

Point/Counterpoint: Single-Use Instruments

Single-use instruments are a viable alternative to sterilization.

BY RANDALL J. OLSON, MD



Recent advances in ophthalmic surgical techniques make it possible for medical professionals to perform more procedures in less time, thereby increasing the number of patients who can benefit from improved vision. With the increase in the number of ophthalmic procedures performed, however, there is growing concern over the sterilization of instruments.

STERILIZATION GUIDELINES

Recently, the Association of Perioperative Registered Nurses amended its standards, recommended practices, and guidelines on sterilization. The document cited as the principal source for this new policy is the Centers for Disease Control and Prevention's (CDC) 1999 Healthcare Infection Control Practices Advisory.¹ I have concerns that, in the name of efficiency, the ophthalmic profession may use practices that do not ensure that each procedure is performed with instruments that are completely clean and sterile.

Ophthalmologists in France have largely adopted single-use instruments as the standard for infectious disease control in surgery. In my practice, I have used single-use instruments and found them to be a highly viable alternative to reusable instruments.

CHANGES TO RECOMMENDED PRACTICES

Why are changes to recommended practices being implemented 9 years after the CDC's advisory? One reason is the findings of a task force's report sponsored by the ASCRS in response to a spike in the incidence of toxic anterior segment syndrome that occurred in 2006, with 113 centers reporting cases.² Although the majority of the patients involved recovered, a small number experienced severe inflammation and ongoing ocular problems. The report of the task force did not find conclusive data to tie the outbreak to any single factor, but it did identify multiple potential etiologic factors linked to cleaning and sterilization processes.

Some of the factors identified in the report as poten-

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tial sources of toxic anterior segment syndrome were the use of reusable instruments of any kind, including cannulated handpieces, tips, and phaco tubing; tips occluded with residual cortex, viscoelastic, and other materials; contaminated cleaning solutions, enzymes, and detergents; ultrasonic baths contaminated with gram-negative bacteria with subsequent heat-stable endotoxin production; and endotoxin contamination within the filters, water chamber, and autoclave of the steam sterilizer itself.

WHERE DO WE GO FROM HERE?

The scope of the ASCRS task force's aforementioned findings leads me to conclude that the revisions to sterilization standards must go beyond creating an incentive to use full-cycle sterilization in lieu of flash sterilization. Problems with contamination can extend throughout the precleaning and cleaning processes, all the way to the delivery of instruments to the surgeon. Identifying and eliminating the sources of possible contamination are going to take a comprehensive, multipronged approach, including the acceptance of single-use instruments in surgery as a viable alternative to reusable instruments and their attendant problems of effective sterilization.

SINGLE-USE OPTIONS

Because it is extremely unlikely that the number of procedures we surgeons perform is going to decrease, we need to examine every option available to make cer-

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Versus Sterilization

The sterilization controversy.

BY PAUL N. ARNOLD, MD



Cataract surgeons are always concerned about preventing endophthalmitis in their patients. Fortunately, the incidence of postoperative endophthalmitis is far lower than that of postoperative infection in many other specialty surgical procedures. The rarity of infection after cataract surgery, however, has made it difficult to study different variables by means of controlled clinical trials. Nonetheless, a couple of clinically valid steps have been shown in large-scale studies to reduce the incidence of endophthalmitis—cleansing the ocular surface with povidone-iodine and administering intracameral antibiotics at the conclusion of surgery.^{1,2}

Compounding our concern about endophthalmitis is that we worry about noninfectious contamination such as toxic anterior segment syndrome (TASS). Various outbreaks of TASS have occurred in isolated facilities or as a result of specific products used in surgery. Excellent detective work usually leads to the discovery of the offending agent particular to each isolated outbreak. Because of such vigilance, there has never been a wide-spread TASS epidemic.

Endophthalmitis and TASS are extremely rare after modern cataract surgery in the United States, which indicates that the generally accepted techniques of cleaning and sterilization utilized by most accredited hospitals and ambulatory surgery centers over the past 30 years are amazingly effective.

CAUSES OF ENDOPHTHALMITIS AND TASS

Endophthalmitis is most commonly the result of bacteria from the ocular/periocular surface entering the eye, rather than bacteria growing on the surface of an instrument inserted into the eye during surgery. TASS unrelated to products inserted into the eye (eg, toxic IOLs, endotoxin-contaminated solutions, preservatives in liquids, impure viscosurgical devices, etc.) is usually due to problems with cleaning the instruments, not sterilizing them, unless the sterilization water is contam-

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inated. Specifically, the accumulation of bioburden (denatured debris, viscosurgical devices, etc.) or heat-stable endotoxins from contaminated ultrasonic baths on the instruments we use represent a problem with cleaning and have nothing to do with the sterilization cycle.

Properly cleaned surgical instruments are usually not responsible for endophthalmitis or TASS. Therefore, the generally accepted protocol for sterilization cycles after the proper cleaning of instruments has proven very effective. Ensuring clean and sterile instruments is a process, not just a function of the sterilization time. In the processing of our surgical instruments, it is the cleaning, rinsing, and inspecting side of the equation that needs our assiduous attention.

FLASH STERILIZATION

It is pertinent that the ASCRS task force’s guidance makes no specific recommendation about sterilization cycle times other than “flash sterilization should not be used to save time or as a substitute for sufficient instrument inventory.”³ What constitutes flash sterilization?

Flash sterilization can take many forms. The standards of the American National Standards Institute and the Association for the Advancement of Medical Instrumentation define it as follows. For metal, nonporous instruments without lumens, flash sterilization is 3 minutes at 270° in a gravity-displacement steam sterilizer. For porous or metallic instruments with lumens, it is 10 minutes at 270°.⁴ In my experience, flash sterilization

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has been described by OR personnel as any sterilization cycle lasting from 3 minutes to under an hour. My conclusion is that the word *flash* has no precise practical meaning when defining sterilization cycles. I suggest we surgeons abandon such an imprecise term and define our cycles by time and temperature.

PERSONAL EXPERIENCE

During the past 28 years, I have operated in a hospital setting, my own single-surgeon ambulatory surgery center (ASC), and a multiophthalmologist ASC. I am a longtime board member of the Outpatient Ophthalmic Surgery Society, in which role I have observed other ophthalmic ASCs and participated in national policy issues affecting them. I wrote and edited *The ABCs of ASCs: Everything You Need To Know About Getting Started, Operating, And Successfully Maintaining An Ophthalmic Ambulatory Surgery Center*,⁵ a book incorporating the views of some of the nation's experts on this topic.

Every setting in which I have operated has included a strict process of cleaning and sterilizing surgical instruments. Each entity has used a sterilization cycle of 10 minutes at 270° for cataract trays during surgery (different autoclaves have taken longer or shorter times to achieve that temperature and then cool down, causing different total cycle times, but the time at peak temperature has always been 10 minutes). We have reused metallic and gemstone instruments, including “disposable” knives. We have reused cannulated instruments such as I/A tips, phaco tips, and cystotomes after careful cleansing and flushing prior to sterilization.

What about other steps taken to prevent infection? For the past 20 years, I have cleansed the ocular surface, not just the eyelids, with a solution of 5% to 10% povidone-iodine, and I have instilled balanced salt solution with vancomycin (100 µg/mL) during the procedure. For the past decade, I have used a topical third- or fourth-generation fluoroquinolone eye drop. For the 10 years prior to that, I prescribed no topical antibiotic at all postoperatively.

In my more than 15,000 cataract procedures, I have had three cases of endophthalmitis and three cases of TASS, each of which was isolated (I remember every one). I do not think any of them had anything to do with the sterilization cycle time. Not only have studies shown that 10 minutes at 270° achieves the necessary sterility assurance levels, but my long experience assures me that this type of sterilization works.

Based on my experience and that of many reputable ophthalmic surgeons, it is perfectly safe to reuse surgical trays of instruments on the same surgical day after proper cleaning, inspection, and sterilization (as described earlier). This process includes reusing instru-

ments with lumens, as long as one takes special care to flush them properly immediately after use.

CONCLUSION

Based on a review of the data and my extensive personal experience, I believe that the incidence of endophthalmitis can be minimized by the preoperative decontamination of the ocular surface and intracameral antibiotics and that TASS can best be prevented by the compulsive cleaning of instruments and the avoidance of toxic solutions (enzymatic detergents, old ultrasonic solution, etc.). The vastly greater expense of using disposable instruments or quadrupling the number of surgical trays to treat the phantom “sterilization problem” is not a prudent use of precious, shrinking health-care resources. ■

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tain our patients are treated with sterile instruments. The need for the rapid turnaround of instrument sets is one of the reasons often given for expeditious techniques. Single-use cannulas, handpieces, and ophthalmic surgical blades can be used to replace or supplement existing instrument sets in facilities where the number of procedures requires the immediate availability of sterile instruments. At the very least, single-use instruments should be available as a backup set should there be any difficulties/irregularities with reprocessing instruments.

NEW GUIDELINES EXPECTED

The CDC is expected to issue new sterilization guidelines this summer. If they follow the direction of the Association of Perioperative Registered Nurses' standards, they may advise full-cycle sterilization between procedures, which will require hospitals and outpatient facilities to purchase more autoclaves and hire full-time processing technicians in addition to buying extra complete trays. Single-use instruments are a secure and convenient alternative. In any cost analysis, the entire price of each aspect of instruments' reuse should be considered, including lost productivity, technician time, damage to or loss of instruments, the purchase of new

instruments, etc. Such a thorough analysis may show we have been penny-smart and pound-foolish at times.

CONCLUSION

Infections and toxic insults arising after ophthalmic procedures can undo any surgeon's finest work and put a patient's vision at risk. It is our duty, as medical professionals, to do everything we can to ensure that every surgery is performed with sterile instruments.

During the coming discussions on safeguarding patients' health through improved sterilization techniques, I would recommend that single-use instruments be tried and evaluated as an alternative to reusable instruments in ophthalmic surgery. ■

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