

Looking Good: Safe Use and Care of Contact Lenses

Helene D. Clayton-Jeter, OD

Approximately 30 million U.S. contact lens wearers use a variety of lens care products available in most pharmacies. Contact lenses may provide better vision and more freedom of movement for some users, but improper care and cleansing of these products can cause serious eye infections.

Because pharmacists are frequently consulted by patients on health care issues, they should be aware of the following:

- Types of contact lenses and lens care products
- Proper cleaning of soft contact lenses
- Eye infections from contact lens care products
- FDA’s strategies for reducing risks of eye infections
- Tips for counseling consumers

Soft lenses are the culprits

There are two main kinds of contact lenses: soft and gas permeable. Soft contact lenses are made of a plastic polymer and contain at least 10% water. They contribute to more eye infections than rigid or gas-permeable contact lenses. Wearers of these lenses are at a greater risk of developing eye infections and corneal ulcers. These conditions can develop quickly — usually within 24 hours of exposure to the offending agent; they can be very serious and, in rare cases, cause blindness. Educating patients about the importance of proper lens care can help reduce the risks of eye infections.

The numerous contact lens care systems sold in the United States comprise four basic types: heat, chemical plus saline, peroxide, and

multipurpose. The evolution of contact lens care systems, starting in 1973 with heat disinfection, has progressed to multipurpose contact lens care systems, which were introduced in 1995; heating units for heat disinfection are no longer readily available. Multipurpose products are those that can be used to clean and disinfect using one lens care product. Multipurpose contact lens solutions are the dominant disinfection method used by contact lens wearers today.

Proper cleaning is essential

Standard daily-wear soft contact lenses should be cleaned daily. Several professional groups that represent optometrists and ophthalmologists recommend rubbing each lens in the palm of the hand with a few drops of solution, even if using a “no rub”¹ product. James Saviola, OD, of the Division of Ophthalmic and Ear, Nose, and Throat Devices in the FDA’s Center for Devices and Radiological Health, which regulates contact lenses and lens care products as medical devices, stated, “FDA recommends that consumers rub and rinse contact lenses as directed by their eye care professionals.” The center requires manufacturers to conduct testing and obtain clearance from the agency before marketing these products.

After the lenses have been cleaned with the recommended solution, they should be rinsed for the specified

length of time on the package insert and then placed in a clean case or lens holder filled with fresh disinfecting solution. Disinfection time varies from product to product, so check the package for details. Cleaning removes eye-produced protein, calcium build-up, and other debris, such as cosmetics. Disinfecting kills microorganisms on the contact lens. Some optometrists and ophthalmologists recommend a protein remover for specific kinds of contact lenses or for those patients whose eyes produce more than the average amount of protein. Typically, protein removal is necessary for contact lenses that are worn between 6 months and 1 year. Disposable contact lenses rarely need the addition of a protein remover.

Beware of eye infections

Improper care of contact lenses can lead to a variety of eye infections including infectious keratitis. Experts in the eye care field agree that estimated rates of microbial keratitis in the contact lens-wearing population has not substantially declined since the first disinfection method using heat, despite the evolution of contact lens disinfection systems. Risk factors associated with an increased risk for eye infections include inadequate hygiene, noncompliance with schedules for wearing contact lenses or contact lens care systems, and contamination of contact lens materials.

Over the past 3 years, there have been two major outbreaks of eye infections, both associated with a single brand of contact lens multipurpose care systems. In 2006, there was an outbreak of *Fusarium keratitis*, which is a rare but serious eye infec-

¹ No rub means rinsing instead of digitally rubbing the contact lens with a multipurpose solution; this is a passive type of cleaning.

tion caused by a fungus. The implicated product was recalled and is no longer sold although it performed well in the tests FDA required prior to the product being cleared for marketing.

An outbreak of *Acanthamoeba keratitis* occurred in 2007; this is another rare but serious eye infection caused by a parasite commonly found in nature. It is one of the most painful and debilitating corneal infections. Patients could lose their eye as a consequence of the infection. It can cause permanent loss of vision that can require corneal transplants, a surgical procedure to replace the clear outer covering of the eye. Contact lens wearers represent 90% of *A. keratitis* cases. It is estimated that the U.S. incidence of this infection is between 1.49 and 2.01 cases per million per year. Corneal transplantation has a 15% to 20% occurrence rate during the course of the infection, and 15% to 20% of these infections result in corneal transplants.

The contact lens solution that caused this outbreak was not tested against the *Acanthamoeba* organism because it had not been part of the current panel of organisms. These outbreaks led FDA to convene a meeting of the Ophthalmic Devices Advisory Committee in June 2008, to re-assess current guidance recommendations for testing multipurpose contact lens care products before issuing FDA marketing clearance.

FDA works to reduce risks of eye infections

The unexpected keratitis outbreaks prompted FDA to explore the various risk factors involved with using mul-

tipurpose contact lens solutions. In both outbreaks, FDA's investigation revealed that reusing previously used solution and adding to it fresh, unused solution reduced the antimicrobial effectiveness of the lens care product. Therefore, FDA recommended that contact lens care solution should be emptied out of the contact lens case after each use. The solution left over in the contact lens case after a disinfection cycle is "dirty," said Bernard Lepri, OD, MS, MEd, of the Division of Ophthalmic and Ear, Nose, and Throat Devices in the FDA's Center for Devices and Radiological Health. Lepri stated, "The left-over solution can have little disinfecting chemical left to kill bacteria and other micro-organisms that may contaminate your contact lenses and lead to serious eye infections. The solution no longer has the same effectiveness for disinfection as when it was freshly placed in the case."

On June 10, 2008, FDA sought additional input from the Ophthalmic Devices Advisory Panel on the pre-clinical and clinical tests and labeling for multipurpose contact lens care products. The discussions at the panel meeting supported FDA's assessment that the current microbiological pre-clinical tests be updated to better evaluate the activity of contact lens care products against *Acanthamoeba* and performance criteria for new or modified disinfection efficacy test methods that simulate real-world, worst-case use conditions.

Based on the recommendations of the advisory panel and a request from the ophthalmic community, the Microbiological Testing of Contact Lens Care Products Workshop con-

vened on January 22–23, 2009, with the goals of reaching consensus on these issues. Data presented at the workshop revealed that multipurpose contact lens solutions can have a profound effect in either prohibiting or promoting the two previously described and usually rare infections. These findings differed from data previously presented in 2006 which identified the usual risk factors of poor patient hygiene practices, non-compliance with wearing regimens and lens materials as the causes of the increase in infectious keratitis.

The FDA workshop participants found that the lack of compliance to proper contact lens care procedures and improper patient hygiene practices did not change the incidence of the *Fusarium* outbreak. Neither lens rubbing nor hand washing had a protective effect during either outbreak.

As a general rule, rubbing and rinsing contact lenses are beneficial in removing protein deposits and microorganisms, but it is not the only contributing factor to antimicrobial efficacy. To further protect consumers against eye infections, workshop participants made the following additional recommendations for lens care product labeling and directions for use:

- Contact lens solution manufacturers should include a discard date on their products in addition to the usual expiration date.
- Consumers should never use expired products.
- Contact lens wearers should rub and rinse their lenses for added effectiveness of cleaning and disinfection.

Counseling tips for Pharmacists

Pharmacists play a key role in patient education as it relates to contact lens care and safe use. Their knowledge of contact lenses and contact lens products is crucial in delivering accurate information to consumers. Pharmacists can advise patients of the following:

- Do not top off used lens cleaning solutions or reuse them.
- Use a contact lens solution to clean and rinse; then air dry contact lens cases after each use.
- Rub and rinse contact lenses for added effectiveness of cleaning and disinfection.
- Do not expose contact lenses or lens storage cases to any type of water or other non-sterile solutions.
- Do not use contact lens solutions beyond their expiration date.
- Consult an eye care professional in the event of eye irritation or infection.

Information on contact lenses and contact solutions is available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/default.htm>.

Information on the Advisory Committee Meeting can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OphthalmicDevicesPanel/ucm125428.htm>.

— Helene D. Clayton-Jeter, OD,
Contributing writer

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