TRIOLOGY

KEEP YOUR EYES ON OPHTHALMOLOGY

A CLOSER LOOK INTO INFECTIOUS DISEASES, DEVICES AND DISINFECTANTS

KEYWORDS

Endogenous – Growing or originating within an organism

Epibulbar – Situated on the eye

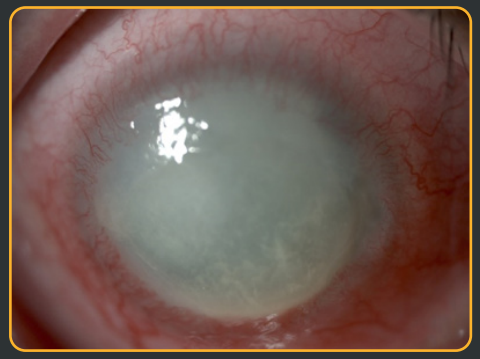
Exogenous – Growing or originating outside an organism

Ophthalmology – A branch of medicine and surgery which deals with the diagnosis and treatment of eye disorders

Pathogen – A microorganism that can cause disease

Parasitic/Protozoan Cysts – The more resistant form that parasites/protozoa take when under stress or in an unfavourable environment

The Spaulding Classification System - Developed by Dr. Earle H. Spaulding in 1968, this classification scheme defines how an item for patient care (e.g. medical device) should be disinfected based on where it is used in or on the body.



Acanthamoeba keratitis.
Source: https://commons.wikimedia.org/wiki/File:Parasite140120-fig1_Acanthamoeba_keratitis_Figure_1A.png

ABSTRACT

Ophthalmic practice is unpredictable and dynamic. It ranges from lens prescription and standard medical treatment to the most delicate and precise surgical manipulations. In a typical workweek, ophthalmologists can see more than 100 patients and perform three or more major surgical procedures[1].

Infection prevention and control is a fundamental part of the broader infrastructure required for safe ophthalmic practice. To avoid infection transmission from patient-to-patient, and patient-to-healthcare worker, appropriate and routine reprocessing of reusable devices is critical. Yet, a direct consensus on a reprocessing solution between infection prevention departments and ophthalmologists is difficult to find in the absence of a clearly suitable solution[2].

The pathogens of concern and their associated disease will be explained in this paper along with the importance of choosing the right disinfectant, and Tristel's purpose to provide solutions that meet all the needs of ophthalmologists, orthoptists, and IPAC specialists.

COMMON INFECTIONS IN OPHTHALMOLOGY AND OPTOMETRY

KERATITIS

This is a condition in which the eye's cornea becomes inflamed. Symptoms can include moderate to intense pain, impaired eyesight, corneal ulceration, sensitivity to light (photophobia) and red eye.

The causative organisms include bacteria (commonly *Pseudomonas aeruginosa* and *Staphylococcus aureus*), parasites (e.g. *Acanthamoeba* spp.), and fungi (yeasts, moulds and microsporidia)[4].

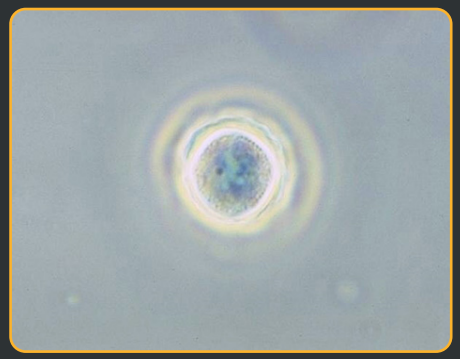
Acanthamoeba keratitis (AK) is a disease of particular concern within ophthalmology. The main route of infection is through the eye, although entry to the body can also occur through the nasal passage and ulcerated skin[5].

AK is caused by a parasite which feeds off the cornea of the eye.

The parasites which cause AK are ubiquitous within the environment. They are commonly found in contact lens accessories, tap water, dust, and swimming pools and are known to act as hosts for several bacterial species causing infections such as bacterial keratitis and legionellosis. Acting as a host provides protection to pathogens in the aquatic environment against standard water treatment methods.

Symptoms of AK can often be confused with common eye infections such as conjunctivitis and herpes simplex virus keratitis. If infection is left untreated, AK has the ability to cause permanent corneal scarring, and in extreme cases, blindness[6].

For medication to have the best chance at effectively treating AK, an early diagnosis for the patient is essential. Individuals who wear contact lenses are most susceptible to contracting AK, although infection can occur in anyone.



Acanthamoeba polyphaga cyst.
Source: https://commons.wikimedia.org/wiki/File:Acanthamoeba_polyphaga_cyst.jpg

Adenoviral epidemic keratoconjunctivitis.
Source: https://en.wikipedia.org/wiki/Adenoviral_keratoconjunctivitis

Slit lamp view of endophthalmitis causing hypopyon (inflammation).
Source: https://commons.wikimedia.org/wiki/File:Hypopyon_1.jpg

Studies have revealed that within the United States approximately 85% of AK infections occur in contact lens wearers. The incidence of the disease in developed countries is approximately one to 33 cases per million contact lens wearers[5].

ADENOVIRAL EPIDEMIC KERATOCONJUNCTIVITIS

Approximately 92% of acute epibulbar infections are caused by the adenovirus. Adenoviral epidemic keratoconjunctivitis (EKC) is a highly contagious, severe form of conjunctivitis, mostly prevalent in late winter, spring and early summer.

Within larger hospitals (>500 beds), for every 1000 treatment cases, 4.7 are estimated to be from EKC. **Major risk factors relating to nosocomial outbreaks of EKC or epidemics include inadequately disinfected ocular instrumentation and insufficient hand washing between healthcare staff and patients**[7].

Human adenovirus (HAdV) is a hostile pathogen as it survives for long periods outside of the human body. It is resistant to adverse pH conditions in the environment and remains stable against many chemical agents.

With studies revealing that **HAdV is viable on ophthalmologic equipment for nine days and up to 30 days** on metals and plastics, the necessity for adequate infection control is therefore critical[8,9].

ENDOPHTHALMITIS

Endophthalmitis is an inflammatory condition of the intraocular cavities, caused by either bacterial or fungal infection. *Candida* spp. are a common cause e.g. *Candida albicans* (also implicated with opportunistic oral and genital infections) is the most common cause of endophthalmitis.

Exogenous endophthalmitis arises through the direct introduction of microorganisms (predominantly *Candida* spp.) into the eye through trauma (including surgery complications) or preceding keratitis. The epidemiological characteristics of patients who contract this infection include:

- **Postoperative infection incurred after lens removal**
- **Postoperative infection incurred after lens implantation**
- **Postoperative infection incurred after corneal transplant**

Endogenous (bloodborne/internal cause) endophthalmitis is the less common form of the disease. This infection occurs through metastatic spread from a distant bodily site[10].

Other notable infections caused by pathogens of concern in ophthalmology include sty, uveitis, cellulitis, and ocular herpes. Eliminating the initial risk of infection is essential in helping prevent the spread of these pathogens.

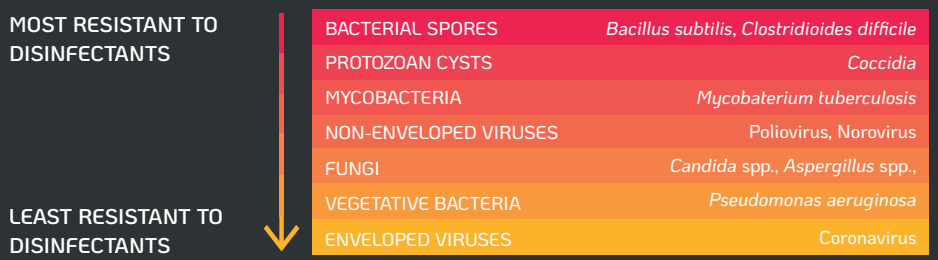


Figure 1. Resistance of microorganisms to disinfectants.
Adapted from Centers for Disease Control and Prevention (2008)[11].

PATIENT CONTACT	DEVICE CLASSIFICATION	DECONTAMINATION METHOD
Intact skin	Non-critical	Low or intermediate-level disinfection
Mucous membranes or non-intact skin	Semi-critical	High-level disinfection
Sterile areas of the body including blood contact	Critical	Sterilisation

Table 1. The Spaulding Classification (1968) developed by Dr. Earle H. Spaulding in 1968, this classification scheme defines how an item for patient care (e.g. medical device) should be disinfected based on where it is used in or on the body.

THE IMPORTANCE OF CHOOSING THE RIGHT DISINFECTANT

Microorganisms vary in their resistance to disinfectants depending on their molecular structure and composition. Bacterial spores have been shown to be the most resistant, followed by parasite cysts (coccidia), mycobacteria (e.g. *M. tuberculosis*), non-enveloped viruses (e.g. Adenovirus), fungi (e.g. *Aspergillus* and *Candida* spp.), vegetative bacteria (e.g. *Pseudomonas* spp. and *Staphylococcus* spp.) and enveloped viruses (e.g. Herpes simplex virus (HSV), coronaviruses) (figure 1.).

High-level disinfectants (HLDs) kill bacteria, fungi, viruses, mycobacteria and small numbers of the highly resistant bacterial spores.

Guidelines referring to the disinfection of reusable ophthalmic devices are usually written by professional advisory bodies or government departments. Differences can be found from one country to another, however, there is a consensus that **devices in direct contact with the eye are classified as semi-critical[2].**

According to the **Spaulding classification** (Table 1.), semi-critical devices require high-level disinfection because they touch mucous membranes or non-intact skin.

Ophthalmic nosocomial outbreaks are often associated to, for example, adenoviruses, and ophthalmic equipment has been identified as sources of such outbreaks.

According to a 2017 Academy Ophthalmic Technology Assessment (OTA), the three most commonly used disinfectants in ophthalmology are alcohols, hydrogen peroxide, and sodium hypochlorite (bleach); only the last was found to be effective disinfection against adenovirus and herpes simplex virus (HSV), the viruses commonly associated with nosocomial outbreaks in eye care[3].

Further studies have shown that other commonly-used disinfection solutions such as accelerated hydrogen peroxide, and quaternary ammonium compounds, are also not effective against adenoviruses. One study reported persistence of adenoviral contamination on a tonometer 9 days after it had been disinfected with alcohol[3,13-17].

Research shows that choosing a proven high-level disinfectant is essential to address all microorganisms of concern and thus reduce the risk of healthcare-associated infections.

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TRISTEL'S ROLE IN OPHTHALMOLOGY

Founded in 1993, Tristel is an Infection Prevention company with headquarters in the United Kingdom and direct operations across Europe and the Asia Pacific.

Our purpose is to prevent the transmission of infections in healthcare facilities. We pursue this purpose because infections place a heavy burden on individuals and society, causing illness and even death. We can achieve our purpose because we have developed disinfection solutions that are powered by a proprietary chlorine dioxide (ClO_2) formulation.

As much as requirements such as choosing the appropriate level of disinfection are important, the disinfectant must be practical and compatible.

A disinfection solution must be fast acting, user-friendly, and correspond to the variability and intensity of ophthalmic practices. It must help tackle, not fuel, current healthcare challenges (i.e., staff shortages and long patient backlogs). And finally, it should pose limited-to-no occupational health risks to the user and no toxic residue to patients.

The OTA panel, referenced to earlier, have also stressed the importance of device compatibility and determined that most disinfectants, "have been identified as causing tonometer prism damage and may result in patient injury". Cracks formed in a prism can cause corneal abrasions and may harbor microorganisms or residual disinfectant[3].

The options for high-level disinfection available to ophthalmologists and IPAC teams are limited[2] and pose a significant challenge for ophthalmologists to maintain a smooth workflow and fast instrument rotation. At the same time, the convenience of alcohol solutions challenges infection control teams to comply with a higher standard of reprocessing, putting patients at risk.

The unique properties of Tristel's proprietary ClO_2 formulation have enabled us to design disinfectant solutions that comply with international guidelines while meeting healthcare needs like no other solution available today. Tristel has designed the first disinfectant for ophthalmology that is high-level, practical, and compatible.

SUPPORTING PRODUCTS FOR OPHTHALMOLOGY

Tristel Duo OPH can be accompanied by various supporting Tristel products to create a complete ophthalmic device decontamination process:

Duo Wipes

When using a dry wipe in your decontamination process, it is essential that the wipe is made of a soft, durable, low-linting material to reduce the risk of leaving scratches and lint build-up on medical devices.

Duo Wipes are designed to apply Tristel Clean and Tristel Duo OPH foam to the medical device with the above requirements in mind. Each wipe has low absorbency to ensure that the maximum amount of foam is distributed on the medical device.

Tristel Clean

To ensure the success of the high-level disinfection step, blood, other bodily fluids, gels, and lubricants must be thoroughly cleaned from the surfaces of medical devices beforehand. Tristel Clean is a triple-enzyme foam designed for the cleaning of medical devices. When using Tristel Clean, no intermediate rinsing is required when using Tristel Duo OPH for high-level disinfection.

Tristel Rinse Wipes

For patient safety, residual disinfectant solution must be removed from the medical device.

Tristel Rinse Wipes are sterile wipes impregnated with deionized water, designed specifically to remove excess disinfectant from a medical device. One rinse is required to remove Tristel Duo OPH residues unless more rinse cycles are specified by the device manufacturer.

Duo DOK

When space is tight Duo DOK keeps Tristel Duo OPH within reach, saving valuable desk and storage space. Duo DOK provides the ideal storage solution for Tristel Duo OPH.

TRISTEL CHLORINE DIOXIDE AND TRISTEL DUO OPH

Tristel's proprietary chlorine dioxide (ClO_2) formulation is a well-documented and highly effective biocide. ClO_2 is a powerful oxidizing agent that packs a punch. It destroys pathogens via electron exchange, sequestering electrons from the microorganism's vital structures such as cell walls, membranes, organelles, and genetic materials.

This causes a molecular imbalance leading to the microorganism's death. This mode of action makes ClO_2 highly efficacious, even at low concentrations.

The advantage of this mode of action over non-oxidising biocides such as alcohols, aldehydes, and quaternary ammonium compounds, is the inability for microorganisms to develop resistance against ClO_2, as well as its broad range of efficacy.

Powered by Tristel ClO_2, Duo OPH is a high-level disinfectant foam, designed specifically for use on cleaned, reusable, non-lumened, semi-critical devices used in Ophthalmology, such as tonometer prisms, diagnostic lenses, pachymeters, and, A-scan and B-scan biometry probes.

Tristel Duo OPH is mycobactericidal, virucidal, fungicidal and bactericidal in a uniform and realistic 2-minute contact time.

A novel dosing bottle brings powerful chemistry to a user-friendly, compact format, enabling high-level disinfection at the point of care.

Tristel Duo OPH carries a low toxicity rating and is not classified as hazardous according to CLP regulations, thus safeguarding the health of the user.

Tristel Duo OPH is authorised by Health Canada as a Class II Medical Device under the Canadian Medical Device Regulations SOR/98-282.

TRISTEL 3T

International guidelines recommend having in place a system that allows medical devices to be tracked through each decontamination process and linked to the patient(s) on whom the device has been used. In the event of a medical device recall, a permanent record will allow tracing from the patient back to the processor[18].

Providing an alternative to paper-based audit trail books, Tristel 3T has been developed into a fully featured cloud-based compliance platform. Combining an intuitive mobile app for use at the point of care, with an interactive web portal provides users with invaluable decontamination compliance tools.

3T guides users through all process steps, tracking decontamination events and making them available to view in real time across their organisation. This allows administrators and decontamination leads to ensure that not only decontamination is taking place at the appropriate intervals, but that users are following the exact process each time.

CONCLUSION

As is the case for many other patient safety issues, healthcare-associated infections create additional suffering and come at a high cost for patients and their families. Infections prolong hospital stays, create long-term disability, increase resistance to antimicrobials, represent a massive additional financial burden for health systems, generate high costs for patients and their family, and cause unnecessary deaths.

Ophthalmic equipment has been identified as sources of ophthalmic nosocomial outbreaks.

A national benchmarking study shows that despite consensus on the appropriate level of disinfection within ophthalmology, there is a dissensus on the recommended solutions between different jurisdictions in Canada, due to the absence of a clearly suitable solution[2].

In line with international guidelines and healthcare needs, Tristel has designed a disinfection solution, Tristel Duo OPH, which can be complemented by various supporting Tristel products to create a complete decontamination process. An option that could potentially fill the role of the clearly suitable solution because it is high level, practical and compatible.

REFERENCES

1. American Academy of Ophthalmology, “What to Expect: The Practice of Ophthalmology”.
2. A. Ragan, S.L. Cote, J.T. Huang, “Applanation tonometer disinfection: a national benchmarking study”.
3. J.S. Griffin, interviewing A.K. Junk, T.C. Chen, N.S. Choudhari, “How to Disinfect and Calibrate Your Goldmann Applanation Tonometer”.
4. S. Tuft MChir and M. Burton, “Focus - Microbial keratitis,” London, 2013
5. Centers for Disease Control and Prevention, “Parasites - Acanthamoeba - Granulomatous Amebic Encephalitis (GAE); Keratitis,” 2017.
6. All About Vision and C. A. Knobble, “Corneal Ulcer: Causes And Treatment,” 2016.
7. A. Bialasiewicz, “Adenoviral Keratoconjunctivitis,” Sult. Qaboos Univ. Med. J., 2007.
8. Centers for Disease Control and Prevention (CDC), “Adenovirusassociated epidemic keratoconjunctivitis outbreaks--four states, 2008-2010.,” MMWR. Morb. Mortal. Wkly. Rep., vol. 62, no. 32, pp. 637–51, 2013.
9. Rutala, W.A., Peacock, J.E., Gergen, M.F., Sobsey, M.D. and Weber, D.J. (2006). “Efficacy of Hospital Germicides against Adenovirus 8, a Common Cause of Epidemic Keratoconjunctivitis in Health Care Facilities. Antimicrobial Agents and Chemotherapy”, 50(4), pp.1419–1424.
10. S. A. Klotz, C. C. Penn, G. J. Negvesky, and S. I. Butrus, “Fungal and Parasitic Infections of the Liver,” Clin. Microbiol. Rev., vol. 13, no. 4, pp. 662–685, 2000.
11. Centers for Disease Control and Prevention, “Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008; Miscellaneous Inactivating Agents,” CDC website, no. May, pp 9–13, 2008, doi: 1.
12. V. Thomas, G. McDonnell, S. P. Denyer, and J. Y. Maillard, “Free-living amoebae and their intracellular pathogenic microorganisms: Risks for water quality,” FEMS Microbiol. Rev., vol. 34, no. 3, pp. 231–259, 2010, doi: 10.1111/j.1574-6976.2009.00190.x.
13. J.S. Sammons, E.H. Graf, S. Townsend, D. Munson, G. Quinn, G. Binenbaum. “Outbreak of Adenovirus in a Neonatal Intensive Care Unit Critical Importance of Equipment Cleaning During Inpatient Ophthalmologic Examinations”.
14. W.A. Rutala, J.E. Peacock, M.F. Gergen, M.D. Sobsey, and D.J. Weber. “Efficacy of Hospital Germicides against Adenovirus 8, a Common Cause of Epidemic Keratoconjunctivitis in Health Care Facilities.”
15. Centers for Disease Control and Prevention (CDC), “Adenovirus-associated epidemic keratoconjunctivitis outbreaks-four states, 2008-2010”.
16. A.K. Junk, P.P. Chen, S.C. Lin, K. Nouri-Mahdavi, S. Radhakrishnan, K. Singh, T.C. Chen.
17. American Academy of Ophthalmology, “Disinfection of tonometers: A Report by the American Academy of Ophthalmology”.
18. World Health Organization. (2016). “Decontamination and reprocessing of medical devices for health-care facilities”. World Health Organization.

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