

Task Force on Ophthalmic Sterilization

Low rates of endophthalmitis, TASS seen in survey.

SUMMARIZED BY WILLIAM J. FISHKIND, MD, FACS



The role of instrument sterilization has received much attention lately due to the recognition of toxic anterior segment syndrome (TASS). As physicians our sworn duty, above all, is to provide the best care we can for our patients. But we also have an ambulatory surgery center (ASC) business to manage. In the interest of economy, have we taken shortcuts? Have we compromised patient care? Have we lost our way?

William J. Fishkind, MD, FACS, past president of The Outpatient Ophthalmic Surgery Society (OOSS), led an important study that answers this question. Under his guidance, OOSS emerged as the leading ophthalmic ASC organization. This study, which is summarized by Dr. Fishkind in this installment of Retina in the ASC, is a prime example of the importance of OOSS in delivering the message that ASCs continue to provide the best in patient care.

-Pravin U. Dugel, MD

The Outpatient Ophthalmic Surgery Society (OOSS) conducted a survey of the OOSS membership in the 25-day period from Thursday, June 26, 2008 to Monday, July 21, 2008. Sixty percent of its membership, or 168 ambulatory surgery centers (ASCs), responded to the survey.

The goal was to ascertain contemporary practices of ophthalmic ASCs in the sterile processing of surgical instruments in the ASC operating room (OR) environment and the patterns of use of sterilizers and sterilization time. The survey incorporated the review of five distinct areas of sterile instrument processing and sterilizer management:

1. Cleaning techniques for surgical instruments
2. Preparation of instruments for sterilization and sterilization cycles
3. Sterilizer selections
4. Maintenance of sterilizer equipment
5. Outcomes

SUMMARY OF FINDINGS

Of the 168 responding ASCs, all the facilities are Medicare-certified. Ninety-one percent of facilities were

reviewed by a regulatory agency during the previous 3 years (Figure 1). Of these ASCs, the decontamination and sterilization techniques of 94% were found acceptable to the certifying authority.

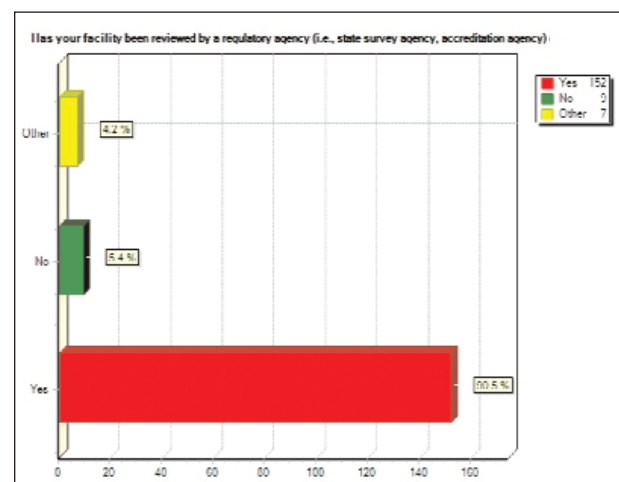


Figure 1. Response of survey participants to the question: Has your facility been reviewed by a regulatory agency (ie, state survey agency, accreditation agency)?

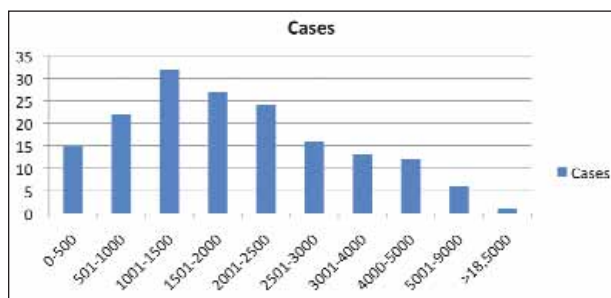


Figure 2. Twelve-month cataract surgery volume reported by survey respondents.

Ninety-eight percent of respondents performed surgery in a freestanding ASC. Eighty-three percent performed surgery in a single-specialty eye ASC. The volume of cataract surgeries performed in the 12 months prior to the survey varied from 0 to 500 to greater than 9,000, with the largest percentage of respondents performing 1,000 to 2,000 cataract surgeries annually (Figure 2).

Responses from respondent facilities encompassed a total of 455,709 ophthalmic surgical procedures, including 368,467 cases of cataract extraction with IOL implantation.

Instrument cleaning and sterilization. Regarding instrument preparation, 73% of respondents reported that their ASC used OR technicians or nurses who assist the surgeon to clean the instruments. The remaining 27% used certified instrument technicians, central supply technicians, or others (Figure 3).

Sixty-two percent began the cleaning process in the OR suite, and 52% began cleaning in the sterile processing room. All those who responded reported the use of sterile or distilled water to wash the instruments. Sixty-

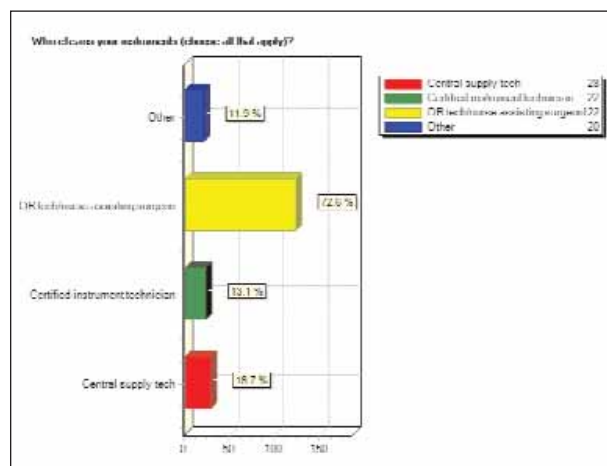


Figure 3. Bar graph indicating who cleans the surgical instruments in the ASCs responding to the survey.

nine percent used a variety of cleaning solutions: 24% used Enzol (Johnson & Johnson Hospital Services, New Brunswick, NJ), and the remainder used Opti-Cide3 (Micro-Scientific Industries, Inc., Rolling Meadows, IL). Eighty-two percent utilized ultrasonic cleaning (Figure 4) and 58% utilized the quick-rinse system to flush lumens.

Respondents reported that they cleaned diamond blades with steam jet, Opti-Kleen cleaning system (Micro-Scientific Industries, Inc.), ultrasound, and a variety of other cleaners (Figure 5).

In regard to preparation of instruments for sterilization and sterilization cycles, four basic preparation methods were used in the ASCs that responded to the survey. Open surgical tray, closed sterilization case, peel-pak wrapping, and central supply wrapped were among the methods cited (Figure 6).

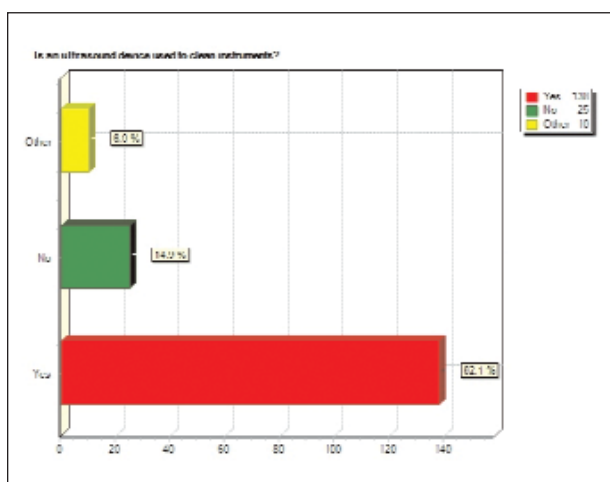


Figure 4. Survey responses to the question: Is an ultrasound device used to clean instruments?

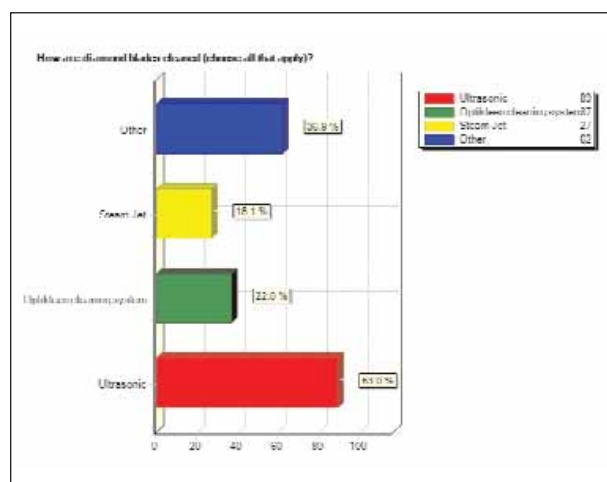


Figure 5. Survey responses to the question: How are diamond blades cleaned (choose all that apply)?

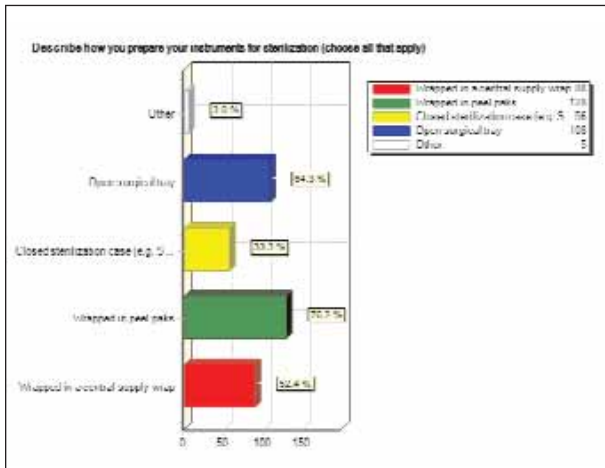


Figure 6. Survey responses describe how instruments are prepared for sterilization (all that apply are noted).

Eighty-five percent of respondents reported that their ASCs rotate two to five sets of instruments, 9.5 % rotate six to 10 instruments sets, and 2% rotate more than 10 sets.

Sterilizer selections. There was a great variety of sterilizing equipment utilized, with the majority using Statim (Alpha Medical, Hempstead, NY), Steris Gravity (Mentor, OH), and Steris Prevac. Figure 7 shows the complete breakdown.

Most facilities utilized short-cycle sterilization (10-minute “flash”) and backed up rotated sets of instruments with wrapped peel-packaged single instruments. Ninety-four percent followed the manufacturer’s recommendations for sterilization time (Figure 8). The 6% who did not modified the manufacturers recommendations using those prescribed by the Association of

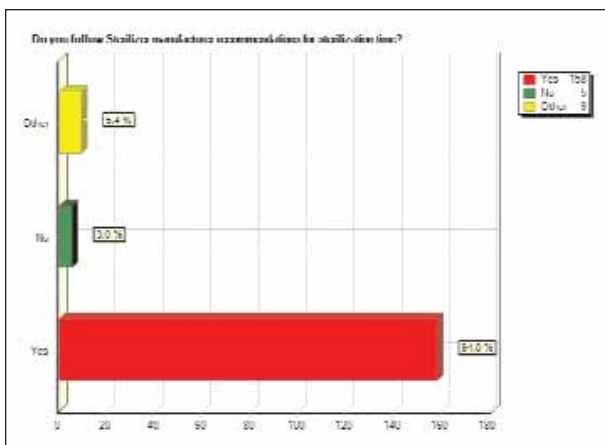


Figure 8. Ninety-four percent of those who responded to the survey reported that they follow the manufacturer recommendations for sterilization time.

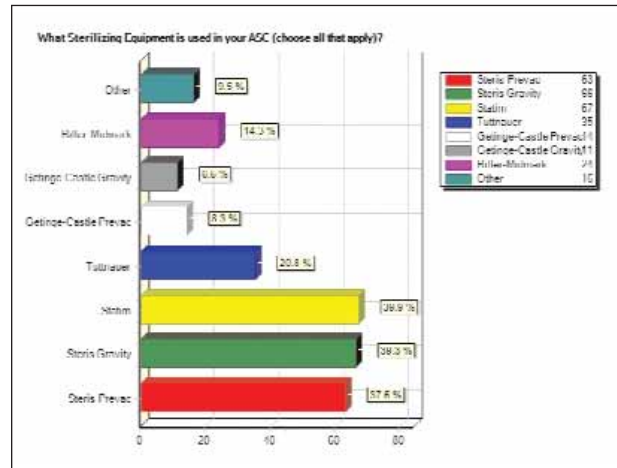


Figure 7. A summary of the sterilization equipment used by survey respondents. (Tuttnauer, Happaug, NY; Ritter-Midmark, Hempstead, NY; Getinge-Castle, Rochester, NY)

Perioperative Registered Nurses.

Maintenance of sterilizing equipment. Seventy-nine percent of respondents said that they cleaned their autoclave weekly to monthly, and 76% had maintenance agreements for regular service.

Seventy-three percent performed daily validation tests. Sterility was validated by Class 5 chemical integrating indicators, onsite incubator with standard indicators, rapid attest, and a variety of other tests (Figure 9). Eighty-two percent cultured sterilizer reservoir water.

OUTCOMES

Of the 455,709 procedures performed in ophthalmic ASCs, 116 facilities reported no cases of endophthalmitis. Fifty-two facilities reported 95 cases of endoph-

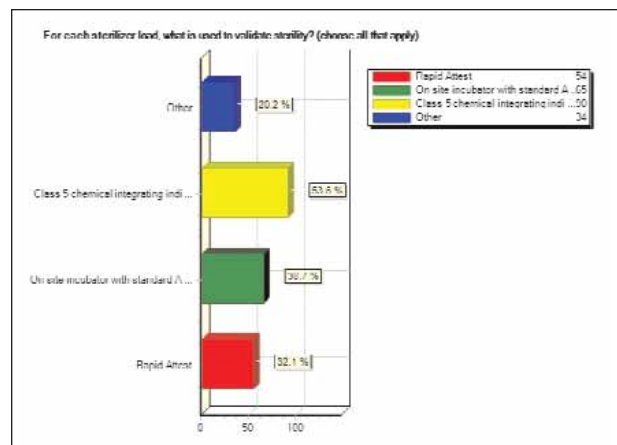


Figure 9. The validation systems that are used to ensure sterility.

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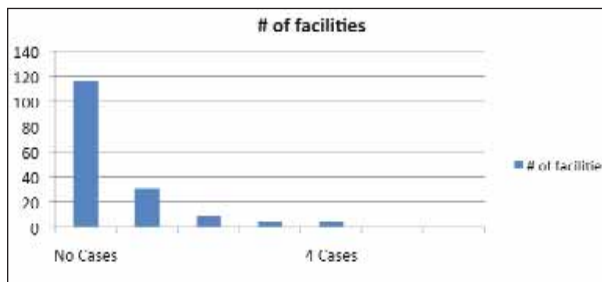


Figure 10. Reported cases of endophthalmitis out of 455,709 procedures.

thlmitis, of which 38 cultured positive, yielding a 0.02% rate of infection (Figure 10).

During this twelve-month period, 16 facilities reported 88 cases of toxic anterior segment syndrome (TASS), resulting in a .019 % rate of TASS.

Studying the entire surgical instrument process demonstrated that, despite dissimilar cleaning practice, dissimilar sterilizers, and dissimilar sterilization time, excellent outcomes resulted.

CONCLUSIONS

We conclude that this is due in large part to utilization of meticulous care in cleaning of surgical instruments coupled with adequate appropriate sterilization cycles based upon manufacturers' recommendations.

We suggest that the term "flash sterilization," which we consider an outmoded expression, be dropped from our policies and procedures and be replaced with the term "short-cycle steam sterilization." We also suggest that we document our meticulous care of instrument management and cleaning, substantiation of their cleanliness, and verification of validation tests. ■

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