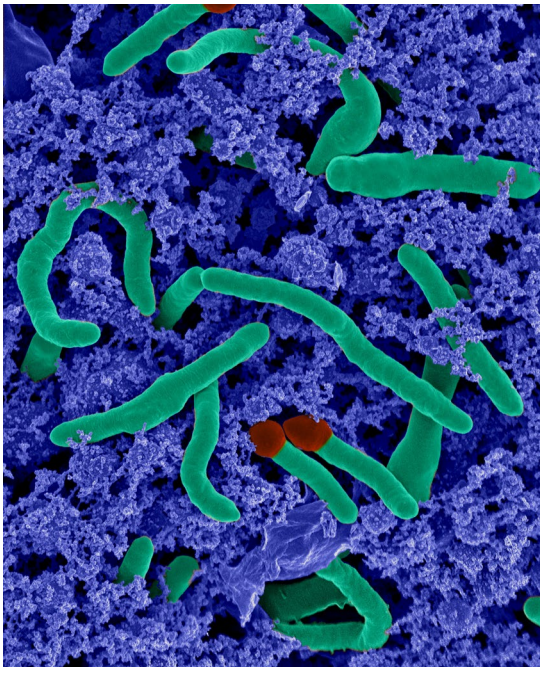
Investigation. The OICS task force initiated several studies to test the effectiveness of short-cycle sterilization practices commonly followed by ophthalmic ambulatory surgery centers (ASCs). In an initial 2014 survey of 182 ophthalmic ASCs, the task force found that short-cycle sterilization was routinely used between same-day cases by more than half of respondents. Results of the survey also indicated that the AMSCO (Steris) and STATIM (SciCan) brands were the most popular sterilizers.

Bacterial challenge. For this study, the task force evaluated a STATIM 2000 with the STATIM metal cassette and an AMSCO Century V116 with a SteriTite container system (Case Medical). Surgical instruments consisted of phaco tips and handpieces from 3 major manufacturers, all of which were contaminated with the highly heat-resistant bacterium *Geobacillus stearothermophilus.*

Findings. "Our analysis confirmed that the wrapped inoculated instruments completing the full sterilization and drying cycles with either sterilizer brand were sterile with no growth of the target organism after being stored for 7 days," the task force reported.[1]

What about recontamination risk? However, in busy cataract surgery centers, instruments are sterilized between cases, repeatedly over the course of a day, and then reused in sequential surgeries on the same day. Consequently, it is common for the drying cycle to be interrupted, when allowed by the IFU (instructions for use), Dr. Chang said.

"Because of a potential wicking effect, instrument moisture can compromise the microbial barrier of a packaging system and allow contamination from the environment or nonsterile hands," he said. "However, we were able to show that unwrapped, sterilized instruments that were still wet could be transferred to the OR within a rigid, covered containment device without recontamination for up to 3 minutes of transit time."



VALIDATION. *Colored scanning electron micrograph of* G. stearothermophilus, *which was used as the challenge organism.*

These OICS guidelines provide "new evidence and support for common short-cycle sterilization practices for sequential same-day anterior segment surgery. They will hopefully assist surveyors in determining whether specific practices are safe and acceptable," Dr. Chang said.

He added, "I understand that one accrediting organization, the Institute for Medical Quality, is already training their surveyors with the new OICS guidelines." *—Linda Roach*

1 Chang DF et al. *Ophthalmology*. Published online March 27, 2018.

Relevant financial disclosures—Dr. Chang: None.

RETINA

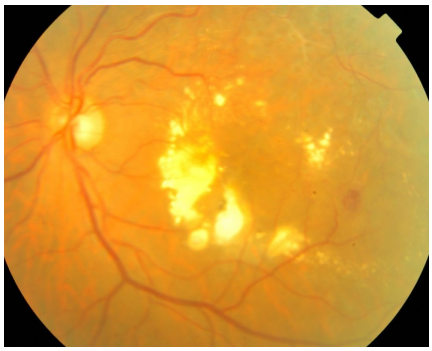
Signs That DME Is Being Undertreated

A RETROSPECTIVE STUDY OF DIA-betic macular edema (DME) patients in a large health care system found that—when compared to patients in landmark clinical trials— these "real-world" patients received fewer intravitreal injections over the first 12 months of treatment, were monitored less frequently, and achieved inferior vision outcomes.[1]

Too few injections? The findings are comparable to earlier studies based on large Medicare and commercial datasets that reported significant undertreatment of DME with anti–vascular endothelial growth factor (VEGF) drugs.

"There may be widespread underutilization of anti-VEGF agents in treating DME," said lead author Nancy M. Holekamp, MD, a retina specialist in Chesterfield, Missouri. "I think many of us are not aware of this phenomenon, which may compromise clinical outcomes."

Study details. The study involved 110 patients (121 eyes) who received intravitreal anti-VEGF therapy for DME with either bevacizumab or ranibizumab from January 2007 through May 2012 (aflibercept was not available during this time). Most eyes (n = 116, 95.9%) received bevacizumab.



DME. *Abundant foveal hard exudates in the left eye of a 55-year-old patient with diabetes, hypertension, and normal serum lipid levels.*

Surprise outcome. "The most surprising finding was the extremely low number of anti-VEGF injections given to DME patients in the first year of treatment," Dr. Holekamp said. For instance, the mean number of injec-

CORNEA

Treating Dry Eye in GVHD

PATIENTS UNDERGOING HEMATOPOIETIC STEM CELL transplantation for cancers such as leukemia and lymphoma are at a high risk of graft-versus-host disease (GVHD). And the most common ocular manifestation of GVHD is dry eye disease (DED)—a condition for which clinical management remains problematic despite ongoing research.

But does DED associated with GVHD pose a particularly difficult treatment challenge? A team at the Massachusetts Eye and Ear Infirmary confirmed that it does—and they found evidence suggesting that topical steroids and artificial tears may be of limited benefit.[1]

Study specifics. In this single-center study, the researchers compared the efficacy of a low-dose topical steroid for treating patients who have moderate-to-severe DED associated with GVHD versus patients with DED from other causes. Over the course of 4 weeks, both groups received 0.5% loteprednol. For non-GVHD patients, the treatment decreased average Ocular Surface Disease Index scores by 34% and average corneal fluorescein staining scores by 41%. Treatment with artificial tears also decreased those 2 scores by 22% and 32%, respectively. The same treatments, however, had a minimal effect in patients with GVHD.

Why it matters. The clinical manifestation of DED associated with GVHD is often very similar to cases of DED associated with other causes. However, as Jia Yin, MD, PhD, pointed out, treatment protocols should differ. "Our own clinical experience has shown that moderate-to-severe DED associated with GVHD is more challenging to manage and might require alternative therapeutics. And we now have scientific evidence to back that up."

Need for new treatments. Dr. Yin noted that very few rigorous clinical studies have focused on patients with DED and GVHD, despite the fact that DED is recognized as a major ocular morbidity in this population. Thus, her team hopes that these results will help others look beyond currently available treatment regimens and develop new options.

"Our study confirms the impression of many ophthalmologists caring for GVHD patients that their significant DED is very difficult to treat. We also conclusively demonstrate the limitation of a commonly used short-term topical steroid for treating moderate-to-severe DED in these patients. These findings warrant both a more in-depth understanding of the DED mechanisms in GVHD and a quest for more effective treatments," she said. *—Mike Mott*

1 Yin J et al. *Am J Ophthalmol.* 2018;190:17-23.

Relevant financial disclosures—Dr. Yin: None.

tions was 3.1 (range, 1-12, versus 9-12 in landmark trials such as RISE/RIDE).

Additional findings. Other outcomes of note include the following:

- More than 68% of the eyes received 3 or fewer injections, and just 3% received 10 or more injections.
- Visual acuity improved by 4.7 Early Treatment Diabetic Retinopathy Study letters (converted from Snellen charts to approximate ETDRS letter scores), compared to an average of about 12.0 ETDRS letters in RISE/RIDE.
- The percentage of eyes losing ≥10 or ≥15 letters was 10.8% and 8.3%, respectively, about 2-fold higher than clinical trial eyes.
- Only 59% of patients had regular (at least quarterly) visits, while fewer than 2% had monthly visits, comparable to patients in the landmark trials.

Clinical implications. Dr. Holekamp said she hopes the study raises awareness "of our potential deficits as practicing retina specialists." She advised her colleagues to pay attention to their DME treatment patterns: "Look back over a year of treating each individual patient. Did you see the patient often enough? Did you give a sufficient number of injections to give this patient the very best chance of gaining and maintaining vision?" —*Miriam Karmel*

1 Holekamp NM et al. *Am J Ophthalmol.* Published online April 20, 2018.

Relevant financial disclosures—Dr. Holekamp: Alimera Sciences: C,L,S; Allergan: C,L,S; BioTime: C; Genentech: C,L,S; Katalyst: C,P; NotalVision: S; Novartis: C; Ophthotech: S; Ohr Pharmaceuticals: S; Regeneron: C,L.

WORLD HEALTH

Cataract Surgery Safe After Ebola

CATARACT SURGERY MAY BE PER-formed safely in patients who have survived infection with the Ebola virus and who test negative for the virus in ocular fluid specimens.[1] This finding, from the EVICT (Ebola Virus Persistence in Ocular Tissues and Fluids) study, could potentially affect thousands of West Africans who are Ebola virus disease (EVD) survivors and are now at risk for ocular complications that may require surgery.

"Following their acute illness, EVD survivors in West Africa remain at very high risk for uveitis, which can lead to blindness and cataract," said lead author Jessica G. Shantha, MD, at the Emory Eye Center in Atlanta. Uveitis has been estimated to affect 13% to 34% of EVD survivors.[1]

Steven Yeh, MD

EBOLA SURGERY. *Moges Teshome, MD, from Christian Blind Mission International, performs cataract surgery with the assistance of Johnny Sawyer and Hannah Dowie.*

EVICT. This study is the first to evaluate the persistence of the Ebola virus in the eyes of EVD survivors with cataract or active inflammation. The stepwise approach employed in this cross-sectional study involved ocular screening, ocular fluid sampling, and subsequent manual small-incision cataract surgery in selected patients.

All told, 137 EVD survivors were screened, and 50 were enrolled. All tested negative for Ebola at 2 time points. Study findings include the following:

- Of the 50 patients in the study, 46 (92%) had visually significant cataract and a history of uveitis, and 2 (4%) had active uveitis.
- Thirty-four patients (34 eyes) underwent cataract surgery (surgery was deferred in the remaining 12).
- Postoperative visual acuity (VA) improved by ≥3 lines in 27 of the 34 patients, with 20 (59%) achieving a postoperative VA of ≥20/40.

The VA of 5 patients remained poorer than counting fingers due to vitreoretinal pathology.

Lessons learned. "We feel confident that cataract surgery can be performed safely with vision restorative outcomes at the time points assessed in our study," said coauthor Steven Yeh, MD, also at Emory. "However, strict infection control precautions are recommended." (For instance, in this study, eye care providers performed the ocular fluid sampling procedure while wearing full personal protective equipment.)

Looking ahead. Dr. Yeh stressed the need for formal consensus guidelines regarding timing of surgery and necessary surgical precautions. He also noted that more research is needed about the potential for Ebola to remain in ocular fluids and tissues.

The study does offer lessons about patients with uveitis syndromes related to other pathogens, such as herpes simplex virus or the Zika virus, Dr. Yeh noted. For instance, operating on inflamed eyes in patients with infectious uveitis should be avoided.

As for EVD, he said, "There is currently no known risk of Ebola virus transmission through casual contact, including the eye exam of a survivor. Strict hand-washing precautions and clinic sterilization strategies are recommended for medical care of EVD survivors." —*Miriam Karmel*

1 Shantha JG et al. *EBioMedicine.* 2018;30:217-224.

Relevant financial disclosures—Dr. Shantha: Santen; C. Dr. Yeh: Alcon: S; Clearside Biomedical: C; Santen: C.

See the financial disclosure key, page 8. **For full disclosures,** including category descriptions, view this News in Review at aao.org/eyenet.