

Assessment of the Necessity for High-Level Disinfection (HLD) of Reusable Ophthalmic Devices: A Multisociety Position Statement

Based on American Academy of Ophthalmology (AAO) guidelines, more than 100 million tonometry examinations are indicated annually in the United States alone.¹⁻³ Worldwide, reusable clinic devices that contact the ocular surface, such as Goldmann applanation tonometer (GAT) tips, gonioscopy lenses, and laser lenses, are likely used, in aggregate, more than 1 billion times each year. However, there is no globally accepted, evidence-based standard for processing these reusable devices. Given the high-frequency use of these devices, the optimal method must be practical, efficient, inexpensive, environmentally sustainable, and effective in maintaining patient safety, while preserving device integrity and reliability.

In the United States (U.S.), many regulatory authorities require high-level disinfection (HLD) for all reusable devices that contact the ocular surface despite the absence of evidence demonstrating that HLD improves patient safety compared with established cleaning and disinfection practices. To address this requirement, an HLD task force was formed with representatives from the AAO, the American Society of Cataract and Refractive Surgery (ASCRS), the American Glaucoma Society (AGS), the American Society of Retina Specialists (ASRS), the Outpatient Ophthalmic Surgery Society (OOSS), and EyeSustain. This position statement, endorsed by the six organizations represented on the Task Force, reviews the available evidence regarding whether HLD is necessary for these commonly utilized reusable ophthalmic devices.

DEVICE DISINFECTION STANDARDS

HLD eliminates most microorganisms, except for bacterial spores, and is the recommended method for reprocessing semi-critical medical devices such as laryngoscopes and flexible endoscopes. In contrast, sterilization destroys all microorganisms, including bacterial spores, and is required for critical devices, such as surgical instruments, that enter sterile tissue or the vascular system. The Spaulding classification was developed in the 1930s, before the advent of modern ophthalmic instruments and other devices with complex designs. Nevertheless, it remains the principal framework used by manufacturers and regulatory agencies to determine appropriate reprocessing requirements for reusable medical devices.⁴ Under this framework, devices that contact mucous membranes are classified as semi-critical and are expected to undergo sterilization or HLD.⁴

The Spaulding system was developed before the ocular surface and its microbiome were well characterized.⁵ As a result, it erroneously treats the entire eye as a mucous membrane for the purpose of determining device reprocessing requirements. However, the ocular surface differs fundamentally from heavily contaminated mucosal surfaces in both histology and microbial burden. Moreover, antimicrobial components of the tear film and involuntary blinking protect the ocular surface.⁶ No

bacteria can be recovered in the conjunctiva in approximately 40% of the population,⁷ whereas the colon contains 10^{11} to 10^{13} bacteria per milliliter (mL), a dental plaque has similar bacterial density, and the vagina has 10^6 to 10^8 bacteria per mL.⁸ Furthermore, despite the substantially greater bacterial burden of the skin compared with the ocular surface (approximately 10^{11} times more bacteria per mL), devices such as stethoscopes, external cardiac echography transducers (“probes”), and blood pressure cuffs are classified as non-critical devices and require only low-level disinfection.^{9,10} It is difficult to justify a framework for device reprocessing that groups ophthalmic devices with anal manometers, vaginal endoscopes, and bronchoscopes.⁹ Reprocessing requirements should instead reflect the distinct anatomy, microbial burden, and infection risk of the ocular surface rather than treating all mucous membranes as equivalent. Suggestions and recommendations for device processing contained in manufacturers’ instructions for use (IFU) reflect regulatory and liability considerations and are not always fully supported by scientific evidence.

Mandating HLD reprocessing for commonly used ophthalmic devices without evidence of improved patient safety imposes substantial clinical, operational, economic, and environmental burdens. These include the need for additional equipment, staff time, chemical handling, and device inventory, as well as reduced clinic efficiency and productivity. Repeated HLD may also damage ophthalmic devices, shorten their useful lifespan, and potentially compromise patient care. Furthermore, HLD requirements may encourage the use of disposable, single-use devices and accelerate the replacement of reusable devices through cumulative damage. Collectively, these practices increase healthcare costs, plastic waste, and the carbon footprint of ophthalmic care.

APPLANATION TONOMETRY TIPS

Goldmann applanation tonometry provides the most reliable method of intraocular pressure (IOP) measurement essential to the optimal care of patients with glaucoma. However, immersion in sodium hypochlorite for longer than 5 minutes, as well as repeated exposure to heat or steam sterilization, can irreversibly damage the GAT tip.⁹ Such damage may compromise the accuracy of IOP measurements. Microscopic cracks in the tip surface can harbor microorganisms and retain residual disinfectant that may subsequently leach onto the corneal epithelium during applanation.¹¹ Accordingly, ocular surface chemical injury has been reported with bleach disinfection.^{11,12}

Noncontact tonometers, an alternative to HLD, may overestimate or underestimate IOP when it is outside the normal range.¹³⁻¹⁵ Disposable, single-use GAT tips are another option, but may produce less reliable IOP measurements compared with reusable GAT tips.¹⁶⁻¹⁸ Their use also results in higher costs and greater environmental waste. In one analysis at a large ophthalmology department with 64,000 annual visits, converting to single-use GAT tips was estimated to generate more than \$60,000 in additional costs and 100 kg of additional plastic waste over reusable tips per year.¹⁹

In a survey of more than 1,000 members of HLD Task Force societies, most respondents (73%) reported reprocessing reusable GAT tips by wiping them with an alcohol swab or pad.¹² Nearly all respondents (98.6%) reported never having observed a convincing case of ocular surface infection transmission associated with applanation tonometry. These findings closely mirror those of a survey published in 2020 in which approximately 70% of respondents reported using alcohol wipes to disinfect tonometry tips, indicating that alcohol wiping has remained the predominant method of GAT tip reprocessing despite regulatory pressure to do otherwise.²⁰

In a comprehensive review of the literature, adenoviral epidemic keratoconjunctivitis (EKC) was the sole infection for which transmission through tonometry had been implicated.^{21, 22-27, 28} However, in several published outbreak investigations implicating tonometry transmission, GAT tips were either not sampled for viral culture or molecular testing or, when sampled, adenovirus was not detected.^{22, 24, 27} Most published reports do not include genotypic analyses capable of distinguishing the causative virus from other strains circulating in the community, thus failing to confirm the clinic or GAT tip as the source of the infection. Furthermore, in cases of possible clinic-acquired EKC, transmission also could have occurred via contaminated hands or environmental fomites.⁵ There is no indication in the literature that the transmission of serious eye or systemic infections has occurred via tonometry.^{21, 28}

DIAGNOSTIC AND LASER CONTACT LENSES

Each year, approximately 450,000 U.S. Medicare beneficiaries in Medicare Part B undergo Nd:YAG laser capsulotomy surgeries, and another 150,000 undergo selective laser trabeculoplasty surgery (SLT).²⁹ A similar number of procedures are performed among Medicare Advantage beneficiaries. There is no published evidence indicating that gonioscopy, retinal diagnostic, or laser lenses have transmitted infection. Investigators reported no cases of infectious conjunctivitis in more than 2,285 consecutive SLTs and Nd:YAG surgeries performed at a single academic center using reusable lenses cleaned with a 70% isopropyl alcohol wipe followed by soap and water; HLD was not used.³⁰

In the HLD Task Force survey, alcohol swabs or wipes were the most reported method for reprocessing diagnostic (63%) and laser (50%) contact lenses.¹² The second most common approach was cleaning with soap and water, used by 21% and 27% of the respondents, respectively. Dilute bleach or another HLD chemical was used by 6% of respondents for diagnostic lenses and 10% for laser lenses. Despite the infrequent use of HLD, nearly all respondents reported never having observed a convincing case of infection transmission associated with diagnostic lenses (99.7%) or laser lenses (99.6%). More than half of respondents using chemical disinfection also reported that it had damaged their diagnostic (53%) and laser (55%) lenses.

An analysis reported that disposable SLT or Nd:YAG laser lenses cost about \$17 each, compared with \$700 to \$750 for a reusable lens.³⁰ Based on this study's cost analysis, reusable lenses become more cost-effective than disposable lenses after approximately 86 SLTs and 91 Nd:YAG laser surgeries.³⁰ Another study suggested that SLT treatment effect was diminished when disposable laser lenses were used.³¹

A- AND B-SCAN ULTRASOUND PROBES

A-scan probes are used either in direct contact with the cornea or in an immersion technique in which the probe is suspended in fluid, while B-scan probes are placed on the globe or against the eyelids. In a review of the literature, no published reports of cross-contamination or infection transmission between patients undergoing A- or B-scan ultrasonography were found.⁵ Nevertheless, some hospital infection control groups require HLD for these devices because they contact the ocular surface.⁵

SUMMARY RECOMMENDATIONS

- The published medical literature does not provide evidence that sight- or life-threatening systemic infections are transmitted via reusable applanation tonometers, laser lenses, or other devices that contact the ocular surface during routine clinical care.
- Current regulatory requirements are based on the application of the nearly century-old Spaulding classification, which incorrectly categorizes the ocular surface as equivalent to other mucous membranes with extremely high microbial burden.
- There is no evidence that HLD for reusable ophthalmic devices reduces infection transmission compared with more commonly used cleaning or disinfecting methods.
- Routine use of chemical HLD increases healthcare costs, reduces clinical efficiency and productivity, generates more plastic and chemical waste, and may damage the surface of reusable ophthalmic devices, compromising patient care. Routine chemical soaking of GAT tips with dilute bleach has been associated with ocular surface chemical injury that may outweigh any theoretical benefit in reducing microbial transmission.
- For patients without signs or symptoms of ocular surface infection and without a known history of chronic systemic viral disease, using alcohol wipes is a sufficient, environmentally sustainable method for reprocessing reusable GAT tips.
- Available evidence does not support the need for HLD for reusable diagnostic and laser contact lenses or A- and B-scan ultrasound probes in the absence of symptoms and signs of ocular infection, ocular inflammation, or a history of chronic systemic viral disease.
- Reprocessing with HLD or other methods recommended in manufacturers' IFUs or using single-use devices or tips, should be considered for higher-risk situations, such as for patients with signs and symptoms of possible ocular surface infection (e.g., discharge, conjunctival injection, periocular erythema, or eye irritation) or for those with chronic systemic viral disease although no evidence exists for transmission of systemic disease.
- Manufacturers' IFUs regarding reprocessing of reusable ophthalmic devices may reflect generic recommendations rather than science- or evidence-based requirements. Ultimately, decisions regarding the reprocessing of reusable ophthalmic devices should remain within the discretion of the treating clinician, considering the clinical setting and patient-specific risk factors.

We urge regulatory agencies, accrediting organizations, manufacturers, and other policymakers, including The Joint Commission, to revise their recommendations and requirements to reflect current evidence and to permit clinician discretion consistent with this guidance in selecting the most appropriate method for reprocessing reusable ophthalmic devices.

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This position statement is intended to educate and guide accrediting organizations, manufacturers, and other policymakers regarding high level disinfection of certain ophthalmic devices in light of available evidence. It is not intended to supersede applicable law or regulations, nor to prescribe physicians' procurement choices.

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