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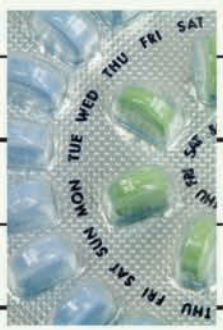
Review of Cornea & Contact Lenses

MARCH 2013

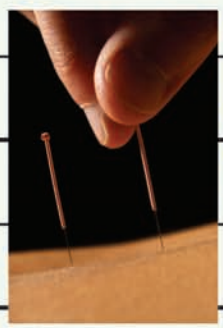
Dry Eye Treatment: The Unusual Suspects



Hormonal Therapy

Steroids/Anti-Inflammatories

Lifestyle Changes



Acupuncture

Biologic Therapeutics

Nutritional Considerations

ALSO INSIDE THIS ISSUE:

Supplement to REVIEW® OF OPTOMETRY
March 2013

Earn 1 CE credit in this issue. See "A Lens Fit for Dry Eye," p. 15.

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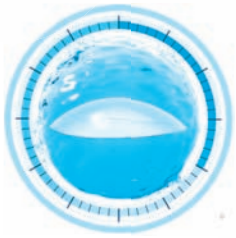

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1. Data on file, Alcon Research Ltd. **2.** Lally J, Ketelson H, Borazjani R, et al. A new lens care solution provides moisture and comfort with today's CLs. *Optician* 4/1/2011, Vol 241 Issue 6296, 42 -46. **3.** Campbell R, Kame G, Leach N, et al. Clinical benefits of a new multi-purpose disinfecting solution in silicone hydrogel and soft contact lens users. *Eye & Contact Lens* 2012:38(2);93-101. **4.** Davis J, Ketelson HA, Shows A, Meadows DL. A lens care solution designed for wetting silicone hydrogel materials. Poster presented at: ARVO; May 2010; Fort Lauderdale, FL.

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contents

Review of Cornea & Contact Lenses | March 2013

Allergy & Dry Eye Issue

ON THE COVER

Departments

VOL. 150, No. 2

In The News

• **Atlantis,** a new scleral lens from **X-Cel Contacts**, is suited for irregular cornea conditions such as keratoconus, pellucid marginal degeneration, corneal transplants, post-refractive surgery, post-corneal rings and ocular surface disease. It has also been successful on regular corneas, dry eye and in athletic wear. Visit www.xcelcontacts.com.

• The **VSP Eye on Diabetes** campaign continues, with an upcoming visit in Baltimore on March 30. This initiative seeks to provide disadvantaged residents with free health services, such as comprehensive eye exams and risk assessments for diabetes and high blood pressure. A free COPE-approved CE course will be offered in each city stop for licensed ODs. To register, visit www.vspeyeondiabetes.com.

• New promotional materials for **PureVision2** and **SofLens** daily disposables from **Bausch + Lomb** include a waiting room movie trivia game that might win your patients a free movie rental or the grand prize of a 46" Samsung HDTV—on the spot. The campaign promotes the lenses' performance in low-light conditions such as a movie theater. Visit www.bausch.com.

• A new year, a new look. The **International Association of Contact Lens Educations** (IACLE) has launched a new website with updated information and additional resources for educators, including a global member e-newsletter, an IACLE Fellows directory, the latest news and press releases, as well as profiles of board and staff members. For more information, visit www.iacle.org.

• The **University of Houston College of Optometry** has opened its first ASC, the **Vision Source Ambulatory Surgical Center,** at the Molly and Doug Barnes Vision Institute. It is one of only 50 nationwide that will perform ophthalmic surgery of all kinds and the only one to offer femto cataract surgery.

ASCRS: Reconsider Operative Medications

The American Society of Cataract and Refractive Surgery's Cornea and Refractive Surgery Committees issued a joint statement recommending that certain medications not be used immediately prior to or during LASIK or PRK while the stromal bed is exposed until further studies can be completed. The main concern is that vehicles within these medications (and some artificial tears and lubricating drops) can potentially be isolated underneath the LASIK flap or bandage contact lens following PRK and not absorbed.

"The joint statement highlights the concerns of some medications designed for increased contact time and the potential for a greater likelihood for adverse events when used immediately prior to or during LASIK or surface ablation with bandage contact lens use," said Joseph Shovlin, OD, of the Northeastern Eye Institute, clinical editor of *Review of Cornea & Contact Lenses*. "A 'polymer package' can potentially be sequestered, especially under a newly created flap or bandage contact lens, and not be absorbed in a timely fashion. Of particular note, this alert includes a number of recently released highly viscous artificial tears that tout an improved contact time and consistent dosing."

The medications listed include:

• *Azasite* (azithromycin 1%, Merck) with a vehicle of polycarbophil, edetate disodium and sodium chloride.

• *Besivance* (besifloxacin 0.6%, Bausch + Lomb) with a vehicle of polycarbophil, edetate disodium and sodium chloride.

• *Restasis* (cyclosporine 0.05%, Allergan) with a vehicle that includes castor oil.

• *Durezol* (difluprednate 0.05%, Alcon) with a vehicle that includes castor oil.

• *Acuvail* (ketorolac 0.45%, Allergan) with a vehicle of carboxymethylcellulose sodium.

• *Lotemax* gel (loteprednol 0.5%, Bausch + Lomb) with a vehicle that includes glycerin, polycarbophil, propylene glycol and tyloxapol.

• *Moxeza* (moxifloxacin 0.5%, Alcon) with a vehicle that includes xanthan gum and tyloxapol.

• *Nevanac* (nepafanac 0.3%, Alcon) with a vehicle that includes mannitol, carbomer 974P, sodium chloride, tyloxapol and edetate disodium.

• *Ilevro* (nepafanac 0.3%, Alcon) with a vehicle that includes propylene glycol, carbomer 974P, guar gum and carboxymethlycellulose sodium.

Any artificial tear or lubricating drop that contains the abovementioned inactive ingredients could also create similar complications when used pre- or intraoperatively in LASIK and PRK.

There have been no documented problems with these medications when used postoperatively or in the FDA-approved solution or suspension formulas without advanced vehicles.

For more information, visit www.ascrs.org.

Review of Cornea & Contact Lenses

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New Software Offers Improved Tear Film Measurements

With FDA clearance, the LipiView v2.0 ocular surface interferometer (TearScience) can now be used to measure absolute thickness (opposed to relative thickness) of the tear film lipid layer in nanometers. The upgraded software also monitors a patient's blinking process during examination. This information allows practitioners to identify patients who are partial blinkers, a condition that may limit lipid production and impact the ocular surface.

LipiView v2.0 software will be available to all new customers; current customers will be upgraded in the second quarter of 2013. For more information, visit www.tearscience.com.

One-Week Disposable Lenses Launched

For patients who are interested in frequent lens replacement but do not want to incur the cost of daily disposables, Hydrogel Vision introduces Icuity H_20, a one-week disposable soft contact lens.

Frequent replacement can help alleviate problems of dryness, discomfort and lens deposits. However, many patients are deterred from switching to daily disposables due to the higher cost. The Icuity H_20 allows for weekly replacements at the same price as the two-week modality.

According to the company, Icuity H_2O is made with hioxiflcon A—a non-ionic ultra hydrating material that retains 99% of its water content throughout the wearing time. The lens is available in median and steep base curves: median +6.00D to -10.00D and steep -0.25D to -10.00D.

For more information, visit www.hydrogelvision.com.

A New Preservative-Free Solution

When it comes to dry eye management, the more tools, the better. Allergan's latest addition to its portfolio, Refresh Optive Advanced Preservative-Free lubricant eye drops, is designed to work on all three layers of the tear film to relieve dry eye symptoms. According to the company, the solution stabilizes the lipid layer to help reduce tear evaporation, hydrates the aqueous layer and provides an advanced lubricating and protective shield to the mucin layer, protecting epithelial cells from hypertonic stress.

Refresh Optive Advanced Preservative-Free delivers <0.1µL of liquid per drop and is available in 30 count single-use vials. For more information, visit www.refreshbrand.com.

Advertiser Index

Editorial

By Joseph P. Shovlin, OD

Is it Time to Expand the FDA Safety Net?

The past decade has highlighted the need to revise solution testing to evaluate safety measures *and* potential hygienic behaviors.

The FDA has recently proposed changes to its guidance document for lens care approval and lens material classification. This has provoked a great deal of discussion about solution testing revisions, such as the addition of *Acanthamoeba* to protocol testing. Will more stringent endpoints with additional testing impact safety without placing a heavy emphasis on human factors testing?

Human Factors Validation

Because the FDA is risk averse and 510(k) submissions do not always typify the real world, human factors validation testing helps satisfy FDA concerns for safety. Looking for risky behavior—in particular, evaluating environmental and situational factors that affect care product performance—seems crucial to help assure safe lens wear. And, we don't have to look too far to see the value in this.

In the past decade, we have seen two solution recalls that highlight the importance of not only evaluating safety measures, but also scrutinizing hygiene practices and patient behaviors. The voluntarily recalled solutions had a low margin for safety when placed under stress, but the recalls were prudent, because better solutions were available at the time.

It is important to note that the solutions recalled were not "unsafe." When used properly, the products were effective for many thousands of patients and did not yield a significant number of adverse events. But the need for ongoing surveillance cannot be reiterated enough; the problems in the solutions described above likely could have been identified earlier if additional measures were in place.

The FDA Guidelines

From 1982 to 1990, the FDA modified its guidelines for contact lens care products at least six times. A short time later the agency issued guidance documents, "Pre-Market Notification 510(k) Guidance Document for Contact Lens Care Products," for soft lenses.[1] Another important milestone, the International Organization for Standardization (ISO), was developed between 1990 and 2003.

However, by most standards, not much has been modified over the past decade. Current testing protocols do not include using a lens or case for the microbial testing regimen. In addition, the library of isolates tested under the current guidance is outdated. For example, the current American Type Culture Collection strain of *Fusarium* does not form a robust biofilm and may not adequately predict disinfection efficacy in the lens storage case today. It seems prudent to select clinical isolates based on virulence, and to manage the testing in such a way as to maintain a wild-type capacity for disease.

Real World Disinfection

In 2009, the FDA consortium on lens care addressed the topic of disinfection. At that meeting, proposals for testing under "real world" conditions—specifically for examining both lenses and their cases—were suggested. In addition, *Acanthamoeba* testing requirements were heartily debated. The conversation addressed several points:

- The necessity for protozoan testing and the most effective methods to do so.
- "Uptake and release" of preservative studies to evaluate the impact on disinfection efficacy.
- Establishing the simulated care scenario using lenses and cases.
- Human factors studies looking at risky behavior (e.g., not rubbing and rinsing, topping off solution, behaviors that promote evaporation, etc.).

Testing under "real world" and extreme climatic conditions seems reasonable. The testing protocol should be structured to be sufficiently sensitive to capture user-related problems.[2,3] High priority tasks or user scenarios, including environmental and situational factors that affect performance, also must be part of the protocol. Most importantly, monitoring usage during the clinical trial, as well as post-marketing surveillance, is a key component in assessing any user-generated issues.[3]

(continued on pg. 8)

By Jason Jedlicka, OD

Small Change, Big Improvement

It may now be time to use larger diameter GP lenses instead of their smaller, corneal counterparts.

The last decade has brought a shift in the thinking of many contact lens practitioners. Ten years ago, gas-permeable lenses that landed beyond the limbus were an uncommonly used, and often unsuccessful, means of correction. Today, those same lenses are the first choice for a majority of GP lens wearers.

Is it time to replace our corneal GP lenses with corneoscleral, mini-scleral and scleral lenses?

A Case Study

RH, a 59-year-old white male, arrived at our office for a comprehensive eye exam and contact lens evaluation. He was referred by his wife, a long-time patient who was fit in 14.0mm corneoscleral lenses a few years prior. She had been so pleased with her lens experience that she recommended RH also be fitted in corneoscleral lenses instead of the toric GP lenses he had worn for the past 30 years.

RH presented wearing his monovision toric GP lenses—right eye for near and left eye for distance. He thought he needed an updated prescription and said that while he tolerated his GP lenses, his eyes were dry and that he used artificial tears a few times each day. His lenses were obtained elsewhere and the parameters were not known.

Visual acuity with his current GP lenses was 20/30 OD at near and 20/20-1 OS at distance. The fit of the lenses was acceptable and an over-refraction revealed mild astigmatism over each lens. The lenses were removed and refraction was calculated: -10.00 +3.75 x 117 OD and -9.75 +2.50 x87 OS, both to 20/20 vision. A slit lamp exam revealed mild conjunctival injection and limbal staining OU. All other exam findings were normal.

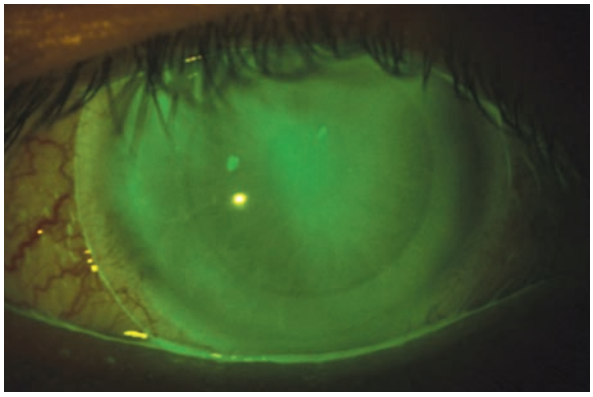
We discussed the options, including staying with his current lenses or perhaps reordering them with a slight update to the prescription to better correct the astigmatism. We also discussed going to a corneoscleral or mini-scleral lens, both with and without a multifocal, as opposed to staying with monovision. Ultimately, RH opted to try the corneoscleral lenses with monovision correction.

A fitting was performed on each eye with the SoClear (Dakota Sciences) standard design lens. After trying a few lenses on each eye, a final order was placed with these parameters: 43.50mm base curve, -7.00D power, 14.2mm diameter, 0.5D steep peripheral curves and 0.33mm minimum center thickness with no fenestration OD; 44.00mm base curve, -7.75D power, 14.2mm diameter, standard peripheral curves and 0.24 minimum center thickness, with no fenestration OS.

RH returned for a dispensing visit three weeks later. The lenses were applied to the eyes and allowed to settle. Acuity measured 20/20 OD at near and 20/30+ 1 OS at distance. An over-refraction of -0.50 OS improved the left eye vision to 20/20 and a new lens was ordered. The fit looked as expected (*figures 1 and 2*). We dispensed the lenses and instructed the patient to begin using the new left lens upon arrival, and to return for a check-up a few weeks later.

RH returned three weeks later for follow-up. He reported improved comfort and night vision over his old GP lenses. His vision with the new lenses was 20/25 at near OD at near and 20/20 OS at distance. An over-refraction demonstrated more plus acceptance for near OD and plano at distance OS. After discussing the option of adjusting the right lens for near at the risk of losing range, RH opted to keep the current specifications.

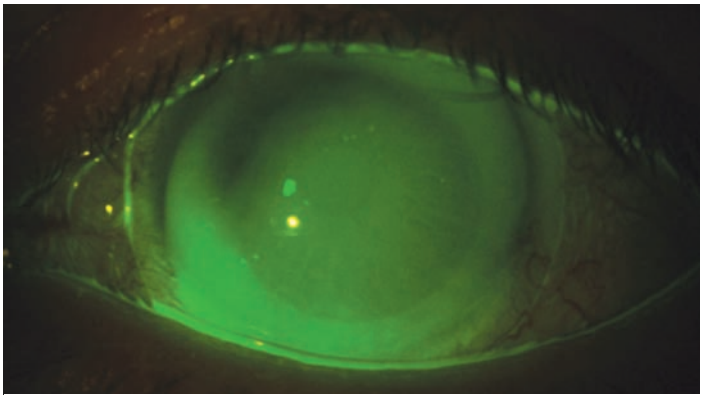
This case highlights the importance of specifying center thickness in our larger diameter lens patients.



1. A SoClear corneoscleral lens OD at the dispensing visit.

Traditionally, the lab determined this parameter. However, patients with higher degrees of astigmatism, particularly when it is regular in nature, will often need lens center thicknesses of 0.30 or greater; this increase in thickness almost never affects comfort, but does aid visual quality. I always specify center thickness on all my corneoscleral and scleral lens orders so that I can optimize vision. In the case of RH, the right eye had more astigmatism, and therefore required a thicker lens to mask that cylinder.

Note: Because the number of practitioners that use these larger diameter designs is still relatively small, happy scleral and corneoscleral wearers (word-of-mouth referrals are key!) will tend to funnel patients your way, further building your specialty practice.



2. A SoClear corneoscleral lens OS at the dispensing visit.

Larger diameter GP lenses can often provide better comfort, more stability and similar visual acuity as their corneal GP counterparts. While not always the solution, the use of corneoscleral, mini-scleral and scleral GP lenses is expected to rise and may eventually become the preferred mode of correction for the majority of individuals using GP lenses. In addition to our irregular cornea patients, we should consider individuals with specific visual demands or corneal configurations for larger diameter GP lenses. RCCL

*(**continued from** **Editorial**, pg. 6)*

Unfortunately, there hasn't been a similar consensus on best testing methods for *Acanthamoeba*; challenges include size, strain(s) to be tested, culturing techniques for growth, cyst stage production (easier to kill when they lose characteristics with passes in sub-cultures), how to measure survivors, protocol for testing solution efficacy in the presence of a lens and case, and whether to measure encystment.[3,4] Remember that cysts, although part of the life cycle, don't cause infection. Trophozoites, however, do.

Mind you, the testing process has served us well and is not entirely broken. But clearly, an overhaul and upgrade is needed. Regulatory mandates that include more stringent endpoints and added testing for protozoa may not, however, be the complete answer. While many experts are uncertain that such testing will significantly impact the rate of rare, non-bacterial infections, the fact that the public has an extremely low tolerance for rare infections makes any preemptive steps that we can take a necessity. We encourage the FDA to place a continued emphasis on human factors testing and analyze the behaviors that can lead to problems in contact lens wear. Appropriate analysis with adequate product labeling and surveillance should be protective.

In addition, human factors testing can be the "safety net" we need to enhance the margin of protection and assure effective lens wear. With these enhanced steps, we'll not only learn what's happening in the lens case, but also perhaps we will find out what's going on in our patients' heads! RCCL

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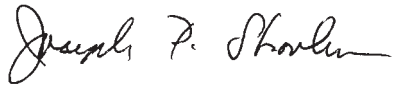

Joseph P. Shovlin, OD, Clinical Editor

By Christine W. Sindt, OD

A New and Improved FDA Regulation

Contact lens solutions will now be subjected to more comprehensive "real world" testing.

With the introduction of any new technology comes the subsequent barrage of complications that we previously never considered. From new materials to new chemical compounds in solutions, the last two decades have brought in the good, and the bad. As a result, in 1997, the FDA—which regulates Class II (moderate risk) medical devices, such as contact lenses—issued a "Premarket notification (510(k)) guidance document for contact lenses," which outlined the necessary information on solution safety and efficacy needed by the FDA to evaluate a solution for market clearance.[1] In addition to working with industry on marketing, the FDA approves all package labeling to inform consumers of the appropriate use and potential risks of lens care products (solution packaging, package insert and solution bottle). As a final step to ensure consumer safety, the FDA maintains a consumer-oriented website to emphasize the importance of proper lens care.[2]

However, since that first guidance document, the contact lens care market has changed. It now is predominantly composed of multipurpose solutions (MPSs). However, MPSs reportedly have a very high rate (79%) of noncompliance to labelled instructions, including topping off.[3]

In 2006 and 2007, there were microbial keratitis outbreaks that were determined to be solution-related. In response, the FDA held a two-day workshop in January 2009 to reach a consensus on the testing methods for evaluating contact lens products against *Acanthamoeba* and to discuss critical elements for a modified disinfection efficacy test to better simulate real world conditions.[4] The FDA decided to sponsor independent research and those findings were published in November 2012.[5]

MPS vs. Silicone Hydrogels

MPSs are a complex mixture of preservatives, disinfectants, surfactants, buffers and other chemicals designed to clean and disinfect a contact lens, while not altering the contact lens and remaining neutral on the eye. The FDA developed classifications of hydrophilic contact lens materials (Group 1 through Group 4) based on iconicity and water content, so that solutions could be systematically tested for lens alterations.

Silicone hydrogel materials have significantly different lens surface characteristics than hydrogel materials, including wettability and deposition of proteins and lipids. These differences in materials could lead to very different lens solution interactions, such as biofilm formation on the lens or lens case, changes in preservative or biocide efficacy, or biocide sequestration. The FDA evaluated these variances and proposed a new material grouping system of silicone hydrogel lenses for solution testing.[6]

Solutions vs. Pathogens

Arguments have been made that the combination of lack of "real world" testing, changes in solutions and lens material, patient noncompliance, and the emergence of new pathogens led to the outbreaks of *Fusarium* (2006) and *Acanthamoeba* (2007), which resulted in the voluntary removal of lens care products from the market. As a result, starting in 2008, the FDA undertook a large-scale review of lens care products and the factors involving these pathogen outbreaks. It was determined that how organisms are cultured and the methods used to encyst the *Acanthamoeba* do affect the outcome of solution testing. Both of these criteria, and the need to address multiple strains, were proposed in the new protocol for testing microbial efficacy.

To support the safe use of lens care products, the FDA has developed a comprehensive research plan to improve testing of contact lenses and solutions. This plan includes evaluating the physiochemical properties of silicone hydrogel lenses, examining the antimicrobial effectiveness of a solution, determining the preservative/biocide depletion in the presence of a contact lens in real world scenarios, and adding *Acanthamoeba* as a test organism.[5]

In addition, the FDA has changed the direct-to-consumer messaging by developing a website, with supporting audio and video, on proper lens care. They also have started increasing the guidance provided to the industry on product labeling, including instructions to remove the "no-rub" from packaging and to provide a timeframe for when to discard open products.[5]

The next few columns will delve into the new FDA guidelines. RCCL

References are available at www.reviewofcontactlenses.com.

By Mile Brujic, OD, and Jason Miller, OD, MBA

Loose Lips Sink Ships

When fitting specialty lenses, patient expectations can make or break the outcome. Choose your words with care.

Thanks to a renewed interest in contact lens research, we are now seeing the unveiling of new several specialty lens options. With advanced technologies that allow an individualized approach, eye care practitioners now have the ability to expand the contact lens population, reaching patients who may have previously been unable to wear lenses. For our current patients, we can provide an optimal wearing experience that minimizes the chances of dropout.

Our patient's expectations, however, can be the difference between success and failure when fitting specialty—particularly astigmatic and multifocal—contact lenses. Careful communication with each patient will orient and clarify expectations and help the experience get off to a good start. By contrast, careless or off-the-cuff explanations that fail to set realistic expectations might torpedo the entire experience.

This column will discuss how to interact with your patients, as well as provide a framework for obtaining information and providing feedback, to lay the groundwork for success.

Pre-Fit Consultation

At the pre-fitting appointment, identify your patient's occupation, hobbies and daily visual requirements. This will help you provide your patient with the most comprehensive information about available options. Use this opportunity to gauge your patient's interest and offer an overview of the expected fitting timeline (e.g., customizing the prescription and fit) and the corresponding fees. Take the time to describe the specialty process of the technology you plan to fit. Collect and record a thorough history—knowing your patient's past lens experience can help you decide what may be a better fit.

As an eye care professional, it is important to maintain a fully operational tool bag; stay abreast of the latest developments in contact lens technology, including specialty toric, multifocal, hybrid, rigid gas-permeable and scleral designs. Present all of these options in a positive way while setting realistic expectations.

Continue the consultation by discussing appropriate visual expectations and stressing the importance of follow-up care. Try to describe the basics of the design, and the anticipated time it would take for the fitting, fabrication, shipping and subsequent progress visits with the new custom-made lenses.

Presbyopia Discussion

When discussing presbyopic contact lens fittings, avoid using the terms *compromised* or *loss of visual clarity* in your communication. Instead, add a positive spin: Describe multifocal lenses as a customized approach to each patient's visual system and daily visual demands. Be upfront about the challenges, and the rewards. Identify stressors, such as the phone book or medicine labels, that likely will be difficult to read, but also explain how these lenses will eliminate their need for reading glasses 90% of the time.

Spend time going over the technology, and explain how the vision design delivers near, intermediate and distance correction simultaneously. The multifocal lenses have more of a gradual change between viewing zones vs. the "jump" between zones that comes with translating designs. When beginning to fit a patient, let them know you may err on the side of better distance vision, but will improve the near area as the fitting process continues.

Explaining Astigmatism

Unfortunately, many patients don't have a solid understanding of what *astigmatism* means. Some even associate the word with a disease. As the eye care practitioner, start by explaining that astigmatism

A Case Study

A 35-year-old female, presented with a history of unsuccessful contact lens wear. She had previously found GP lenses uncomfortable and felt soft, toric contact lenses moved on her eyes too much. Subsequently, she was told that she was not a good candidate for contact lenses. Her prescription was -3.00-3.00x048 OD and -2.75-3.00x131 OS. She was motivated to try switching to lens wear again and wanted to review the available options.

She was diagnostically fit with Duette HD (Synergeyes) lenses. Her initial reaction was positive, and after making an adjustment in the fit and Rx at the follow-up visit, she was very happy with her outcome. She has comparable vision to her glasses and is able to wear her lenses comfortably for nearly 12 hours a day.

is simply a different way of focusing images, and debunk the prevalent misconception that astigmatic patients can't wear contact lenses. Then discuss the latest breakthroughs in technology to best meet their visual needs.

Today's contact lens industry has increased our ability to provide a customized lens for a specific prescription, even for patients with high amounts of astigmatism and oblique astigmatic needs. Toric multifocal or GP lenses are available options for presbyopic patients with astigmatism. Reach out to your lab consultants for advice on these fits.

Hybrid technology is an excellent example of how material science can help those with unique visual needs comfortably wear contact lenses. For astigmatic patients, these designs provide better visual acuity with comfort comparable to soft contact lenses. A fitting set is great, but can be ordered empirically.

The biggest challenge for eye care practitioners is deciding which technology will work best. When talking your patients, be sure to reiterate that if one lens is not the best fit, you will try something else. Outline how you gauge success, thank them in advance for their patience and charge them appropriately for your time and expertise. Remember to be flexible and commit the time initially to make slight adjustments as needed. Even a small change in a prescription can make a large improvement in your patient's visual abilities.

Our patient's expectations can be the difference between success and failure when fitting specialty contact lenses.

Several soft, RGP and hybrid contact lens options available today may provide better optics and comfort to our patients, allowing us to reach previously untapped demographics. This, in turn, will translate to new referrals and increased profitability for your practice. In order to successfully incorporate these specialized contact lens services into your practice, education is key. Understand the different materials and designs on the market and review the recommended fitting guides to best address your patient's needs. RCCL


By Tammy P. Than, OD, MS, and Elyse L. Chaglasian, OD

A Supplemental Treatment

Adding a pill or two of essential fatty acids to your patient's diet may help you more easily manage ocular surface disease.

Managing ocular surface disease in contact lens patients poses additional challenges for the eye care practitioner. For example, we must also factor in lens-solution compatibility and preservative-related reactions. An often overlooked, but potentially beneficial, means of managing these patients is through nutritional supplements.

While the use of supplements is frequently mentioned in anecdotal reports, recent studies have provided evidence-based literature to help guide us in the use of essential fatty acids in the management of ocular surface disease. While there are still some unanswered questions and larger, additional studies are needed, this column will offer an understanding of the research to date.

Fatty Acids

Essential fatty acids (EFAs) are polyunsaturated fats with multiple double bonds in the carbon chain. These EFAs are necessary for development, for certain biological processes and cannot be synthesized by the body. Linoleic acid (LA) and alpha-linoleic acid (ALA) are the shortest chain EFAs and once in the liver are converted to longer-chain, polyunsaturated fatty acids.

Omega-3 (n-3) and omega-6 (n-6) are fatty acids and are precursors for the production of eicosanoids—prostaglandins, thromboxanes and leukotrienes—that regulate inflammatory processes. Some of these compounds possess proinflammatory effects and others manifest as anti-inflammatory.[1,2]

Examples of n-3 fatty acids are ALA, docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA). Food sources high in n-3s include cold water, dark fish (e.g. salmon, sardines, tuna, mackerel and herring), flaxseed oil and walnuts.[1] These fatty acids tend to be anti-inflammatory.

Some n-6 fatty acids are healthy while others are not. Examples of n-6 fatty acids are LA, gamma-linolenic acid (GLA), dihomo-gamma-linolenic acid (DGLA) and arachidonic acid (AA). Sources of n-6 include soybean oil, palm oil, canola oil, sunflower oil, poultry, nuts, eggs and cereals.[1,2]

Although it may seem counter-intuitive, the use of certain n-6 compounds appear to have anti-inflammatory effects. In particular, GLA is converted to DGLA—which increases the synthesis of 1-series prostaglandins (e.g. PGE_1) that have a negative feedback role in inflammation and also minimizes the production of PGE_2 and 4-series leukotrienes, which are inflammatory.[3] Consumption of evening primrose oil or borage oil are good sources of LA and GLA, which are "good" n-6s.

EPA (n-3) and AA (n-6) compete for cyclooxygenase and 5-lipoxygenase enzymes. The anti-inflammatory effects of EPA are due to the synthesis of PGE_3 and leukotriene B_5. These prevent the conversion of AA to inflammatory mediators such as PGE_2 and leukotriene B_4.[4] Therefore, a diet high in EPA can reduce the production of AA by competitive enzyme inhibition. Altering the consumption of fatty acids either by diet or with supplementation can alter the ratio and the inflammatory effects.

Consumption Guidelines

The current thinking is that the dietary intake ratio of n-6 to n-3 should be between 1:1 and 4:1. The American diet is reported to be as high as 15:1 to 30:1, which may correlate with the high rates of heart disease, autoimmune conditions and cancers prevalent in Western populations.[1,2]

The benefits of a healthy n-6:n-3 ratio relative to ocular surface disease are multifactorial—these fatty acids appear to enhance the lipid layer by dcreasing evaporation, increasing tear production and reducing the inflammatory component of dry eye.

The Research

Several studies have evaluated n-3s, n-6s or a combination of these. GLA and LA (both n-6s) have been shown to improve symptoms in conditions associated with inflammation, such as rheumatoid arthritis and dry eye.[3,5] In a study conducted by Karolien H. Kokke, MSc, MCOptom, of Sussex Eye Hospital, United Kingdom, and colleagues, the use of evening primrose oil (a source of n-6s) alleviated symptoms and improved comfort in contact lens associated dry eye. An increase in tear production was also noted.[3]

A study by Antonio Pinna, MD, of the Institute of Ophthalmology at the University of Sassari, Italy, and colleagues showed that

increasing n-6, along with lid hygiene, improved symptoms and inflammation associated with meibomian gland dysfunction. The authors suggested that the EFAs helped normalize the melting point of the meibomian gland secretions.[6]

Biljana Miljanovíc, MD, MPH, MSc, has reported that when n-6 to n-3 ratio exceeds 15:1, the likelihood of dry eye symptoms increases.[3] Data from the Women's Health Study, which surveyed 32,000 women, noted that both low intake of n-3 and high n-6:n-3 ratio were associated with an increased risk of dry eye.[3]

A study by Mitchell A. Jackson, MD, director of Jacksoneye in Lake Villa, Ill., and colleagues showed that using Tears Again Hydrate (OcuSoft) as a n-3 and n-6 prescription supplement improved tear break-up time and patient symptoms.[7] Using a dietary supplement of n-3, Jadwiga Cristina Wojtowicz, MD, and colleagues reported no change in meibum composition, but noted that tear production did increase.[8]

A multi-center study by Françoise Bignole-Baudouin, MD, PhD, and colleagues at the Institut de La Vision in Paris, demonstrated that supplementing with EFAs reduced the HLA-DR conjunctival inflammatory marker.[9] While a few studies did not find any significant improvement in clinical findings with the addition of nutritional supplements, most published studies demonstrate improvements subjectively and/or objectively.[1-3,9,10]

On the Shelf

There are hundreds of commercially available EFA nutritional supplements on the market today. Most are not FDA-regulated, so selecting an appropriate supplement can be challenging. Flaxseed is comprised of approximately 50% ALA, but only a very small percentage is transformed to an anti-inflammatory compound. Fish oil capsules usually contain approximately 300mg of EPA/DHA per 1,000mg capsule but this varies greatly; products have also been found to over-report the amount of EPA/DHA. Prescription-only Lovaza (GlaxoSmithKline), which is labeled for the treatment of severe hypertriglyceridemia (≥ 500mg/dL), has 465mg of EPA and 375mg of DHA per 1,000mg capsule.

The current thinking is that the dietary intake ratio of n-6 to n-3 should be between 1:1 and 4:1. The American diet is reported to be as high as 15:1 to 30:1.

All of the above supplements are merely a source of n-3. From the limited studies and understanding of the importance of certain n-6s, a supplement that provides both n-3 and n-6 might be the best option to recommend to patients to manage dry eye symptoms. There are many of these products available, but some examples include Tears Again Hydrate, TheraTears Nutrition (Advanced Vision Research), HydroEye (ScienceBased Health), BioTears (Biosyntrx) and Dry Eye Relief (VisiVite). Side effects are minimal but some patients may complain of some stomach upset and belching. A consultation with a patient's prescribing physician is warranted prior to recommending these supplements to patients on blood thinners.

Taking a capsule or two daily to manage dry eye symptoms is an often very effective and a convenient management strategy for patients, especially those wearing contact lenses. RCCL

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Review of Cornea & Contact Lenses

A Lens Fit for Dry Eye

Here are some clinical pearls to help treat and fit contact lens patients who present with dry eye.

By Lakshman N. Subbaraman, PhD, BSOptom, MSc, and Sruthi Srinivasan, PhD, BSOptom

Almost 50% to 80% of contact lens wearers experience symptoms of dry eye.[1] Contact lens-related dry eye (CLDE) may be reported as dryness, discomfort, gritty sensation, irritation, stinging, burning or foreign body sensation.[2,3] Discontinuations and dropouts from lens wear are primarily due to symptoms of discomfort and dryness.

CLDE is complex and multifactorial. Increased tear evaporation, altered tear osmolarity, poor or low tear film quality and quantity, oxygen deprivation, lens deposits, reactions to lens care solutions and non-wetting surfaces are some of the factors that exacerbate dry eye in contact lens wearers. Environmental components, allergies and lid disease can also influence this condition.

This article provides an overview of the factors that influence CLDE and outlines some strategies for effective treatment.

Materials

Clinicians should start by determining which time of day is most problematic for the patient who complains of CLDE. Symptoms that develop two to three hours into lens wear are normally indicative of solution toxicity. On the other hand, end-of-day dryness may be due to lack of lens surface wetting or other material-related factors.

The FDA classifies commercially available hydrogel contact lens materials into four groups, depending upon their charge and water content: non-ionic, low water content (Group I); non-ionic, high water content (Group II); ionic, low water content (Group III); and ionic, high water content (Group IV). This material classification seems to be a very strong predictor of CLDE.

• ***Deposition.*** Hydrogel contact lenses absorb components from the tear film, particularly proteins, lipids and mucins.[4-7] Deposits are associated with diminished visual acuity, dryness and discomfort, and lid-related inflammatory changes.[8-13]

High water content materials have been associated with significant tear

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film deposition.[9,14-16] In particular, Group II lenses are prone to lipid deposition whereas Group IV lenses have been shown to attract more protein than lipids.[6,17] Further, once tear proteins (such as lysozyme) firmly adsorb onto contact lens materials, the protein undergoes conformational changes and denaturation.[7,15,18,19] Protein denaturation is closely linked to inflammatory conditions, such as papillary conjunctivitis, and can also impact subjective comfort.[11-13,20,21]

Practitioners should advise their patients to maintain a clean and deposit-free lens surface, as well as review appropriate lens replacement schedules. Practitioners should also recommend that their patients rehydrate the lenses with rewetting drops since proteins exposed to hydrophobic surfaces are more likely to denature, which could potentially result in reduced comfort. Heavy lipid depositors should be advised to use a separate surfactant cleaner.

• ***Wettability.*** Deposition of tear film-derived material reduces wettability due to denatured protein and increased lipid deposition.[17,22,23] This produces areas of hydrophobicity, resulting in further deposition and comfort problems. If patients do exhibit reductions in wettability, changing to another lens material will likely have a minimal impact. Such patients are best managed by switching to lenses that are replaced more frequently, such as daily disposable lenses, or by prescribing rewetting drops that contain surfactants.[24]

• ***Water content and ionicity.*** Non-ionic, high water content (Group II) and ionic, high water content (Group IV) contact lens wearers have a two to three times greater likelihood of experiencing dry eye than individuals wearing Group I lenses.[25] Further, Group II lens materials are more commonly

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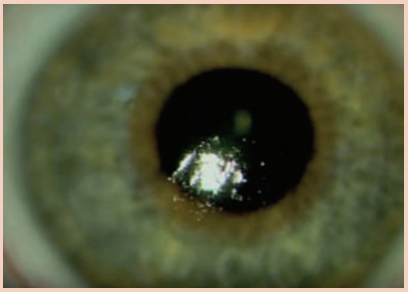

1. Contact lens showing poor wettability.

associated with dry eye than the Group IV lens materials.[25] This could be because the polar head groups associated with the tear film lipid molecules may be attracted to higher water content lens materials, which would leave their non-polar tails away from the surface of the lens and potentially lead to evaporation and/or dewetting. Patients who wore low water content lenses and maintained their hydration generally reported that their eyes "never felt dry" during lens wear.[26] Thus, evidence to date suggests that patients wearing lower water content contact lenses are less likely to complain of CLDE.

• ***Dehydration.*** Dehydration is influenced by several factors, including the surrounding environment, water content, water binding properties, thickness and wearing period.[30-38] Dryness symptoms occur more frequently in soft lens wearers during open-eye wear, when conditions are favorable for greater dehydration.[27] Previous studies have shown that wearing thin, high water content lenses can result in increased epithelial staining due to pervaporation. Pervaporation is a process in which a permeate passes through a membrane and subsequent evaporation in the vapor phase.[28,30] Factors that explain dehydration-induced discomfort include increased lid to lens interaction, changes in lens surface wettability or lens fit, and the development of epithelial staining due to pervaporation and subsequent desiccation.[28-30]

Conventional hydrogel material dehydrates more than silicone hydrogel lens materials.[33,34] Remember, dehydration can affect the fit of a hydrogel lens by both altering the lens parameters and lowering the oxygen transmissibility.[39]

Clinicians must examine the patient for corneal staining after lens removal. The dye of choice in most clinical practices globally is sodium fluorescein. This dye aids in highlighting the extent of cellular damage/exposure of epithelial cells by staining in the form of punctate or coalescent areas. The use of a yellow barrier filter, in addition to cobalt blue excitation filter, is essential to visualize subtle changes. Examine the location of staining (i.e., mid-inferior smile staining patterns), advise proper blinking habits for patients with incomplete blinks and

A Checklist for Your Patient Visit

• Start by collecting a detailed medical history to understand the patient's general health and corresponding treatments. Medications that cause ocular surface dryness (e.g., oral antihistamines, anticholinergics, antihypertensives, cardiac antiarrhythmics, antidepressants and oral contraceptives) should be minimized.

• Confirm that you are not dealing with a masquerading disease (e.g., conjunctivochalasis, Sjögren's, etc).

• An inappropriate lens fit may cause symptoms that can be misinterpreted as dry eye. Carefully examine the fit, centration and movement of the lenses. Measure the iris diameter and check the lens and lid position. Remember to allow the lenses to settle on the eye before judging the fit.

• Finally, advise your patient that alcohol and smoking will worsen dry eye symptoms during contact lens wear.

prescribe artificial tear supplements if necessary.

• ***Silicone hydrogel.*** Several studies have shown that silicone hydrogel lens wearers reported reduced dryness and end-of-day discomfort compared to hydrogel contact lens patients.[40-42] Silicone hydrogel lens wearers also reported better comfort after napping or sleeping, and in dry air or smoky environments because silicone hydrogel lens materials are less prone to evaporation (possibly due to their lower water content) and absorb fewer airborne pollutants than lenses with higher water content.[40,43-46]

Clinicians should consider refitting the patient with a high-Dk lens if oxygen deficiency is suspected. Practitioners should be careful when using lenses with an increased modulus of elasticity or poor surface wettability as they may cause other conditions, including contact lens-associated papillary conjunctivitis.

Environment

In dry and low-humidity environments, such as artificially heated rooms or during the winter months, quicker and greater lens dehydration likely exacerbate dryness in existing patients or induce symptoms in otherwise asymptomatic patients. Those who complain of CLDE due to such environmental conditions would benefit by rehydrating their lenses with rewetting drops.

Lens Care

• ***Solutions.*** Hydrogen peroxide solutions are considered the gold standard for disinfecting contact lenses. However, when residual peroxide is present on the lenses in sufficiently high concentrations, it can be toxic to the cornea and can cause discomfort. When peroxide-based systems are used at the right concentration, they can provide improved comfort in contact lens wearers.[47,48]

Over the last few years, several novel components have been added to multipurpose solutions, such as surfactants or ocular demulcents, to improve comfort, enhance water retention and improve surface wetting properties of contact lenses.

Clinicians should examine the lens and corneal surface carefully, ensure the appropriate cleaning solution is being used and check for patient compliance. Examine corneal staining to check if solution induced-corneal staining (SICS) is present. If SICS exists, advise appropriate lens-solution combinations or switch to daily disposables.

• ***Rewetting drops.*** Rewetting (or comfort) drops can be used to alleviate discomfort that is caused by dryness. Although they provide temporary relief from these symptoms, there is currently no rewetting drop that can provide sustained comfort and relief from dry eye symptoms for the length of an entire wearing day. The drops drain through the patient's nasolacrimal duct quickly after instillation, with the remainder absorbed by the cornea, conjunctiva and nasal mucosa. With at least 90% loss in each application, rewetting drops have to be re-instilled frequently throughout the day to provide effective comfort.[49]

Instilling rewetting drops in the eye prior to lens wear may increase the hours of comfortable wear time. Remember, methylcellulose-containing drops instilled upon lens insertion will neutralize the effects of the preservative on the ocular surface.[50] Preservative-free rewetting drops will be beneficial for patients with sensitive eyes. The use of lubricant drops prior to lens wear and after lens removal may increase the hours of comfortable wear time.[50]

Lid Disease

Meibomian gland dysfunction (MGD) is one of the major causes

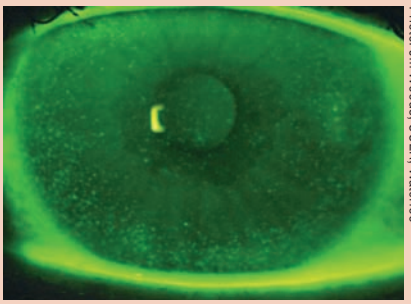

Photo: Jill Woods, CCLR, Waterloo

2. Solution induced corneal staining (SICS).

of evaporative dry eye and often is under-diagnosed by clinicians. Evaluation of the eyelids, meibomian gland orifices, the ocular surface and tear film (tear break-up time, tear meniscus height, debris in tears and Schirmer test) are necessary to administer appropriate treatment.

The novel LipiFlow device (TearScience) is a thermal pulsation system believed to effectively relieve the meibomian gland blockage. This tool applies a controlled amount of heat and massage to the eyelids, treating the upper and lower lids simultaneously. LipiView (TearScience) is an interferometer to evaluate lipid layer thickness. It is valuable to obtain the lipid layer thickness using LipiView before and after the treatment of MGD with the LipiFlow.

Based on the evaluation, interventions such as lid hygiene techniques (lid scrubs and warm compresses), nutraceuticals (omega-3 fatty acids), rewetting drops/artificial tears, and topical cyclosporine or doxycycline for dry eye and severe MGD may be required.

Because CLDE cannot easily be traced to one cause, preventing contact lens dropouts can be quite a challenge with patients suffering from this condition. Several factors, such as lens material and solutions, can play a role in exacerbating or improving dry eye symptoms. Clinicians should stay abreast of

the latest research and developments to identify underlying causes of this condition and, ultimately, better treat their patients. RCCL

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CE TEST

1. The primary reason for contact lens dropout and discontinuation is:

a. Burning.
b. Foreign body sensation.
c. Discomfort and dryness.
d. Itching.

2. Symptoms that develop two to three hours into lens wear normally are indicative of:

a. Contact lens-related dry eye (CLDE) secondary to contact lens material properties.
b. Solution toxicity.
c. CLDE secondary to meibomian gland dysfunction (MGD).
d. Vitamin A deficiency.

3. The FDA Group IV contact lens materials are known to deposit significantly higher

amounts of:
a. Lipids.
b. Proteins.
c. Cosmetics.
d. Bacteria.

4. Subtle changes in corneal staining can be best visualized using a slit lamp under:
a. White light.
b. White light with a yellow barrier filter.
c. Cobalt blue excitation filter.
d. Cobalt blue excitation filter with a yellow barrier filter.

5. Which statement about silicone hydrogel (SiHy) contact lenses is NOT accurate?
a. Most currently available SiHy lenses have low water content.
b. When compared to conventional hydrogel lens wearers, SiHy lens wearers reported better comfort after napping or sleeping.
c. SiHy lens materials are more prone to evaporation in typical or dry environments.
d. SiHy lens materials are less prone to evaporation in typical or dry environments.

6. Patients who attribute CLDE to environmental conditions would have maximum symptomatic relief by:
a. Switching to high water content lenses.
b. Using peroxide-based lens solutions.
c. Rehydrating their lenses with rewetting drops.
d. Wearing sunglasses.

7. Which statement is FALSE?
a. Rewetting drops should be instilled frequently throughout the day to provide effective symptomatic relief.
b. Rewetting drops have great retention time on the ocular surface.
c. Instilling rewetting drops in the eye prior to lens wear may increase the hours of comfortable wear time.
d. Rewetting drops drain through the patient's nasolacrimal duct quickly after instillation.

8. MGD is one of the major causes of:
a. Aqueous-deficient dry eye.
b. Sjögren's syndrome dry eye.
c. Non-Sjögren's syndrome dry eye.
d. Evaporative dry eye.

9. A patient presents with CLDE and you diagnose MGD. What is the first line of treatment?
a. Switching to a high Dk lens material.
b. Switching to daily disposables.
c. Artificial tears.
d. Lid scrubs and warm compresses.

10. Which of the following conditions exacerbate symptoms of dry eye?
a. Smoking.
b. Alcohol consumption.
c. Oral antihistamine use.
d. All of the above.

Examination Answer Sheet

Valid for credit through March 1, 2016

This exam can be taken online at www.reviewofcontactlenses.com.
Upon passing the exam, you can view your results immediately.
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A Lens Fit for Dry Eye

Directions: Select one answer for each question in the exam and completely darken the appropriate circle. A minimum score of 70% is required to earn credit.

Mail to: Jobson - Optometric CE, PO Box 488, Canal Street Station, New York, NY 10013

Payment: Remit $20 with this exam. Make check payable to Jobson Medical Information LLC.

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1. Ⓐ Ⓑ Ⓒ Ⓓ
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8. Ⓐ Ⓑ Ⓒ Ⓓ
9. Ⓐ Ⓑ Ⓒ Ⓓ
10. Ⓐ Ⓑ Ⓒ Ⓓ

1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor

Rate the effectiveness of how well the activity:

11. Met the goal statement: ① ② ③ ④ ⑤
12. Related to your practice needs: ① ② ③ ④ ⑤
13. Will help you improve patient care: ① ② ③ ④ ⑤
14. Avoided commercial bias/influence: ① ② ③ ④ ⑤
15. How would you rate the overall quality of the material presented? ① ② ③ ④ ⑤
16. Your knowledge of the subject was increased:
◯ Greatly ◯ Somewhat ◯ Little
17. The difficulty of the course was:
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The following is your: ☐ Home Address ☐ Business Address

Business Name ____

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By submitting this answer sheet, I certify that I have read the lesson in its entirety and completed the self-assessment exam personally based on the material presented. I have not obtained the answers to this exam by any fraudulent or improper means.

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Lesson 108933 RO-RCCL-0313

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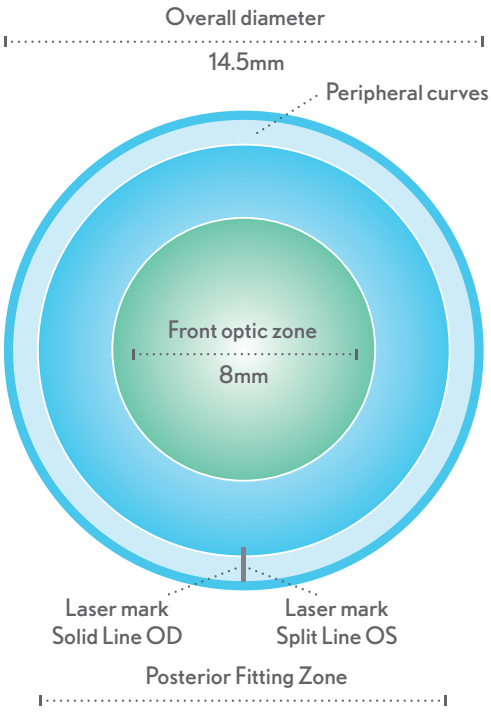

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Keratoconus Coding: The Battle of the Bulge

Insurance constraints complicate the management of an already tricky disease. Here's a winning strategy—but you have to talk to your patients.

By John Rumpakis, OD, MBA

Unlike many diseases, the challenges of keratoconus do not end when your treatment begins. While a recognized and legitimate medical condition and medical diagnosis, keratoconus poses a unique challenge in the insurance reimbursement arena.

Think about it this way: Medical carriers cover medical conditions; therefore, the professional service aspect of managing the keratoconic patient may be covered by that entity. However, the treatment aspect of keratoconus involves contact lenses, which—despite being an approved medical device by the FDA—are generally not covered by the patient's medical insurance. If the patient doesn't have a specific refractive insurance plan with generous material benefits, the largest portion of significant cost is not covered.

This poses considerable challenges for the average optometrist who is diagnosing and treating keratoconus patients. Why? The dilemma here is mostly psychological. Optometrists typically don't want the patient to have to pay for anything out-of-pocket and tend to want to treat things that have some insurance coverage.

That being said, the smartest practitioners (the ones who actually follow the rules that are in place) have figured out that keratoconus is analogous to orthodontics—patients have a condition that requires treatment and may have limited or no coverage for its treatment and the patient is required to pay the full dollar amount out-of-pocket. This means no reductions, no insurance maximum allowances and no write-offs. Admittedly, this isn't easy to do, since most practitioners have a hard time reconciling profitability for their practice with the expense on the patient. But remember: if they don't pay you, they'll pay someone else.

Dr. Rumpakis is President of PRMI, a healthcare-based consulting firm. He is a nationally known expert in the area of medical coding and compliance and is the founder of ReimbursementPLUS.com, an industry leading cloud-based CPT Data & Information Service. He can be reached at John@PRMI.com.

-52 Reduced Services

Under certain circumstances, a service or procedure is partially reduced or eliminated at the physician's discretion. Under these circumstances, the service provided can be identified by its usual procedure number and the addition of -52 modifier that signifies that the service is reduced. This provides a means of reporting reduced services without disturbing the identification of the basic service.

Note: In 2012, the CPT specifically designated -52 as the modifier to use when fitting a unilateral traditional lens in place of –RT or –LT.

Simply put, although we clearly recognize keratoconus as a medical condition, many medical carriers and refractive carriers don't recognize it as a covered service or condition. (One notable exception is VSP, who actually has, in my opinion, a fairly generous keratoconus benefit.)

This brings up a critical concept: You cannot create coverage for a patient where no coverage exists. If the patient doesn't have coverage (benefits) for keratoconus treatment, they simply will have to pay out-of-pocket; while unfortunate for the patient, this translates to greater profitability for your practice.

New Codes, New Coverage?

Keratoconus patients often present optometrists with several challenges. First, it can be very difficult to provide clear, comfortable vision without investing considerable chair time. The next greatest hurdle is receiving proper reimbursement for that time you invested.

Let's look at how to navigate these obstacles together to help you offer the highest level of clinical services to your patients while making sure that you are 100% compliant with the current rules.

Initial Exam and Diagnosis

The diagnosis of keratoconus is typically suspected or made during your general examination, and then confirmed by corneal topography and/or pachymetry. Medical carriers vary considerably in their reimbursement policies for topography reimbursement. Unfortunately, many won't pay for the procedure, regardless of your appeals. It is important that you know your carrier's policies and use an ABN form appropriately to ensure that you are still getting paid for this service (more on that later).

Once you confirm the diagnosis and counsel the patient, finalize your decision to fit the patient in contact lenses. Make sure to record this as an order in your patient's medical records. This compliance step is critical to establishing the medical necessity for the subsequent fitting and management office visits.

The initial visit—a general exam—is generally billed either to the patient or the refractive carrier. Keep in mind that it is the chief complaint that drives the responsible party, not the ultimate diagnosis. Also remember that, for patients who have refractive as well as medical benefits, we have to adhere to the coordination of benefits requirements specific to the individual policy. This means that often the refractive carrier will be covering the 920X4 and 92015. Unfortunately, this is the first step where many offices fail to bill correctly and try to improperly bill the medical carrier because of the keratoconus diagnosis.

The First Fitting

Despite the efforts of many, the code for bandage lens fitting and supply (92070) was a poor choice for keratoconus, and in fact was eliminated by the CPT in January 2012. It is no longer a code that is recognized by either medical or refractive carriers.

Instead, a new CPT code developed in January 2012 was specifically designed for the fitting of a keratoconus patient. Note: The CPT is very specific about how a practitioner is to use the code and how to bill for the initial fitting and all subsequent office visits. This code is different than the CPT code used for traditional non-keratoconic fits.

• ***CPT Code 92310***: For a traditional contact lens fit, this code correlates with a "prescription of optical and physical characteristics of and fitting of a contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia." This code encompasses all services that are provided until you write a contact lens prescription. It is charged at each visit during which a new lens is placed on a patient's eye or a fit is altered, but does not include contact lens follow-up care after the lenses have been dispensed.

Keep in mind that the modifier (-52) should be used if fitting only one eye (*see "-52 Reduced Services" above*). This is a change from 2011.

• ***CPT Code 92072***: This code is used for the fitting of a contact lens for the management of keratoconus. Using code 92072 covers the initial fitting examination for professional services only. In mid-2012, this code was changed from a unilateral code to a bilateral code, so you get paid once for fitting both eyes.

All subsequent office visits are to be billed using the appropriate level evaluation and management codes 9921X or the appropriate level ophthalmic codes 9201X. Please report materials (lenses) in addition to this code using either 99070 or the appropriate HCPCS Level II material code (such as V2513 or V2531) for gas-permeable extended wear lens.

Sample Billing Forms and the Appropriate Codes

Diagnosis: 367.1, Myopia

	Dates of Service		Place of Service	Type of Service	Procedures, Services, Supplies (Explain Unusual Circumstances)	Diagnosis Code	Charges	Days or Units
	From MM/DD/YY	To MM/DD/YY			CPT-HCPCS - Modifier			
1	1/17/2013		11		92004	1	$151.61	1
2	1/17/2013		11		92015	1	$19.76	1

Diagnosis: 371.60, Keratoconus

	Dates of Service		Place of Service	Type of Service	Procedures, Services, Supplies (Explain Unusual Circumstances)	Diagnosis Code	Charges	Days or Units
	From MM/DD/YY	To MM/DD/YY			CPT-HCPCS - Modifier			
1	1/31/2013		11		92072	1	$128.08	1
2	1/31/2013		11		92025	1	$38.50	1
3	1/31/2013		11		V2513	1	$800.00	2

Diagnosis: 371.60, Keratoconus

	Dates of Service		Place of Service	Type of Service	Procedures, Services, Supplies (Explain Unusual Circumstances)	Diagnosis Code	Charges	Days or Units
	From MM/DD/YY	To MM/DD/YY			CPT-HCPCS - Modifier			
1	2/6/2013		11		99213	1	$72.91	1

Diagnosis: 371.60, Keratoconus

	Dates of Service		Place of Service	Type of Service	Procedures, Services, Supplies (Explain Unusual Circumstances)	Diagnosis Code	Charges	Days or Units
	From MM/DD/YY	To MM/DD/YY			CPT-HCPCS - Modifier			
1	4/6/2013		11		99213	1	$72.91	1

Each and every visit should be properly documented in the medical record with your patient's reason for visit and subsequent treatment plan. Always remember that the record should reflect your thoughts and impressions as well as physical findings. Again, if the patient doesn't have coverage for the materials, they will have to pay out-of-pocket for them.

Refitting and Monitoring

CPT contact lens services state: "The fitting of contact lens includes instruction and training of the wearer and incidental revision of the lens during the training period." If complications arise, the most appropriate way to bill for office visits is using the established patient ophthalmologic (9201X) or evaluation and management (9921X) codes.

When billing the medical carrier for these office visits, keep in mind the need to use the appropriate diagnosis for the corneal condition you are monitoring. Note: You're not performing a contact lens follow-up; the reason for the office visit is to monitor the corneal condition, not the lens!

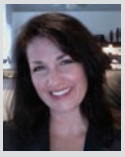
To summarize, never consider a fitting fee to be a global, year-long obligation to provide unlimited service at no charge. If you refit a patient, it is not just an "incidental revision of the contact lens;" according to the CPT, you should refit the patient using a 9201X or 9921X code, along with the appropriate materials V-code for lens supply.

And a final word of advice: Don't make the mistake of discounting your services if the patient has to pay directly. Bill all parties equally and without bias. RCCL

Dry Eye Treatment: The Unusual Suspects

New breakthroughs in OTC drops, anti-inflammatory therapies and nutrition may help practitioners better treat recalcitrant dry eye.

By Kimberly Reed, OD



Dr. Reed is an associate professor at Nova Southeastern University College of Optometry in Fort Lauderdale, FL. She teaches and writes extensively about ocular disease, ocular pharmacology, and nutrition.

Complaints against repeat offender dry eye syndrome, otherwise known by the alias ocular surface disease (OSD), keep coming into our optometric practices at an alarming rate. Today, OSD is estimated to be prevalent in 6% to 20% of the adult population—with some subgroups reporting much higher levels.[1-4] And for most patients, OSD has a measurably negative impact on quality of life.[5]

Upon further investigation, we find that the treatment and management of OSD signs and symptoms often is unsatisfactory, especially with conventional therapy—e.g., tear supplementation and preservation. The alternative: More contemporary measures, such as anti-inflammatory therapies, nutritional supplementation and autologous serum eye drops, may show promise.

Target Inflammation

Anti-inflammatory therapies have become increasingly popular in first-line OSD treatment, particularly as our understanding of the significance of inflammation's role in OSD evolves.[6,7] A typical treatment regimen includes artificial tear supplementation, a several-week course of a topical steroid (dosed QID the first week to month, and then tapered to BID for up to two months)—a site-specific steroid like loteprednol 0.2% or 0.5% is ideal for this therapy—and a long-term course of twice-daily cyclosporine. Although generally considered an effective therapy, drawbacks to this approach include its relatively high cost, the risk of side effects from topical steroid use such as potential increased IOP, depressed immune system and delay in corneal wound healing, as well as complaints of stinging upon instillation of cyclosporine.[6,8] While cyclosporine is FDA-approved for the treatment of dry eye caused by inflammation, the use of topical steroids for the treatment of dry eye is still considered off-label.

Nutritional Support

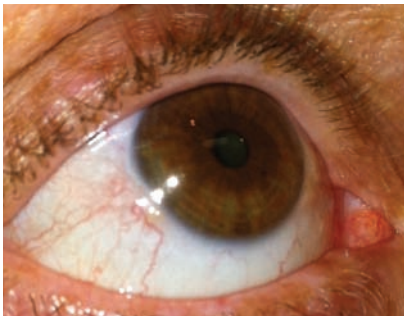
The role of nutritional supplementation, particularly omega-3 fatty acids, is well-established and becoming mainstream in optometric practices (*see "A Supplemental Treatment," page 12*). However, practitioners

stumble in building awareness of the potential benefits of omega-3-containing foods and supplements in their practices. Why? Many optometrists feel that they lack the depth of knowledge to make informed recommendations to their patients; others believe that there isn't enough time in a routine eye exam to allow for nutritional counseling. It doesn't help that the literature, while rich in quantity, is often contradictory regarding intake recommendations.

Before making any firm recommendations, it's critical to understand your patient's current food and supplement consumption. For example, an easy way to calculate omega-3 fatty acid intake is to ask how often your patient eats fish that is broiled, baked or grilled. The key is in the type of fish, as well as its preparation. Fried fish sticks do more harm than good, while grilled salmon is a nutritional winner. Patients who eat healthy fish three or more times per week are less likely to even have dry eye. For patients who eat fish that frequently, remember to recommend a lower supplemental intake than for those who rarely, if ever, eat healthy fish.

Initial supplementation should range from 1500mg and 3000mg per day, depending on fish intake, body weight (heavier patients should take a bit more than leaner patients), presence of other systemic diseases (hypertension, diabetes, hypercholesterolemia, hypertriglyceridemia and depression can benefit from higher intakes) and other lifestyle factors. While some experts may suggest lower (as low as 600mg per day) or even much higher (as high as 6,000mg per day) levels, the 1,500mg to 3,000mg is unlikely to yield adverse systemic side effects.[9,10]

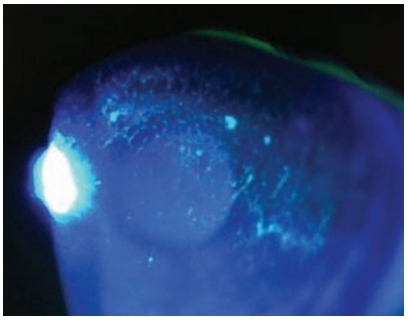
Further, this intake range refers specifically to the supplement's sum of EPA and DHA. These values usually are included near the bottom of the label, if they are included at all. (Note: Think twice before recommending any supplements without full nutritional labeling.) Ideally, the total amount of EPA+DHA shouldn't be less than half of the total omega-3 fatty acids; most of the high-quality supplements have 75% to 80% or more EPA+DHA. If OSD is the only ailment being addressed with omega-3 fatty acid supplementation, and symptoms have improved, the intake can be reduced to the range of 1,000mg to 1,500mg (EPA+DHA) for maintenance therapy.[8,9]



1. Severe dry eye can result in corneal epithelial disruption. Autologous serum preparations have been shown to restore corneal structural damage.

Biologic Therapeutics

First introduced in the late 1980s, biologic therapeutics—products derived from the patient's own whole blood (also known as autologous serum eye drops or platelet-rich plasma) are relatively new treatments for OSD.[7,11]



2. Patients with mild to moderate dry eye usually have mild injection and a tear film meniscus less than 0.5mm in height.

To create autologous serum drops, a patient's blood is drawn, allowed to clot and then centrifuged to allow separation of serum from the whole blood sample. The serum is then diluted with saline or another appropriate product, filtered or sterilized, and placed into droppers to be used up to eight times a day.[12] One session typically yields 100ml of blood, 30ml to 35ml of serum, and approximately a three-months supply of eye drops that are dosed six to eight times per day.

Serum eye drops must be kept frozen until needed, and any remaining drops must be discarded at the end of the day of use. Although it takes just a few hours to prepare the vials of tears, they are not dispensed until appropriate microbiological tests are concluded, to ensure they are safe for topical use.[13]

There are significant advantages to blood-derived eye drops. In dry eye disease, there is a lack of the so-called epitheliotrophic factors—substances in the tear film that promote proliferation and differentiation of ocular surface cells. These substances include fibronectin, vitamins and growth factors. Autologous serum contains similar biochemical properties, and is non-allergenic because it is derived from the patient's own blood. Several clinical trials have shown that autologous serum drops are superior to artificial tear substitutes in ameliorating the signs and symptoms of OSD.[14] When produced by a licensed physician for use in his or own professional practice, FDA registration or approval is not required for autologous serum eye drops—despite their classification as a medical product.[13]

Hormonal Therapy

Hormonal influences on the ocular surface have been under

investigation for several years. Because of the increased prevalence of OSD in perimenopausal and postmenopausal women, estrogen was long believed to play an important role in maintenance of the ocular surface. However, androgens are now thought to play an even more essential role in promoting lacrimal gland, salivary gland and meibomian gland function.[15-18] Dehydroepiandrosterone (DHEA) is a critical substance involved in maintenance of secretory glands; in estrogen-deficient individuals, there is a proportional deficiency in DHEA.

The result of several complex biochemical reactions is a disruption in the estrogen/androgen balance, which then can lead to autoantigen formation and ultimately autoinflammatory and autoimmune disease.[18] This may, in part, explain the pathogenesis in some Sjögren's syndrome patients, where the ratio of occurrence in females is approximately 9:1.[19] It would seem logical that supplementation with oral DHEA might marginalize the symptoms of Sjögren's syndrome, but some studies have found limited or no benefit with this therapy.[20,21]

More recently, topical DHEA drops in varying concentrations are being used off-label with mixed anecdotal results. It should be noted that, to date, there is a lack of evidence from large-scale clinical trials for either oral or topical DHEA in treating dry eye associated with Sjögren's syndrome.

Acupuncture

Acupuncture can hardly be considered a new therapy, but its appearance in Western literature regarding potential applications in OSD is relatively recent. Many studies suggest it can help improve the signs and symptoms of dry eye.[22,23] Currently, there is no standard treatment protocol. Some practitioners report improvement after a single treatment, but long-lasting effects are elusive. One drawback in interpreting these results is that the methodology is not always consistent between studies. Further, because the nature of acupuncture is patient- and symptom-specific, it is difficult to replicate the precise methodology from one study to another. Nevertheless, many patients seek acupuncture as a complementary therapy and report positive results.

As with other acupuncture therapies, the theory of its mechanism of action in ameliorating the signs and symptoms of dry eye rests with a balancing of the autonomic nervous system. Specifically, acupuncture seems to provide a cholinergic anti-inflammatory effect by enhancing vagus nerve activity.[24]

Lifestyle

Finally, we should never underestimate the benefits of lifestyle and environmental changes and how they can enhance comfort in OSD patients. Some familiar examples include smoking cessation, adequate sleep, proper hydration and taking frequent breaks when performing near tasks (e.g., working on the computer).

As our understanding of the pathogenesis of ocular surface disease evolves, so do our options in treatment. Tear supplementation, nutrition, environmental modifications and anti-inflammatory therapies are established and have become the standard of care for dry eye sufferers. However, newer therapies like autologous serum eye drops, hormonal therapy and acupuncture may move into the mainstream as we continue to expand our knowledge in this area. RCCL

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VKC: The Rite of Spring

Vernal conjunctivitis is an uncommon—but more serious and severe—ocular allergy presentation. Here's a guide to treating this pernicious condition.

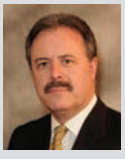
By J. James Thimons, OD

Ocular allergy is one of the most rapidly developing disease states seen in primary eye care. There have been several proposed etiologies for this increased rate, such as climate change, dietary patterns and the "hygiene hypothesis"—a theory that attributes the rise to a decrease in the normal environmental stimuli required to activate a healthy immune system secondary to a decrease in outdoor activities in childhood and the subsequent inappropriate stimulation of the IgE aspect of the immune system.[1]

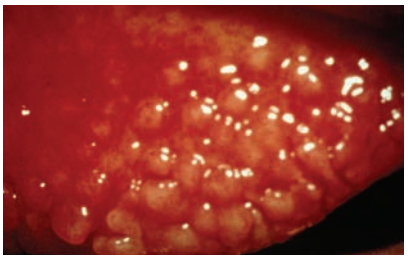
Because of this rise in ocular allergies, all clinicians need to be comfortable with both diagnosing and treating the entire range of allergic disease. Seasonal allergies have increased over the last several decades; for ocular allergies, clinicians have found topical antihistamine/mast cell stabilizing agents to be most effective. We have also seen loteprednol begin to play a significant role in recent years.

There are several additional complex allergies with associated ocular complications, such as atopic keratoconjunctivitis, which can demonstrate periorbital dermatitis and significant inflammatory cascade, and requires steroid therapy or immunomodulating agents like tacrolimus or promiculimus.

A significant but less frequent variant of allergic ocular disease is vernal conjunctivitis (VKC). This article reviews its symptoms and treatments.



Dr. Thimons graduated from Ohio State University College of Optometry and has served as chief, Optometric Service at the VA Medical Center in Chillicothe, center director and chairman at Omni Eye Services in Fairfax, Va., director at the Glaucoma Institute at SUNY and executive director at TLC Connecticut. In 2002, he founded the Ophthalmic Consultants of Connecticut and serves as ophthalmic medical director.



Developing tarsal papillae.

What is Vernal Conjunctivitis?

Vernal conjunctivitis, a condition most commonly seen in younger males between the ages of three and 20, is frequently associated with atopic disease. Seasonal activity is usually observed in the Northern hemisphere, but it can be a perennial disease in warmer climates. It is a persistent condition—half of patients show significant clinical activity at five years.[2]

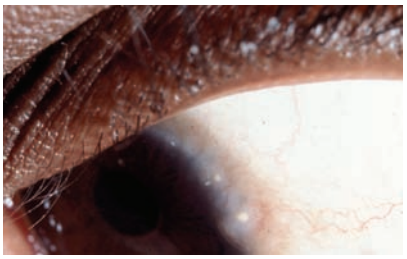
Ocular complications involve early stage changes such as enlarged papillae of the upper lid that can develop into plaque-like structures that play a role in the pathophysiology of the corneal findings. This occurs as a result of mechanical debridement of the epithelium as the plaques enlarge. Additional early signs include bilateral inflammation of the upper limbal area, Horner-Trantas dots, limbal follicles and thick mucin-based discharge.

As the disease progresses, corneal involvement typically develops; it can present anywhere from mild superficial punctate keratitis (SPK) to advanced shield ulcers. One study showed corneal involvement in up to 50% of treated patients.[3]

The disease shows a predilection for increased limbal involvement in patients who live in warmer climates and those who have increased epidermal pigment. This usually involves conjunctival hyperemia and papillae at the limbal junction, along with Horner-Trantas dots.[4] Some patients demonstrate a pannus that invades the cornea from the superior limbal arcade and can lead to severe vision loss if not treated adequately.

Shield ulcers are common in more advanced cases and are etiologically related to both mechanical irritation by the upper lid plaques as well as a complex inflammatory response that recruits eosinophils to the ocular surface.

Conjunctival changes include subconjunctival fibrosis, keratinization and symblepharon.[2-4] Clinical complications of this type are uncommon in northern climates, but are seen in geographies closer to the equator.



Horner-Trantas dots.

What is the Treatment?

• ***Antihistamine/mast cell stabilizers.*** Vernal conjunctivitis is best treated in its earliest presentation with topical antihistamine/mast cell stabilizing agents. These should be used during the entire allergy season, or year-round if the condition is perennial. This therapy is effective as a baseline intervention, but is frequently insufficient as the disease worsens. At that point, a topical steroid is the best choice.

• ***Topical steroids.*** Steroid dosage varies based on the severity of symptoms, and the level and duration of the disease.

In a comparison study looking at prednisolone, fluorometholone and loteprednol, researchers found no difference in clinical efficacy between the agents but did find a notable IOP spike in the prednisolone group.[5]

• ***Cyclosporine.*** Several authors are currently investigating the use of cyclosporine over prolonged periods of time. One study of 2,597 patients with VKC using cyclosporine therapy reported a significant decrease in symptoms at the six-month follow up. In addition, 30% of topical steroid users were able to discontinue use within three months of cyclosporine therapy.[6]

Another study monitored 156 children with VKC who were treated with either a 1% or 2% concentration of cyclosporine two to three times per day for up to seven years; patients reported a very good response and minimal side effects.[7] Due to the increased concentration of the drug vs. what is available in standard commercial preparations, yearly lab tests were conducted to monitor kidney and liver functions as well as serum levels. No notable levels were recorded over the duration of the study.[7]

Stepwise by Severity

• ***Initial therapy.*** In my practice, I initiate treatment with antihistamine/mast cell agents BID, followed by Lotemax (loteprednol, Bausch + Lomb) if available on the patient's formulary, or generic fluorometholone alcohol 0.1%. Dosage varies from QID to QH in advanced cases. I taper the steroid therapy over several weeks once the disease state is under control.

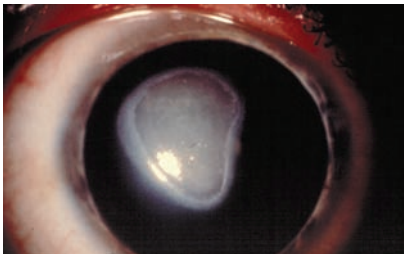
• ***Persistent cases.*** If the patient has a previous history of the disease or is slow to respond to the initial therapy, I institute cyclosporine treatment QID and taper the steroid over a longer period of time. This treatment protocol,

reviewed by Osmo Kari, MD, and K. Matti Sarri, MD, was found very effective in managing recurrent or perennial patients.[8]

• ***Corneal involvement.*** If the disease still progresses and the patient develops corneal involvement, more aggressive intervention is required to prevent vision loss. In most cases, I increase the intensity of the steroid by switching to an agent like Durezol (difluprednate hydrochloride 0.05%, Alcon) while maintaining the cyclosporine and antihistamine agents. The goal is to prevent corneal complications at all costs, which is achieved by targeting the plaque-like papillae on the upper tarsal plate.

In patients with SPK, institute bandage contact lens (BCL) therapy to give protection against the low-grade trauma from the upper lid.[9] Silicone hydrogel BCLs are excellent choices for the average VKC patient; in addition, published cases recommend using larger diameter lenses (e.g., 22mm hydrogel, Contaflex T75) in individuals with both corneal and conjunctival complications.[10]

• ***Shield ulcers.*** If shield ulcers develop, aggressive therapy includes maximizing the anti-inflammatory therapy, increasing Durezol to Q2H and fitting an appropriate diameter BCL with prophylactic antibiotic to reduce the potential for secondary infection. Remember to debride mucus plaques before using BCLs or immediately after they appear.[11] Also start homatropine 5% BID to TID (dependent on iris color) to minimize the impact of the photophobia commonly associated with this stage of the disease. Patients at this level need to be monitored carefully for disease progression and any signs of infection that might include an infiltrative response or increased pain, and



Shield ulcer.

complications in therapy, such as IOP spikes.

• ***Non-responsive cases.*** The use of topical 0.005% tacrolimus has been shown to be a reasonable alternative to steroid therapy in non-responsive patients.[12] In rare instances the cornea will either not respond to the above treatments or develop additional complications, such as limbal stem cell disease (LSCD), as a result of the VKC. One study evaluated 2,225 VKC patients, of which 49 eyes were noted to have LSCD complications related to VKC. Interestingly, just half of the eyes developed this complication in the active phase of the disease. Treatment in the study included the use of amniotic membrane graft.[13]

In these non-responsive cases, clinicians have the option to use a new commercial product, ProKera (BioTissue). It is constructed of preserved human amniotic membrane (AmnioGraft, BioTissue) that is clipped into a dual PMMA scleral ring. ProKera has been reportedly effective for a variety of non-healing corneal lesions, including the indicated shield ulcers.[14] Personally, I have found repeated success with the ProKera system and would recommend it as a viable alternative in patients at risk of vision loss who are non-responsive to more traditional therapy.

The management of VKC is best accomplished by vigilance in observation and treatment of the disease. In advanced cases, you may need to see the patient daily during the initial phase of therapy, with weekly monitoring for individuals who have responded well or have a previous history and are reliable to be monitored by phone after initial consultation.

Stay aggressive at every level of therapy to minimize cellular damage from repeated episodes that could progress to vision loss over time, but also reduce dosing when possible to avoid complications associated with prolonged steroid usage. Patients may benefit from desensitization therapy when the disease progresses in spite of maximum clinical intervention.

Finally, a collaborative team approach with the eye care practitioner, pediatrician and allergist is needed to effectively treat VKC. RCCL

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Advertorial

Contact Lens Choices: The Daily Disposable Option

By Gina Wesley, OD, MS, FAAO

There are many choices to consider when prescribing contact lenses. Worldwide, about 90% of contact lens fittings are soft lenses. A 2012 survey of eye care practitioners (ECPs) from 36 countries (including the United States [US])[1] showed that overall, daily disposable lenses were fitted for 33% of patients. In the past, US patients have been fitted with daily disposables far less frequently than patients in other countries - only about 15% of US patients were fitted with daily disposables in 2011 compared to the proportion of patients from Japan (43%), Denmark (60%), Hong Kong (54%), and Norway (52%) who were fitted with daily disposables in the same year. While daily disposable contact lenses are currently prescribed less frequently in the US than in other parts of the world, these lenses may be the best option for many patients for the following reasons:

- The lenses are **more convenient** to use because they simplify replacement and lens care regimens. Who doesn't want to simplify their life when they can?
- The lenses may offer **added health benefits** by reducing the risk of irritation. Who doesn't want to live a healthier life?
- Many patients find daily disposable contact lenses are **more comfortable** to wear. Why sacrifice comfort?

So, which of your patients would benefit the most by using daily disposables?

FOR CONVENIENCE

Daily disposable lenses keep things simple. You don't have to clean and/or disinfect these lenses. You wear them for the day, and then you throw them away! This is a real bonus to ***busy patients*** and to the ***parents of younger patients*** who don't enjoy constantly reminding their children to follow the lens care regimen.

Daily disposable lenses are also convenient for ***travelers*** – there's no need to worry about packing additional lens care solutions or to worry about the airline restrictions surrounding the solutions!

These lenses are also great for ***occasional contact lens wearers and athletes*** – patients who prefer to wear their glasses most of the time, but like to wear contacts for special events or while participating in sports/athletics. Because these patients only wear their contacts occasionally, they may not remember to routinely change the disinfecting solutions while the contacts are stored in the lens cases, or even to remember to clean the lens cases. This may increase the risk of complications related to bacterial contamination of contact lenses.

FOR COMPLIANCE, SAFETY, AND HEALTH BENEFITS

Busy schedules can make it difficult for many people to remain compliant with their contact lens wear, replacement, and cleaning/disinfecting schedules. When US contact lens wearers were surveyed about how well they complied with their recommended contact replacement schedules,[2] the majority of daily disposable lens wearers (82%) said they always followed the recommended lens replacement schedule compared to the small number of daily wear contact lens wearers who said they always followed their recommended two-week (25%) or one-month (34%) lens replacement schedules. More than half (53%) of the daily wear two-week and one-month contact wearers said that not being able to remember which day they needed to replace their lenses was their main reason for non-compliance.

FOR COMFORT

Your patients may not be telling you about all of their comfort problems. Yet discomfort is one of the main reasons for contact lens dropout![3, 4] Some patients are more likely to blame themselves for their symptoms (dry eyes, tired eyes, computer/eye strain, allergies) rather than the contact lens they are wearing.[5] Contact lenses can become more uncomfortable over time due to protein deposits, debris buildup (including allergens for ***allergy sufferers),*** and/or interaction of solutions with contact lens materials. Additionally, some daily disposables add wetting agents to the packaging solution or additives to the lenses that are released during the day to improve comfort.[6]

PRACTICE BUILDING OPPORTUNITY

Each patient trusts their ECP to recommend and prescribe the healthiest vision-correction option based on their vision requirements. However, some ECPs are reluctant to suggest daily disposables to their patients because of a perceived patient concern over the cost of the lenses. If cost is a concern, it is good to remind the patient that they will save money over time because they will not need to buy the lens care products required for cleaning and disinfection. Some estimates put the difference in the cost of daily disposables and conventional contact lenses as little as 30 cents a day.[7] Additionally, remind the patient that they will be saving time by eliminating the time needed to care for the lenses.

Recommending daily disposable lenses, such as the Biotrue®ONEday lens, can build your practice through a high level of patient satisfaction. Biotrue®ONEday lenses are made of a high-moisture hydrogel material, designed to work like the eye, matching the cornea's water content (78%)[8] and mimicking the tear film's lipid layer to retain moisture throughout the day. My patients have been very happy with the comfort and vision these new lenses provide.

Give your patients the information they need to choose the contact lens option that will provide them with comfortable vision. Remind your patient that daily disposable lenses can be as affordable as other daily wear lenses, especially when they factor in the money saved on not buying cleaning/disinfecting solutions. Simply providing this information will empower your patient to make an educated decision. By increasing your patients' level of satisfaction, improving their eye health, and improving patient lens replacement compliance you will improve patient retention rates for your practice – a win for you and a win for your patients. Recommend Biotrue®ONEday lenses with confidence.

Gina Wesley, OD, MS, FAAO, is in private practice at Complete Eye Care of Medina in Minnesota.

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Carpe Diem: Why the Time is Right For Daily Disposables

Clinical observations and scientific data lead this optometrist to believe it's well over time to seize the opportunity that daily lens replacement offers.

By Alan P. Saks, MCOptom, DipOptom

In November 2011, I was invited to the Global Contact Lens Care Summit to deliver a presentation on evidence and lens care in practice. It was the closing clinical presentation after two days of largely academic, rapid-fire conversations among a who's who in contact lens research that included epidemiologists, microbiologists and representatives from administrative bodies, such as the FDA and standards organizations.

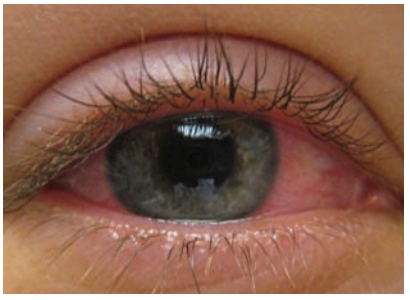
I was initially a bit apprehensive about discussing my clinical impression that daily disposables represent the future of most soft lens wear. As a clinician, I am fully aware of the skepticism with which those who focus on scientific evidence regard anecdotal observations. However, I have always supported my clinical observations with good science—and as such, have kept a close eye on the evidence as it has continued to expand and evolve over the years.

After all, sometimes clinical practice guides the direction of research and, at other times, science drives clinical practice. The two are synergistic in nature.

The Daily Disposable Plunge

Approximately 15 years ago, I made the decision to fit new soft lens patients and refit symptomatic wearers into single-use disposable lenses whenever possible. Based on personal clinical observations, I found this modality to be the best, safest, most convenient and trouble-free option available. In the following decade,

Dr. Saks is a third-generation optometrist and has served multiple terms as president of the Contact Lens Societies of South Africa & New Zealand. He has served as examiner in contact lenses and clinical optometry, lectures worldwide, participates in workshops and arranged conferences, and has served on the editorial boards for The South African Optometrist *and* International Contact Lens Clinic *and as a referee for* Clinical and Experimental Optometry.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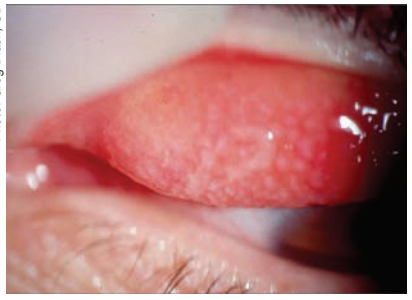
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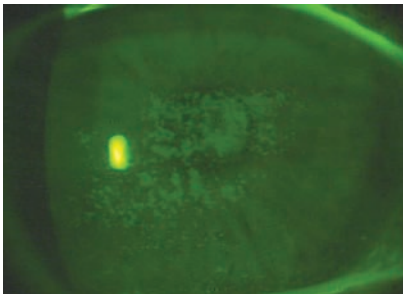
Photo: Jason Jedlicka, OD

Avoid, minimize or reduce these complications (*left to right*, dry eye, giant papillary conjunctivitis, corneal staining) with daily disposable lenses.

our practice supplied more than one million single-use lenses. Only rigid gas-permeable (RGP) lenses can beat the safety record of one-day soft contact lenses.[1-4]

Studies over the past two decades—and the measureable reduction in symptoms, signs and complications through the use of one-day lenses—confirm my observations.[4-9] The Dart study, however, found that daily disposables had a 1.56x relative risk of microbial keratitis (MK) when compared with planned replacement disposables.[10] The results of this study may have been skewed by a possible bias in the subject sample, as eye care practitioners may have prescribed the daily disposable lenses to their highest risk patients first.

Keep in mind that this is not unexpected: When new technologies (such as single-use lenses) are launched, the patients who are more likely to be "risk-takers" are at the front of the line to try them.[11,12] There may also have been some contaminating factors in this study, such as undisclosed overnight wear or re-use of daily disposables.

However, one important takeaway from the Dart study was that MK cases in daily disposable wearers seemed to be less severe than in other soft lens wearers. We should, however, not obsess over the very rare incidence of MK in single-use lens wearers.

Compliance and Lens Handling

Two of the last few barriers for enhanced contact lens safety are compliance and lens handling. Researchers have personally communicated to me that the natural tear film is relatively microbe-free, implying that contact lenses (through lens care and handling) are the vehicle for introducing pathogens or their endotoxins. Most of the time, the eye's amazing natural defenses, particularly the tear film, do an admirable job of preventing infection.[13,14]

As eye care practitioners, we struggle with compliance. The facts are astonishing: One study found 98% of lens wearers were non-compliant in some aspect of lens wear and care.[15-17] As we know, single-use lenses eliminate many steps in lens care, which alone is enough to improve compliance. In addition, daily disposables eliminate the need for the often contaminated lens cases, as well as allow us to sidestep the myriad heavily debated issues that surround multipurpose disinfecting solutions (e.g., infection, allergy, toxicity, incompatibility, inflammation, solution-induced corneal staining or preservative-associated transient hyperfluorescence, contact lens papillary conjunctivitis, and the like).[18-20]

Our last hurdle is to eliminate digital contact, and the transfer of and contamination by microbes and pollutants (such as moisturizers) from dirty fingers.

The Total Cost

After sitting through numerous conferences and lectures on the topic, I keep coming back to the same conclusion: One-day lenses should be our "go-to" choice in the majority of soft lens fittings, piggybacking and problem-solving cases. Yet the majority of contact lens prescribers in the US and worldwide don't seem to understand that daily disposables are best.

I often hear cost mentioned as a deterrence. I respond by saying that daily disposables cost the equivalent (or less!) than a cup of coffee per day. Nathan Efron, BScOptom, PhD, DSc, compared spherical daily disposables to other planned replacement disposables and found that the costs break even at five days of use per week.[21] In other words, two cups of coffee per week would cover the difference.

Now, factor in the total cost of ownership. If a regular disposable wearer has just one unscheduled visit every year or two, or an infection needing expensive eye drops or ophthalmological care, then suddenly the finances favor daily disposable lenses. In my experience, one-day lenses require less chair time and aftercare, fewer unscheduled visits and less time

spent instructing patients on how to use disinfecting solutions. In addition, we see fewer complications such as red eye, dry eye, allergy, infiltrates, solution reactions, comfort problems and infections.

When comparing price, it is important for eye care practitioners to remind patients to consider the full cost of lenses *and* solutions. Often patients fail to add the cost of solutions that they may purchase elsewhere into their running tally.

Remember, addressing objections is a minor but a pivotal part of the philosophical switch to daily disposables. Cost is only a problem when the perceived value doesn't align with the price. Try shifting the focus from cost to benefits, such as convenience and comfort. With fresh lenses, patients no longer have to worry about uncomfortable denatured protein or lipid build-up.

International Trends

In the US, we are *starting* to see the transition of daily disposables into the primary modality of choice; both the US and Canada have increased from single to double-digit percentages over the past few years.[22]

This trend seems to be continuing worldwide. In Australasia, daily disposable lens prescribing is now between 20% and 40%, with ever-increasing levels in some Asian regions, such as Hong Kong and Taiwan. Japan and some European nations (including Norway, Denmark, Italy and the United Kingdom) already have high levels of single-use prescribing, within the 40% to 60% range.

However, some of their immediate neighbors (e.g., The Netherlands at 8%) are reporting lower percentages of 5% to 20%, similar to the US and Canada.[22] These low numbers can be attributed to many factors, such as affluence, a high rate of RGP lens prescribing (The Netherlands has among the highest in the world), clinical training and the educator's philosophy.

We already cover the bulk of the refractive bell curve in daily disposables, with an ever-widening range of astigmatic corrections. We have low surface friction lenses, low modulus, moisture-retaining and lubricating options, and an increasing number of high-Dk hydrogel and silicone hydrogels (SiHy). New myopia-controlling and multifocal daily contact lenses have recently appeared on the market, as well as flat-packs, a gradient-water SiHy and a novel 78% water hydrogel with a lipomimetic surface, UV block and aspheric optics. Antimicrobial surfaces, enhanced materials and unique packaging strategies are likely to be seen in the not-too-distant future.

In the US, we are starting to see the transition of daily disposables into the primary modality of choice; both the US and Canada have increased from single to double-digit percentages over the past few years.

Isn't it time that you consider switching your patients to daily disposables? The evidence almost unanimously tells me that it's the right thing to do. RCCL

Editorial assistance provided by BioScience Communications.

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By Gary Gerber, OD

Does Extra Work Equal Extra Income?

Work smarter, not harder. Re-examining your office hours may pay off—you may find extra time in your work week.

How many days (or hours) per week is your practice operating? Say the answer is five days, or roughly 40 hours, per week. If you increased your availability to 50 hours a week—a 25% increase—do you think you'd see a corresponding 25% increase in patients and/or revenue? Probably not. If it were that easy to increase the financial metrics of your practice, you could stay open throughout the night, see insomniac patients and increase your revenue by nearly 400%.

The Financial Bottom Line

An increase in financial performance is not linearly related to the amount of hours your practice stays open. In the early 1900s, Henry Ford instituted the work week as we know it today—after deducing that 40 hours was the ideal amount of work time for maximizing productivity. In fact, he found that asking employees to work more than 40 hours decreased productivity. So, what would happen in your practice if, in the quest to achieve a better work/life balance, you decreased the hours your doors remained open?

Let's consider an extreme example. Say a 40-hour-per-week practice suddenly reduced its weekly availability to 20 hours? Would you expect a corresponding 50% decrease in revenue? We wouldn't. What we would expect is that each hour spent in the office would be significantly more demanding—probably not twice as busy, but certainly hectic. Also, with fewer available hours, the productivity per hour will increase—to a point. Obviously it is impossible to complete 40 hours of work in only one hour, for example.

If you could theoretically earn similar revenue in half the time, why do you have your current office hours? When we ask our clients this question, the most common answers suggest it is simply part of the routine or based on times that are most convenient for the patients. But, is that true?

Rethinking Office Hours

Let's see if it is possible to find a few more productive and profitable hours for your practice without adding any extra time to your schedule.

- ***"That's the way things have always been."*** For entrepreneurial practice owners, those hours may have made sense 10 years ago—and, in fact, they may still make sense today. But, to continue to increase revenue, you must continually challenge the way you do things and make improvements, even if they are minor tweaks.

For example, think back to the last time you closed your practice early for a special event. Maybe last Thursday you ended the day at 3:30 pm, an hour and half earlier than usual, so you could attend your son's baseball game. Was your office production decimated and/or did your patients write dozens of negative online reviews? Of course not, and that's because *no one noticed*. Think back to the day after and you will likely remember that you were not measurably stressed or overwhelmed with piles of backed-up admin tasks. Why is that? It is because any extra details that you would have addressed during that time instead got absorbed into the rest of your daily schedule.

Following that logic, what would happen if you consistently closed on Thursdays at 3:30 pm? The odds are that, other than working fewer hours, not much would change financially. And, if you repurpose that extra time, at least initially, for management, you may even see an increase in your practice's profits.

- ***"That's when my patients want to come in."*** Have you asked them? Start by asking your patients to complete a simple survey asking their preferred day and time to make appointments. A recent survey at one of our clients' offices found that Saturday hours were not as big a draw as the practitioner believed, which easily answered the question about whether to stay open on Saturdays or not. And, in fact, after eliminating Saturday hours, there were no corresponding changes to the incoming revenue. Instead, the practitioner saw a savings in staff wages and an increase in personal quality of life with uninterrupted weekends!

While there is no one-size-fits-all model for every eye care practice, it is important to take the time to periodically reexamine the way you run your business. A few small adjustments can potentially make significant improvements in both your business *and* your personal life. RCCL

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