



**CLAO**



## **Recommendations for Improving Contact Lens Safety**

The American Academy of Ophthalmology, the Contact Lens Association of Ophthalmologists, the Cornea Society and the American Society of Cataract and Refractive Surgery have issued the following joint guidelines and recommendations.

### **Improving Product Safety through Testing and Research**

Now is the time to tighten the safety net around contact lens products. It is recommended that the FDA work closely with industry to expand and strengthen contact lens solution and product testing to better protect consumers.

#### **Pre-clinical testing of contact lens products (solutions and lenses)**

- Pre-clinical testing of efficacy against organisms is complex and challenging. The testing protocol should be standardized and validated by the FDA to ensure all products are meeting the same demands.
- Pre-clinical testing should include more rigorous and standardized “real-world” scenarios that more accurately replicate the conditions and environment that contact lens products will be exposed to when used by consumers. For example:
  - Effectiveness while in a contact lens case
  - Effectiveness when exposure time (amount of time the lenses are in the case) is less than recommended
  - Effectiveness when the solution evaporates
- Testing requirements should be updated to ensure products are effective against a more diverse and representative set of infectious organisms, including *Acanthamoeba*. At the same time, tests currently required should be continued because of their historic use and for comparison purposes.
- Given the complexity of contact lens solutions and the environment within which they are expected to work, the FDA should re-examine the concept of equivalency testing when a revised formula is submitted. Each product should be evaluated on its own.

Expanded and strengthened testing of contact lens solutions does not guarantee that the next outbreak of eye infections will be able to be prevented or predicted. However, it will increase overall safety for contact lens wearers.

#### **Research and monitoring to safeguard public health**

- Experts agree that the number of cases of microbial keratitis, particularly *Acanthamoeba* keratitis, have not substantially declined, despite attempts to improve contact lens disinfection regimens over the years. Research shows that the disinfection regimen is but one element of the risk of infection. Other factors, such as use of extended wear lenses, reduced tear exchange under the lens with current designs, environmental factors and poor consumer hygiene, are likely of equal or greater importance. These factors deserve additional research, as well.

- Some mechanism for monitoring contact lens infections and the frequency and distribution of the organisms causing those infections could prove beneficial in protecting the public from eye infections.

#### **Discard date on lens care products (in addition to expiration dates)**

- The FDA should encourage manufacturers to determine if an “opened expiration date” is needed on contact lens solutions to ensure that consumers are not using products that may have lost some efficacy.

#### **Extended storage**

- The FDA should encourage industry to conduct additional research to verify the duration for safe extended storage of lenses.

#### **Labeling contact lens solutions for use with specific lens types**

- Additional information should be gathered regarding biocompatibility of solutions and lenses. This is particularly important as new materials and lenses are developed and introduced.

### **Better Lens Care**

For patients, the single best way to avoid eye infections is to follow proper lens care guidelines as prescribed by your eye care professional. In particular, including a “rub and rinse” step in the lens cleaning process, minimizing contact with water while wearing contact lenses and replacing the lens case frequently can help reduce the risk of infection. For more contact lens care guidelines go to [geteyesmart.org](http://geteyesmart.org).

#### **Taking care of your lenses**

- Before handling contact lenses, wash your hands with soap and water, then rinse and dry them with a lint-free towel.
- Minimize contact with water, including removing lenses before going swimming or in a hot tub.
- Contact lenses should not be rinsed with or stored in water (tap or sterile water).
- Do not put your lenses in your mouth to wet them. Saliva is not a sterile solution.
- Do not use saline solution and rewetting drops to disinfect lenses. Neither is an effective or approved disinfectant.
- Wear and replace contact lenses according to the schedule prescribed by your eye care professional.
- Follow the specific contact lens cleaning and storage guidelines from your eye care professional and the solution manufacturer.
- During cleaning, rub your contact lenses with your fingers, then rinse the lenses with solution before soaking them. This “rub and rinse” method is considered by some experts to be a superior method of cleaning, even if the solution you are using is a “no-rub” variety.
- Rinse the contact lens case with fresh solution — not water. Then leave the empty case open to air dry.
- Keep the contact lens case clean and replace it regularly, at least every three months. Lens cases can be a source of contamination and infection. Do not use cracked or damaged lens cases.
- Handle your contact lens solution with care:
  - Do not re-use old solution or “top off” the solution in your lens case.
  - Do not transfer contact lens solution into smaller travel-size containers. This can affect the sterility of the solution, which can lead to an eye infection.

- Do not allow the tip of the solution bottle to come in contact with any surface, and keep the bottle tightly closed when not in use.
- If you store your lenses in the case for an extended period of time, consult the instructions for your lenses or the contact lens solution to determine if re-disinfecting the lenses is appropriate before you wear them. In no case should you wear your lenses after storage for 30 or more days without re-disinfecting.
- Some experts recommend that if you use contact lenses sporadically, consider using single-use daily disposable lenses.

### **Selecting lenses**

- Single-use daily disposable lenses are the safest type of soft contact lens, in terms of reducing the risk of infection.
- Rigid gas permeable lenses are a safer alternative than any type of soft contact lens.

### **Extended wear contact lenses**

- Extended wear lenses may be an appropriate choice for some consumers, but you should be aware that wearing lenses overnight increases the risk of infection.
- If you wear lenses overnight, only do so at the recommendation of your eye care professional and only use extended wear lenses that are specifically approved for this use.
- Lenses worn overnight for orthokeratology (reshaping of the cornea to improve refraction) increase the risk of eye infections.

### **Eye Care**

Eye infections can lead to serious vision loss in some cases. If you think you have an eye infection, immediately see an ophthalmologist, an Eye MD, who is medically and surgically trained to treat eye infections, injuries and diseases.

### **Taking care of your eyes**

- Remove the contact lenses and consult an ophthalmologist immediately if you experience symptoms such as redness, pain, tearing, increased light sensitivity, blurry vision, discharge or swelling.
- If you smoke, stop. Studies show that contact lens wearers who smoke have a higher rate of problems than nonsmokers.

### **Exams and prescriptions**

- If you wear contact lenses, you should be examined by an eye care provider annually, and more often as needed.
- As with any prescription, contact lens prescriptions do expire—typically within one year. You should see your eye care professional yearly to ensure they continue to have an accurate and appropriate prescription. These regular exams are also important opportunities for reinforcing proper lens care.
- Ophthalmologists remain concerned about the practice of “passive verification” of contact lens prescriptions. Under this system, third-party sellers (such as online vendors) of contact lenses notify eye care professionals of customer requests to purchase contact lenses. Unless the eye care professional affirmatively notifies the seller within eight business hours that the prescription is incorrect, expired or otherwise problematic, the seller may presume that the prescription is correct and valid and complete the sale. Passive verification may lead to the fulfillment of an expired prescription and may extend the period between eye exams, which can increase the risk to consumers’ eye health.