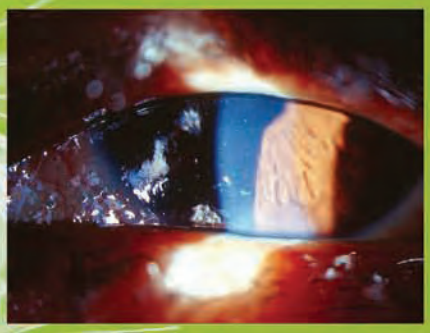
Review of Cornea & Contact Lenses

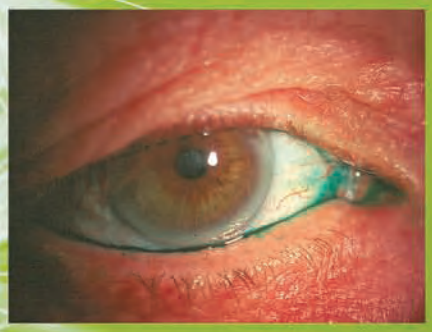
MARCH 2009

Allergy and Dry Eye Issue

Rx vs. OTC for Ocular Surface Disease

Clinicians debate the safety and efficacy of prescription vs. over-the-counter medications in this point/counterpoint discussion.





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SUPPLEMENT TO REVIEW OF OPTOMETRY

MARCH 2009

By Joseph P. Shovlin, O.D., F.A.A.O.

Recession Impact

Will compliance and hygiene suffer?

To some extent, everyone has experienced the effects of the current recession. Patients, practitioners and staff will likely continue to experience the fallout for months to come; current projections by economists tell us that financial repercussions will likely last well into 2010.

Fortunately, in a recession, the health care industry faces a less dramatic blow than other sectors. Nonetheless, we are not immune to the repercussions of an economic setback. Services that are considered "self-pay" rather than covered by insurance will likely be the hardest hit. Dentistry, aesthetics, elective surgery and eye-care can be postponed until they are affordable.[1] In addition, companies will be less inclined to invest in R&D for cutting-edge technology, as costly innovations run an inherent risk of being too expensive. And, until the economy recovers, new product development is likely to come to a standstill.

Although the likelihood of patients compromising contact lens care because of expense is purely speculative, we can surmise that some patients will attempt to do so, even at the risk of causing contact lens-related problems. In an effort to save on the cost of solutions, patients may "top off" the solution bottle with tap water, rinse their lenses sparingly, or re-use solutions. Similarly, contact lens cases may not be replaced as frequently as needed. Penny-pinched patients may turn that two-week replacement lens into a four-week (or longer) lens, unaware of the risk they are entering into. Fewer patients will be purchasing spectacles, too. Money that previously would have been spent to purchase back-up glasses is likely to be allocated to an expenditure with higher priority; furthermore, patients may skip the new spectacle purchase altogether if funds are tight.

Although patients will seemingly save money, their eye-care will suffer if they elect to cut expenditures by not showing up for their yearly eye exam. In addition, large insurance deductibles discourage patients to come in when they have an eye emergency. Just recently, I had a patient who called and asked for me to phone in a prescription for her acute red eye response; she couldn't afford to pay the deductible for her office visit. For those with no insurance, a visit to the eye doctor may be out of the question, whether for routine or emergency care.

How, then, should we adjust our practices to effectively care for patients in this economy? It may be tempting to adjust your services by providing free samples beyond what is customary and prudent, or to discount products or eye exam fees. Many may say "Desperate times call for desperate measures," but don't resort to such drastic means. Patient education is the key to surviving this economic slump. Each and every time we chat with our patients, we must bring home the importance of continuity of care. A caring attitude and warm, approachable practitioner can enhance patient satisfaction and compliance. Honesty with our patients is important: advise them to find other ways to save their hard-earned dollars and stress the importance of maintaining eye-care and compliance regimens.

If we care about our patients, we must have a solid plan to educate them about the potential pitfalls and landmines that await them if they sacrifice hygiene and compliance. Money saved in this regard may cost them more in the long run if they cause damage as a result of these attempts to be frugal. Remember: Teaching our patients now to be wise about caring for their eyes may save them from a future lifetime of misery. Here's hoping for a short recession! RCCL

1. Ravikumar K. The recession paintbrush: A picture of health? Frost & Sullivan Newsletter January 2009.

Joseph P. Shovlin, O.D., F.A.A.O., Clinical Editor

VOL. 146, NO. 2

IN THE NEWS

• During a **workshop** co-sponsored by the **American Optometric Association** (AOA) and the **U.S. Food and Drug Administration's Center for Devices and Radiological Health** (FDA/CDRH) participants reached **consensus on testing parameters and new criteria for disinfection efficacy test methods**. Specifically, they found agreement on the particular ***Acanthamoeba*** parasite species and strains to test as well as an acceptable threshold for disinfection efficacy.

• **OASIS Medical, Inc**. has introduced a **SOFT PLUG Flow Control silicone plug**. Flow Control plugs are intended for **partial occlusion with limited tear drainage**. They are preloaded on a disposable inserter, come in two sterile plugs per box, and are available in 0.6mm and 0.7mm sizes.

• **VisionWeb** launched a new and improved **contact lens ordering service** for its members. Similar to VisionWeb's spectacle lens and frame engines, **the contact lens engine displays product catalogs** for each contact lens supplier. Only products carried by the supplier will be displayed, making it easier to locate and order the desired product. A **new advanced search feature** allows users to find contact lenses based on several categories, including lens type, manufacturer, color, series, wear schedule, pack, and UPC.

Good News For Patients With Astigmatism

According to a recent survey conducted by Decision Analyst and sponsored by Bausch & Lomb more than four in 10 astigmats believe that their astigmatism is the reason they cannot wear contact lenses.

A total of 993 vision-corrected astigmatic consumers between the ages of 18 and 49 completed this online survey. 150 respondents had never worn contact lenses, and 178 had worn contact lenses in the past. The results of the survey also showed that seven out of 10 of those who have never worn lenses would be highly motivated to wear contact lenses if they were available, and if their eye-care practitioner made the recommendation. Half of previous lens wearers would be motivated to try contact lenses again if they were available.

"I'm surprised that such a large segment of the population is unaware of our ability to correct astigmatism with contact lenses. This is particularly remarkable in light of excellent clinical results and clinical studies that demonstrate today's astigmatic correcting lenses are quite effective in providing clear, comfortable vision," comments Thomas G. Quinn, O.D., M.S., a private practitioner from Athens, Ohio and avid lecturer on the subject of toric contact lenses.

For more information, visit www.bausch.com.

New Web Sites

Ocusoft now offers free sample and broad-based education Web Sites. These sites make it easy to acquire fresh samples of Ocusoft Lid Scrub for patient distribution and provide useful production information for both practitioners and patients.

For more information, visit www.ocusoftlidscrubsamples.com and www.ocusofteducation.com.

Review of Cornea & Contact Lenses

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Parameter Expansion

Avaira two-week replacement silicone hydrogel lenses from CooperVision are now available in a new sphere power range of up to -12.00D. Currently approved for daily wear, Avaira is now available with sphere powers from -0.25D to -12.00D (in 0.50D steps above -6.00D). The lens has a base curve of 8.5mm and a diameter of 14.2mm. Dk is 100, Dk/t is 125 with a water content of 46%. Avaira comes in a six-lens pack or a three-lens trial carton.

Avaira is manufactured from enfilcon A and features a UV blocker and CooperVision's aberration neutralizing system. For more information, visit www.coopervision.com.

New Thin GP Lens

Art Optical Contact Lens, Inc. introduces Thinsite 2, a new and improved version of the Thinsite. Thinsite 2 was crafted using patented lathing techniques and advanced mathematical concepts, which resulted in a thinner overall lens profile that reduces lens mass and increases oxygen transmissibility while maintaining lens stability, the company says. Combined with the hyper-Dk permeability of Boston XO_2 material, Thinsite2 lenses are especially beneficial for patients with extreme cases of myopia and hyperopia. For more information, visit www.artoptical.com or call 1-800-253-9364.

Contact Lens Delivery Service

Acuvue Direct from Vistakon is a new service that allows patients to pay for their annual supply of contact lenses in four equal installments, while still being able to take advantage of cost-saving rebates. It is designed to enhance patient convenience, improve patient compliance and drive health education.

Acuvue Direct also allows providers to keep track of orders. Each month, participating doctors receive a report and invoice for the shipped lenses, notice of cancelled or postponed orders, and a list of patients nearing their prescription expiration. While patients can postpone a shipment, they can't order any lenses beyond the expiration of their prescription.

For more information, visit www.jnjvisioncare.com/goacuvuedirect.

Advertiser Index

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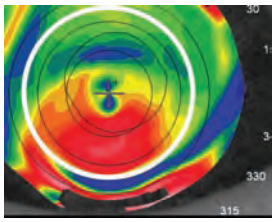
ON THE COVER



Departments

By Mark Abelson, M.D., C.M., F.R.C.S.C., and Daniel Dewey-Mattia

Sjögren's Syndrome and Dry Eye, Part Two

In order to prescribe the appropriate therapy, a clinician must link the symptoms of dry eye and dry mouth with accurate histological and immunological testing.

In last month's column, we summarized the history and epidemiology of Sjögren's Syndrome (SS), an autoimmune disorder characterized by aqueous deficiency. That leaves us with the controversial topic of diagnosis and treatment of SS.

Diagnosis

A wide range of conditions can cause dry eye, so it is not plausible to diagnosis SS dry eye based solely on tear function tests. However, these measurements can be a useful part of the process; SS dry eyes exhibit, on average, a severe reduction in the tear meniscus, a large decrease in tear production (<3mm per second) in the Jones test, and lower mucin production than non-SS dry eyes.[1] Wetting below 5mm per five minutes in the Schirmer I test is also suggestive of SS, but this method has shown low reproducibility over a one-year interval.[2] Interpalpebral rose bengal staining can be used to look for a punctate pattern of filamentary keratitis associated with the disorder.[1]

Alternatively, a high score (above 33) on the ocular surface disease index (OSDI) questionnaire has shown both specificity and sensitivity as a diagnostic tool.[3] It is also useful to test for the presence of reflex-tearing following nasal stimulation as non-SS dry eye usually does not involve lacrimal gland destruction and patients can still produce tears in response to strong stimuli.[4]

Asking dry eye patients during the initial exam whether their mouth is dry or whether they experience hand stiffness in the morning (an early sign of rheumatoid arthritis) can speed up the diagnosis. Complaints of foreign body sensation, ocular and systemic fatigue, pain, and swelling are more common in SS dry eye patients than non-SS dry eye patients, which is why thorough patient interviews regarding ocular and systemic symptoms are necessary for proper diagnosis.

SS can be definitively differentiated from other autoimmune disorders and non-SS dry eye with the use of blood testing for systemic serologic markers of immunological dysfunction. Immunoglobulins are more abundant in lymphocytic infiltrations of SS patients compared to those with systemic lupus erythematosus or rheumatoid arthritis, and about 60% to 70% of SS sufferers are positive for La and Ro autoantibodies in serum.[5]

Treatment

When determining the treatment of a patient's dry eye, we should always investigate the underlying cause of the condition. Sjögren's dry eye, like most dry eye conditions, is typically treated topically with an eye drop that does not remotely resemble the chemical composition of the tear film. This bizarre treatment strategy does not address the underlying cause of the condition: inflammation and destruction of the lacrimal gland. Thus, patients with SS may not respond to artificial tear therapy alone and may require treatment with an oral cholinergic agent.[2] Studies have shown that orally administered pilocarpine can safely improve rose bengal staining and subjective symptoms of SS dry eye.[6] Supplemental treatment with topical clotrimazole and oral cevimeline can help with dryness of the mouth.[1] Corticosteroids have been suggested as a possible treatment for inflammation related to SS, but they are associated with a range of side effects, and there is currently no substantial evidence in favor of their use.

Differentiation is Key

Considering the ocular and non-ocular ramifications, it is important to differentiate SS from other causes of dry eye. Effective treatment relies on knowledgeable diagnosis and sometimes, the consideration of non-conventional dry eye therapies, such as flax seed or fish oil supplementation. The clinician must also stress the importance of environmental awareness and maintaining adequate levels of airflow, air quality and humidity in the management of SS dry eye. RCCL

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By John M. Rinehart, O.D., F.A.A.O.

Innovations for Presbyopes

There are many options available for our presbyopic patients, and by working with the numerous great GP labs, we are able to meet most of their visual needs.

More and more of our patients need multifocal contact lenses with higher add powers to meet their needs. But, many of the aspheric multifocal lenses will not accommodate patients who require add powers above +2.00D. So, what is available to assist this ever-growing population?

Lens Options with More Add

Aspheric multifocal lenses produce add power because the optical area flattens toward the periphery. This difference is referred to as eccentricity. The greater the eccentricity, the greater the rate of flattening, and therefore, the greater the potential add. The rate of flattening produces different amounts of change, depending on the base curve. A lens with a steep base curve changes more than a lens with a flat base curve using the same eccentricity. Thus, a patient with a 46.00D flat K cornea will achieve more add power than a patient with a 41.00D flat K cornea when the same eccentricity (0.80D) is used. In this case, using a material with an index of refraction of approximately 1.45, the resultant add for the steeper cornea is 1.42D, while it is 1.05D for the flatter cornea. As this example shows, it may be difficult to serve the needs of our older patients with flat corneas utilizing only a back-surface aspheric lens.

The index of refraction (N) of the lens material is the other variable that greatly impacts the potential add power. Using the example above but changing the material to an index of refraction of approximately 1.48, the resultant add for the steeper cornea would be 1.80D, and for the flatter cornea 1.32D.

Combining these two examples, there is a difference of 0.75D between the flat cornea using the lower index of refraction as compared to the steeper cornea and higher index of refraction. We obviously cannot control the radius of curvature of our patients' corneas, but we can choose lens materials that work to our advantage. We can also counsel patients with flat corneas and explain that they may not achieve the full advantage for their multifocal lenses.

Here are the options available for patients who need more add than their current lenses provide:

- Increasing the eccentricity works to a certain extent, but when the eccentricity becomes very high, distance vision may be compromised because rapid change of curvature results in a smaller area of full distance correction.
- Using a lens material with a higher index of refraction also has limitations. The highest index of refraction material I am familiar with is PMMA (N = 1.49) and that is not a practical choice because it allows no oxygen through.
- Additional add power can be incorporated on the front of the lens. This can be done with either an aspheric curve or a spherical curve. Generally, it is very easy to increase the add power of the lens by as much as 1.00D this way.
- Creating a modified monovision in which the distance power on the non-dominate eye is "over-plussed" by 0.50D to 0.75D results in minimal compromise of distance vision while providing the extra add needed for near tasks.
- Concentric bifocal lenses may be a good option in cases when higher add powers are needed. The drawback is that there is not a gradual change of powers, so while near objects material may be viewed more clearly, the video display terminal may become blurry.
- Lastly, when high add powers are necessary, translating bifocals and trifocals are very good options. The most undesirable feature of translating lenses vs. simultaneous multifocals is that the add power is only in the bottom portion of the lens. So, while near items below eye level look great, near items at and above eye level will be blurred.

All Eyes Toward the Future

On my personal short list of future innovations that would make it easier to satisfy more of our presbyopic patients: a high refractive index GP lens material. A wettable GP lens with an index of refraction higher than that of PMMA would allow for high adds using aspheric lenses without crowding sophisticated optics into a very small area. RCCL

By Ernie Bowling, O.D., M.S., F.A.A.O., Dipl.

Addressing Antibiotic Resistance

The introduction of antibiotics into clinical use is one of the landmark advances of modern medicine. But, how can we prevent bacterial resistance?

Antibiotics allow treatment of infections that were once widely fatal, and they safeguard procedures that were once unimaginable. Since the introduction of antibiotics six decades ago, practitioners have taken comfort in the relative safety and exceptional efficacy of these drugs. Health care providers have used antibiotics enthusiastically, and patients have come to expect them for the treatment of many ailments—even some that are not caused by bacteria. But, the widespread use of antibiotics has raised the issue of antimicrobial resistance. Recently, clinicians have begun to witness increasing rates of in vitro resistance among previously susceptible organisms.[1]

Ocular Infections

Antibiotics are potent weapons for fighting common infections of the eye. Keratitis, conjunctivitis and blepharitis are frequently occurring ocular infections caused by a variety of bacteria that are generally treated with topical antibiotics. In most cases, antibiotics effectively treat ocular infections; however, "holes" in therapy emerge because bacteria develop resistance to the antibiotics. Bacterial resistance can be limited by reducing the prophylactic use of antibiotics, by culturing patients with serious infections to obtain bacterial identification and susceptibility profiles and by choosing antibiotics appropriately.[2]

Prophylactic Use

Although most eye-care practitioners prescribe antibiotics responsibly, many prescribe antibiotics prophylactically to prevent possible infections (e.g., in cases of epithelial defect or sterile corneal infiltrates). This practice, while prudent, may contribute to antibiotic resistance. Cycling—or using different antibiotics for different ocular infections—is a wise course of action that has been adopted by most practitioners. Antibiotics such as erythromycin and bacitracin have been used for the treatment of blepharitis, and a host of antibiotics (e.g., fluoroquinolones, tobramycin) have been used for keratitis therapy. Problems with bacterial antibiotic resistance generally occur when chronic infections are treated with the same antibiotic. The bacteria that cause recurrent infections, such as blepharitis, may acquire antibiotic resistance because of the repeated use of one particular agent for therapy (e.g., erythromycin). These problems are compounded when infections involve the cornea.

The general opinion among most eye-care practitioners is that effective empiric therapy negates the need to culture to confirm an infection, or to determine the causative organism. This situation is apparent in the successful treatment of benign cases of conjunctivitis and in those keratitis cases that present with minimal corneal involvement. Patients with serious keratitis should be cultured for the causative agent—whether for bacteria, viruses, fungi or protozoa—to ensure proper therapy.[2] The concentrations are greater in the eye than systemically; therefore, the bacteria are eradicated much more rapidly, and there is less chance for bacterial resistance.

Trends of Resistance

Narrow-spectrum antibiotics like bacitracin, vancomycin and cefazolin have retained gram-positive bacterial effectiveness. Except for vancomycin, these antibiotics may not be used systemically as a general rule, representing a clear advantage for treating ocular infections as acquired resistance to overexposure is less likely. Because many of the older antibiotics are no longer useful for treating systemic infections, their use and associated acquired resistance have been reduced. These antibiotics, therefore, will likely continue to be effective for treating ophthalmic infections. Although the broad-spectrum antibiotics (e.g., gentamycin, tobramycin, neomycin, trimethoprim and sulfacetamides) have produced varied susceptibility profiles for the treatment of gram-positive and gram-negative bacteria, no increasing trends of resistance have been noted.[2] Trends in increased bacterial resistance have been noted for erythromycin in coagulase-negative *Staphylococci*.[2]

The last group of antibiotics introduced for ophthalmic use was the fluoroquinolones, and it has been noted that bacteria treated with fluoroquinolones acquire resistance readily because of widespread oral treatment and overuse of this class of drug.[3] Because fluoroquinolones are

concentration-dependent antibiotics, when bacteria are exposed to sublethal concentrations, they can induce resistance. Resistance trends of *Staphylococcus aureus* to the second-generation fluoroquinolones have been confirmed, and new trends of resistance for *Pseudomonas aeruginosa* have emerged.[3] A report from the March 2006 issue of the *Journal of Cataract and Refractive Surgery* details two cases of culture proven fourth-generation fluoroquinolone resistance post-LASIK.[4] An even more recent report shows a surprising increase in community-acquired methicillin-resistant *Staphylococcus aureus* (MRSA) infections. For years, MRSA was found only in hospital-acquired infections. The report shows that it has now escaped the confines of the hospital and is becoming more common in the general population. Thirteen cases of culture-positive MRSA keratitis following refractive surgery were reported in patients with no known exposure to a healthcare facility and were treated prophylactically with fourth-generation fluoroquinolones.[5]

Curtailing the development and spread of antimicrobial resistance will require both the preservation of current antimicrobials through their appropriate use, as well as the discovery and development of new agents.[1]

Our Responsibility

The eye-care community is fortunate to have a wide array of antibiotics to treat infections. And, while opthalmic use of antimicrobials is unlikely to contribute to antibiotic resistance, we should all do our part as members of the medical community-at-large to minimize antibiotic resistance. RCCL

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By Christine W. Sindt, O.D., F.A.A.O.

Workshop on *Acanthamoeba* Testing

The FDA works with the eye-care community to improve patient safety.

The U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) hosted a workshop on Microbiological Testing for Contact Lens Care Products in January, 2009. It brought together scientists, clinicians and industry for the common goal of improving contact lens care product safety and effectiveness. Specifically, the workshop focused on the recent outbreak and continued rise of *Acanthamoeba* keratitis (AK) associated with contact lens use.

The FDA does not require testing of *Acanthamoeba* species with lens care products. There was strong consensus among workshop participants that this organism not only should be included, but testing should include as many "real-world" conditions as possible.

Acanthamoeba is a ubiquitous protozoan found nearly everywhere, including water sources, sediment, organic materials and animals. Classically, AK is thought to affect one to two per million contact lens wearers, but recent evidence shows that the infection rate is on the rise globally.[1] It survives in two phases, an active trophozoite phase and a protective encysted phase when the organism is stressed. Even after twenty years of dessication and encystment, 70% of *Acanthamoeba* cysts will survive and thrive under the right conditions.[2]

Setting a disinfection standard for *Acanthamoeba* is difficult because its species, and even the strains within each species, differ drastically in their abilities to form biofilms and resistance to biocides. Even a single strain cycled through cultures four or more times will change its virulence; therefore, wild *Acanthamoeba* may be more difficult to kill than lab strains. It is nearly impossible to compare current literature on *Acanthamoeba* susceptibility to biocides, because not only do species and strains differ, but so do the methods of cultivating the trophozoites, encystment, inoculum preparation and size (250 cells to 1 million cells per milliliter)—not to mention the different ways to assay the test solution (plate, microtiter, or centrifuge and resuspension) and quantify viable organisms.

Not only can the organism itself form biofilms, but the surfactants and humectants within the contact lens care products form biofilms on the lens case. These solution-related biofilms harbor and protect microorganisms, and therefore, lens case care may be the most important step of contact lens hygiene. While contact with water is discouraged, everyone agreed that scrubbing the case regularly and boiling the case for five minutes in water was effective in sterilizing the case. But, some participants had the opinion that rinsing the case with contact lens solution and allowing the case to air dry would increase biofilm formation.

At the conclusion of the meeting, the panel agreed on a preliminary standard for FDA contact lens solution testing. Although the panelists agreed a certain strain of *A. castellanii* should be used, they left room for adding new strains as they become available. They agreed on methods for cultivating and encysting *Acanthamoeba*, methods for testing biocide efficacy, which include using a contact lens in the system (current testing does not) and continued monitoring of efficacy.

Even when new standards for testing are in place, remind patients to follow the guidelines recommended by the American Optometric Association Contact Lens and Cornea Section:[3]

- Always wash your hands before handling contact lenses.
- Rub and rinse the surface of the contact lens before storing.
- Use only sterile products recommended by your eye-care practitioners to clean and disinfect your lenses. Saline solution and rewetting drops are not designed to disinfect lenses.
- Avoid using tap water to wash or store contact lenses.
- Contact lens solution must be discarded upon opening the case, and fresh solution must be used each time the lens is placed in the case.
- Replace lenses using your doctor's prescribed schedule.
- Do not sleep in contact lenses unless prescribed by your doctor and never after swimming.
- Never swap lenses with someone else.
- Never put contact lenses in your mouth.
- See your eye-care practitioner regularly for contact lens evaluation.
- If you experience RSVP (redness, secretions, visual blurring or pain), return to your practitioner's office immediately! RCCL

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By Michael Slusky, O.D.

Make the Solution Choice Clear

It's a cold, yet sunny January day in Chicago as a silver sports car coasts to a halt, with smoke emanating from the engine compartment. The disappointment on the driver's face is unmistakable as he reaches for his mobile phone. Do our patients feel the same disappointment when they struggle through the discomforts associated with contact lens wear? Do they immediately reach for the phone and call you, or do they just accept that it is the price of spectacle-free vision? Much like the finely tuned engine of an exotic automobile, our eyes are precision machines, with constantly moving parts that require the proper lubrication to perform at optimal levels.

In the same way the engineer designs an engine for performance, we select the most biocompatible contact lens and solution combination for a patient's success. This process is ongoing, just as the engineer recommends the most compatible lubrication system for maintenance to ensure long lasting optimal performance. We place our emphasis on the brand and design of contact lenses, but are we taking into account the value of lens maintenance to ensure an optimal lens wearing experience?

Studies show that contact lens materials vary in their biocompatibility with each multipurpose solution (MPS), and it is essential to keep the individual lens groups in mind.[1] Corneal compromise is observed in the first two hours after lens insertion. Superficial punctate keratitis (SPK), primarily seen with certain PHMB-based solutions and some contact lens materials, is the result of a mismatched lens material to the contact lens solution.[2] Surprisingly, these contact lens wearers may be perceived as asymptomatic, despite exhibiting significant corneal staining, which may lead to an increased risk of corneal inflammation associated with solution toxicity.[3,4] There is data that demonstrates that a disruption of the epithelial barrier exists from a bioincompatibility of solutions with different lens materials.[5] Just like the motorist whose engine failed without much warning, our patients may continue wearing their lenses without significant signs of bulbar hyperemia in the presence of solution toxicity.[6]

As vision care providers, our goal is to minimize the patient's risk while wearing contact lenses. Studies have demonstrated that contact lens comfort and corneal presentation are influenced by the choice of MPS.[7] A non-PHMB solution such as OPTI-FREE® RepleniSH® MPDS with POLYQUAD® and ALDOX® preservatives has demonstrated biocompatibility across a range of soft contact lens materials.[8]

There is tremendous strength in a specific solution recommendation a doctor makes to their patient. Selecting the best contact lens may carry limited patient results when the solution used to care for them is not a biocompatible match. Although we can control the lens type our patients wear, we are challenged by the choice of which solution they purchase at the store. The Andrasko grid serves as a powerful visual tool in my practice.

When asked if there is a difference between the lens care solutions, I am able to show my patients the supporting research for my clinical recommendations. I avoid generalized statements and focus on the specifics. When I hand my patient an OPTI-FREE® RepleniSH® MPDS starter kit, I inform them that not all solutions are the same. OPTI-FREE® RepleniSH® MPDS is designed to help keep their lenses comfortable during wear and is biocompatible with their prescribed contact lenses. That brief statement gives my patients a rationale of why they should use the brand that I recommend and avoid switching to a store brand product. This allows my patients to get the most out of their contact lens wear experience. Furthermore, it reinforces the importance of my role as their vision care specialist now and in the future.

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By Mile Brujic, O.D., and Jason Miller, O.D., M.B.A.

Alternative Uses For Contact Lenses

When you embrace different avenues of contact lens use, both your patients and your practice will benefit.

Over the past year, we have focused most of our efforts on strategies to minimize contact lens dropouts. This month, we will look at common alternative uses for contact lenses and peek into the future of contact lens utilization with therapeutics.

Orthokeratology

Contact lens wear may have failed some patients with active lifestyles that include activities such as camping, working out and swimming. But, those patients who do not wish to continue contact lens wear may be good candidates for orthokeratology, which is an excellent opportunity for both our patients and our practice. If patients have an issue with daily contact lens wear, be it comfort or convenience, make sure to take the time and offer a contact lens that can correct their vision while they sleep.

Orthokeratology is a process that has been around for decades, but it was only FDA approved for overnight treatment a few years ago. The process has improved greatly since its inception, and in 2002, Paragon Vision Science developed a system called Corneal Refractive Therapy (CRT). Recently, Bausch & Lomb also developed an orthokeratology system called Vision Shaping Treatment (VST). Both are fit only by eye-care practitioners who have completed the certification process. These "appliances" (as many eye-care providers refer to them) are made with high Dk/t gas-permeable lenses with reverse-geometry designs.

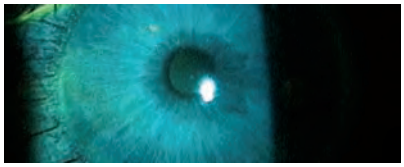
The concept is simple: The lens redistributes and compresses the epithelial tissue, decreasing corneal thickness in the center of the cornea while increasing it toward the periphery.[1,2] This change redistributes the refractive power of the cornea while achieving the desired vision correction.

A reverse-geometry system uses different zones to perform this function, and a perfect fit is the key to successful treatment. A contact lens fitting set and a corneal topographer are necessary to analyze both the progressive corneal flattening and the treatment zone. Also, utilizing these tools allows for troubleshooting, in the event of a decentered treatment zone and/or inadequate treatment due to fit.

In our experience, these lenses are safe and well-tolerated by patients. Patients may require some "hand-holding" through the first week, depending on the amount of correction needed. It is important to manage patient expectations; be sure to discuss the process and ways to ease the transition. For example, many practitioners provide daily disposable soft lenses to help with refractive instabilities that may occur in the beginning. This instability is due to regression, which is common during the first few days.

Bandage Contact Lenses

In addition to correcting refractive errors, bandage contact lenses (BCLs) can help relieve pain and promote healing in patients with trauma to the cornea. The cornea is richly innervated, originating with the long ciliary nerve, a branch of the nasociliary nerve that stems from the ophthalmic nerve of the cranial nerve V.[3] So, when the corneal epithelium is compromised by disease, toxicity or mechanical injury, it can have a negative impact on the comfort of the ocular surface.



1. Four-day progression of an abrasion healing with the aid of a bandage contact lens. The lens was removed only for examination purposes.

2. Significant keratitis in a patient with severe dry eye and a reduced best-corrected visual acuity, which improved with a bandage contact lens.

Corneal abrasion is one of the most common uses for BCLs in primary care practices. In the presence of a corneal abrasion, BCLs shield the corneal surface from the constant mechanical irritation of the blinking eyelids *(figure 1)*. This results in a high level of comfort almost immediately after the lens is placed on the eye and allows

FDA Approved Therapeutic Contact Lenses

Contact Lens	Manufacturer
Acuvue Oasys	Vistakon
Focus Night & Day	CIBAVision
Purevision	Bausch & Lomb

patients to return to normal function by controlling the pain.[4]

Eye-care prctitioners have learned much about bandage contact lenses from our experience with postoperative photorefractive keratectomy patients and the use of lenses after the procedure. Recent studies that compared patient experiences while wearing silicone hydrogel lenses vs. hydrogels showed less pain and better postoperative results in those patients wearing silicone hydrogel lenses.5,6 Table " FDA Approved Therapeutic Contact Lenses" summarizes those contact lenses that have been approved for therapeutic use.[7]

An antibiotic can be used on a t.i.d. or q.i.d. dosing schedule over the contact lens to help reduce the risk of a concurrent infection while the epithelium is healing. Some practitioners advocate utilizing topical non-steroidal anti-inflammatory agents in addition to antibiotics to help with general inflammation and pain reduction.[8,9] Many practitioners develop a protocol for treating and coding in these situations:

There are cases in which patients' dry eye symptoms cannot be controlled with the use of over-the-counter options or prescription therapies. In such cases, daily wear BCLs can be utilized to shield the cornea and make the patient significantly more comfortable. Additionally, scleral lenses are utilized as bandage lenses in severe dry eye patients and for ocular pemphigoid. The scleral lens acts as a tear reservoir and helps ptotect the cornea from further insult.

The eye-care practitioner has the ability to turn a negative experience into a positive one with contact lenses. Additional conditions that may warrant BCLs include those causing epithelial defects, such as bullous keratopathy and recurrent corneal erosions.[10]

Therapeutic Contact Lenses

Theoretically, contact lenses can act as a reservoir for therapeutics to be delivered to the eye. In this manner, we would be able to deliver medications to the eye by simply inserting a contact lens. This could benefit glaucoma patients—a steady state of medicine could conceivably be delivered to the eye, providing good intraocular pressure control throughout the day. Dry eye and allergy medications embedded in contact lenses could also provide significant benefits to patients who suffer from these conditions and having problems wearing contact lenses comfortably.

Although these contact lens options are not commercially available, we hope to see them come to fruition in the coming years.

A Case in Point

A new 33-year-old patient, "Lisa," reported having dry eyes with significantly blurred vision. She had been treated with multiple artificial tears and prescription medications unsuccessfully. Lisa's best-corrected visual acuity was 20/50 O.S. Her cornea was remarkable for significant keratitis, consistent with severe dry eyes *(figure 2)*.

Lisa was successfully fit with a senofilcon A contact lens as a BCL. Shortly after lens insertion, her vision improved to 20/25 O.U. She was very satisfied; this was the best she could remember seeing in a long time. RCCL

Corneal Abrasion (918.1)

- Appropriate level visit (99212-99214 most likely).
- Instill appropriate medication. This most often includes a cycloplegic and an antibiotic eye drop.
- Insert bandage contact lens (code 92070). This bundled code implies fitting of contact lens for treatment of disease, including supply of lens—not for the actual contact lens. Make sure to append the RT or LT modifier.
- Schedule a follow-up appointment, depending on severity.

Please note: The use of bandage contact lenses is contraindicated if the injury is caused by plant material, as this scenario represents a high risk for infectious keratitis.[11]

The authors would like to thank Dr. John Archer for help on the case presented.

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By Gary Gerber, O.D.

Know What Your Patients Want

Market research isn't just for manufacturers anymore. Find out how to plan, devise and implement your own practice research.

The term "market research" might seem foreign or scary to contact lens practitioners, and many might think it's a task best reserved for contact lens companies rather than fitters.

Yet, you have access to a huge amount of data that can help you set the course of your practice in the right and profitable direction. By tapping into your own patient base, you can identify the trends and desires of your patients, which, as a cohort of responses directly reflective of your own practice's region. Once you collect and analyze the data, you can set yourself up to meet the expectations of your patients and position your practice as one that is acutely in tune and receptive to your patients' needs and wants.

Be in the Know

Let's explore a good way to go about running your own market research program. First, set specific goals about what you want to uncover and research: the more specific, the better. Let's say that you are looking to uncover trends in your patients' wearing schedules and compliance habits. Start your exercise with a premise (or hypothesis), which in this case could be: "Compliance isn't as good as expected because patients aren't returning to buy replacement lenses at the expected interval. This is due to either their buying lenses someplace other than my office or their wearing lenses longer than they should."

Next, you have to devise a mechanism by which you will collect data. Keep in mind that while this information is important to you, it's not a priority for your patients. Your patients have little desire or time to help you build and analyze your practice. So, it's best to keep the data collection process simple, fast and very easy. To that end, you could send surveys via email, mail or the telephone and ask two or three questions. In this case something like this:

1. If you wear daily disposable lenses, how often do you wear them?

a. Every day.
b. Three to five days per week.
c. One to three days per week.
d. Less than once per week.

2. If you wear your daily disposable lenses less than five days per week, why do you do so?

a. My lenses are not as comfortable as I'd like.
b. My corrected vision is not acceptable for full-time use of the lenses.
c. I'm trying to save money, so I wear them less.

3. Where did you buy your last supply of lenses?

a. Our office.
b. A big box warehouse.
c. An Internet supplier.

Keep It Simple

Note that you might be tempted to follow up the last question with, "If you didn't buy lenses from us, why did you go elsewhere?" But keep in mind your original goal of helping to analyze compliance and striving to keep the process simple for patients. While asking why they bought lenses elsewhere could help you in future endeavors, it might detract from the number of responses to this exercise and could be saved for another project. That fourth question could very well be the one that causes your response rate to drop from 35% to 5%. Remember, short and simple!

If you find that most of your patients are saying that they wear their lenses every day but not buying them from your office, then you have answered why your findings (artificially) indicate poor compliance. Only then should you address ways to keep your contact lens prescriptions in-house. But, if the results show that patients do buy lenses from you, but only wear them one to three days per week, then there wouldn't be a need to focus on reducing walking prescriptions.

Be proactive when you follow up on your findings. For example, in the first case, your follow-up research could certainly focus on pricing expectations and other customer service-related needs. From here, you can also discover any predatory tactics of competitors and make any adjustments necessary to keep your patients satisfied with the lenses you offer. RCCL

When Eyes Dry Out

Differentiating between dry eye disease and contact lens-related dry eye is just the first step. What lens materials will help your patient?

By Robin L. Chalmers, O.D., F.A.A.O.

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Dry eye disease is very common, especially among the elderly, post-menopausal women, and patients who have undergone refractive surgery. Depending on the definition of dry eye and the age of the study population, its prevalence has been estimated at anywhere from 5% to more than 30%.[1]

In the typical contact lens practice, there almost certainly is a subset of patients with true dry eye disease who will find it challenging or impossible to successfully wear contact lenses without treatment. But, even more common is a subset of patients struggling with contact lens-related dryness, whose symptoms disappear when lens wear is stopped. While these two groups may overlap, my research has shown that they are distinct.[2,3]

If contact lens wear simply added to pre-existing dry eye, or if lens wear was the tipping point for borderline dry eyes, we would expect to see similar demographic trends between the two groups, and we clearly do not. For example, dryness intensity is not correlated with gender and is inversely correlated with age among contact lens wearers—a pattern that differs significantly from that evident among non-lens wearers.[2]

Contact lens wear itself—and especially hydrogel lens wear—causes symptoms that are very similar to dry eye but are not necessarily the result of an underlying pathology.[4-6] This may be due in part to an increase in the rate of tear film evaporation in contact lens wearers. A recent study showed that lens wearers in a normal environment had an evaporation rate higher than that of non-lens wearers in low-humidity environments.[7] Lens wear mimics a very dry environment, which can then be exacerbated by low ambient humidity, medication use, low blink rate, allergies, poor fit and many other factors. Additionally, the interaction of the lens with lens care solutions may also drive some of the variability we see in comfort and quality of vision.

Lens wearers' struggle with hydrogel contact lenses begins early on. Even in their twenties, more than four out of 10 hydrogel lens wearers studied were beginning to experience marked end-of-day discomfort.[3] And,

it has been known for some time now that dryness and discomfort, regardless of etiology, have long been the leading reasons for contact lens dropout.[8]

A recent Gallup poll reinforces these findings. According to the poll, 36% of spectacle wearers who used to wear contact lenses gave them up due to discomfort issues—more than three times the number who gave up lenses due to specific vision issues.[9] The average age of dropout was 34 years old. The same survey revealed that more than 40% of current contact lens wearers experience dryness and nearly 30% experience end-of-day discomfort.[9]

Targeting Improved Comfort: Latest-Generation Contact Lens Materials

Brand	Manufacturer	Material
Silicone Hydrogel Frequent Replacement		
Acuvue Oasys Acuvue Oasys for Astigmatism	Vistakon	Senofilcon A
Acuvue Advance Acuvue Advance for Astigmatism	Vistakon	Galyfilcon A
Air Optix Aqua O_2Optix	CIBA Vision	Lotrafilcon B
Avaira	CooperVision	Enfilcon A
Biofinity	CooperVision	Comfilcon A
Focus Night & Day	CIBA Vision	Lotrafilcon A
PureVision	Bausch & Lomb	Balafilcon A
Silicone Hydrogel Single-Use		
1-Day Acuvue TruEye (UK only)	Johnson & Johnson Vision Care	Narafilcon A
Hydrogel Frequent Replacement		
Extreme H_2O	Hydrogel Vision Corp.	Hioxifilcon A/B
Proclear	CooperVision	Omafilcon A
Hydrogel Single-Use		
1-Day Acuvue Moist	Vistakon	Etafilcon A
Focus Dailies	CIBA Vision	Nelfilcon A

Our studies have shown that dry eye negatively impacts patients' lives and that clinicians often underestimate the severity of discomfort from dry eye.[10,11] Often, clinicians tend to focus on the lens fit and vision, without asking enough questions about patients' lens wear experience—if and for how long the lenses feel comfortable, for example. Because of this, contact lens-related dry eye is often ignored or simply unrecognized.

Lens-Related Dry Eye

A brief set of questions about dry eye symptoms may be the best starting point for the clinician who wants to make comfort central to his or her contact lens evaluation. These questions take little of the doctor's time and can really inform the decision about performing further testing and a more detailed examination.

Gregg Russell, O.D., a private practitioner in Atlanta, conducts an informal, oral questionnaire. "I quickly form a tentative opinion on their likeliness to struggle with dryness, just based on their age, medications and career or daily activities," he says. Next, Dr. Russell asks a few key questions:

- On a scale of one to ten, rate how dry your eyes feel, with one being "not dry at all" and ten being "the Sahara desert."
- Do your eyes feel worse at the beginning of the day, the end of the day, or about the same all day?
- Does your vision fluctuate during the day? How would you rate your quality of vision at the end of the day as compared to the beginning?

Fluctuating vision is a critical symptom. In my current research with Carolyn Begley, O.D., M.S., Professor at Indiana University School of Optometry, we are finding that patients with lens-related dryness commonly report poor or fluctuating vision. As the tear film breaks up more quickly, optical quality declines. That functional loss of vision, on top of chronic discomfort, may be what motivates the patient to make an appointment with his eye-care provider in the first place.

There are many tests and components we can incorporate into a dry eye exam, including fluorescein and lissamine green staining, Schirmer's, TBUT, lid eversion, and careful examination of the lid margins and meibomian gland secretions. Many experts even recommend reappointing symptomatic patients for a separately billed dry eye consultation with enough time for a thorough examination and discussion of treatment.

In my opinion, clinicians should be guided by symptomology more than anything else. The tear film is challenging to assess quantitatively, and many patients with very real symptoms may not have objective findings in any case. In patients under the age of 50 with no obvious lid disease or other factors predisposing them to dry eye disease, we should begin by addressing the contact lens system.

New Lens Materials

There is evidence that newer hydrogel materials may address dryness much better than their predecessors. Symptoms and ocular surface staining associated with contact lens-related dryness can be

significantly alleviated by the use of hioxifilcon or omafilcon lenses, for example.[12] But the most important change that clinicians can make to extend lens wearers' comfort is to upgrade them to silicone hydrogel lenses. Our research has shown that refitting hydrogel wearers into silicone hydrogel materials, such as lotrafilcon B or senofilcon A, significantly reduces the frequency and severity of contact lens-related dryness symptoms and improves comfort and wearing time.[4,5] The improvement is not short-term; rather, it has been shown to last through at least three years of wear.[6]

Silicone's great advantage is that it transmits oxygen extremely well. But, it is hydrophobic and must be combined with other materials to make it more wettable. Manufacturers have taken various approaches to making silicone biocompatible, including embedded wetting agents, such as the Hydraclear technology used in Acuvue Advance and Acuvue Oasys (Vistakon) lenses, and surface treatments or coatings used in the Focus Night & Day (CIBA Vision) and PureVision (Bausch & Lomb) lenses. Some of the most recent silicone hydrogel entrants to the market, such as Avaira (CooperVision) lenses, claim to be "inherently wettable," without embedded agents or surface treatments.

Originally, silicone hydrogel lenses were available in limited parameters and with a relatively stiff modulus, so many early wearers may have been poorly fit. This may account for the myth that a silicone hydrogel lens is not as comfortable as a hydrogel lens. But, this observation is simply not supported by the empirical data that others and I have gathered.

"The science is there to show that silicone hydrogel materials are better for most patients than HEMA," agrees Glenda Secor, O.D., a private practitioner in Huntington Beach, Calif. "Patients may find that silicone hydrogel feels a little different, but that new sensation or awareness generally disappears after just a few days of adaptation," she says. Moreover, practitioners today have a wealth of choices in silicone hydrogel lenses from different manufacturers *(see "Targeting Improved Comfort: Latest-Generation Contact Lens Materials," pg. 17)*.

"We have enough alternatives to be able to play with modulus and fitting parameters to maximize comfort for each patient," Dr. Secor says. She believes that fitting skill is more important than ever. "You really need to make sure the lens is well centered and not too flat or loose," she says. "The lower water content of silicone hydrogel lenses means they won't tighten up during wear, so a good initial fit is essential to reducing the mechanical irritation, and even giant papillary conjunctivitis, that can arise from poor interaction between the lens and the lids or cornea."

There is great opportunity for refitting patients who currently wear hydrogel lenses into silicone hydrogel lenses. Market data indicate that only about half of contact lens fits, including new fits, are silicone hydrogel lenses, which means that a huge percentage of people are wearing materials that are 15 or more years old.[13]

"Really comfortable materials like senofilcon A are now available in toric versions," Dr. Secor notes. And, we are likely to see new silicone hydrogel options for presbyopes and daily disposable wearers in the near future. A single-use lens made from narafilcon A (1-Day Acuvue TruEye, Johnson & Johnson Vision Care) is already available in the United Kingdom. "These ongoing polymer innovations just expand the range of people we can fit with healthier, more comfortable materials," she says.

Material and Design Features

So, how do we choose a material that will improve our patients' comfort from the myriad new-generation materials currently available? Reading the lens label is not the answer. The only lens material with an approved labeling claim related to dryness symptoms is the hydrogel omafilcon A used in Proclear lenses (CooperVision).[14] Every labeling claim is based on scientific data; however, other lens materials with similar study data submitted to the FDA have not succeeded in obtaining the dryness claim. There may have been a changing regulatory environment for the later submissions. Instead of focusing on the label, peer-reviewed research is where the practitioner should look for direction.

One potentially important material property is the lubricity, or coefficient of friction, which measures the ability of the eyelid to travel smoothly across the front surface of the contact lens. With more than 10,000 blinks per day on average, the lid/lens interaction is critical to comfort. Dr. Donald Korb and colleagues have described the upper lid margin staining that may result from too much friction between the lid and lens.[15] This "lid-wiper epitheliopathy," as they dubbed it, is sometimes the only clinical sign of dryness in an otherwise asymptomatic patient.[16] In one recent laboratory study, senofilcon A lenses were shown to have significantly less friction than lotrafilcon B lenses, both straight out of the package and following exposure to proteins and lipids to mimic two weeks of wear.[17]

Lens manufacturers also present

Beyond the Lens

Here are 10 tips you can share with patients so they are able to achieve the best vision and comfort possible in their contact lenses:

- Rub your lenses during your daily cleaning regimen to remove deposits without compromising wettability.
- Consider switching to a peroxide-based cleaning system.
- Pay attention to blinking habits during activities associated with reduced blink rates, such as watching television, driving or using a computer. Take breaks if necessary.
- Switch to a laptop screen or position computer monitor so that gaze is downward. The natural reading position minimizes exposure and evaporation of the tear film and ensures a thicker tear layer for better optical quality.
- Consider part-time wear or alternating daily disposable and spectacle wear.
- Avoid allergens and irritants (e.g., smoke, pets or dust) in or near the bed.
- Consider using a humidifier in dry indoor environments.
- While driving, angle the heating and air conditioning vents away from your face.
- Consider taking omega-3 dietary supplements and drinking more water.
- Use re-wetting drops, especially toward the end of the day.

dynamic contact angles. The lower the angle, the more effectively the surface can be coated with fluid and the better the wettability. The new AirOptix Aqua (CIBA Vision) and Acuvue Oasys (Vistakon) lenses, for example, are both purported to have low angles of contact. The wettability of a lens after wear, cleaning and exposure to surfactants in lens care systems may be different from its wettability out of the package, so the clinical impact must still be assessed by the practitioner.

Water content and lens dehydration were once the subject of great debates at meetings and in the clinical literature, but they do not drive comfort with silicone hydrogels as much as with hydrogel materials that depended on water content to transmit oxygen.

"Most people will find a softer modulus more comfortable," says Dr. Secor, "but that is very patient-specific. In fact, this kind of variation in patient preference is one of the reasons to try different lenses if your 'go-to' lens doesn't work for a particular patient."

Dr. Russell has also found that modulus preference can be hard to predict, although he has established a few guidelines for himself. "I have found success with a stiffer-modulus lens like Focus Night & Day in post-hyperopic LASIK patients, while the post-myopic patient does better with a softer modulus lens such as Acuvue Oasys or Proclear." He also uses stiffer modulus silicone hydrogels (e.g., O_2Optix, Biofinity, or PureVision) for patients with significant basement membrane degeneration. "Those patients with basement membrane changes in their line of sight will actually have better quality of vision with contact lenses than with glasses," he says.

His experience highlights the fact individual patients do not always conform to the mean of population-based data sets. Real patients' success with any given lens is dependent on their unique physiology, tear film dynamics and wearing habits, as well as effective interaction with a knowledgeable clinician.

For the average clinician, it is nearly impossible to tease out which aspects of a contact lens—from proprietary material components to design elements—are most important for comfort. But, there is no doubt in my mind that newer polymers, especially the advanced silicone hydrogel lenses, are more comfortable for patients and have reduced the incidence of contact lens-related dryness, especially at the end of the wearing day.

With ongoing patient education and the right contact lens materials and care systems, many more patients should be able to remain comfortable in their contact lenses and avoid or postpone dropout. RCCL

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Rx vs. OTC for Ocular Surface Disease

Clinicians debate the safety and efficacy of prescription vs. over-the-counter medications in this point/counterpoint discussion.

By Alan G. Kabat , O.D., F.A.A.O., and William D. Townsend, O.D., F.A.A.O.

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Pro Rx

When it comes to ocular surface disease (OSD), and particularly dry eye and allergic conjunctivitis, we have myriad treatment options. But, unlike some of the more sight-threatening conditions that we manage (e.g., glaucoma and uveitis), many of the remedies for OSD are OTC. This is both a blessing and a curse; the benefits of OTC medications are that they are often less expensive and more easily obtainable than those requiring a prescription. The downside, unfortunately, is that these products are often of inferior quality and in some cases, even detrimental to ocular health.

The FDA Difference

Before we can adequately compare OTC and Rx medications, it is helpful to understand the differences between them in terms of governmental oversight. OTC products are regulated by the FDA based upon specific monographs. The OTC monographs represent regulatory standards for the marketing of non-prescription drug products. The stipulations are straightforward: Active ingredients must be recognized as safe, effective and properly labeled for their intended uses.[1] The FDA publishes OTC drug monographs that list active ingredients, allowed combinations and required labeling for classes of drug products (e.g., cough-cold remedies, ophthalmic lubricants, etc.). In general, to market an OTC product, the product must meet the standards of the OTC monograph. Interestingly, OTC applications do not require any clinical studies to be submitted to the FDA, although evidence supporting any specific claims must be available upon request.

In stark contrast, Rx drug products must go through an extensive journey in order to reach consumers. After discovery processes involving animal models and/or human tissue, new drugs are subjected to three phases of human study to determine their safety, tolerability and optimal dosage. They must demonstrate clinical efficacy in a series of well-controlled prospective clinical trials, sometimes involving hundreds or even thousands of subjects.

Once all testing has been completed, the manufacturer must submit the results of their research by filing a new drug application (NDA); this initiates an exhaustive review of the data by the FDA. Rx products become available for distribution and consumer use only after the FDA endorses the indications and label claims and grants "approval to market" status. All together, the process from drug discovery to FDA approval can take

from 10 to 12 years, or even longer in some cases.[2]

Treatment Options for Dry Eye

Examining dry eye remedies, there is a huge discrepancy between OTC and Rx products, with the vast majority of options being OTC. "Artificial tears"—as we refer to them collectively—comprise the mainstay of therapy for virtually all dry eye patients. In recent years, we've witnessed the introduction of several fine products with unique mechanisms of action and therapeutic abilities as demonstrated by well-designed clinical studies.[3,4]

There are, however, numerous other available agents that have few if any distinctive qualities, merely serving as "rewetting drops" for the ocular surface. In some cases, approved products may consist of nothing more than pure water![5] Confounding the issue even further, the sheer number of artificial tear agents that are available today is staggering. On a given drugstore shelf, the consumer may encounter in excess of 25 or even 30 different products for relief of dry, red or irritated eyes. And to the dismay of practitioners, a large percentage of these options contain unwanted components, such as irritating preservatives (e.g., benzalkonium chloride) or topical decongestants (e.g., naphazoline, tetrahydrozaline) that can be detrimental to patients with excessive or prolonged use.[6,7]

In contradistinction, there is only one FDA-approved prescription drug that is indicated for the treatment of dry eye: Restasis (cyclosporine 0.05%, Allergan). Restasis has been widely utilized within eye care since its introduction in 2003, and it has been advocated as a viable treatment modality in the most significant dry eye-related publication of the last decade, the DEWS report.[8] Restasis is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.[9] Another powerful option for acute management of dry eye disease is a topical corticosteroid, Lotemax (0.5% loteprednol etabonate, Bausch & Lomb). While not specifically indicated for dry eye, Lotemax is approved for the treatment of steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.[10] However, since the recent DEWS definition stipulates that dry eye is accompanied by inflammation of the ocular surface, many have taken this as an extended indication to employ Lotemax in the management of dry eye.[11] Like Restasis, topical corticosteroids have been endorsed by DEWS, and the clinical value of these agents in dry eye therapy is well-established in the literature.[8,12-14]

The Rx Advantage For Allergy Patients

Regarding options for ocular allergy, the benefits of Rx vs. OTC products are even more obvious. OTC choices include numerous decongestant products such as Visine (tetrahydrozoline, Pfizer) or Murine (tetrahydrozoline, Prestige Brands) or combination decongestant-antihistamine drops like Naphcon-A (naphazoline hydrochloride/pheniramine maleate, Alcon). As mentioned above, the prolonged use of topical decongestants can result in toxic and/or inflammatory responses in ocular tissues.[6] Moreover, the antihistamines in these OTC products—which include agents like pheniramine maleate and antazoline phosphate—are older and comparatively weaker than newer Rx antihistamines.[6]

This allergy patient was abusing topical vasoconstrictors (i.e., Visine). His eyes are white, but he was still suffering from pronounced ocular itching and tearing, as well as eyelid edema, which is evident in the photo.

For the last 12 years, the standard of care for ocular allergy management has been the use of topical antihistamine mast cell-stabilizer combinations, commencing with Patanol in 1996. Other drugs in this category, all of which are Rx, include Optivar (azelastine 0.05%, Meda Pharmaceuticals), Elestat (epinastine 0.05%, Allergan/Inspire) and Pataday (olopatadine 0.2%, Alcon). These agents afford patients both acute symptomatic relief and prophylactic intervention from allergic conjunctivitis, with the convenience of once or twice daily dosing. Another such drug is Zaditor (ketotifen 0.025%, Novartis). Recently, Zaditor made the Rx-to-OTC switch, and several generic versions of ketotifen followed, including Alaway (Bausch & Lomb) and Refresh Eye Itch Relief (Allergan). While this option is certainly better than topical decongestants, it still poses some of the same difficulties as other OTC offerings. Studies have shown ketotifen to be less effective and less tolerable than several other antihistamine-mast cell stabilizing agents, particularly olopatadine.[15,16]

Simple, Safe, Successful

While OTC products may offer convenience and cost-savings to our patients, there is still an overwhelming advantage favoring Rx products. Whether it be for dry eye, allergic conjunctivitis or any other

Dry eye products, OTC allergy medications and contact lens solutions are sold side-by-side in settings such as these. Unless patients are specifically directed toward a certain product, it becomes a guessing game.

ocular malady, prescription products afford the practitioner greater oversight of the condition by stipulating the precise ingredient, dosage and administration of the treatment regimen. By removing guesswork and interpretation on the part of the patient, the Rx agent ensures better compliance and, hence, greater efficacy in disease management. Also, the mere act of writing the Rx helps communicate to our patients the seriousness of the condition and the importance of therapy. Costs are a real concern in today's economy, and the high price of medications affects us all. Still, this cannot and should not be the practitioner's main concern; rather, doctors have the obligation to offer patients the best and most effective treatment for their particular disorder. OTC remedies should remain an option for adjunctive therapy or, in rare cases, an alternative to prescription medications that are simply not affordable, but patients must be alerted as to the actual "value" of these products. In all cases, proactive recommendations and proper patient education are paramount, regardless of the mode of therapy.

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Pro OTC

"The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded." With this statement, the FDA defined the crucial elements necessary for classifying a drug as over-the-counter (OTC).[1] To understand how this determination is made, it helps to know something about the origins of the FDA and how it functions.

There was a time when all drugs were OTC—in the sense that they were totally unregulated. Drugs such as cocaine, heroin, chloroform, cannabis and morphine were found in many "patent medicines." The modern era of the FDA began in 1906 with the passage of the Federal Food and Drugs Act (the Wiley Act), which focused primarily on regulation of foodstuffs.[2] The Wiley Act required that medicine labels acknowledge the inclusion of potentially dangerous or addictive substances and name those substances, but it fell short of regulating or prohibiting their use in consumer products.[3]

There was essentially no regulation of medications until June 25, 1938, when the Food, Drug, and Cosmetic Act was signed into law.[4] It mandated federal control of cosmetic and medical devices and required pre-market approval of all new drugs. Under this law, drug

manufacturers were generally free to determine if their drug belonged in the "prescription" category. The ensuing debates among the FDA, industry and health care providers over what constituted a prescription (Rx) drug vs. an OTC drug were finally resolved by the Durham-Humphrey Amendment in 1951.[5]

The Durham-Humphrey Amendment also addressed the conversion of a prescription drug to OTC status. The chief concerns were: Can the condition be adequately self-recognized? Can the condition be successfully self-treated? And, is the self-treatment product safe and effective during consumer use?[6] Today, the FDA considers several factors, including whether a drug has an acceptable margin of safety, whether there is a high or low potential for abuse, and whether the medication can be used with minimal or no physician supervision. When the panel determines that these guidelines are met, it issues a ruling (monograph) allowing OTC status.[6]

Managing Dry Eye Disease

In eye-care, conditions such as infectious keratitis or glaucoma are obviously outside the guidelines. Other ocular conditions are quite amenable to management with OTC products, particularly when there is input from the patient's provider. For example, dry eye diseases are often well managed with OTC products, commonly referred to as "artificial tears." The two critical issues in successful management with these products are product formulation and input from a practitioner. For instance, the inclusion of BAK as a preservative in a product that may be instilled multiple times each day is counterproductive. Göbbels and Spitznas demonstrated that dry eye patients treated with polyvinyl pyrrolidone 2% drops preserved with BAK 0.005% showed increased epithelial permeability.[7] In contrast, patients treated with non-preserved PVP showed reduced epithelial permeability.[7] Practitioners can inform dry eye patients of the potential for exacerbation of dry eye symptoms through the use of inappropriate products and direct them to OTC products that are optimized to preserve the ocular surface.

The advent of non-preserved artificial tears and artificial tears containing preservatives with reduced toxicity allows a patient to purchase products that are effective and "eye friendly." Artificial tears containing agents such as carboxymethyl cellulose and HP-guar have been shown to reduce dry eye related symptoms and ocular surface changes in as quickly as one week.[8,9] Recently introduced products, such as Soothe XP (Bausch & Lomb) contain molecules that increase contact time and mineral oil, which to some extent, mimics the function of meibomian secretion in natural tears.

Restasis (cyclosporine 0.05%, Allergan) is the only currently available true prescription dry eye medication. Restasis is "indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca."[10] According to the package insert, "Four multicenter, randomized, adequate and well-controlled clinical studies were performed in approximately 1200 patients with moderate to severe keratoconjunctivitis sicca. Restasis demonstrated statistically significant increases in Schirmer wetting of 10mm vs. vehicle at six months in patients whose tear production was presumed to be suppressed due to ocular inflammation. This effect was seen in approximately 15% of Restasis ophthalmic emulsion treated patients vs. approximately 5% of vehicle treated patients."[10]

But, in a randomized double-masked prospective clinical trial, Salib and associates compared patients treated before and after LASIK with Restasis or artificial tears. There were no significant differences in Schirmer scores or SPK measured by fluorescein staining between the two treatment groups.[11]

Dry eye is a very common condition, and although Restasis has been beneficial to many patients, OTC dry eye products are often very effective agents in the treatment of these conditions. It is important to "prescribe" these OTC products and educate patients on the importance of adhering to the recommended regimen.

Itching to Help the Ocular Allergy Patient

Hypersensitivity disorders are a common finding in health care: an estimated 58 million Americans suffer from allergic rhinitis.[12] In developed nations 15% to 20% of the population suffer from ocular allergy, and of that population, approximately 95% have perennial or seasonal allergic conjunctivitis.[13] Allergic rhinitis is the fifth leading cause of chronic illness in terms of the overall economic burden.[14] Approximately 50% of patients with allergic rhinitis have concomitant allergic conjunctivitis. The estimated cost of allergic rhinoconjunctivitis in the U.S. in 2002

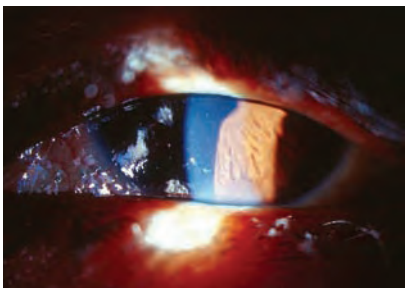
This patient has dry eye and pronounced lissamine green staining of the conjunctiva and cornea.

was $7.3 billion.[15] Allergic conjunctivitis occurs in 18% to 20% of adults.[16]

Ocular allergic diseases comprise a number of conditions with widely varying degrees of potential morbidity. Seasonal allergic conjunctivitis is symptomatic, but not sight threatening, while vernal keratoconjunctivitis and atopic keratoconjunctivitis carry the potential for severe vision loss.[17] For the purpose of the discussion of OTC therapy, we restrict our discussion to non-sight threatening allergic eye diseases.

Type 1 hypersensitivity (allergy) occurs when previously sensitized mast cells encounter an allergen specific to the IgE molecules that reside on the mast cell surface. If the allergen bridges the gap between two such immunoglobulin molecules, a change in the molecular structure of the mast cell occurs, and preformed granules of histamine, chymase, tryptase, and other mediators are released, which results in classic signs of itching, swelling, injection, and watering. Management of ocular allergy focuses on neutralizing the effects of the mediators or preventing their release altogether.[18]

Treatment options range widely, the simplest of which is dilution and removal of allergens from the ocular surface with artificial tears. While this form of therapy may work briefly, it fails to address the underlying cause of ocular allergy. Over-the counter agents containing H1 antagonists, decongestants and vasoconstrictors have been available for years.[19] They block the actions of histamine, but their duration of action is brief. In 1996, FDA approval of Patanol (olopatadine 0.1%, Alcon) ushered in a new class of ophthalmic agents that stabilize mast cell membranes, block degranulation and act as H1 antagonists.[20] Approval of Zaditor (ketotifen 0.025%, CIBA Vision), Optivar (azelastine 0.05%, Med-Pointe) and Elestat (epinastine 0.05%, Inspire) soon followed. All of these products are dosed q12h. Pataday (Olopatadine 0.2%, Alcon) was approved in 2004, and while the once-daily dosing of Pataday is optimal, OTC antihistamine-mast cell stabilizer products with proven efficacy and safety are now available. Ketotifen 0.025% is now marketed as Alaway (Bausch & Lomb) and Zaditor (Novartis); both are available without a prescription. The products must be used every 12 hours and have demonstrated value in managing allergic conjunctivitis.[21,22]



This image shows a dysfunctional tear film in dry eye.

The Patient-Centered Approach

Without a doubt, we now have a large selection of excellent prescription products at our disposal for the treatment of dry eye and allergic eye disease. That being the case, many individuals do not have insurance or are simply unable to afford prescription products for these conditions. The FDA has evaluated several products for safety and efficacy and has now approved them for OTC status. Recent studies show conclusively that numerous OTC products are efficacious and safe agents that we can recommend to our patients. In many cases, they cost far less than their prescriptive counterparts. The critical issue in this discussion is that we as professionals be involved in the choice of OTC medications that our patients use for ocular surface diseases. RCCL

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Rare Infections in GP Wear

Although gas-permeable contact lenses offer patients a reduced risk of infection, remember that microbial keratitis is still possible in this population.

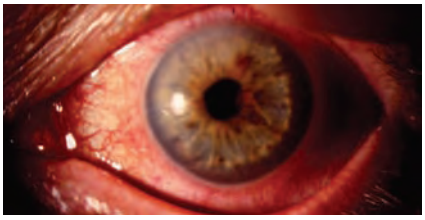
By Keshia S. Elder, M.S., O.D., F.A.A.O.

In the United States, millions of Americans who require vision correction choose contact lenses—and while there are many advantages to contact lens wear, some patients run the risk of developing an infection. Microbial keratitis, an infection of the cornea, affects approximately five in 10,000 contact lens wearers annually—the infection rate varies by type of lens.[1-4] Overall, gas-permeable (GP) lenses have an infection rate that ranges from 0.4 to four per 10,000 patients, one-third the rate of infection in soft lens wearers.[1-5] Modifiable risk factors that can play a role in patients' likelihood to contract a microbial infection include smoking, poor hygiene, lens material, oxygen permeability, wear schedule and purchasing from an Internet distributor, while non-modifiable risk factors include such things as male gender and high refractive error.[6-7]

The advent of silicone hydrogel lens materials with higher oxygen permeability than traditional hydrogel materials have decreased the rate of hypoxic complications in silicone hydrogel wearers, but it has not decreased the adverse events associated with contact lens wear.[8] However, complications with silicone hydrogel wear appear to respond to management more quickly and are less severe than complications with hydrogel wear.[9] In fact, cases of infectious keratitis in GP lens wearers have been documented with daily and overnight lens wear. We will review the prevalence of ocular infections in contact lens wearers, with a special focus on GP lenses and the pathogen profiles of microbial keratitis in that population.

Microbial Keratitis in SiHy Wearers

Adverse effects that can occur with contact lens wear include hypoxia, corneal edema, neovascularization, sterile infiltrates and microbial keratitis. These problems have been shown to increase with overnight wear of contact lenses; patients who wear hydrogel lenses on an extended-wear basis are nearly four times more likely to develop microbial keratitis than daily wear patients.[3,7] Hypoxic events can sometimes accompany contact lens wear,



CLARE patient after overnight wear of rigid lenses.

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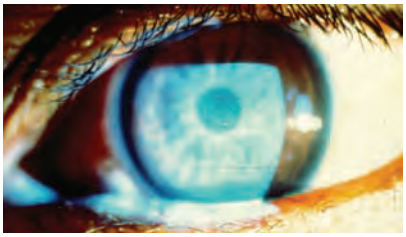
yet silicone hydrogel contact lenses are associated with fewer hypoxic events.[8] On the other hand, the incidence of microbial keratitis in silicone hydrogel lens wearers has not decreased. Microbial keratitis for 30-day extended wear of silicone hydrogel contact occurs at an annual rate of 18 per 10,000 lens wearers, which is about the same rate as that for patients who wear seven-day extended wear hydrogel lenses.[9,10] One study found that the risk of severe keratitis was five times less likely in overnight wear of silicone hydrogel lenses than in overnight wear of hydrogel lenses, but the researchers attribute their finding of higher rates of keratitis compared to previous studies in this area to the single-center methodology of the study.[11]

How Safe is GP Wear?

GP lenses are less harmful to ocular health and have a lower incidence of corneal staining and giant papillary conjunctivitis than soft contact lenses.[12] The smaller diameter of GP lenses results in less peripheral corneal complications due to the lack of limbal compression that may occur with soft contact lenses.[12] Overnight wear, poor contact lens and contact lens case hygiene and prolonged corneal hypoxia are all factors that have been linked with microbial keratitis in contact lens wearers.[6,7] Microbial keratitis occurs in about one in 10,000 daily-wear GP lens wearers, compared to three to four in 10,000 daily wear soft lens wearers and 10 to 20 in 10,000 extended wear soft lens wearers.[10]

A prospective study conducted to assess the incidence of contact lens microbial keratitis found a lower rate of microbial keratitis in GP wearers and a higher rate of microbial keratitis in silicone hydrogel lens wearers than hydrogel lens



Diffuse keratitis secondary to overwear of a hydrogel contact lens.

wearers. Specifically, investigators found an annual incidence of microbial keratitis of 1.2 per 10,000 daily-wear GP wearers, 1.9 per 10,000 daily-wear soft lens wearers, 2.2 per 10.000 soft lens wearers with occasional overnight wear, 19.5 per 10,000 overnight soft lens wearers, 2.0 per 10,000 daily-disposable soft lens wearers, 4.2 per 10,000 daily-disposable soft lens wearers with occasional overnight wear, 11.9 per 10,000 daily wear silicone hydrogel contact lens wearers, 5.5 per 10,000 daily-wear silicone hydrogel wearers with occasional overnight wear, and 25.4 per 10,000 overnight wearers of silicone hydrogel lenses. But, after adjusting for risk factors, the difference in microbial keratitis incidence for silicone hydrogel wearers compared to hydrogel wearers was no longer statistically significant.[6]

Another study evaluated the safety and efficacy of Menicon Z (Menicon), a high oxygen permeability GP lens, worn on a 30-day extended-wear schedule and compared it to Acuvue (Johnson & Johnson Vision Care), a control lower oxygen permeability soft hydrogel lens, worn on a seven-day extended wear basis. The investigators did not find any statistically significant differences in the rate of significant adverse events in Menicon Z wearers compared to Acuvue wearers (8.2% vs. 10.5%, respectively, P=0.31).[13] Nor did they find any statistically significant difference in the time to the first significant adverse event in either contact lens group. But, when researchers questioned whether the adverse events were definitely not related to the device, unlikely related, possibly related, probably related and definitely related to the device, there was a statistically significant lower rate of adverse events considered definitely related to the Menicon Z lens. And, of the 661 patients enrolled in the study, there were only two reported incidents of corneal ulcer, one with a Menicon Z wearer and one with an Acuvue wearer.[13]

A normal flora of microbes colonizes the conjunctiva and eyelids. In non-contact lens wearers, it consists predominantly of coagulase-negative *Staphylococci*, *Corynebacterium sp*., and *Propionibacterium sp*. There is no consensus on whether the types of microorganisms that colonize the eye differ in contact lens wearers and non-contact lens wearers. The most common cause of microbial keratitis in contact lens wearers is Pseudomonas aeruginosa.[14] Contact lens acute red eye (CLARE) is frequently associated with gram-negative bacteria, and *Haemophilus influenza* is the most common bacterium isolated, while contact lens peripheral ulcers (CLPUs) are normally associated with gram-positive bacteria.[14] Similar pathogens are implicated in GP and soft contact lens microbial keratitis.[14] A small study conducted in Japan, where approximately 35.4% of the contact lens wearers wear GP lenses, found that 91% (n=11) of microbial keratitis cases in their study population was caused by gram-positive bacteria, and that 1% was caused by the gram-negative bacterium *Pseudomonas aeruginosa*.[15] Eighty percent of the microbial keratitis caused by gram-positive bacteria was from the *Staphylococcus species*. Overall, *Staphylococcus epidermidis* was the

most frequent isolate 36.1% (n=13), followed by *Staphylococcus aureus* 14.3% (n=5).[15] This study outcome differs from other studies, which generally find that more gram-negative bacteria cause infections in contact lens wearers.[1,16]

Infection Rates in Corneal Reshaping

Orthokeratology is the use of a reverse-geometry GP lens, typically overnight, to improve vision by reshaping the cornea. Since overnight wear is one of the major risk factors associated with microbial keratitis, numerous studies have evaluated the rate of microbial keratitis associated with orthokeratology. Both the decrease in corneal oxygen that occurs during overnight wear and the possible epithelial compromise due to the flat fitting reverse-geometry lens may contribute to microbial keratitis in orthokeratology patients. Case reports have been published documenting *Serratia marcescens* corneal ulcers, P*seudomonas aeruginosa* infectious keratitis and *Acanthamoeba* keratitis in adults and children who wear orthokeratology lenses overnight.[17-24]

Several studies have evaluated the pathogens associated with overnight orthokeratology. Watt and associates examined both reported and confirmed cases of microbial keratitis associated with orthokeratology to determine any trends in the affiliated microbes. They reviewed 123 cases of orthokeratology-associated microbial keratitis published in peer-reviewed journals or presented at optometry, ophthalmology, or vision science conferences between 2001 and 2007. Of the 123 cases reviewed, 92% of patients wore their lenses overnight. Reasearchers found that *Pseudomonas aeruginosa* was implicated in 46 cases (37% of all cases and 45% of culture-positive cases), and *Acanthamoeba* caused 41 cases (33% of all cases and 40% of culture-positive cases).[25] Additional pathogens that caused microbial keratitis included *Serratia marcescens*, *Xanthomonas maltophilia*, *Pseudomonas putida*, *Staphylocci* and *Haemophilus influenazae*, as well as three fungal infections.[25] The prevalence of *Acanthamoeba* infections was higher than the expected 3% in contact lens wear.[1]

Other studies looking at the causative organisms of microbial keratitis in orthokeratology patients found similar microbes. In one study, 69% of corneal ulcers studied were due to Pseudomonas aeruginosa, 15% were due to coagulase-negative Staphylococcus sp., and Serratia marcescens and Acanthamoeba each accounted for 7% of the cases.[18] Although microbial keratitis in orthokeratology patients is usually attributed to the increased risk factor of overnight wear of the shaping lens, a case of microbial keratitis has been reported in an orthokeratology patient who wore lenses during the day only.[25]

Microbial keratitis is a vision-threatening complication of contact lens wear. Although microbial keratitis does not occur as often in GP contact lens wearers as it does in some of the other contact lens populations, its incidence is significant enough that we need to continue to be vigilant in monitoring the ocular health of our GP contact lens patients. RCCL

Epithelial compromise secondary to a flat-fitting rigid lens in a keratoconic patient.

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Nutraceuticals and the Ocular Surface

Nutrition, exercise, sunlight and specific OTC supplements can all be used when managing corneal disease. How effective are your strategies?

By Stuart Richer, O.D., Ph.D., F.A.A.O.

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Any discussion concerning nutrition and the ocular surface must begin with an overview of the state of American health. A recent review in the cardiac literature notes that 80% of cardiovascular disease (CVD) in western culture is a direct consequence of diet and lifestyle, that 70% of Americans are overweight or obese, that 90% of Americans will develop hypertension (HTN) some time during their lifetime, and that 36% of Americans have diabetes or pre-diabetes.[1] CVD will kill almost half of us.

Intake of foods that cause supra-physiological surges in blood glucose and triglycerides spikes the production of free radicals. Diet-induced oxidant stress further stimulates systemic inflammation and is a fundamental driver in the development of cardiovascular risk factors, adverse cardiovascular events and many other diseases, including Type II diabetes, Alzheimer's and cancer.[2]

The American diet, high in saturated fat and simple carbohydrates, low in nutrients and particularly high in trans fat and omega-6, is a generator of inflammatory mediators in all tissues.[3] These pro-inflammatory cytokines include IL-6, TNF-α, TNF-α R1, sICAMS, ICAM-1, VCAM-1 and PGE-2 and are reflected in rising high-sensitivity C-reactive protein (hs-CRP) and erythrocyte sedimentation rate (ESR) values.

Nuclear factor kappa-beta (NFkB) is a signaling factor that is derived from ribonucleic acid (RNA) and resides in the cytoplasm of all cells in an inactive state. This pro-inflammatory mediator stimulates nuclear surface receptors by translocating into the nucleus, where it acts as a transcription-signaling factor. NFkB is involved in cellular response to common stimuli, such as stress, free radicals and cytokines. It activates many immunoregulatory genes in response to pro-inflammatory stimuli.

In this article, we discuss how the clinician can use natural substances to reduce both cytokines and activation of NFkB.

The Human Diet

Modern food staples and food-processing procedures introduced during the Industrial ages have fundamentally altered seven crucial

nutritional characteristics of ancestral human diets: glycemic load, fatty acid composition; macronutrient composition, micronutrient density, acid-base balance, sodium-potassium ratio; and fiber content.[4] According to Loren Cordain, Ph.D., author of *The Paleo Diet*, "The evolutionary collision of our ancient genome with the nutritional qualities of recently introduced foods may underlie many of the chronic diseases of Western civilization."[4] Moreover, researchers have shown that the traditional eating patterns of the Japanese Okinawans or Mediterranean cuisines have in both epidemiological and experimental studies improved CVD risk factors and health, as well as reduced systemic inflammation.[5]

Unlike the typical American diet, these diets are high in minimally processed, high-fiber, plant-based foods, such as vegetables, fruits, nuts, legumes and whole grains, with moderate amounts of lean protein, such as fish. These diets are also much higher in plant-based antioxidants, other nutrients and essential fats compared with the typical Westernized diet of processed foods, cheese burgers, French fries, pizza, soda, candy, ice cream and snack chips.

To help cultivate healthy eating habits, the USDA has recently introduced the fifth iteration of the "Food Pyramid" for Americans over the age of two.[6] Besides increasing plant food consumption to nine to 13 portions of fruits and vegetables daily, the new guidelines stress exercise, moderate caloric intake, personalization, dietary variety and gradual improvement.[6] In nutrition, one size does not fit everyone or every ethnic group—there are several diet plans offered, based on age, gender and physical activity level.

The Role of Inflammation

Inflammation, first described by Celsus in the first century AD, involves redness, swelling, heat and pain. Inflammation beneficially engages the innate and adaptive immune systems when challenged. In turn, a robust immune system destroys pathogens, promotes clotting and complementary activation, and initiates repair mechanisms. We can't live without the inflammatory response, yet we will surely die with too much. Balance, along with increasing immunocompetence, is the key.

Inflammation involves the generation of reactive oxygen species and gene expression of activating NFkB. Various antioxidants—N-acetylcysteine, vitamin E derivatives and resveratrol (found in red wine)—can all inhibit NFkB activation. And, certain foods, such as curcumin, garlic, licorice, ginger, rosemary, grapes, pomegranate and cold-water fish, can also inhibit NFkB.[7]

Essential Fatty Acids and Eiconsanoids

The ideal omega-3 to omega-6 ratio is between 1:1 and 1:3, but the ratio of the typical American diet is somewhere between 1:15 and 1:25. The American food chain includes grain-fed beef and pork, corn and corn oil, sunflower seeds and oil, soybeans and oil and cotton seed and oil—all foods that contain the generally pro-inflammatory omega-6 fatty acids.[5]

But, omega-3 fatty acids are found as eicosapentaenoic acid (EPA) and docohexaenoic acid (DHA) in cold-water fish—e.g., wild salmon, herring, sardines, mackerel, tuna and halibut). Omega-3 fatty acids can also be derived from plant sources in the form of alpha-linolenic acid (ALA)—e.g., walnuts, flaxseed, soybeans, spinach/purslane, wheat germ, pecans and canola oil. But generally, the conversion process involving the delta 6-desaturase enzyme is inefficient, requiring a larger intake of these plant-based foods to achieve the same effect as fish or fish oil supplements.[8]

Adding fish or fish oil to one's diet is very beneficial. Specifically, here are some benefits of omega-3 fatty acids:[1]

- They reduce the risk of heart disease by lowering triglycerides and raising HDL cholesterol.
- They reduce the risk of stroke and heart attack.
- They lower blood pressure and heart beat rate.
- They reduce inflammation from rheumatoid arthritis and other inflammatory diseases.
- They lower the risk of developing Alzheimer's disease.
- They reduce depression.
- They improve immune system function and protect against certain cancers and macular degeneration.

First-Line Defense Against Dry Eye

In order to move forward in the management of ocular surface conditions, it must be understood that the health of the anterior segment cannot be completely separated from the management of the patient's overall systemic health. So, fish oil helps dry eye by diminishing inflammatory corneal surface and meibomian gland dysfunction, and it augments the lipid component of the tear film, preventing evaporation.[9] Additionally, it indirectly stimulates tear lacrimal secretion.[9] Omega-3 fatty acids have the distinct advantage of reducing comorbid inflammatory blepharitis, which is found in 60% of dry eye patients.[10]

A women's health study from Harvard University showed that there is epidemiological evidence

that omega-3 fatty acids decrease the risk of dry eye.[9] According to a recent report from the Schepens Eye Institute, omega-3 fatty acids may even work as a topical agent.[11]

There has been little published about nutritrional factors' relation to corneal health beyond malnutrition-induced xerophthalmia. Barbara Caffery, O.D., M.S., F.A.A.O., conducted a review in 1991 that suggested that sufficient dietary protein, vitamin A, vitamin B6, vitamin C, potassium and zinc may be necessary for normal tear function.[12] Excesses of dietary fats, salt, cholesterol, alcohol, protein and sucrose have been associated with or suggested as causes of tear dysfunction.[12] Diabetes, of course, is associated with dry eye syndrome.

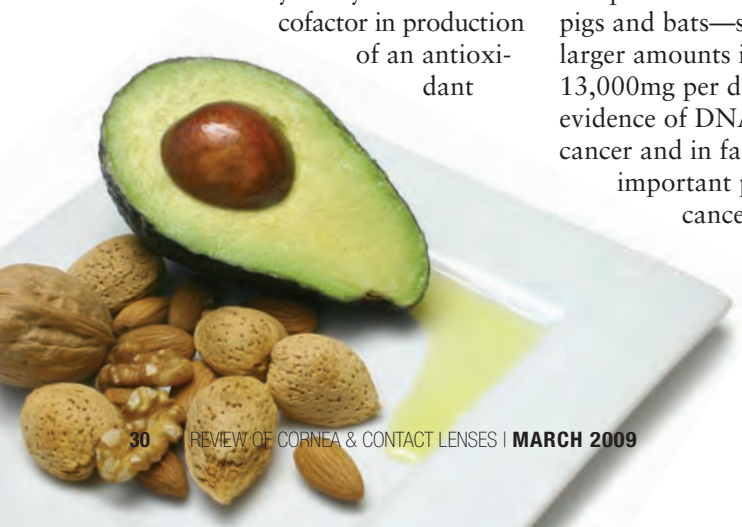
• Vitamin A promotes conjunctival, meibomian gland and lacrimal gland health, including corneal epithelial cell differentiation. Its antioxidant properties prevent free radical epithelial damage from oxidative stress caused by the environment, nutritional deficiencies and aging. It also prevents hyaluronate/protein degradation by airborne pollutants and is needed by genes that express mucin.[12,13]

• Vitamin B2 (riboflavin) is found in organ meats, whole grains and brewers yeast, and just like vitamin B1 (thiamin), it aids in the release of energy from foodstuffs, promoting growth and development.[14] Also, like thiamin, riboflavin is involved with myriad systems and is a cofactor in production of an antioxidant enzyme called GSH reductase. Riboflavin deficiency can cause photophobia, aesthenopia, itching, burning, conjunctival injection and corneal neovasularization, in addition to anemia, cataracts, poor thyroid function, B6 deficiency and fatigue.[14] But, when taken in doses greater than 10mg, it could potentially cause cataracts, vitreous liquefaction and retinal degeneration because riboflavin is a light-sensitive vitamin. In fact, scleral cross-linking with riboflavin and blue light (465 nm) has a stiffening effect on the sclera without histological tissue damage to the retina. This approach is being explored as a treatment for keratoconus.[15] Patients, nonetheless, who take especially high doses should be urged to wear sunglasses outdoors, because of the risk of retinal toxicity.[16]

• Vitamin B6 (pyridoxine) is involved with the metabolism of proteins in the lacrimal gland, as well as gammalinoleic acid synthesis. Gammalinoleic acid is an omega-6 fatty acid with immune dampening attributes and is helpful for irritated dry skin and eyes, when used systemically.[14,16]

• Vitamin C (ascorbic acid) is the major water-soluble extracellular antioxidant found in abundance in fruits and vegetables. It was discovered by the Romanian scientist Svent-Gyorgi, Ph.D., in the 1930s. But, most animals—except modern humans, guinea pigs and bats—synthesize even larger amounts in their liver (up to 13,000mg per day) without any evidence of DNA mutations or cancer and in fact, may be an important pro-drug against cancer.[17] Ascorbic acid is involved in collagen synthesis (e.g., in the connective tissue of the cornea), the promotion of healthy capillaries, gums, teeth and eyes; the healing of wounds; and the stimulation of strong bones.[14] It also promotes the absorption of iron and contributes to hemoglobin and red blood cell (RBC) production by bone marrow. While iron intake is important for young patients, menstruating females and in the prevention of iron-deficient anemia, most men and postmenopausal females should avoid taking ascorbic acid with meals to lessen chances of increasing their intake of iron, an oxidant.[18] There are many speculated benefits of high-dose ascorbic acid intake, but eye-care practitioners should keep in mind that ascorbic acid is taken from the blood stream and actively concentrated by all tissues of the eye. It is also highly concentrated by the brain and the adrenal cortex. Other than diarrhea, there is little scientifically documented risk in taking higher doses. Bowel tolerance, or the "laxative effect," is actually used clinically by integrative medicine practitioners to determine optimal dosing levels. A higher dose of ascorbic acid tends to be less irritating when taken as sodium ascorbate, and serial dosing at regular intervals is preferable to a single large dose. Flavanoids are ascorbic acid-supporting molecules found in nature combined with ascorbic acid.

In a sense, all cells of the body are ascorbic acid-dependent; ascorbic acid is a part of the antioxidant network, and as such, it regenerates both the major cellular membrane antioxidant (vitamin E) and the intracellular antioxidant (glutathione). In the most extreme state of deficiency, scurvy, symptoms such as muscle weakness, swollen and bleeding gums, loss of teeth, tiredness, depression, bleeding



under the skin, anemia and frequent infections are all possible without adequate ascorbic acid. And, scientists have recognized that stressed humans require more ascorbic acid. This patient population includes smokers, alcoholics, diabetics, pregnant/breast feeding females, older patients, athletes, people in vigorous working occupations and patients with chronic diseases or environmental stress (e.g., exposure to heat, cold or radiation).[19] This is why humans and guinea pigs need those nine to 13 portions of fruits and vegetables every day.

The "not-so-dry eye" has puzzled contact lens practitioners, with cries for help regularly appearing in many eye-care forums. According to Sydney Bush, O.D., Ph.D., a Hull, U.K. contact lens practitioner, it is generally accepted that practices lose 30% of contact lens patients per year as a result of dry eye. Dr. Bush thought it was odd when he suddenly realized that complaints of dry eye were becoming less frequent in his contact lens practice. He noticed that contact lens comfort eye drops had begun to linger unused on the shelf, never needing to be replaced. Dr. Bush decided to investigate this phenomenon. While the Efron scale of giant papillary conjunctivitis showed conjunctival papillae, it did not show the wet "eggshell" conjunctival appearance associated with plasma histamine. But, plasma histamine had been shown by Clemetson to drop from 60ng to 20ng as plasma ascorbic acid rises from one to 25mg per liter.[20] If the eye is the most sensitive ascorbic acid-dependent organ in the body, could increasing blink effort related to "loss of gloss" precede detectable papillary formation? We can infer from Dr. Bush's observations that contact lens patients could benefit from extra dietary and supplemental ascorbic acid. Dr. Bush has also pioneered the field of Nutritional Preventive Cardioretinometry and recommends large serial ascorbic acid doses for retinal arteriole atherolysis.[21]

• Vitamin D is good for your bones and teeth—it prevents rickets, osteomalacia and cavities, particularly in people of color (non-Caucasians).[22] But, that is old news. There is now evidence concerning its anti-cancer and anti-calcifying (atherosclerotic) effects, as well as its role in a whole host of diseases, including diabetes and age-related macular degeneration (AMD). There is indeed a brighter side of sunlight, and the potential for a 10-cent per day vitamin to usher in a new golden age of medicine, especially for people living in northern latitudes.[23] Vitamin D deficiency is easily detected with the 25 hydroxyvitamin D serum test and even more easily treated by clinicians. Vitamin D is actually a prehormone-like vitamin that regulates cells, tissues, organs and systems. In fact, it is the most potent steroid hormone in the human body. It is the only vitamin formed with the help of sunlight. Vitamin D synthesis begins when 7-dehydrocholestrol in the skin is converted to pre-vitamin cholcalciferol by UVB radiation (290nm to 320nm). This precursor molecule is then converted to a diagnostically important non-active storage form, 25 hydroxyvitamin D, via hydroxylation in the liver and kidneys. The average person maintains a 60-day supply. The actual biologically active form, which is less important to ascertain from our clinical diagnostic standpoint, is called 1,25 dihydroxyvitamin D. This sunlight-driven process is how 90% of pre-industrial people obtained their supply of vitamin D.[23]

Deficiency, thus far, has been linked to 17 types of cancer, cardiovascular disease, diabetes, multiple sclerosis, schizophrenia and even influenza.[24-26] There is even a theoretical postulation between impaired immunity and *Acanthamoeba* infection.[27] The use of vitamin D3 and its analogs to increase transplant success rates lessens risk of bone loss and opportunistic infection, two important disadvantages of the most widely used transplant rejection drugs—cyclosporine A and the glucocorticoids.[28] A daily dose of 2,000 IU of Vitamin D significantly increases anti-inflammatory cytokine IL-10 and decreases pro-inflammatory TNF-alpha in congestive heart failure patients.[29]

"Vitamin E" refers to a group of lipid-soluble phenols, tocopherols and tocotrienols that possess an aromatic chromanol head and a 16-carbon tail. Vitamin E is an essential component of our anti-inflammatory state. The unsaturated tail of tocotrienols allows for mobility in the membrane bilayer, improving their ability to react with lipid radicals and recycling agents as compared to tocopherols.[30]

For this reason, tocotrienols are

more powerful antioxidants than tocopherols. Regardless, tocopherols and tocotrienols play a critical role against oxidative stress. In a study of 698 people age 65 or older, low-serum vitamin E (alpha tocopherol) was associated with subsequent decline in physical function.[31] Further, alpha and gamma tocopherol reduce oxidative stress and inflammation in the metabolic syndrome. There appears to be a synergy at work contributing to the reduction of CRP and TNF-α.[32]

• Folic acid is involved with nucleic acid synthesis and results in improved tear film break-up time according to Ben Lane, O.D., MS.c., of the Optometric Nutrition Institute, Lake Hiawatha, N.J.

• Minerals, such as magnesium promotes formation of gamma-linoleic acid from linoleic acid. Gamma-linoleic acid, found in borage and evening primrose oil, is independently associated with improvement of dry eye and skin health, especially in female patients.[13,14] Potassium is linked with sodium/chloride electrolyte balance and lacrimal gland output. It regulates intra- and extra-cellular fluid movement and decreases with high dietary sugar.[12] Zinc is a co-factor in more than 200 metalloenzymatic pathways, many of which are involved with corneal health.[14]

Additional Nutrients

Quercetin is found naturally in red onions and red apples. It is a flavanoid iron-binding pigment and is a powerful antioxidant, as well as a natural antihistamine useful against eye allergies.[13] As a group, flavonoids are low molecular-weight phenylbenzopyrones that have various other pharmacological properties, including anti-cancer, bactericidal, and anti-inflammatory properties.[33] In addition to inhibiting diabetic cataracts, quercetin and its metabolites inhibit the herpes simplex virus (HSV).[34] During an HSV outbreak, it is useful to avoid arginine-rich foods, such as chocolate, gelatin and nuts. While L-lysine is often recommended for helping herpes infections, it is slow acting. Useful quercetin clinical supplement doses are 100mg to 1,000mg (and higher) daily.[13]

Drinking green tea blocks corneal neovascularization in mice stimulated by vascular endothelial growth factor at serum concentrations that are achievable in humans by drinking two to three cups of green tea a day (or 171mg of green tea ECCG extract).[35] Other studies suggest that green tea reduces mortality risk from all causes (especially heart disease and stroke), is antimutagenic, antidiabetic, antibacterial and antiviral and may also reduce the risk of cancer, especially breast, prostate, ovarian and lung.[36]

Benefits of "Sensible Sunlight"

Each of us comes in contact with thousands of patients each year—some present with intractable corneal disease. It is now the responsibility of practitioners, particularly those who practice in northern latitudes, to alert patients to the real possibility of vitamin D deficiency. For information on this topic, please review the seminal work of dermatologist Michael Holick, Ph.D., M.D., a leading advocate of "sensible sunlight exposure" and raising the vitamin D recommended daily allowance for all age groups.[24,25] Another great source of emerging information on this topic is www.vitamindcouncil.org, a non-profit organization that is trying to end the epidemic of vitamin D deficiency.[27] Even practitioners in more sunny climates may be surprised to learn that vitamin D deficiency is a real issue among their patients as well.[32] But, our black patients are most vulnerable, plagued by higher prevalence of cancer, cardiovascular disease and auto-immune disorders, some of which I believe can affect the cornea. In contrast, UVR exposure is a minor contributor to the world's disease burden, causing an estimated annual loss of 1.6 million DALYs—i.e., 0.1% of the total global disease burden, while vitamin D deficiency is epidemic.[37]

The Bare Essentials

The natural world provided our ancestors with plenty of sunlight for cutaneous vitamin D and a diet rich in omega-3 fatty acids from lean game, fish, nuts and dark green leafy vegetables.[4] We need to keep these scientific facts in mind when we are treating a patient with intractable ocular surface disease. Many patients may be lacking sun exposure and living a lifestyle of fast food and little exercise, which leaves them predictably deficient in ant-inflammatory defenses. For all these reasons, it is our responsibility to promote healthy diet and exercise habits,

along with moderate sunlight exposure to help patients ward off systemic and ocular disorders. RCCL

Table 1. How to Reduce Systemic Inflammation [38]

- Get an average of seven to eight quality hours of sleep per night.
- Decrease your weight by 10% if your body mass index (BMI) is over 25.
- Get a minimum of 30 minutes (ideally 60 to 90) of moderate exercise per day.
- Train with weights two to three times per week.
- Get 20gm to 25gm grams of dietary fiber per day.
- Eat foods high in omega-3 fatty acids four times per week—at least 3.5oz per serving (e.g., wild salmon, sardines, herring or tuna), and take one to three grams of fish oil capsules daily.
- Eat two tablespoons of ground flaxseed meal most days.
- Eat one to 1.5oz of walnuts five times per week.
- Eat one cup of berries, cherries, purple grapes or 4oz to 8oz of 100% pomegranate juice (or purple grape juice) daily.
- Maintain fasting blood sugar at 75mg/dL.
- Intake two tablespoons of extra virgin cold pressed olive oil most days.
- Eat a diet high in carotenoids.
- Spice it up with garlic, turmeric and ginger.
- Take prebiotics or probiotics.
- Eat unlimited amounts of fruits and vegetables.
- Eat one ounce of dark chocolate daily.
- Maintain sensible sunlight exposure and take Vitamin D supplements.

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Aberration Correction

Part Two

Advances in lens measurement and production technology have transformed the optical correction we are able to offer our patients. But, what is available now, and what options are on the horizon?

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In the January issue, we analyzed potential limitations of aberration corrections, and what steps practitioners and manufacturers are taking to secure a permanent place for optimized optics in clinical patient care. Now, we will look at the technological advances that have lead to optimized optics and closely examine the role of customized contact lenses, spectacles, as well as intraocular lens options in the care of our patients.

Technological Advancements

Before examining the details of the correction options available today, let's briefly discuss the technological advancements that have allowed us to reach this point. There are several methods of measuring the eye's optics, most of which rely on the same basic principle of isolating rays of light. In 1619, Christoph Scheiner, physicist and astronomer, found that if an optically imperfect eye viewed through an opaque disk with multiple pinholes (Scheiner's disk), the single distant point source being viewed would form multiple retinal images.[1] This was the founding principle used in the development of the aberrometers in use today.

J.F. Hartmann modified Scheiner's approach by perforating many small holes across an opaque screen; each hole isolating a narrow bundle of rays from light reflected out of the eye, allowing many rays to be measured simultaneously.[2] The tips of these rays, if connected, form a wavefront of light exiting the eye. Upon measuring an eye, if the only aberration this imperfect eye contained was defocus, a simple spectacle lens could be placed in front of the eye, and the multiple double images would now be focused. However, with additional types of aberrations other than defocus the case was not quite as simple, as a single-spectacle lens could not focus all the multiple point images.

Hartmann's method lay dormant for 70 years before it was improved upon by Shack and Platt.[3] They exchanged the opaque screen for a "honeycomb" of small lenslets, each focusing corresponding small portion of the wavefront of light reflecting back from the measured eye onto a sensor. This advance is analogous to trading a pinhole camera for a camera with a lens and a larger aperture, allowing improved optical quality (due to less diffraction), and more light available. As a result of this significant improvement, the method became known as the Shack-Hartmann (or Hartmann-Shack) method of aberration measurement. It took another 20 years before this method was applied to the measurement of the eye's optics by Junzhong Liang, and the resulting methodology has now become the most commonly employed method of aberration measurement in the eye.[4]

While aberrometers measure the optics of the entire eye, corneal topographers measure the optics of just the cornea. Scheiner was not only the father of aberrometry, but also, in a sense, the father of corneal topography.[5] He measured the curvature of the cornea by holding a series of varying curvature convex mirrors in front of an eye until he found the one that gave an image of the same size as the image formed on the cornea.

Again, centuries passed before Scheiner's work was significantly improved by the development of the lighted keratoscope by Ferdinand Cuignet in 1820. Following this the first spatially resolved measurements of corneal curvature were made by Antonio Placido in 1880, when he observed the cornea through an alternating black-light disc target.[6] In 1854, Helmholtz developed the first keratometer, in which he measured the distance between two pairs of reflected points to give the spherocylindrical curvature of the central 3mm of the cornea through a telescopic eyepiece.[7] In 1896, Allvar Gullstrand applied photography to keratoscopy (photokeratoscopy), allowing objective measurements of the corneal surface to be made.[8] In the early and mid- 1900s, the need to accurately know the corneal shape was rekindled by the development of the contact lens industry. Placido rings made it possible to observe spatial distortions in the cornea, but quantifying these ring images and converting them to topography was quite laborious until the advancements of computer analysis occurred. With these advancements, topography measurements slowly became a clinically useful tool to monitor keratoconus and various other corneal conditions in a timely fashion.[9]

In part one of this article, I told the story of a friend who spent considerable time and money picking out a new high-definition plasma television screen only to sadly find that the picture on this fancy new television was no better than on his old television because the high-definition signal was not available in his neighborhood. The point of this story was to highlight potential similarities between the television industry and the vision correction industry. The take home message of this analogy was that technological developments in the last decade have opened a new realm of possibilities, and while technology is being developed to apply these discoveries to the human eye, the benefits will not be realized until specific conditions are met.

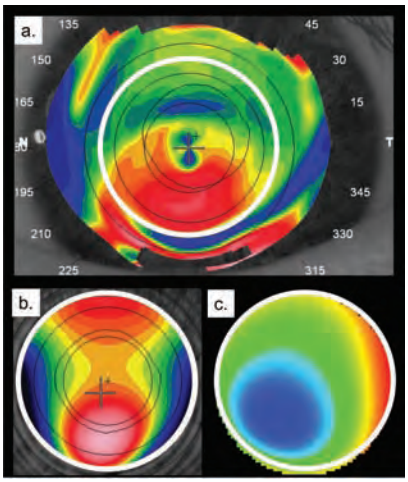
If we continue the analogy of comparing vision attainable with optical corrections to the television industry, just as technology has expanded the options for the quality of the picture on our televisions, the continued growth and development of technology over the last decade has brought many changes to the eye-care profession, particularly the improvements of aberrometry measurement and corneal topography technologies. Once aberrations of the cornea and the whole eye could be easily and reliably measured, the goal naturally shifted to correcting them!

Customized Contact Lenses

In January, we discussed several mass-produced contact lens options that were aimed at correcting specific levels (e.g., the population average) of given aberrations (typically spherical aberration). Now, we will discuss some more customized options, aimed at correcting multiple types of aberrations specific to a single eye—essentially individualized or customized lenses for a given eye. Although none of the major contact lens manufacturers in the U.S. are manufacturing customized aberration-controlling contact lenses, in some cases, lab researchers have achieved quite promising results, either by developing their own lens production methods or in partnership with industry.[10,11] Many of the first attempts to design customized contact lens optics were originally evaluated on keratoconic eyes, which given their disease state and inherent high levels of aberration, may have the most to gain by an customized correction.[10,11] For example, these results include a threefold reduction in aberration and improvement in acuity, even in the presence of on-eye translations and rotations.[10-12] But, to date, little work has been done to show the benefit of these same lenses on normal eyes with lower levels of inherent aberration.

Currently, there are a number of different commercially available customized lens options being produced by some smaller contact lens manufacturers. And, although the products may vary in the method of production, each has the same key production principle: a lens made specifically for an individual's eye that aims to result in better overall visual quality for the wearer, by either correcting the optics of just the cornea or the whole eye (cornea and internal optics).

EyeQuip was one of the first companies to develop commercially available customized lenses. The company, which produces the Wave Contact Lens System, EyeQuip corneal topographers, including the Keratron and the Scout, to take images of thousands of points on the cornea. With this information, the manufacturer is able to custom-lathe the anterior and/or posterior surface of a gas-permeable (GP) or soft contact lens. This has the



1. Axial topography of a moderately keratoconic eye with inferior steepening (top). The anterior surface wavefront obtained from the anterior corneal topography measurement (bottom left). The off-eye measured wavefront of the custom Wave soft lens that was manufactured to correct for these anterior corneal aberrations (bottom right).

potential to provide a lens with improved optics, as well as an improved fit *(figure 1)*.

Based on the theory of aberration correction discussed in the last issue, we would anticipate parts of the lens designed to correct areas of high negative corneal aberration (warmer red colors in figure 1b) to have corresponding positive aberration (cooler blue colors in figure 1c), and the lens design seems to fit this expectation with reasonable success. But, like any lens, this may not be the case when the lens is actually placed on the eye, due to lens flexure, decentration or rotation.

While EyeQuip is focused on corneal-only aberrations, other companies, such as WaveTouch Technologies, create custom soft lenses based on whole-eye aberration measurements. The WaveTouch process calls for two measurements to be taken in the practitioner's office; first, a whole-eye (corneal and internal optics) aberration measurement is taken of the naked eye, followed by a second reading with the patient wearing WaveTouch "acquisition lenses" of a stabilization design and sphere power similar to that of the predicted final lenses. Currently, WaveTouch has approved only two aberrometers for taking these measurements, the iTrace Combo (Tracey Technologies) and the 3D Wave Analyzer (Marco). Both instruments acquire measurements of auto-refraction, corneal topography, aberrometry, pupillometry and auto-keratometry, all of which are useful in designing the customized lens. The results of these measurements are then submitted electronically to the manufacturing facility at WaveTouch, where a customized lens is created for the patient by lathing the aberration-correction into the front surface of the lens.

Spectacle Correction

Unlike contact lenses, no mass-produced aspheric spectacle lenses are designed to correct spherical aberration. There are lens designs, however, in which the unwanted peripheral aberration (e.g., astigmatism or coma)—normally introduced as a result of the lens design—is controlled (e.g., the Varilux Physio 360, or the Zeiss GT2).

There are currently no truly aberration-correcting customized lenses either. But, using whole-eye aberration measurements (called the iPrint) from the Z-View aberrometer, Opthonix manufactures its iZon high resolution lenses. These high refractive index material lenses have a three-layer design: a plano front surface and back freeform-lathed layer of 1.6 plastic sandwiching a center uniform photopolymer (iZonik) layer. Following an iPrint aberration measurement of the lower and higher-order aberrations (third through sixth order), a proprietary algorithm determines the sphere, cylinder and axis values that most optimally correct for all the eye's aberrations.

Although some may think of these lenses as customized, the term "customized" as it applies to these lenses, does not imply a correction of specific higher-order aberrations as discussed above with contact lens corrections. Rather, it is a "customized" prescription generated by determining the best-fit sphere correction of lower and higher-order aberration that is customized for each eye. Still, only this best-fit lower order correction consisting of some measure of sphere and some measure of cylinder is applied to the lens. In an attempt to avoid this confusion of terminology, Opthonix does not call these lenses "custom" lenses, but rather "high resolution" lenses, indicating their goal of trying to provide high-resolution acuity for the wearer.

Recently, a sponsor-funded study evaluated the stages of this measurement and correction process.[13] In this study, the authors screened 178 young, normal eyes and identified 93 as candidates who could be significantly aided with iZon lenses based on the aberration measurement and the instrument's proprietary algorithm. Generally speaking, patients with very low or high levels of aberration are not thought to be optimal candidates for theses lenses because significant benefit would not be achieved and large amounts of aberration would remain following correction. This particular study consisted of several arms or parts, allowing the researchers to test specific questions. In all parts of the study, they obtained objective acuity measures, such as logMAR, glare, contrast and reading acuity, among other measures. In one part of the study, they compared the acuity obtained

by a traditional refraction applied to traditional lenses vs. an aberrometer-determined refraction applied to an iZon lens. The study showed significantly improved glare (p=0.05), intermediate contrast (p=0.02), low contrast (p=0.006) and reading (p=0.04) acuity with the iZon lenses.

In a subset of 52 subjects, researchers then attempted to determine the exact cause of this improvement. Did it come from the lens material, method of refraction, or 3-layer iZon lens? In this analysis, they found that the aberrometer-derived refractions provided significantly improved low-contrast acuity (p=0.006). All other measures were not significant (p=0.05). They also found that the three-layer lens design provided slightly improved SKILL card performance (p=0.04), but there were no significant difference (p=0.05) on any of the other acuity measures.

Although not yet available, PixelOptics is exploring an extremely interesting technology that may possibly create fully-customized spectacles. This technology employs electro-active liquid crystal lenses, which "produce a retardance profile across one of the modal liquid crystal cells in response to an applied voltage" (US Patent 7404636). Although quite complex, this technology could create spectacle lenses aimed to fully correct aberrations, and furthermore, this technology could be adaptable (e.g., the optical power could be changed from one instance to another based on viewing distance).

Intraocular Lenses (IOLs)

Similar to the mass-produced approach adopted by the contact lens industry, the IOL industry has developed mass-produced aspheric IOLs with the goal of correcting some single, specific level of aberration. As with contact lenses, the goals have been to either correct the population average spherical aberration or to not induce any spherical aberration. But, unlike contact lenses, which may aim to correct the population average whole-eye (cornea plus natural lens) spherical aberration, IOLs aim to correct only the average corneal aberration.

Most all of the major IOL manufacturers have adopted one of these approaches in some manner. For example, the Tecnis lens (Advanced Medical Optics) aims to correct 0.27µm of corneal spherical aberration, the AcrySof IQ lens (Alcon) aims to correct 0.20µm of corneal spherical aberration, and the SofPort lens (Bausch & Lomb) aims to not induce any spherical aberration. Studies on these lenses have shown them to effectively reduce levels of spherical aberration and provide improved acuity in certain situations.[14,15] To date, however, no truly customized IOLs have been manufactured.

Impact on the Future

One important fact that should be mentioned is that regardless of the modality (contact lenses, spectacles or IOLs), the creation of aberration-manipulating and/or customized lenses have the potential to impact virtually all aspects of the current lens industry. Merely marketing the fact that a company is capable of producing a customized lens could gain a market share for all of its products. Furthermore, if a lens manufacturer can create a lens with the precision required to produce an optimized single-vision lens, it could also seemingly easily create an optimized multifocal or toric lens. And, whereas today one multifocal design seems "to work" for one person, but fails miserably for another, if a customized approach was developed, each multifocal could be individually optimized to enhance success for each patient depending on their optics and goals.

As with the progress that has been made since the first black and white televisions, simple optical principles have slowly evolved lens measurement and production technology. This technology is now capable of producing many optical corrections that have the ability to revolutionize our ability to correct the vision of our patients. In order to implement this technology, however, we all must be continually aware of the options available, and what the limitations of each of these options are. And, for better or worse, the options are continually changing as technology continues to progress. RCCL

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