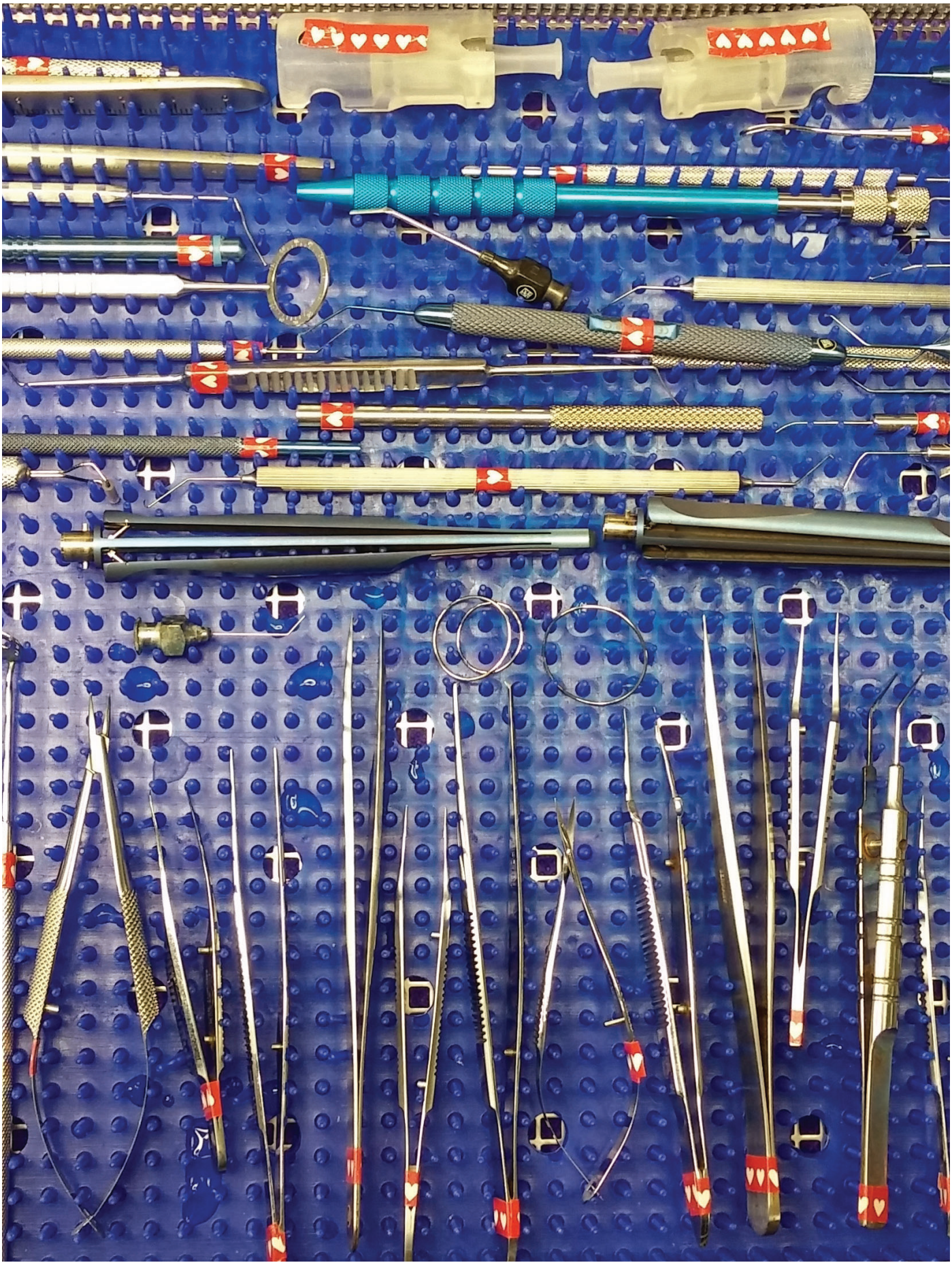

Cleaning and Sterilization of Ophthalmic Surgical Instruments

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LEARNING OBJECTIVES

1. Describe the unique qualities of ophthalmologic surgical instruments and the challenges for cleaning and sterilization
2. Explain adverse events related to the cleaning and sterilization of ophthalmologic surgical instruments
3. Examine the guidelines for the cleaning and sterilization of ophthalmologic surgical instruments

Cleaning and sterilization of medical devices is a complex process that requires compliance with the minimum requirements already defined and supported by scientific evidence. Medical devices that possess narrow lumens, crevices and joints, for example, and instruments that are extremely delicate in their design are considered complex because they offer a significant challenge to the cleaning process. In addition to the challenges presented by design, different types of organic debris such as bone tissue, fats and porous and inorganic residues pose additional risks. These types of debris are considered difficult to remove from surfaces and can compromise the cleaning of the medical device and subsequent reprocessing steps such as sterilization, increasing the risk of adverse events. Within this context, this lesson emphasizes the criticality of the instruments used in intraocular surgeries, both due to their nature and the sensitivity of the ocular tissue. In addition to these challenges, intraocular instruments may play a role in the introduction of foreign bodies into the anterior chamber of the eye, which may result in an acute, noninfectious inflammation of the anterior segment of the eye called Toxic Anterior Segment Syndrome (TASS)[1]; TASS can cause severe visual impairment if not diagnosed and treated in a timely manner.[2, 3]

Objective 1: Describe the unique qualities of ophthalmologic surgical instruments and the challenges for cleaning and sterilization

Extremely delicate instruments with very small functional components are used in ophthalmologic surgeries. These devices may become damaged when handled during manual or automated cleaning processes. To maintain the integrity and functionality

Material	Degree of Fragility	Design Complexity	
		Presence of Lumens	Design Criticality
Reverse irrigating vectus/Irrigating lens loop	Low	Yes	High
Diamond keratome	High	No	Low
Castroviejo caliper	Low	No	No
Phacoemulsification handpiece	Moderate	Yes	High
Irrigation / aspiration handpiece	Moderate	Yes	High
Curettes	No	No	No
Iris spatula	No	No	No
Articulated speculums	Low	No	No
Hooks (Chopper, Lester, Sinskey)	Moderate	No	Low
Hooks for retinal surgeries	No	No	No
Irrigation/Aspiration tubes	No	Yes	High
Castroviejo forceps< 0.15 mm	High	No	Low
Castroviejo forceps > 0.15 mm	Moderate	No	Low
Retinal micro forceps and micro scissors	High	No	High
Delicate/Fine needle holder	Low	No	No
Medium/Heavy needle holder	No	No	No
Vitrectome	Low	Yes	High
Vannas and corneal transplant scissors	High	No	Low
Stevens tenotomy scissors	Low	No	No

Table 1: Classification of materials and ophthalmologic surgical instruments, according to their design, fragility, and presence of lumens

of these instruments, some steps of the standardized operating procedure (SOP) may not be fully performed by Sterile Processing (SP) professionals, which increases the risk of failure in cleaning and sterilization processes. Another important factor that can impact the quality of cleaning and sterilization is the high volume and rapid Operating Room (OR) turnover experienced in cataract surgery, which demand agility in the processing of instrument kits and accessories.[4]

In a didactic way, ophthalmologic surgical instruments can be classified according to the degree of precision and complexity of their design, as presented in Table 1. These two characteristics are most important in selecting the most appropriate cleaning method.[1] Sometimes, SP professionals may use less mechanical action during manual cleaning (out of fear that more mechanical action could damage the instrument); however, such an approach could compromise the effectiveness of manual cleaning.

Instruments with a high degree of fragility include forceps with teeth smaller than 0.15 mm and double-spring cornea and iris scissors. Commonly used instruments with a high degree of complex geometry include phacoemulsification pens, irrigation and aspiration pens, and irrigable handles. Retinal scissors and forceps also have a high degree of fragility and complex design. It is noteworthy that the main characteristic of an instrument with a high degree of complex design is the presence of narrow lumens, which—in the case of ophthalmologic instruments—does not allow mechanical friction by brushing. Thus, the ultrasonic washer mechanism is indispensable to ensure the removal of debris present in the lumens of medical devices.[1]

Phacoemulsification pens are sensitive accessories that are subject to damage because they have components (such as piezoelectric crystals) that, when receiving electric current, vibrate thousands of times per second to produce ultrasonic waves through the movement of their tip. These pens contain sealing rings to prevent water from getting inside (so that there is no electrical short-circuit); however, over time, these seals can lose their effectiveness and allow water or steam to enter during washing and steam sterilization processes.

Considering that phacoemulsification pens are medical devices that produce ultrasound for their operation, the contraindication of the ultrasonic washer is a controversial subject. Similarly, during sterilization there is penetration of steam under pressure, which may condense during cooling; to prevent water from penetrating the pen, it is recommended that the device not be submerged. It is important that the instructions for use (IFU) for these medical devices be followed and that any questions about processing steps be clarified by the manufacturer. A favorable [characteristic] of ophthalmologic surgical instruments is that they have a low load of [debris]

after use;[4] however, this does not justify cleaning without the use of a detergent.[1]

Objective 2: Explain adverse events related to the cleaning and sterilization of ophthalmologic surgical instruments

Adverse events related to cleaning and sterilization of ophthalmological surgical instruments include TASS[2, 3] and endophthalmitis.[3,5] Endophthalmitis is an intraocular infection caused by microorganisms, especially gram-positive bacteria. This is an event with a low rate of incidence, but with devastating results for the patient.[5,6] Endophthalmitis may be caused by several factors, including the use of contaminated instruments due to failures in the cleaning and sterilization process (including the storage and transportation of sterilized materials).[7]

TASS is an intraocular inflammatory reaction caused by toxic agents inoculated in the anterior segment of the eye that cause damage to the corneal endothelium, trabecular mesh, and some other intraocular structures.[2,3,8] Some TASS cases may be severe and may lead to low visual acuity and the need for surgical interventions.[9,10] Different types of substances have been recognized for their ability to cause TASS; among them are substances from the products used during surgery[11-13] and substances from the processing of instruments.[14-17]

As for the possibility that the cause of TASS is related to the processing of instruments, it is very important to make a critical analysis before making changes or adaptations to cleaning and sterilization processes. Among the causes attributed to TASS, the use of aldehyde-based substances[16,17] for high-level disinfection or sterilization of instrumentals is clearly understood as a gross failure because such substances are highly toxic to eye structures.[4]

Regarding enzymatic detergents, many concerns and assumptions were possibly raised due to a misinterpretation of literature stemming from a report of cases of exacerbated inflammation in the eyes of 16 patients.[18] After an investigation, the authors concluded that the probable cause was due to a significant number of bacteria and endotoxins that could have been present in the instruments, even after rinsing of the detergent solution.[18] *Note: In this study, the authors made it clear that the high levels of bacteria and endotoxins were related to the indiscriminate reuse of detergent solution for one week in the ultrasonic washer.[18]*

Another similar report connected the cause of TASS cases to enzymatic detergent solution with an increased concentration obtained from the evaporation of the solution's water. This report noted that the detergent solution was only changed when it was visibly dirty, and it was understood that the instruments were immersed during the weekend.[14] It is possible to identify that in these two cases, the cause was not the enzymatic detergent itself, but rather its incorrect use and, possibly, an inadequate rinse.

To clarify the potential for enzymatic detergent to cause TASS, Leder et al[19] conducted an experiment in which solutions exposed to an inadequate rinse were injected into the anterior chamber in the eyes of mice at concentrations similar to those used in cleaning processes—in a proportion four times greater than the residual present in the surgical instrument after an inadequate rinse. After evaluating the reactions observed in the corneas of the animals, the authors concluded that there were no significant differences between the corneas of the animals that were submitted to the test when compared with the corneas of the animals that were not tested (control group). This study demonstrates that residues of enzymatic detergents from ophthalmic surgical instruments are not the main cause of TASS.

Considering the low load of debris and the potential risk related to the misuse of enzymatic detergent, it has been recommended that this type of detergent not be used,[4, 20, 21] but it is worth noting that another type of detergent that does not contain enzymes should be used for the cleaning of these instruments.[1]

As for sterilization methods, some studies have suggested that ethylene oxide (ETO) sterilization could have been the cause of TASS cases,[8,15] but without presenting research results that demonstrated strong evidence. *Note: The experimental study by Edelhauser et al[22] showed that 250 ppm of ETO, 1250 ppm of ethylene chlordrine and 5000 ppm of ethylene glycol did not present harmful effects to the corneas. In any case, ETO sterilization must be carried out in accordance with the IFU for each product—and in accordance with the safety criteria required by the Association for the Advancement of Medical Instrumentation (AAMI).*

Objective 3: Examine the guidelines for the cleaning and sterilization of ophthalmologic surgical instruments

Following AAMI recommendations for the cleaning and sterilization of all surgical instruments is important. This includes following best practices related to processes and products, such as the need and importance of the chemical action of detergents in the removal of organic and inorganic residues.[1] In the case of instruments for intraocular access, it is necessary to follow some

Orientation	Justification
Regardless of method, type of equipment or type of sterilization cycle, all instruments must be subjected to thorough cleaning.	The presence of dirt/debris on the instrument interferes with the effectiveness of sterilization. Pre-cleaning does not serve as a substitute for thorough cleaning.
Flush cannulated devices with at least 20 ml of distilled water, immediately after surgery, while the devices are still in the Operating Room or in the cleaning area of the Operating Room	Cortical, viscoelastic, and organic material can dry inside the instrument—becoming clogged and leading to the formation of biofilm. The use of saline solution is not recommended because it attaches to organic matter.
Always use a detergent solution, preferably without enzymes, when cleaning ophthalmologic surgical instruments.	The dirt/debris load of ophthalmic surgical instruments is small, which makes it possible to use a detergent without enzymes. The chemical action of detergents is one of the important factors for the effectiveness of cleaning.
Use an ultrasonic washer for cleaning the instruments, especially for devices with lumens.	An ultrasonic washer is effective at removing dirt/debris from complex instruments whose components can make cleaning with manual mechanical action (friction with brushes) more difficult.
Create friction in the lumens using an intraluminal brush.	This is the most effective method for preventing biofilm formation and removing it.
Wash ophthalmological surgical instruments separately from other instruments used in general surgery.	The load of organic matter (dirt) in general surgery instruments is considerably higher than in ophthalmologic surgical instruments. Non-ophthalmologic surgical instruments are generally larger and heavier, which increases the risk of damaging more delicate instruments.
Wash instruments of different metal alloys separately.	Stainless steel, titanium, silver, copper, bronze, or chrome instruments must be washed separately so that their electrolytic action, or ion transfer, is not affected. This can cause a chemical reaction, with the appearance of stains and corrosion spots.
Use a high-pressure rinsing gun to abundantly rinse the instrument and irrigation and suction routes with purified water.	After cleaning, toxic substances such as detergent residues, viscoelastic solution, and endotoxins may be left inside the instrument. These substances may potentially cause TASS, and the only way to remove them is through proper rinsing.
Use purified water for final instrument.	Tap water can contain high levels of microorganisms and endotoxins.
The ultrasonic washer tub should be emptied, cleaned, disinfected, rinsed, and dried at least once a day.	This practice will prevent the formation of biofilm in the vat.
Rigorously inspect instruments after cleaning with the use of magnifying lens to verify that dirt/debris and damage are not present.	Due to the instruments' delicate and complex design, damage and dirt can be difficult to see with the naked eye.
Do not use aldehyde-based solutions for cleaning, disinfection or sterilization of lenses and ophthalmological surgical instruments.	Aldehyde residues are highly toxic to eye structures.
Personnel should be properly trained in proper handling, cleaning and sterilization of intraocular surgical instruments and these staff members should also be subjected to periodic supervision.	The more training staff members receive, the more effective cleaning will become and the less risk an instrument will become damaged.

Table 2: Guidelines for cleaning and sterilization of instruments and their justifications

specific recommendations, as presented in Table 2.

Conclusion

Ophthalmologic surgical instruments have many unique characteristics that should be considered at the time of handling, cleaning and sterilization. Considering the potential for adverse events that can result from inadequate processing of ophthalmological surgical instruments, all processing professionals should follow the latest standards, best practices, and manufacturer IFU. Special precautions must be taken, especially regarding thorough removal of detergents residue. Finally, ophthalmic instruments must be rinsed properly rinsed with abundant water, in accordance with current recommendations from manufacturers, standards or technical informational reports (TIRs).

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