Autoclave Contamination and TASS

BY SIMON HOLLAND, MB, FRCSC, AND DOUGLAS MORCK, DVM, PHD

Endotoxin is a possible cause of toxic anterior segment syndrome (TASS).[1,2] Bacterial endotoxin or lipopolysaccharide (LPS) is produced by gram-negative bacteria and is a potent inflammatory mediator that causes septic shock syndrome. The Lipid A portion of the LPS molecule is thought to be responsible for this potent inflammatory effect. Endotoxin is heat stable and can readily survive short-cycle sterilization.[3] Endotoxins are also recognized as an important cause of diffuse lamellar keratitis (DLK) and have been identified in the steam distillate of the Statim sterilizers (Scican Inc., Pittsburgh, PA).[4] Thus, although bacteria such as *Pseudomonas* are killed by short-cycle sterilization (3.5 minutes at 180ºC), their endotoxins are released from the cells' walls in the sterilizer. These endotoxins remain biologically active and can be deposited on instruments used in anterior segment cataract surgery.

Previous outbreaks of TASS have also been linked to the contamination of the ultrasonic baths with similar bacteria[5] and to the liquid detergent used in the cleaning bath.[1] Our recent experience with an outbreak showed an association between the contamination of an autoclave reservoir with gram-negative, endotoxin-producing bacteria and TASS.[6]

OUTBREAK INVESTIGATED

Our hospital experienced an outbreak of TASS that began with four cases occurring during a 3-week period. After it investigated the incident, the only suggestion to control the outbreak from the hospital's infection control department was for surgeons to switch from multi- to single-use phaco tips. This change in protocol proved ineffective in preventing further cases of TASS (Figure 1). The method of sterilization ophthalmologists in the hospital used was a combination of a short cycle with the Statim sterilizers and a prolonged-cycle system with sterilizers from the hospital's central sterile department. Culturing of the Statim sterilizers showed a heavy growth of gram-negative bacteria (predominantly *Sphingomonas*, *Ralstonia*, and *Pseudomonas*), but no additional action was taken based on these results at that time.

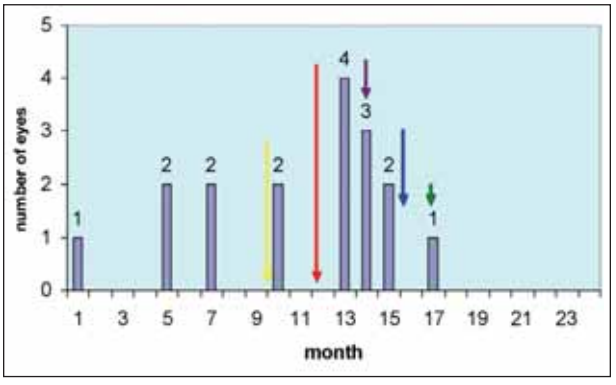

Figure 1. This graph shows the epidemiological curve of a TASS outbreak.

Another cluster of 10 TASS cases occurred between months 13 and 17 of the reported outbreak. Surgeons limited their use of short-cycle sterilization and replaced reusable with disposable cannulas. Although these steps proved partially effective, the outbreak continued. Further bacterial cultures and biofilm sampling of the Statim sterilizer reservoirs showed the same bacteria and associated biofilms within the reservoirs (Figure 2).

Our hospital replaced its three Statim sterilizers and instituted a rigorous cleaning protocol for the new units that included emptying them daily, cleaning their reser-

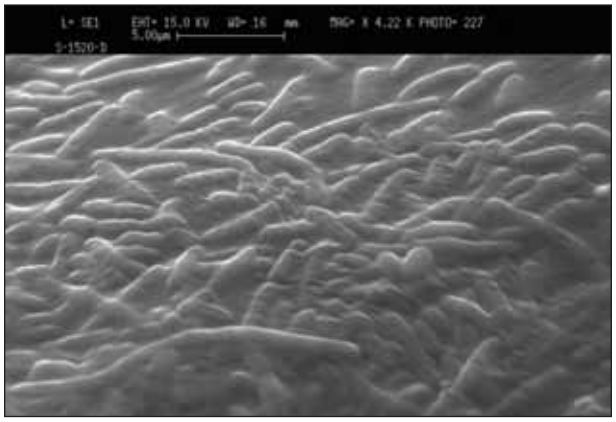

Figure 2. Bacterial biofilm coats the mesh of an in-line filtering system in a Statim sterilizer.

voirs with a quaternary ammonium compound daily, and periodically replacing their inner tubing. The sterilizers had been in use for more than 8 years and had never been serviced or cleaned. Following these interventions, the outbreak ceased, and no further cases have been reported at the hospital in the 2 years since.

PROTOCOLS FOR THE MAINTENANCE OF A STERILIZER'S RESERVOIR

We have found the following protocols effective in controlling biofilm and the contamination of sterilizers' reservoirs with bacterial endotoxin. These procedures are not approved by the sterilizers' manufacturers or the FDA. Maintenance based on the endotoxin theory has thus far proven successful against outbreaks of both TASS and DLK.[3,6] We recommend appropriately cleaning reservoirs to clinics experiencing cases of TASS.

During periods without a case of TASS, a clinic's staff should perform routine maintenance of the sterilizer on each surgical day (see *Routine Maintenance for a Sterilizer*). The unit's inner tubing should be replaced monthly.

During an outbreak of TASS or DLK, the sterilizer may become contaminated (see *Protocol for the Duration of an Outbreak*). Modified protocols may be necessary based on the severity of the outbreak as well as the nature of the bacterial biofilm identified. Although most biofilm produced by bacteria is inactivated by 70% alcohol, we have found a difference in the substance's susceptibility to various biocides depending on the specific bacteria.[7] During confirmed outbreaks, household bleach (sodium hypochlorite) diluted in distilled water may be substituted for 70% alcohol. We recommend seeking further advice from those with experience such as ourselves before using hypochlorite 0.525% (ie, commercial household bleach 5.25% diluted 1:10 with water) due to the potential for damaging the sterilizer's lining and tubes. Our use of this solution in specific outbreaks was based on our assessment of the resistance of involved bacterial biofilm to the biocidal agents that are more easily employed (ie, 70% alcohol).

ROUTINE MAINTENANCE FOR A STERILIZER

- Empty the reservoir at the end of each surgical day using a suction pump and a cloth to dry the inside reservoir as completely as possible.
- Fill with distilled water before each surgical day, empty, and repeat.
- Fill with distilled water and run two cycles without instruments.
- Change inner tubing monthly.

CONCLUSION

Short-cycle, steam-generating, tabletop sterilizers such as the Statim have proven to be efficient in high-volume cataract surgical centers due to their simplicity of use, rapid cycles, cassette-based system, reliability, and economy. Most units use a sterilization time of 3.5 minutes and a total sterilization cycle time of 6 minutes compared with the 45-minute cycles of standard sterilizers. Short-cycle sterilizers are not without their problems, however. One major disadvantage is their inability to deactivate bacterial endotoxin, which can be found in the steam distillate.[4] This drawback creates the potential for the toxic material to be deposited on "sterilized" instruments. Bacterial endotoxin (LPS) is a potent initiator of inflammation; very low levels can incite significant inflammation. Fortunately, relatively simple measures of sterilizer maintenance, although not approved by the manufacturers, have proven highly

PROTOCOL FOR THE DURATION OF AN OUTBREAK

- Empty the sterilizer at the end of each surgical day.
- Fill with boiling tap water and drain. Repeat.
- Fill reservoir with distilled water and empty. Repeat.
- Leave 70% alcohol in reservoir overnight.
- Fill with boiling tap water and drain.
- Fill with distilled water and drain.
- Fill with distilled water and run two cycles.
  Note: Diluted hypochlorite may be substituted for 70% alcohol.
- The inner tubing of the sterilizer must be changed monthly at minimum.

This protocol is not approved by the FDA or the manufacturers of sterilizers.

IMPURE AUTOCLAVE STEAM MOISTURE AND TASS

By Walter C. Hellinger, MD

Reused surgical equipment is a well-recognized source of toxins that cause toxic anterior segment syndrome (TASS). Potentially inflammatory agents include residue from cleaning agents, heat-stable bacterial toxins (ie, endotoxin), titanium flecks from wear on surgical equipment, and copper and zinc released from the surfaces of instruments that have been degraded by plasma-gas sterilization.[1-3]

The residues of cleaning agents and endotoxins may be deposited on surgical tools during cleansing prior to steam sterilization. Although the degree to which endotoxins resist inactivation by steam sterilization is still uncertain,[4] surgeons worry that, under some circumstances, sufficient concentrations of bacterial residues can remain on contaminated equipment and cause clinically significant complications.[5]

PRODUCING SAFE STEAM

The steam used to sterilize medical equipment should be 95% to 100% gas and less than 5% liquid.[6] Some suspended water in liquid form, however, is necessary to produce steam that sterilizes instruments effectively.

Two different types of boiler systems are used to create sterilizing steam. Loop systems are common in large centers such as hospitals and produce steam for multiple purposes, whereas one-way systems produce steam only for autoclaves. Boilers that serve loop systems require continuous monitoring to prevent foaming that can introduce impurities into suspended water. One-way systems rely on the use of clean water and/or regular maintenance of the boiler to prevent the carryover of impurities.

The literature includes a single case report of TASS associated with the suboptimal management of a surgical center's one-way boiler system.[7] The investigators documented the carryover of impurities in the system's feed water and in the rinsates of surgical equipment used during the TASS outbreak. No further cases of TASS occurred after the surgical center re-established the proper maintenance of the boiler and restored the purity of the feed water.

Multiple causes of TASS have been identified, many of which are associated with the cleaning and sterilization of reused surgical equipment. Careful attention to all of the steps of cleaning and sterilization is required for TASS prevention.

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effective at reducing bacterial biofilm, the typical source of endotoxin in short-cycle sterilization systems.

Because TASS is multifactorial, it is often difficult to determine if one or more causes are involved. We have investigated two recent outbreaks in which autoclave contamination appeared to have an important role. Other factors such as the incomplete cleaning of ultrasonic baths[5] and inadequate rinsing of the lumens of reusable cannulas and phaco tips have a greater potential to incite TASS if short-cycle sterilizers are used because of their inability to deactivate endotoxins. ■

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