



AMOTM ADVANCED MEDICAL OPTICS EYE CARE NEWS

Leading the Change in Contact Lens Care



AMO continues to lead the industry with new products and services to help your patients. We've had firsts in the last 50 years before and after we spun off from other companies. Now AMO again leads in contact lens care regimens to provide compliance systems to support effective contact lens cleaning.

On June 10, 2008, the FDA convened a panel to discuss new requirements for contact lens solutions in the wake of product recalls by Bausch & Lomb and AMO. Presentations were delivered by the FDA, the CDC and interested members of the industry during a public input session. There were 18 public presentations, including representatives from the American Academy of Ophthalmology, the American Society of Cataract and Refractive Surgery, Cornea Society, and Contact Lens Association of Ophthalmologists; American Academy of Optometry Cornea and Contact Lens Section; American Optometric Association Contact Lens and Cornea Section and independent ophthalmologists and optometrists.

So, what's the conclusion of these recommendations?

- AMO is the clear industry leader in recommending more specific testing guidelines for contact lens care products.

- AMO is the only manufacturer to endorse the position on rubbing the lenses that is consistent with the recommendations of major professional associations.

- COMPLETE[®] MPS EASY RUB[®] Formula

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FDA Panel Seeks Solutions to Contact Lens Care

The FDA Ophthalmic Devices Advisory Panel met on June 10, 2008, in Washington, D.C., to propose recommendations for the agency to improve the safety and effectiveness of contact lens care products. AMO presented recommendations to the panel. FDA decisions have yet to be released. Typically, the agency follows its panel's recommendations. The following are some of the recommendations presented to the panel.

Change the Compliance Paradigm

Bernard P. Lepri, OD, MS, MEd of the FDA/Center for Devices and Radiological Health, Office of Device Evaluation, showed contact lens care as a subset of the well-known and costly problem of compliance. Noncompliance is higher in complex treatment regimens and asymptomatic health conditions.

"Contact lens products should be designed and tested with consumer use patterns in mind."

— Bernard P. Lepri, OD, MS MEd

One in four physician visits in the year 2000 resulted from not following the physician's treatment regimen.¹ In a study of college students and healthcare workers, only one or two of every four patients adhered consistently to the practitioner's instructions for contact lens care.² Dr. Lepri reported that 80% of contact lens complications

can be traced to inappropriate wear and poor lens care.

The special challenge for contact lens manufacturers, said Lepri, is moving away from seeing compliance as an error on the part of the patient and, instead, designing the product for ease of use by the wearer. Contact lens care products should be designed and tested with consumer use patterns in mind.

Improve the Warnings on Labels

Carol Clayton, from the FDA Center for Devices and Radiological Health, Office of Communication, Education and Radiation Programs, proposed new labeling for contact lens care products. The panel discussed a Rub and Rinse regimen with new, more readable, labeling on the contact lens care packages and bottles.

Improve Testing Regimens

Simon Kilvington, PhD, of the Department of Infection, Immunity and Inflammation at the University of Leicester, England at the time, described the trophozoite and cyst forms of *Acanthamoeba*. The agent causes potentially blinding infection of the cornea in otherwise healthy persons.

Dr. Kilvington discussed the biocidal efficacy of contact lens care solutions and the regimens to remove deposits that develop on the lenses. He concluded that the contact lens industry needs to address the risk of infection through education, promoting the rub step and extended disinfection times. Dr. Kilvington has since joined AMO as director of microbiology.

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Leading the Change in Contact Lens Care

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is the only solution to incorporate Rub and Rinse in its instructions.

■ AMO initiated and supports the removal of "No Rub" from labels on contact lens care products.

The growth of the contact lens industry has been flat for years. Approximately 7% of new wearers enter the market each year and the same percentage discontinue their contact lenses. One reason that patients quit is discomfort. Contact lenses with protein deposits can irritate the cornea. Rubbing and rinsing help break up the deposits.

We know the stories of patients using saline solution or water to clean their lenses or adding new contact lens solution to old in a misguided attempt to make the bottle last as long as possible. We need to remind all patients, "Always use fresh solution." Only fresh solution has the full complement of cleaning and disinfecting agents.

Good hygiene should be modeled in the office. Recommend that patients routinely trade in their old contact lens case for a new one. Demonstrate good hand-washing technique. Demonstrate how to clean the contact lens to remove microscopic irritants from the surface by cleaning the lenses in an outward, rather than a circular, motion.

It's up to all of us in the industry, including contact lens and care product companies, practitioners and staff to join together in encouraging patients to follow the cleaning guidelines. If we can improve patient compliance, we may be able to make these wonderful healthcare devices more appealing. Together we can improve ocular health care.

Sincerely,

David W. Hansen, OD.

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FDA Panel Seeks Solutions to Contact Lens Care (cont.)

Redesign Procedures to Reflect Actual Use and Misuse

Doyle Stulting, MD, PhD, professor of ophthalmology, and director of the section of cornea and external disease at Emory University in Atlanta, Ga., advocated changes in the policies and procedures for the approval and labeling of contact lens care products. Dr. Stulting recommended that the FDA review its procedures for testing contact lens disinfection products.

"Rubbing contact lenses is a scientifically proven way to improve the efficacy and safety margin of modern disinfection solutions."

— Doyle Stulting, MD, PhD

"These procedures should be redesigned to reflect conditions of actual use and misuse, including a methodology for testing the ability of the solutions to support the replication of microbes in drying films, and under conditions in which patients top off their disinfection solution. They should not only include a variety of microbes like *Acanthamoeba*, but also a variety of contact lens polymers, like silicone hydrogels, to determine whether interactions with these polymers themselves might reduce the efficacy of the disinfection products."

Dr. Stulting urged the panel to emphasize efficacy rather than convenience. "The first such change should be the removal of the no rub claim, because rubbing contact lenses is a scientifically proven way to improve the efficacy and the safety margin of modern disinfection solutions." Dr. Stulting recommended the launch of a national campaign to raise awareness about good contact lens care practices and the appropriate and responsible use of contact lenses.

Use Rub and Rinse for All Products

The panel recognized Rub and Rinse as the standard for proper cleaning and disinfecting of contact lenses. "I think that if rubbing gives you one log unit, it's worth it," said William D. Mathers, MD, "and it doesn't mean that you can't have an effective solution that gives you more log units, but an additional log unit of efficacy is worth it for a rub."

Acting Chairperson Neil M. Bressler, MD, commented, "Given what we've heard about compliance, then maybe an additional factor to take into consideration is that we all heard good data to support rubbing and rinsing with the solution."

Timothy McMahon, OD, added, "To summarize, rinsing works somewhat; rubbing works even better. The combination of the two is best of all and not doing either is worst of all." He said to the panel, "We can encourage rub and rinse now so this particular approach re-emerges, and we can urge that the notion of no-rub go away as benchmarks are established."

The full transcript of the meeting is available in four parts at:

fda.gov/ohrms/dockets/ac/08/transcripts/2008-4363t1-01.pdf

fda.gov/ohrms/dockets/ac/08/transcripts/2008-4363t1-02.pdf

fda.gov/ohrms/dockets/ac/08/transcripts/2008-4363t1-03.pdf

fda.gov/ohrms/dockets/ac/08/transcripts/2008-4363t1-04.pdf

Slides presented at the meeting can be found at:

fda.gov/ohrms/dockets/ac/08/slides/2008-4363s1-00-index.html

References

1. DiMatteo, MR. Variations in patients' adherence to medical recommendations: A quantitative review of 50 years of research. *Med Care*. 2004;42:200-209.
2. De Oliveira PR, Temporini-Nastari ER, Ruiz Alves M, Kara-Jose N. Self-evaluation of contact lens wearing and care by college students and health care workers. *Eye Contact Lens*. 2003;29:164-167

A M O N E W S

AMO Partners With Institute for Eye Research to Develop Contact Lens Disinfectant and Cleaning Solutions

Advanced Medical Optics, Inc. has entered into a collaboration with the Institute for Eye Research (IER) to develop contact lens disinfectant and cleaning solutions and related products. IER has headquarters in Sydney, Australia.

IER is a nonprofit research organization that conducts collaborative and contract research with and for industry in the area of vision correction, eye care, the anterior eye, contact lenses, contact lens care and patient management to avoid contact lens complications. The organization is a world leader in the in vitro and clinical evaluation of silicone hydrogel lenses and their interaction with contact lens care products using their propri-

etary modeling systems and databases.

"IER's world-class scientists and clinicians have had a major impact on the development of contact lenses and lens care technologies," said Leonard Borrmann, AMO's executive vice president, research and development. "We look forward to working closely with the IER on the development of next-generation contact lens solutions."

"Through our collaboration with AMO, we will work to develop, test and deliver, through product innovation and education, the best in contact lens care products," said IER CEO Brien Holden, PhD. "Our goal is to develop new, safer, better and more convenient initiatives in the field of contact lens cleaning and

disinfection systems, including the containers for storage, cleaning and disinfection."

Institute for Eye Research

The Institute for Eye Research is dedicated to "Vision excellence for all people." For more than 20 years, the institute has collaborated with the world's leading researchers to bring innovation in vision. An Australian not-for-profit organization, IER has grown to be a major participant and supporter of research worldwide and is committed to the advancement of vision science and the provision of sustainable eyecare services and education in developing communities. For more information please go to ier.org.au.

AMO Teaching Materials for the Clinician's Office

Elevate Your Eye Care

Over the last few years, the public has come to view contact lenses and contact lens solutions as consumer commodities, products that can be switched out at any time, any place. Contact lens solutions are an integral part of contact lens performance and safety.

Choosing the Right Regimen

Contact lens care is specific to each individual. There are multiple options for cleaning, storing and disinfecting contact lenses.

By working closely with your eye care practitioner, you can determine which eye care regimen, whether it be multi-purpose solution or hydrogen peroxide system is right for you. It is always important to speak with your eye care practitioner if you plan on changing your eye care regimen, as using incompatible products could be harmful to your eyes.

Clean, Rinse and Disinfect

- The best way to minimize your risk for eye infection and disease is to properly clean, disinfect and rinse your lenses daily.
- Proper cleaning and rinsing includes rubbing your contact lenses. It is an essential step in your daily lens cleaning regimen. By employing proper rubbing technique, you can help ensure that your contact lenses are cleaned thoroughly while minimizing the risk of infection.
- It is also recommended that you replace your contact lens case every 1 - 3 months or as recommended by your eye care practitioner.

Tips for Healthy Lens Wearing Comfort
Multi-Purpose Lens Care Directions

To help you maintain clean and comfortable lenses and effective disinfection and comfort:

RINSE for lens-wearing comfort
When you insert your lenses:

1. Wash your hands with soap and water and dry with a lint-free towel prior to handling your lenses.
2. Prior to reapplying lenses, RINSE each side of the lens for 5 seconds with fresh solution to remove any debris on the lens.

Don't Forget the Following Guidelines on How Best to Take Care of Your Lenses:

- **Do not** store or rinse lenses in any non-sterile water, including tap water.
- **Do not** swim, shower or use a hot tub while wearing soft contact lenses.
- **Do not** use saliva or put lenses in mouth to rewet.
- **Do not** wear lenses longer than prescribed.
- **Discard** any soft contact lenses that are damaged or dehydrated.
- **Avoid** using aerosols when wearing contact lenses.
- **Discard** any remaining solution in your lens case before disinfecting your lenses again.

RUB, RINSE & SOAK for effective disinfection
When you remove your lenses:

1. Wash your hands with soap and water and dry with a lint-free towel prior to handling your lenses.
2. Place 3 drops or more of solution on one side of the lens surface.
3. **RUB** your lens gently from the center to the edges for at least 10 seconds (Never rub in a circular motion, because it may tear the lens and not clean the outer edge surface).
4. After rubbing for at least 10 seconds, turn the lens over and repeat step 3.
5. **RINSE** each side of the lens for 5 seconds with fresh solution. Place lenses in clean lens case and fill with solution. Close lens case tightly.
6. **SOAK** - Allow lenses to soak for a minimum of six (6) hours for disinfection, cleaning and protein removal.

Caring For Your Lens Case

- Always rinse your lens case daily with fresh solution and let it air dry. Never use tap water.
- It is recommended you replace your lens case every 1-3 months.

AMO Teaching Materials for the Clinician's Office

AMO has developed patient education materials on contact lens hygiene and compliance for the clinician's office. Contact your sales representative or AMO customer service at 800.821.1515.

Did You Know?

- Dry eye syndrome is a common disorder of the eye's tear film and affects millions of people worldwide.

- Dry eye syndrome is the most common treatable eye disorder in North America and is a confounding factor in a wide variety of eye diseases.

- One in four ophthalmic patients report dry eye symptoms.

- Women are twice as likely as men to suffer from dry eye.

- Dry eye syndrome is often associated with other diseases, such as diabetes and autoimmune diseases.

- Dry eye syndrome is prevalent during menopause

- Dry eye syndrome impacts up to 11% of those between 30 and 60 years of age and up to 14% of people over age 65.

- For more information on dry eye, visit yourhealthyyes.com.

Product News

Blink® Tears Lubricating Eye Drops are already favorites among leading optometrists and ophthalmologists who treat patients with dry eye syndrome. Two new products to the family of Blink® Tears are Blink GelTears® Lubricating Eye Drops and Blink® Tears Preservative-Free. Both are made from a unique, viscoadaptive formula to treat the symptoms of dry eye. This formula has a blend of ingredients found naturally in the eye.



Blink GelTears® Lubricating Eye Drops:

- Provides all the advantages of Blink® Tears but with a more viscous formula specially designed for enhanced comfort in moderate-severe dry eye patients
- Provides longer-lasting relief for daytime and nighttime use
- Adapts to an individual's dry eye needs by thickening when the eye opens and thinning when the eye closes
- Restores the tear film with every blink
- Improved tear film stability
- Dissipating preservative in the eye.

Blink® Tears Preservative-Free Lubricating Eye Drops:

- Blink® Tears Preservative-Free is the only preservative-free eye drop that adapts to patients' dry eye needs and provides satisfying,



longer-lasting relief without blurring, while also promoting the health and well-being of the eye

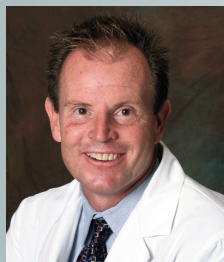
- Greater than 60 minutes retention time¹
- Significant improvement in comfort and vision quality over time²
- Significantly less blur vs. Systane® drops²
- Patients preferred Blink® Tears vs. previous eye drops
- Blink® Tears Preservative-Free is safely provided to patients with allergies, sensitive eyes or post-LASIK in a sterile, single-use vial.²

References

1. Data on file, 2007, Interferometry clinical study. Advanced Medical Optics, Inc., Santa Ana, CA
2. Data on file, 2007. Donnenfeld ED, Ophthalmic Consultants of Long Island, Rockville Center, NY

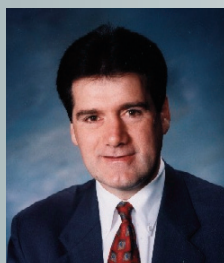
Blink Tears Product Family

- The family of Blink® Tears products is now available over the counter to help the estimated 55 million Americans who suffer from occasional or chronic dry eye.
- AMO launched Blink® Tears in Europe in June 2008.



"I've been impressed that Blink Tears unpreserved drops gives patients the best vision correction and the fewest complaints of any other dry eye drops."

Jim Owen, OD, FAAO – La Jolla, CA



"Blink epitomizes what clinicians and patients are looking for in a dry eye treatment — it's comfortable, gentle, long-lasting, and doesn't interfere with vision."

Michael DePaolis, OD, FAAO – Rochester, NY

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