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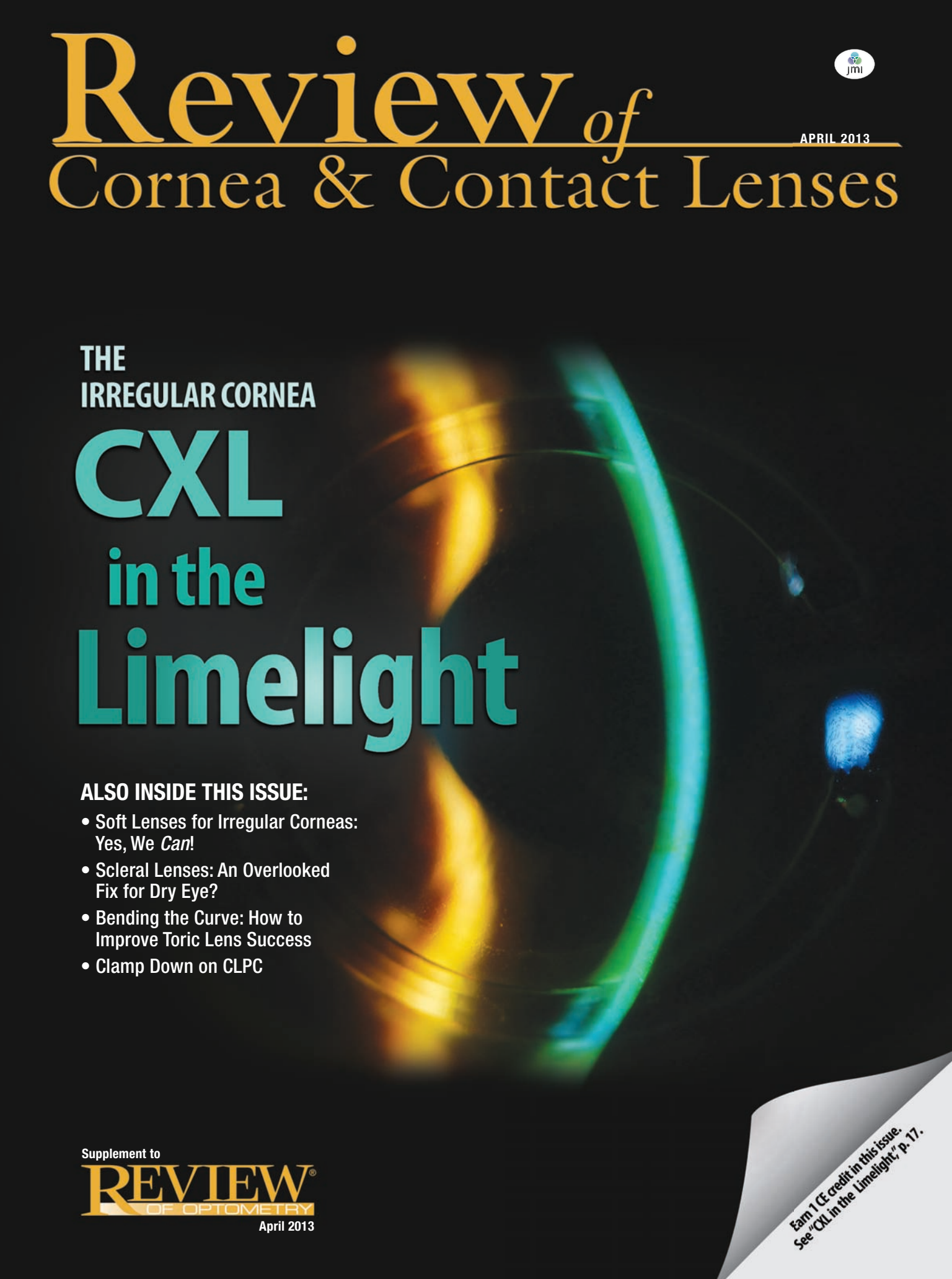
Review of Cornea & Contact Lenses

APRIL 2013



THE IRREGULAR CORNEA

CXL in the Limelight

ALSO INSIDE THIS ISSUE:

- Soft Lenses for Irregular Corneas: Yes, We *Can*!
- Scleral Lenses: An Overlooked Fix for Dry Eye?
- Bending the Curve: How to Improve Toric Lens Success
- Clamp Down on CLPC

Supplement to
REVIEW® OF OPTOMETRY
April 2013

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See "CXL in the Limelight," p. 17.

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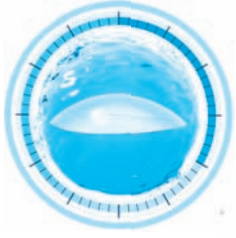

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Review of Cornea & Contact Lenses | April 2013

The Irregular Cornea

ON THE COVER

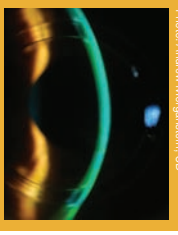
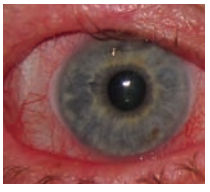
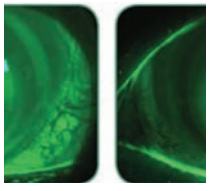


Photo: Andrew Morgenstern, OD





Departments

VOL. 150, No. 3

In The News

• Looking for an easy-to-use online reference guide to fit specialty lenses? **Bausch + Lomb** is introducing four downloadable **educational guides**: scleral lenses (http://commons.pacificu.edu/mono/4), keratoconus and presbyopia with GP (http://cclr.uwaterloo.ca/education-resources) and Boston (http://fit-boston.com).

• **TearScience** has just named **Duke Eye Center** in Durham, NC, a **Center of Excellence**—the Center will now host eye care physicians, practice administrators and eye care technicians involved in dry eye patient education and assessments to help develop familiarity and expertise on the TearScience system. The TearScience system includes the Lipiview ocular surface interferometer and the Lipiflow thermal pulsation system. For more information, visit www.tearscience.com.

• **Prevent Blindness America** announces the second annual **PBA Focus on Eye Health National Summit** to be held on June 18, 2013 in Washington, DC. The free event will include presentations from leaders in vision and public health. To register, visit www.preventblindness.org/eyesummit.

• A corneal inlay to treat presbyopia is now being considered for FDA approval. **AcuFocus** has submitted the final module of its premarket approval application to the FDA for the **Kamra** corneal inlay. Kamra is currently approved in 47 countries, and nearly 20,000 inlays have been implanted to date. For more information, visit www.acufocus.com.

• A new semi-scleral lens design, **Rose K2 XL** (**Menicon**) has a standard diameter of 14.6mm (range from 13.6mm to 15.6mm) and a wide range of parameters, including base curves from 5.8mm to 8.4mm. It also has nine edge-lift options to control the landing zone on the scleral. For more information, visit www.meniconamerica.com.

A Customizable Sceral Prosthetic for KC

Researchers have found that customized scleral lens prosthetic devices (SLPD) with wavefront-guided optics can successfully correct higher-order aberrations in advanced keratoconus patients.

In a small study of six advanced keratoconus patients, 11 eyes were fitted with an SLPD with conventional spherical optics. A custom Shack-Hartmann wavefront sensor measured aberrations through a dilated pupil with the lens in place. In addition, the horizontal and vertical decentration relative to the pupil and rotation were measured. Best-corrected high-contrast visual acuity and contrast sensitivity were recorded between the natural mesopic pupil and the SLPDs.

Higher-order aberrations were effectively corrected by the customized SLPD with wavefront-guided optics and the root mean square was reduced 3.1 times on average. This correction resulted in 1.9 lines improvement in mean visual acuity ($p<0.05$). Contrast sensitivity was also significantly improved. Residual aberration was comparable to that of normal eyes, but the average visual acuity in logMAR with the customized SLPD was 0.21—substantially worse than normal acuity.

The study is published in the April issue of *Optometry & Vision Science*.

The Final Countdown

Stock up today! Vistakon has just announced that it plans to discontinue three Acuvue products as of July 1, 2013. Acuvue contact lenses will no longer be available in all 9.1 base curves, and 8.4 and 8.8 base curves of parameters -6.50D to -11.0D are being discontinued. The 8.4 and 8.8 base curve lenses will continue to be available in the -0.50D to -6.00D parameters. All parameters of Acuvue Bifocal and Acuvue 2 Colors will be discontinued as of December 31, 2013.

Practitioners can upgrade patients from these older lenses to their next-generation counterparts Acuvue Oasys, 1-Day Acuvue Moist and 1-Day Acuvue TruEye brands.

Vistakon also announced the US introduction of 1-Day Acuvue TruEye with narafilcon A, which will gradually replace the narafilcon B product. The narafilcon A solution is available in two additional base curves (8.5 and 9.0). For more information, visit www.acuvueprofessional.com.

Next-generation Hybrid Lens for Irregular Corneas

Capitalizing on the success of the Jupiter scleral lens, Visionary Optics has released the second-generation Europa, which features a reverse geometry curve design. The lens has an expanded optic zone to allow increased sagittal depth and corneal clearance without having to steepen the base or peripheral curves, allowing for better corneal vault. Europa uses Boston XO and XO2 materials. A seven- and 14-lens diagnostic fitting set is available. For more information, visit www.visionary-optics.com.

Review of Cornea & Contact Lenses

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An Automated Communicator

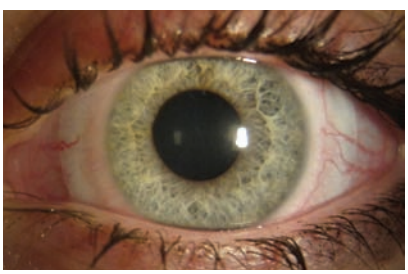
Eye care practitioners can now communicate with patients automatically using custom web-based software. Building on CV+, CooperVision's partnership program with optometrists, Websystems 3 allows practices to automate key communications such as practice-branded email marketing campaigns, newsletters, survey requests, push text messages and Facebook posts. An integrated mobile application and automated voice messaging are also available.

Websystems 3 is a cloud-based software created by Michael Arnell, OD, that assists practitioners in automating scheduling of available appointment times and connecting satisfied patients to online review sites.

For more information, visit www.coopervision.com.

Next-generation Hybrid Lens for Irregular Corneas

If you're looking for a lens versatile enough to fit a wide range of keratoconic patients, the UltraHealth (SynergEyes) hybrid contact lens is designed for emerging, mid-stage and advanced keratoconus, the company says. The lens uses a reverse geometry design that combines a soft skirt (84 Dk) and central rigid gas-permeable material (130 Dk). The central area of vault is available in several heights to ensure clearance, and the silicone hydrogel skirt is available in three curves (flat, medium and steep) to ensure centration and patient comfort.



The reverse geometry design allows the lens to achieve the vault needed to contain the cone with a flatter base curve than a standard geometry design, which the company says results in an ideal lacrimal lens and lower minus lens power. The flatter base curve also allows the centration to be less dependent on the location of the curve. The lens, with better centration and lower power, reduces aberrations, increases vision quality and provides high oxygen permeability.

For more information, visit www.synergeyes.com.

Advertiser Index

Editorial

By Joseph P. Shovlin, OD

The Doctor's New Digital Assistant

Practitioners and patients alike are continuously connected to the digital world. How can eye care practitioners take advantage?

We now live in a world where 87% of adults own a cell phone and, coincidentally, 87% of physicians use a smartphone or tablet in their practice.[1] Technology is literally at our fingertips and we have to be diligent in our efforts to stay abreast of new developments. For example, do you use mobile health (mHealth) apps?

mHealth

In 2010, more than $200 million was reported in sales of health care apps.[1] Furthermore, 600 million health apps were downloaded in 2012, and we know that one in three smartphone owners have at least one mHealth app.[1] By 2015, an estimated 500 million smartphone users worldwide will be using health care apps.[1]

There are more than 40,000 mHealth apps on the market today to assist health care professionals in improving patient care and educating consumers to manage their own health and wellness.[1] This influx of innovation is fraught with its own set of difficulties.

The speed at which this technology has advanced has not matched the speed in which the regulatory landscape has developed. In fact, there is currently little to no barrier preventing or guiding entry into the emerging mHealth app market.

On the one hand, this is good. It encourages technologically sophisticated developers who are eager to make their mark in the industry, while simultaneously providing consumers and health care providers with the tools to transform a patient's health.

On the other hand, this leaves the industry open to pitfalls. No credibility is required to launch a new app, which leaves the industry quite vulnerable to a new breed of inventors who have an idea and the technological capability, but no professional health credentials—to say nothing of charlatans and shysters who also muddy the waters.

In response, private industry has developed and released credentialing programs such as Happtique, Inc., a certification program to be used as a tool for clinicians and patients to identify technically and professionally valid mHealth applications. Happtique is also developing mRx, a mobile health platform that doctors can use to "prescribe" apps, videos and educational documents to patients through their mobile device.[2] Someday soon we may be prescribing as many medical apps as we do prescription medicines and lenses.

FDA Regulation

The rapid expansion and broad applicability of the mHealth industry prompted the FDA to issue a draft guidance in 2011 "to inform manufacturers, distributors, and other entities about how the FDA intends to apply its regulatory authorities to select software applications intended for use on mobile platforms."[3] Regardless of the platform, if a mobile app is intended for a medical function, it is considered a medical device and subject to regulations.

The draft guidance clarifies the types of mobile apps to which the FDA intends to apply its authority and excludes mobile apps that are electronic copies of textbooks or reference materials, apps that log records or track general health and wellness, and apps that perform the functionality of an electronic health record system or personal health record.[4] This past week, the FDA further clarified its intention not to tax mobile devices—relieving a concern of many in the industry that the mobile devices could be viewed as a medical device used for delivery or collection of health data.[3]

We still have many unanswered questions about privacy, security and legal issues, as well as incentives and reimbursement for health care providers. In this newly emerging field, we can surely expect a few wrinkles as the specifics are ironed out. Nevertheless, it will be exciting to see how the eye care profession carves its niche within this new technological arena.

My advice: If you have a good idea for an app, go for it! There is no better time than now. RCCL

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Joseph P. Shovlin, OD, Clinical Editor

By Christine W. Sindt, OD

SiHy Challenges FDA Solution Testing

A new subdivision separating silicone hydrogels into their own lens category is the first step in addressing the need to test solutions with lenses.

We do not like to think of contact lenses as vehicles of infection, but the truth is that they often deliver microbes to the eye. We know that colonized lenses are present in wearers both symptomatic and asymptomatic of inflammatory and microbial keratitis events.[1] Therefore, managing the microbial load is vital to maintaining a healthy eye.

Lenses need to be cleaned of debris and deposits, and should maintain a wettable, biocompatible surface. But silicone hydrogel (SiHy) lenses present different concerns for contact lens/solution management than hydrogel lenses, and the FDA is now looking at ways to more effectively test this modality.

Silicone Hydrogels

The complexities of how microorganisms adhere to SiHy materials can be traced back to the physiochemical properties of the lens. For solution testing, the FDA currently categorizes SiHy with hydrogel materials. However, there are differing amounts of lipid and protein deposition, absorption of surfactants, and preservative uptake and release in SiHy vs. hydrogel lenses (and even between different SiHy lenses) that may affect microbial disinfection, lens safety and comfort.

Many microbes form biofilms on lenses and in lens cases. Biofilm-forming bacteria have altered phenotypes and may promote the ability of bacteria to cause microbial keratitis. Some studies have shown that a greater number of bacteria adhere to silicone hydrogel lenses than their hydrogel counterparts.

The SiHy Subdivision

Group 5-A: low water content, non-ionic, surface treated lenses.
Group 5 B1: low water content, non-ionic, non-surface treated and hydrophilic monomer containing-lenses.
Group 5 B2: low water content, non-ionic, non-surface treated and semi-interpenetration network-containing lenses.
Group 5-C: high water content and non-ionic lenses.
Group 5-D: ionic material, both low- and high-water lenses.

While SiHy lenses do not necessarily have increased adhesion to fungi (e.g., *Fusarium solani*), penetration into the lens does occur more rapidly on some silicone hydrogel lenses vs. hydrogels.[1]

In short, microorganisms need to be tested differently on SiHy lenses than on hydrogels.

The ideal contact lens solution would be able to remove deposits, kill biofilm-forming microbes, increase surface wetting and also be well-tolerated by the ocular surface. Silicone hydrogel lenses are problematic because their chemical properties and surface treatments/hydrophobicity are so unique. The only definite way to determine deleterious lens/solution interactions would be to test each SiHy lens and solution combination separately. Certainly this would be both time consuming and cost prohibitive, particularly when you consider that new lenses and solutions are constantly under development.

The FDA Solution

As a result, the FDA set out to find a new way to look at solution/lens incompatibilities with three goals in mind: lower cost, increased safety and improved test predictability. It was concluded that preservative uptake and release is best predicted by water content and lens ionicity. Surface hydrophobicity adds an additional challenge to solution interactions. Based on these three properties, silicone hydrogel lenses have been subdivided into five categories (see *"The SiHy Subdivision"*).[2] The FDA will also begin to incubate materials with solutions to look for depleting disinfection levels, and add *Acanthamoeba* as a test organism.

Creating this new standard for SiHy disinfection was a joint effort between the FDA, consumers, industry, academia and other regulatory bodies. Through significant research it was determined that water content, ionicity, hydrophilicity and surface treatments were the key factors in determining lens/solution interactions. Hopefully, the new lens grouping will help ensure the safety of our patients and continue to allow new products to come to market in a timely fashion. RCCL

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

When 'Collateral Damage' Strikes the Cornea

Drugs that combat systemic diseases can often afflict the cornea with side effects that mirror other disease symptoms. Here are a few to watch for.

Corneal manifestations of systemic disease have long been on the radar of anterior segment specialists, but keep in mind that some slit-lamp findings can be caused by the medications our patients are prescribed, and may mimic the changes associated with the disease itself. Systemic medications reach the cornea through the tear film, aqueous humor and limbal vasculature. Access from the tear film leads to deposition in the epithelium, from the limbal vasculature into the stroma, and from the aqueous into the endothelium, epithelium and stroma.[1]

Fortunately, these corneal abnormalities usually are not visually debilitating or permanent. It is, however, important to recognize these associations and to openly communicate your concerns with the primary care physician or specialist who prescribed the systemic drug, as they can be a precursor to lens, optic nerve or retinal changes that can cause permanent and serious vision impairment. A thorough case history that elicits all medical conditions and medications—dosage and length of treatment—is essential to identify the genesis of the abnormal slit-lamp findings.

In the January/February column, we introduced Cystaran 0.44% (cysteamine ophthalmic solution, Sigma-Tau Pharmaceuticals), a topical ophthalmic drop for the treatment of patients suffering from corneal cystine crystal accumulation secondary to cystinosis. This medication is expressly intended to treat an ocular side effect of a systemic disease. It is rare to have such a remedy at hand; more often, careful monitoring and judicious use of the systemic agent is the best approach.

Here are a just a few examples of medications that are associated with corneal changes.

Epithelium

• ***Vortex keratopathy***, or corneal verticillata, is a common side effect of a number of systemic medications—e.g., amiodarone, aminoquinolones, indomethacin, tamoxifen, atovaquone and tilorone—and results from the intralysosomal accumulation of lipids. This condition presents with golden-brown deposits in a whorl-like pattern normally seen in the inferior corneal epithelium. This configuration is a result of the corneal epithelium's growth and repair process.[2] Patients who present with this finding are typically asymptomatic, though they may report photophobia or halos around lights. Vortex keratopathy as a side effect is indistinguishable from what we see in Fabry's disease, an inherited lysosomal storage disease.

• ***Amiodarone***, an anti-arrhythmic agent, is strongly linked to the development of corneal verticillata. In fact, it is present in 69% to 100% of patients taking 200mg to 2,400mg daily, and is detectable within four to six months. It is concentrated in the tears and appears to be more severe in contact lens wearers.[3] Discontinuation of the drug typically allows for resolution of the keratopathy within three to 20 months.[4-6]

John Dovie, OD, and Andrew Gurwood, OD, reported on a case of amiodarone-induced keratopathy with acute onset of bilateral corneal edema and subepithelial cysts that caused decreased acuity, glare and halos, which persisted for two months after discontinuation of the medication.[7] Mesut Erdurmus, MD, and colleagues reported a rare case of amiodarone-associated endothelial deposition, seen with a confocal laser scanning microscope, in a patient taking 200mg daily for six years.[8] Amiodarone has also been linked to lenticular opacities and optic neuropathy.[9,10]

• ***Chloroquine*** (Aralen, Sanofi Aventis) and ***hydroxychloroquine*** (Plaquenil, Sanofi Aventis) are antimalarial agents used in the management of rheumatoid arthritis and lupus. Corneal manifestations include vortex keratopathy and decreased corneal sensation. The corneal findings are benign, but the retinal toxicity is concerning, as it is irreversible (even with discontinuation of the drug) and can lead to

Amiodarone, an anti-arrhythmic agent, is strongly linked to the development of corneal verticillata. In fact, it is present in 69% to 100% of patients taking 200mg to 2,400mg daily, and is detectable within four to six months.

permanent central and peripheral vision loss.[11]

While corneal findings had been thought to have no correlation with the development of retinal toxicity, Aljoscha Neubauer, MD, and colleagues conducted a screening of 93 patients with marked corneal deposits who were taking either chloroquine or hydroxychloroquine, and using electro-oculogram and computerized color vision testing, found a 50% sensitivity and 90% specificity for retinopathy.[12,13]

• ***Tamoxifen***, an estrogen antagonist used in the long-term treatment of breast cancer, creates bilateral, white or multi-colored, whorl-like, central subepithelial opacities that can cause reduced visual acuity.[14] Tamoxifen retinopathy is rare, but has been detected at even low levels of treatment. After tamoxifen cessation, almost all of the ocular abnormalities are reversible—except for the retinal opacities, which can include bilateral macular edema, and yellow-white dots in the paramacular and foveal areas.[15]

Stroma /Endothelium

• ***Chlorpromazine*** (Thorazine, GlaxoSmithKline) is a phenothiazine antipsychotic associated with pigmentary deposition in multiple ocular tissues—including the eyelid, cornea, conjunctiva and lens—when taken at high doses for prolonged periods.[16] Chlorpromazine has been noted to cause dramatic skin discoloration and multiple corneal crystalline deposits.[17] White deposits have been detected in deeper layers of the cornea—including subepithelial stroma, Descemet's and endothelium—via HRT II cornea module and confocal microscopy.[18,19]

• ***Amantadine*** (Symmetrel, Endo Pharmaceuticals) is prescribed to reduce tremors associated with Parkinson's disease and treat fatigue associated with multiple sclerosis. It has been implicated as the cause for otherwise unexplainable corneal edema that begins several months after institution of therapy and is usually reversible after cessation.[20-22]

• ***Gold***. Arun D. Singh, MD, reported a case of an asymptomatic patient receiving regular intramuscular injections of colloidal gold for rheumatoid arthritis who had fine, diffuse yellow-brown deposits in the central corneal epithelium and confluent deposits in the deep central corneal stroma. Discontinuation of the medication is not required.[23]

Though not nearly a comprehensive list, this column should serve as a reminder to the eye care practitioner that a thorough medical case history that includes all medications, dosage and duration of treatment is incredibly important. While corneal manifestations of systemic medications are typically benign and generally require no treatment, artificial tears in some cases may help minimize corneal deposition, especially from the tear film.

Sometimes these manifestations can be linked to more serious lenticular, optic nerve or retinal findings, and this should be reported to the patient's primary care physician in a timely manner. Report ocular side effects to the National Registry of Drug-Induced Ocular Side Effects at www.eyedrugregistry.com. RCCL

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

A New Twist on Correcting Astigmatism

When soft toric and large-diameter GP lenses fail, it may be time to consider sclerals.

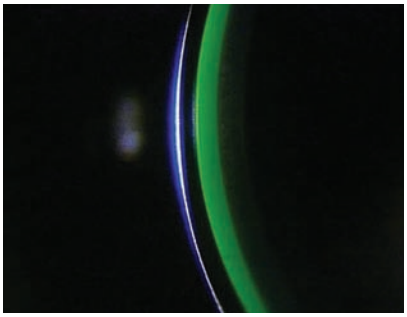
When it comes to fitting irregular corneas, practitioners often choose scleral lenses. We want to recreate a new refractive surface through a rigid gas-permeable (GP) lens. As with more traditional, smaller-diameter GPs, the rigid surface of scleral lenses renormalizes the surface.

But scleral lenses have two additional qualities. By vaulting over the cornea, scleral lenses are not dependent on lens-to-cornea interaction. And by bearing the weight on the surrounding conjunctiva and underlying sclera, large-diameter lenses do not move like traditional GP lenses. Thus, there is significantly less lens awareness.

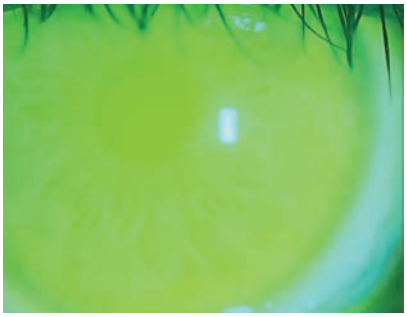
Traditionally, we have considered scleral lenses for corneas with significant irregularities. But, can these lenses also benefit other patients with high visual demands?

Fitting the Astigmatic Patient

We generally tend to fit our astigmatic patients in toric soft lenses, even though this may be a suboptimal choice due to rotational stability issues. What if, instead, we considered using GP lenses?



1. Central clearance that is equal to the thickness of the contact lens.



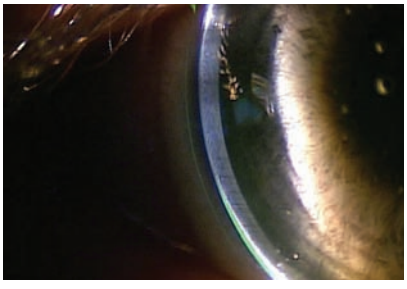
2. View of the lens showing fluorescein over the whole cornea.

Depending on the level of corneal astigmatism and its relationship to refractive astigmatism, a patient may do well in a standard spherical, a back surface or a bitoric GP design. These designs correct the astigmatism that is dependent upon a tear layer between the posterior surface of the lens and corneal surface, as well as address toric surfaces that may be made in the lens.

A potential disadvantage to a traditional GP, however, is the initial additional lens awareness that a patient may experience relative to a soft toric lens. On the other hand, a scleral lens bears its weight on the conjunctiva and underlying sclera as opposed to the cornea. Because it rests on the conjunctiva, it does not move like a corneal GP lens and thus patients experience very little lens awareness while still benefitting from the optics of a GP.

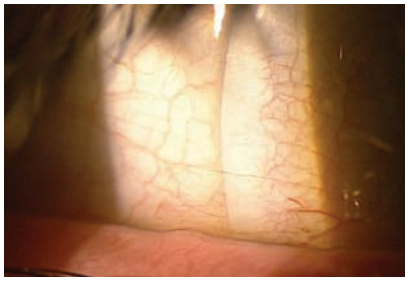
Here, we will review the three major considerations when fitting scleral lenses so as to improve your chances for success.

1. ***Central corneal clearance.*** Because a scleral lens rests on the conjunctiva, an ideal fit will vault over the cornea without ever touching it. Although there has been no standard as to how much or how little clearance is required, many practitioners have adopted a clearance of 100µm to 300µm.[1] Although the clearance can be measured with an anterior segment OCT, most practitioners will estimate the clearance



3. No fluorescein present in the limbal area between the cornea and scleral lens.

4. Ideal landing zone relationship.



5. A steep landing zone causing conjunctival blanching inside the edge of the lens.

using the corneal thickness as a reference.

Before the lens is placed on the eye, the bowl is filled with non-preserved saline. Fluorescein is then added to the bowl, usually via a strip, to help easily visualize the saline between the posterior surface of the lens and the front surface of the cornea. After the lens is placed on the eye, an optical section through the lens and cornea will reveal the amount of clearance the lens demonstrates.

Because you already know the thickness of the contact lens that you are fitting, you can approximate the clearance by estimating the thickness of the fluorescein as compared to the thickness of the lens *(figure 1)*.

2. ***Limbal clearance.*** The guidelines for the amount of clearance in the limbal area are less specific. The most important point to remember is that the lens must clear the limbal region, which can be seen by visualizing that the fluorescein completely covers the cornea beneath the lens *(figure 2)*. Additionally, viewing the clearance with an optical section should reveal fluorescein present between the posterior surface of the lens and the front surface of the cornea.

If no fluorescein is present, the lens is bearing on the limbus *(figure 3)*. In this instance, the peripheral relationship of the lens will likely need to be steepened in order to prevent limbal bearing.

3. ***Landing zone.*** Ideally, the landing zone will rest tangentially on the conjunctival surface and will distribute the weight of the lens evenly throughout this area. This should cause no change in the architecture of the conjunctival vasculature *(figure 4)*. If the landing zone is steeper or flatter than the surrounding scleral trajectory, there will be unintended pressure on the surrounding conjunctival tissue—potentially causing either vascular blanching or vascular engorgement *(figure 5)*.

Understanding how scleral lenses can potentially deliver our astigmatic patients more stable vision can fill a void in the care we provide. In fact, it can help patients who may have otherwise discontinued contact lens wear to stay in their lenses and derail potential dropouts. RCCL

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By Jason Jedlicka, OD

My Son the Myope—And What I Did About It

The research supporting orthokeratology lenses for myopia control grows stronger every day. When do we introduce this option to our patients?

The last 10 years have brought us a number of studies that looked at the effects of orthokeratology on the progression of myopia. For the most part, these studies found ortho-k to be a safe and effective means for correcting vision and slowing myopia progression.[1-3] Participants in the studies reported no serious adverse events, good daytime vision and reduction in the progression of myopia by 40% to 50% vs. the control groups.

The Fitting

I had the opportunity to fit my own son—AJ, a then nine-year-old -3.00D myope—and two of his friends in orthokeratology lenses at approximately the same time nearly three years ago. The two other boys had the following specs: KI was 10-year-old and had progressed to a -4.25 prescription in each eye, while DB was an 8-year-old who refracted at -3.75 OU. All three children had seen their prescription jump by at least one diopter at each of their previous two eye exams. They were all actively involved in sports and dealing with the issues of eyeglass wear, or not wear, in many cases.

Our family has low to moderate myopia, while the two other children had parents with highly myopic corrections.

In all three instances, the fitting of lenses was straightforward and typical. Using CRT (Paragon) lenses, manifest refraction and corneal topography, I followed the fitting guidelines and made recommended modifications to achieve optimal results. All three children achieved 20/20 to 20/25 vision in each eye, and all three had 20/20 vision OU.

The Follow-Up

Since the initial fitting, I have seen all three boys for two annual exams (*see table below*). All three have continued in the same lens parameters for the past three years. An excellent way to monitor for change in Rx is by over-refracting through the orthokeratology lens. This gives you a repeatable method to routinely check the prescription for progression without impacting the quality of treatment.

In over two years, none of children progressed by more than 0.25D, as compared to the change of 1.00D or greater in the three years prior. Not only are the children happy with their vision and freedom from corrective lenses, the parents (myself included) are thrilled to know that their child's visual decline has slowed significantly.

Thinking Ahead

Early studies show that orthokeratology can account for a roughly 50% reduction in the progression of myopia.[2,4] Newer studies seem to confirm these findings.[1] Do we now have enough compelling evidence that this slowing of myopia is real and permanent?

We are seeing that the topic of myopia control—and the treatment of orthokeratology—is increasingly mentioned within the field of eye care. The evidence to support the positive impact of orthokeratology is strong and growing. But all literature aside, there is nothing like seeing first-hand the impact that you can make on your young patients. RCCL

References available at www.reviewofcontactlenses.com.

When to Introduce Myopia Control

In my practice, I mention the option of orthokeratology to all my young patients as soon as they become myopic. The benefit of bringing out orthokeratology at this stage is two-fold. First, it gives them the option of beginning this treatment immediately if they so choose. Second, if they do not opt for orthokeratology at this initial diagnosis of myopia, and we find that the prescription does increase noticeably the following year, everybody is prepared for the subsequent discussion of myopia control. I find that this approach makes the transition to orthokeratology easier and allows the eye care practitioner to intervene at an earlier stage when the prescription is milder.

	AJ	KI	DB
Pre-treatment Rx	-3.00/-3.00	-4.25/-4.00	-3.75/-3.75
Post-treatment Rx	Plano/Plano	Plano/Plano	Plano/+0.25
Post-treatment lens over-refraction	+0.50/+0.50	+0.50/+0.50	+0.50/+0.50
Two-year Rx	Plano/-0.25	+0.25/Plano	-0.25/+0.25
Two-year lens over-refraction	+0.25/+0.25	+0.50/+0.25	+0.25/+0.50

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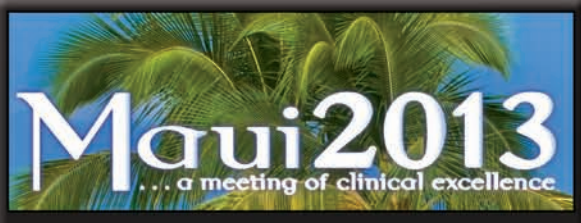

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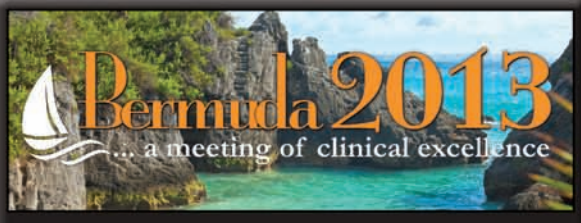

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REVIEW OF OPTOMETRY

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Opinion

By Mitch Cassel, OD

Niche Product or Emerging Opportunity?

New silicone hydrogel options have the potential to rejuvenate the otherwise stagnant colored lens category.

We all recall the great fanfare that accompanied the debut of colored contact lenses. It was a breakthrough using new technology, enabling us to offer another fashion-forward aspect of a product that was already making strides due to its aesthetic benefits. For multifaceted reasons the category has since waned, but industry experts remain bullish on the prospects for silicone soft lens materials to renew enthusiasm among doctors and patients alike.

Currently, the industry does not have any FDA-approved silicone hydrogel colored contact lenses for cosmetic enhancement on the market—or in the immediate pipeline. However, with the possibility of using silicone in colored materials in the not-so-distant future, more eye care practitioners than ever before will be interested in promoting this material. The benefits are to maximize eye health and comfort.

The industry anticipates a favorable response from practitioners and a commensurate increase in sales within this category. We could see an immediate surge by simply expanding the natural color spectrum of available silicone hydrogel lenses. As practitioners, it is important for us to prepare now for future colored lens sales and the impact they can have on our practices.

Boom and Bust

We currently have several colored soft lens options, including basic transparent tints, standard opaque designs and custom hand-painted lenses. The best choice varies based on each individual patient's needs and expectations—natural coloring, cost factors, time constraints and therapeutic/visual needs. Tinted lenses first hit the market in the early 1980s, followed by opaque colors in 1987, and disposable lenses in 1992. According to freelance marketing consultant Tom Steiner, the colored lens market reached its peak in 2002, accounting for 14% of all soft lens sales, and now has 4% of all market shares.

There were several reasons for the decline of colored lens sales, including a reduction in consumer promotion. According to industry reports, there has been a decline of colored lens sales since 2002, including a drop in the original Wesley Jessen lenses' market share following the company's acquisition by Ciba Vision and previous competition from Vistakon's release of Acuvue Colors. In addition, the more influential contact lens manufacturers reduced their budget for consumer-focused marketing.

The next trend was the decision to stop marketing colored lenses to doctors, in favor of non-color silicone and disposable options, which manufacturers viewed as more important to increase contact lens sales. To date, this resulted in eye care practitioners losing interest in colored contact lens products. And ultimately, the growing lack of interest, decreased support from parent companies, increased chair time, less attractive materials vs. silicone alternatives and limited options for specialty lenses contributed to practitioners choosing to skip introducing these lens options. Sales became dependent upon consumer request.

It is important to note that an introduction of SiHy colored lenses alone will not rejuvenate the category unless there is a revamping of color patterns and tones—particularly adding more natural hues to satisfy the majority of patient requests.

With newer silicone materials offering increased eye health and comfort, increased consumer advertising should follow. Eye care practitioners should take the initiative and educate their staffs to properly rejuvenate this opportunity.

A Second Boom Coming?

I believe colored lenses will once again become a substantial segment of the contact lens market. Remember, colored lenses can command a premium price—from the initial eye examination for first-time wearers to profits on the revenue of prescription material. Currently, there are approximately 20,000 independent practices and 9,000 chains in the US market. The majority of private practices are still somewhat passive in their approach to colored lens sales, but the chains have shown a higher level of interest in this revenue stream.

Colored contact lenses are an excellent opportunity to attract new contact lens wearers. Let's start with teenagers. Half of all first-time contact lens wearers are teens, and two-thirds are women. Early Wesley Jessen and Ciba Vision market research studies found that one-third of all women wearing contact lenses are interested in colored contact lenses. Personal appearance and individual spending habits are the two major factors driving the

skewed market share.

Ethnicity also plays a key factor for lens sales. There is a high interest in colored lenses within the Hispanic, African-American and Asian communities. It has been very apparent in my own specialty cosmetic colored lens practice that patients are more interested in changing brown irises to lighter color tones.

It will take time for new SiHy-based products to become available, but manufacturers are already rethinking their approach to the market. Vistakon recently noted that it will discontinue the Acuvue 2 Colors contact lenses as of December 31, 2013. "We see 'beauty' as an emerging global platform for growth within the contact lens category. Women want far more than just to change the color of their eyes. They want a beauty contact lens suitable for everyday wear; one that offers natural effects," said Luciana Balduino, Vistakon senior director global strategic marketing and beauty.

The company currently markets 1-Day Acuvue Define contact lens in Asia and Japan, where it is considered a popular beauty secret amongst wearers.

Clinical Applications

Aside from cosmetic improvements, colored lenses can also be very helpful for prosthetic use. This includes therapeutic benefits such as:

• ***Eliminating diplopia.*** For preferred over-lens patching, practitioners can use a black opaque lens design to provide full coverage to overlap the patient's pupil in dim illumination. Recommended size: 2mm to 3mm larger than the patient's maximum pupil dilation.

• ***Eliminating photophobia.*** Extreme light sensitivity can occur from trauma or surgical complications. Several companies can offer prosthetic lens designs, including opaque lenses with clear openings, to recreate a normal pupil size and tinted uniform colors.

• ***Enhancing contrast and vision.*** Tinted transparent soft lenses can be used as a sunglass effect to reduce light sensitivity. They are often used in sports to maximize vision using gray, green and amber colors.

• ***Color balance.*** There are companies that offer magenta or red soft lenses—to be placed in the non-dominant eye—to address certain color deficiencies to help interpret color differences. This does not, however, normalize color.

• ***Epilepsy.*** Blue-tinted lenses help some epileptic patients who are photosensitive. Consult with the patient's neurologist before fitting any lenses.

• ***Psychological.*** A prosthetic lens can help patients with unusual eye complications (i.e., congenital defects and traumatic injuries)—both emotionally and psychologically. Most of these patients may never have engaged in any prior discussion with an eye care professional about such options to mask their atypical eyes, but a change could be extremely gratifying.

Although the colored lens category comprises only a small percentage of your contact lens profitability, it would be prudent to prepare for new products. Taking the lead in presenting the latest opportunities will help you stand out from your competition. That difference could have a substantial impact on your bottom line. RCCL

A Simplified Process

Here are some helpful tips to easily incorporate colored lens sales into your practice:

1. Schedule regular staff meetings to review products, availability, pricing and patient flow (maximizing chair time).
2. Create set scripts for your staff for introducing the lenses, offering realistic expectations and reviewing trial procedures.
3. As the practitioner, review the fitting guides and other lens material carefully and familiarize yourself with possible concerns, such as pupil size, base curves, etc.
4. Try to narrow down the color offerings to limit the decisions. Also consider online tools such as virtual try-on options.
5. Remember to charge appropriately for your professional time. Inform your patients about the entire fitting process, starting with an eye examination.

Dr. Cassel has a group practice in New York City, specializing in primary eye care and colored contact lenses. He is the owner of Custom Color Contacts. He has been a consultant, lecturer and investigator for several contact lens companies including Vistakon, CooperVision and Ciba Vision.

Thanks to Tom Steiner for providing pertinent information about industry trends.

In 2013, a new lens will change everything.

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CXL in the Limelight

From treating keratoconus and ectasia to killing bacteria, collagen crosslinking could prove to be a must-know procedure for all practitioners.

By Andrew S. Morgenstern, OD

We all universally share the same hope that collagen crosslinking will be the technology that puts an end to a lifetime of suffering for our present and future keratoconus patients. Through early detection of corneal ectatic disease and access to cost-effective interventions, we hope to do to keratoconus what vaccinations did to measles, mumps and rubella.

Keratoconus and Corneal Transplants

The first human tissue transplant—a cornea—was successfully performed without a microscope or proper anesthesia in 1905 by Eduard Zirm, MD, an ophthalmologist based in what is now the Czech Republic. In the process, Dr. Zirm unintentionally created the first surgical solution to keratoconus.

While corneal transplantation is a successful treatment strategy, the recovery process can take up to two years and the tissue has approximately a 10% chance of allograft rejection—even with today's advanced medical technology.[1] Corneal transplants are some of the most successful transplants in the human body, but we have learned that the better alternative to surgery is early prevention.

Keratoconus, typically a bilateral and progressive corneal disease, is a very common condition and one of the main indications for corneal transplants (particularly in younger patients) in the US today. Similar corneal diseases include pellucid marginal degeneration, post-LASIK ectasia and post-radial keratotomy visual fluctuations.

More than 46,000 corneal transplants were performed in the US in 2011, according to the Eye Bank Association of America.[2] Keratoconus was estimated to present in one in every 1,500 people within the US in 2012.[3] Compared to estimates three or more decades earlier of two per 100,000 patients, we are seeing a dramatic decrease in its overall prevalence.[4] Why? This is largely due to the popularity of laser refractive surgery.[4] As LASIK and other procedures became more commonplace in our society, patients were increasingly screened for keratoconus and other corneal ectatic diseases that were contraindicated for most refractive surgery procedures. As such, we have found a large population of mild cases of keratoconus that typically would have gone undetected at a regular eye exam. Interestingly, although more than 46,000 corneal transplants were performed in 2011, the need for corneal tissue is never satisfied.[5]

Research and improved technology are other contributing factors. Corneal researchers including Michael Belin, MD, Renato Ambrisio, MD, and Cynthia Roberts, PhD, have started to develop algorithms and software packages for devices that measure several different corneal properties—such as the Pentacam (Oculus) and the new CorVis (Oculus).

Release Date: April 2013
Expiration Date: April 1, 2016
Goal Statement: This article provides an overview of collagen crosslinking for keratoconus and reviews other potential clinical applications.
Faculty/Editorial Board: Andrew S. Morgenstern, OD
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Dr. Morgenstern is a healthcare consultant and subject matter expert for Booz Allen Hamilton at the Walter Reed National Military Medical Center in Bethesda, Md. He is an American Academy of Optometry fellow and president of the Optometric Collagen Cross Linking Society, www.ocxls.org. He can be reached at andrewmorgenstern@gmail.com.

The Pentacam can measure the posterior side of the cornea. In cases of keratoconus and ectatic diseases, it is very common for the posterior side of the cornea to have a noticeably larger elevation as compared to the anterior side. Elevation, opposed to curvature, is the more accurate way to evaluate the keratoconic cornea. The CorVis device is designed to measure biomechanical properties (the strength or weakness of the cornea) that are consistent with corneal diseases. A weaker cornea is more suspect to be keratoconic.

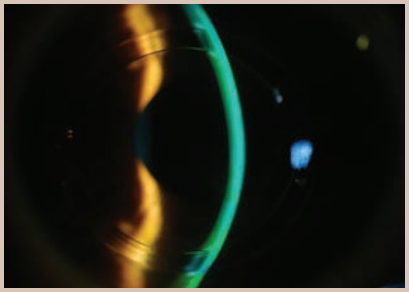
In addition, our existing technologies have become more sensitive to aid in early detection. Keep in mind that the tests designed to help identify keratoconus and other corneal ectasias are noninvasive and take just minutes to complete. The hope is that eventually all children and teenagers will be screened every few years at their regular eye exam.

History of CXL

It is first important to note that corneal crosslinking (CXL) is a non-FDA approved procedure in the US.

CXL was developed in 1998 by Theo Seiler, MD, PhD, at the University of Dresden. Dr. Seiler, in conjunction with Eberhard Spoerl, PhD, and Gregor Wollensak, MD, found that the application of UV-A light (365nm to 370nm) following riboflavin saturation significantly increased corneal rigidity in 98% to 99% of the studied population.[6,7] In keratoconus patients, this strengthening of the corneal collagen either halted or significantly slowed the progressively degenerative nature of the disease.

Originally named "The Dresden Protocol," this protocol involved anesthetizing the eye, preparing the cornea by removing the epithelium in approximately an 8mm to 10mm diameter, applying liquid riboflavin (0.1% isotonic in 20% dextran

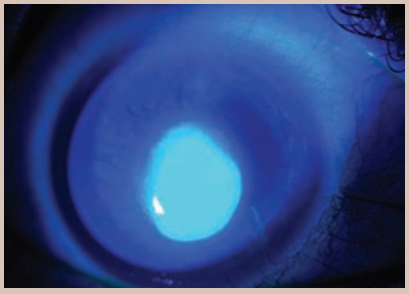


Collagen crosslinking cornea with Intacs.

solution) drops for 30 minutes, applying the UV-A light (5.4J/cm^2 [3mW/cm^2]) for 30 minutes, and finally placing a bandage contact lens on the eye to promote epithelial recovery.[8]

The postoperative course of treatment and follow-up is very similar to PRK. However, one of the downsides to this technique is slower epithelial recovery. This delay is due, in part, to the architecture of the keratoconic cornea. Because of the complex shape of the cone, the normal epithelial migration alters itself within 3mm to 5mm of the apex of the cone and begins the "epithelial swirl."

The swirl, which can be documented on most epi-off procedures in the first two to three weeks after the procedure with fluorescein and cobalt blue light at the slit lamp, is believed to slow the normal course of healing, because there is more surface area to cover and the epithelial motion does not have the ability to power up the cone in a linear fashion. The slower an epithelial defect heals, the greater the likelihood that



Large epithelial defect.

an infection can occur.

A keratoconic patient with a large epithelial defect will take longer to heal than an otherwise healthy individual with the same size epithelial defect.

Epi-On vs. Epi-Off

Currently, there are two basic ways to perform CXL—both of which involve the application of riboflavin. Specifically, the riboflavin needs to saturate the collagen layer and needs to get past the epithelium and Bowman's membrane. The epithelium can either be left in place (epi-on) or removed (epi-off), which naturally raises the question of whether epi-on and epi-off procedures are equally effective. The answer is: No one really knows.

There is a lot of conflicting information on this topic; one way in which it varies is based on geography. In the US, the common belief is that epi-on is a very viable procedure. On the other hand, in most of Europe (except Italy), epi-off is the technique of choice.

- ***Epi-off:*** In a classic epi-off procedure, the cornea is debrided by the surgeon via number of techniques and/or devices. Typically, the epithelial wound is 8mm to 10mm in diameter. After the epithelium is removed, the riboflavin is free to soak into the corneal collagen. This procedure generally lasts 30 minutes.
- ***Epi-on:*** In this CXL procedure, the riboflavin flows through the epithelium to saturate the collagen. While the process takes longer, studies have shown the effectiveness of the technique.[9,10] This procedure generally lasts 50 minutes.

In early 2009, a study by Dr. Wollensak showed that epi-on should only be done when the corneas are not thick enough for standard epi-off CXL.[11] Others have shown that

epi-on CXL is just as effective, considering all parameters of patients.[12] According to William Trattler, MD, "Even if transepithelial CXL stiffens the cornea slightly less than the epi-off version does, it is less painful and eliminates the risks of haze, delays in epithelial healing and infection."[13]

If CXL is going to become commonplace, questions of workflow may become relevant. However, keep in mind that fees can be adjusted to compensate for treatment time, especially if it is a cash, out-of-pocket, non-insurance procedure.

Therefore, as practitioners with conflicting information, we have an obligation to tell our patients with ectatic disease that there is a non-FDA approved procedure that could possibly stop, slow or stabilize the progression of the disease and it might be worth completing an evaluation—especially when treating early onset disease in young/pediatric patients. We have the ability and technology to stop a lifetime of bad night vision, halos and glare, challenging contact lens fits, expensive optical devices that rarely work perfectly and even corneal transplants. We are also likely to see fewer grafts.[14]

Bacteria and Fungi

CXL also promises to have other successful applications, such as the ability to kill bacteria. Bacteria are neutralized by ultraviolet light; in fact, our public water supply is purified by ultraviolet light. In late 2008, there were documented reports that showed CXL could act as a bactericidal agent against *Staphylococcus aureus* and *Streptococcus pneumoniae*.[15] In addition, this same study showed almost no susceptibility against *Pseudomonas aeruginosa* and almost nothing with regard to *Candida albicans*.[16]

So, how does CXL kill bacteria? The UV-A light either can block cell wall synthesis and stop the repair of the bacteria cell wall, or CXL can block the digestive enzymes produced by bacteria and fungi, per the findings of Hans Peter Iseli, MD, and colleagues.[17-19]

The researchers suggested two possible mechanisms to achieve positive outcomes. First, they noted that the CXL process induced greatly enhanced collagen resistance to digestive enzymes, such as those produced by bacteria and fungi in infectious keratitis.[6,7] Additionally, they noted that directed UV-A can inhibit the growth of bacteria and fungi, and the oxygen-free radicals produced during the CXL procedure were believed to interfere with microbial cell wall synthesis and repair.[8,11]

Through ongoing research, we continue to learn of more applications for CXL. One thing is for certain: This is a multipurpose technology that all practitioners should be familiar with, as it has several practical implications for your patient's everyday treatment. RCCL

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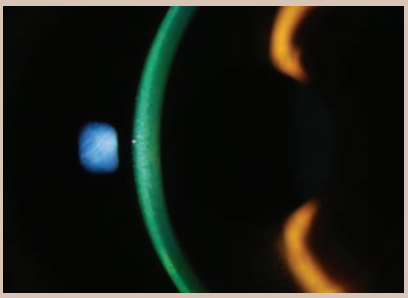

Epi-on CXL with riboflavin completely penetrating to posterior cornea.

Important Notice: Processing Answer Sheets and CE Certificates

Review of Cornea & Contact Lenses is strengthening our commitment to the environment and "going green."

Effective immediately, we will send the results of any CE post-course test that is manually submitted (via mail or fax) to the email address provided on your answer sheet.

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We appreciate your support of this new process. Please contact us via email at cecustomerservice@jobson.com with any questions. Thank you!

CE TEST

1. What is the prevalence of keratoconus in the general US population?
a. 1/100.
b. 1/1,500.
c. 1/10,000.
d. 1/10,0000.

2. How many corneal transplant procedures were performed in the US in 2011?
a. 2,112.
b. 4,600.
c. 14,000.
d. 46,000.

3. Which corneal property is measured by the Oculus CorVis?
a. Elevation.
b. Curvature.
c. Pachymetry.
d. Biomechanics.

4. The father of modern corneal collagen crosslinking (CXL) is:
a. Abu Nazir.
b. Neil Peart.
c. Theo Seiler.
d. Daenerys Targaryen.

5. What is the preferred wavelength of UV-A light for riboflavin absorption?
a. 200nm to 210nm.
b. 365nm to 370nm.
c. 390nm to 400 nm.
d. 613nm to 615nm.

6. The goal of CXL is to:
a. Increase the amount of collagen.
b. Decrease the amount of collagen.
c. Strengthen the collagen.
d. Weaken the collagen.

7. Which of the following is NOT a step in The Dresden Protocol:
a. Prepare the cornea by applying fluorescein to the cul-de-sac.
b. Prepare the cornea by removing the epithelium in an 8mm to 10mm diameter.
c. Apply liquid riboflavin (0.1% isotonic in 20% dextran solution) drops for 30 minutes
d. Apply the UV-A light (5.4J/cm^2 [3mW/cm^2]) for 30 minutes.

8. In an epi-off CXL procedure:
a. The cornea is debrided by the surgeon via number of techniques and/or devices.
b. The epithelial wound is 8mm to 10mm in diameter.
c. After the epithelium is removed, the riboflavin is free to soak into the corneal collagen.
d. All of the above.

9. CXL demonstrates bactericidal activity against:
a. *Staphylococcus aureus* and *Streptococcus pneumoniae.*
b. *Pseudomonas aeruginosa* and *Candida albicans.*
c. *Staphylococcus aureus* and *Candida albicans.*
d. *Pseudomonas aeruginosa* and *Streptococcus pneumoniae.*

10. How does CXL kill bacteria?
a. The UV-A light can block cell wall synthesis and stop the repair of the bacteria cell wall.
b. CXL can block the digestive enzymes produced by bacteria and fungi.
c. Both a and b.
d. None of the above.

Examination Answer Sheet

Valid for credit through April 1, 2016

This exam can be taken online at www.reviewofcontactlenses.com.
Upon passing the exam, you can view your results immediately.
You can also view your test history at any time from the website.

CXL in the Limelight

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

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

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

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

Rate the effectiveness of how well the activity:

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

How long did it take to complete this course?

Comments on this course:

Suggested topics for future CE articles:

Please retain a copy for your records. Please print clearly.

You must choose and complete one of the following three identifier types:

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Last 4 digits of your SS # and date of birth

② ____ · ____

State Code and License #: (Example: NY12345678)

③ ____

First Name

Last Name

Email

The following is your: ☐ Home Address ☐ Business Address

Business Name

Address

City State

ZIP

Telephone # ___ - ___ - ____

Fax # ___ - ___ - ____

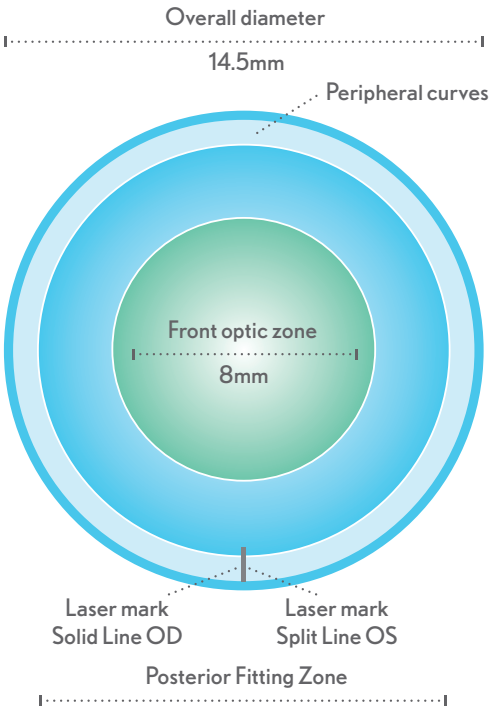
By submitting this answer sheet, I certify that I have read the lesson in its entirety and completed the self-assessment exam personally based on the material presented. I have not obtained the answers to this exam by any fraudulent or improper means.

Signature _____ Date _____

Lesson 109007 RO-RCCL-0413

BAUSCH + LOMB

KERASOFT® IC



A revolutionary design for keratoconus and other irregular corneas.

KeraSoft® IC soft contact lenses feature:

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- Adjustable periphery which fits any corneal shape
- Silicone hydrogel for excellent comfort and a higher level of oxygen

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Soft Lenses for Irregular Corneas: Yes, We *Can*!

For patients with high levels of astigmatism and keratoconus, the go-to GP lenses may not always solve the problem. Here are three soft lens options to consider. **By Joel A. Silbert, OD**

Dr. Silbert is professor of optometry at the Pennsylvania College of Optometry at Salus University and the director of Contact Lens Programs. He is also the director of the Cornea and Specialty Contact Lens Service at The Eye Institute of Salus University. In addition to being a diplomate of the Cornea, Contact Lens and Refractive Technology Section of the American Academy of Optometry, a charter member of the Cornea & Contact Lens Section of the American Optometric Association and a former chair of the Association of Contact Lens Educators, Dr. Silbert was the principal investigator of the NIH-funded CLEK Study at PCO-Salus.

For years, practitioners have known that thicker soft lenses have the ability to mask some corneal astigmatism. While lenses made from stiffer materials than HEMA-based hydrogels (e.g., the CSI lens of the past or first-generation silicone hydrogels with a high modulus of elasticity) may work for patients with low corneal astigmatism, they rarely were successful for any patient manifesting significant amounts of astigmatism, irregular astigmatism or keratoconus.

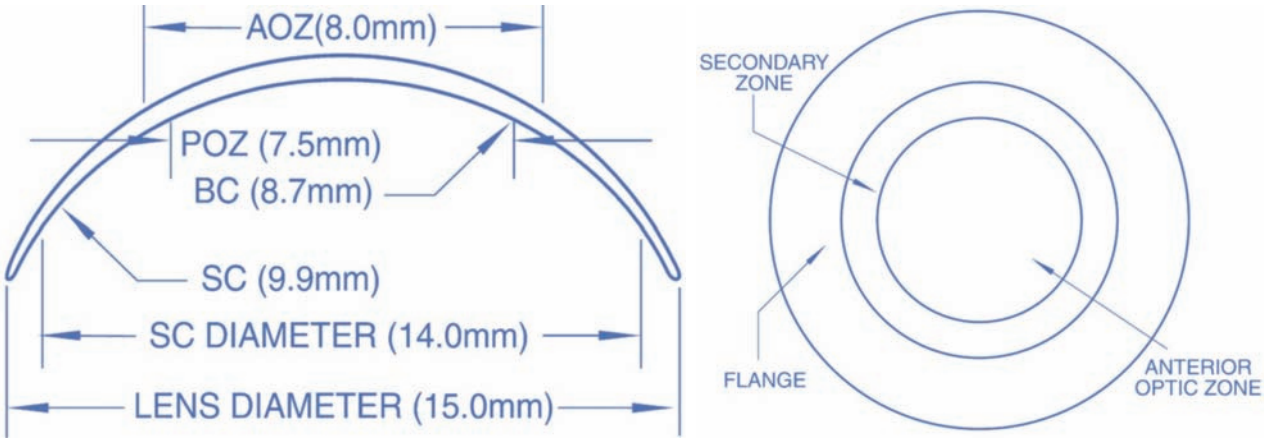
To manage keratoconus, practitioners have tried using toric soft lenses. But, exempting patients in the early stages of disease, the results generally have been poor. The mainstay of keratoconus management has thus been through the use of rigid gas-permeable (GP) lenses, which provide outstanding vision. But keratoconic patients consistently reveal that the discomfort with GP lenses—although tolerated—is a significant detriment to quality of life.

Piggyback systems, as well as the hybrid-type lenses that combine a rigid lens center with a soft periphery (e.g., SynergEyes' ClearKone or SynergEyes KC), can improve comfort, although to varying degrees. While both are helpful in improving vision and comfort, the hybrid lenses may result in tighter fits despite our best efforts, which sometimes can facilitate the development of corneal neovascularization.

Wouldn't it be nice to have a single, non-hybrid soft lens that could provide improved comfort over the above-mentioned modalities and still correct the patient's vision to a degree competitive with GP lenses? Let's look at several lenses that strive to play this role.

Flexlens Tri-curve Keratoconus and Flexlens Piggyback

To address the need for significantly increased lens thickness, Flexlens Tri-curve Keratoconus (X-Cel Contacts) is a hydrogel lens that has been available for several years. The lens is available in both 49% or 59% water hioxifilcon, in 55% methalfilcon and, more recently, in the newest customizable Definitive material by Contamac (60Dk, 74% silicone



1. Flexlens Tri-curve lens for keratoconus.

hydrogel) to offset the reduced oxygen transmission associated with thick hydrogels.

The Tri-curve lens incorporates two peripheral curves and has a center thickness ranging from 0.40mm to 0.65mm thick *(figure 1)*. A flat secondary curve (1.2mm to 1.8mm) and a peripheral scleral curve (2.2mm to 2.8mm) are used to aid alignment. Toric powers have not yet been offered with this lens design.

These lenses are best for keratoconic patients with moderate amounts of irregular astigmatism. Patients with significant residual astigmatism, however, will still need a piggyback design.

The Flexlens Piggyback design uses a soft lens with a central cut-out depression to keep a GP lens securely centered over the cornea. This is a notable advantage over other piggyback systems in which GP lenses ride low *(figure 2)*. A wide range of parameters for the soft lens base and the anterior cut-out are available to accommodate GP lenses of varying diameters. The soft lens base is now available as a monthly replacement lens.

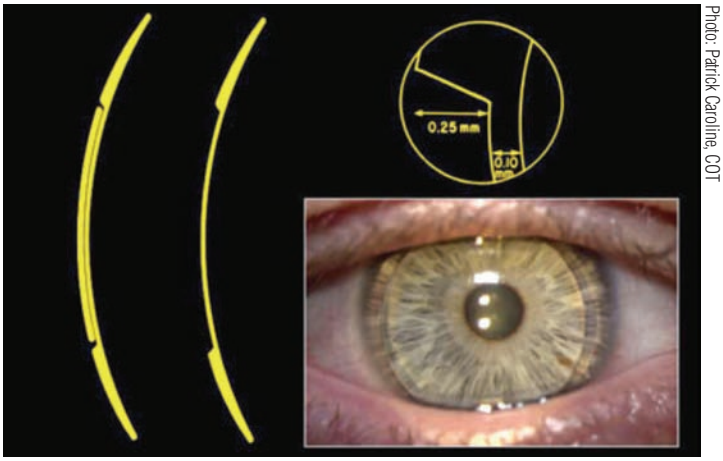


Photo: Patrick Caroline, COT

2. FlexLens piggyback lens with cut-out. Note good centration of GP over pupil zone.

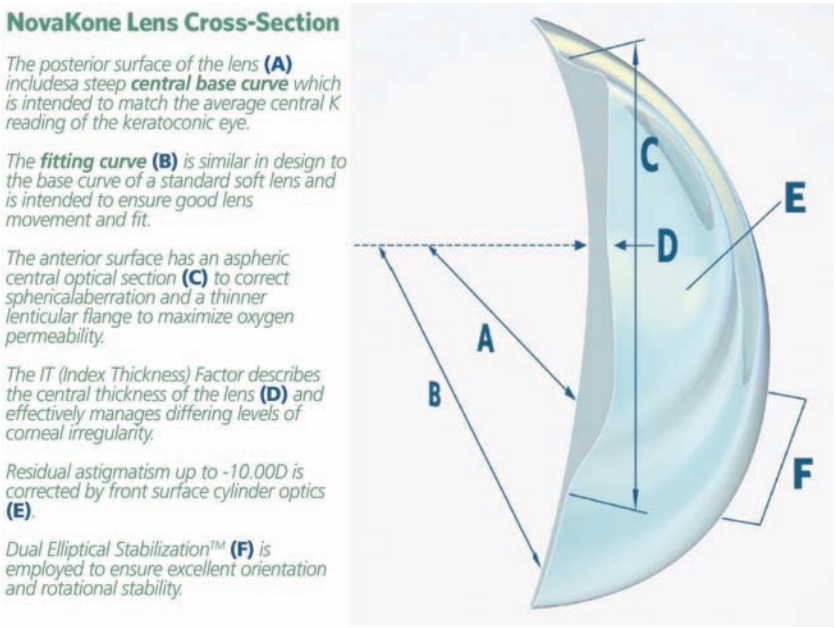
NovaKone

NovaKone (Alden Optical) is a relatively new lens that uses increased thickness as a tool to control corneal irregularity. The optical zone of this soft lens functions much like a GP, which helps to neutralize irregular corneal astigmatism. The big advantage, however, is that it also allows for the essential correction of residual astigmatism. Rotational stability for the toric application comes from the company's dual elliptical stabilization design *(see figure 3 and table 1)*.

The lens is made of Benz G4X 54% hioxifilcon D and comes in a standard 15.0mm diameter. An 18-lens diagnostic set, which contains a wide range of base curves and fitting curves (flatter curves for the corneal regions outside of the cone), is necessary to fit this lens. These lenses contain significant amounts of minus power and varying thicknesses.

Thickness control with the NovaKone lens is critical to its success. It is designated as the "IT factor," which stands for increased thickness, and ranges from thinnest (0) to thickest (4) in incremental steps. Steeper curves for advanced cones are naturally provided in the diagnostic set, along with several IT factors to help correct the irregular corneal astigmatism. This is gauged not only by the level of visual acuity obtained through spherocylindrical over-refraction (SCOR) performed during the spherical test lens, but also by assessing the quality of the front surface of the lens with an "over-K" measurement. As long as the clinician observes good quality of the over-K mires with

Photo: Alden Optical



3. NovaKone uses increased thickness as a tool to control corneal irregularity.

the test lens (despite the amount of astigmatism measured), we know that the test lens has achieved regular astigmatism and a SCOR should result in good visual acuity.

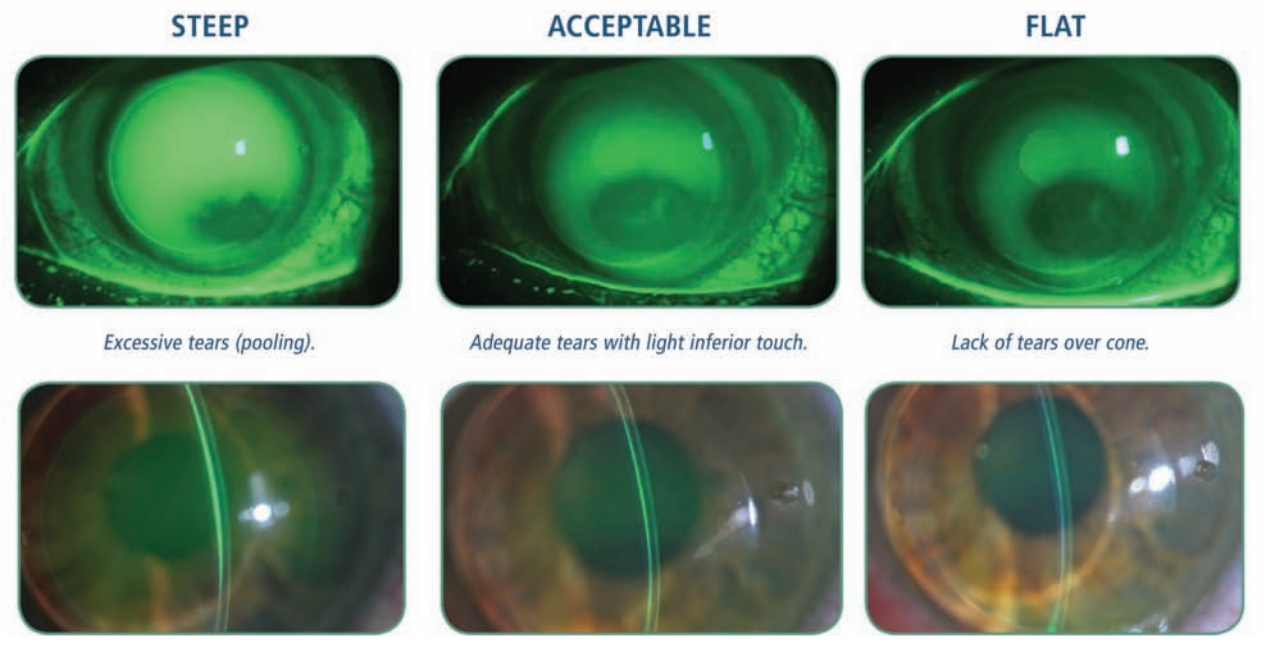
This astigmatism is then incorporated into the rotationally stabilized toric lens design. (Be sure to compensate for rotation as you would normally do with any toric lens, assuming good lens movement and centration is observed.) There are two laser marks on the lens's horizontal axis that aid in toric rotational measurement. You may have to repeat this process with more than one IT factor to determine the best lens. It is not uncommon to find that higher IT factors can achieve better acuity with less additional toric refractive correction. That said, the clinician should still attempt to use the lowest level of IT thickness that produces a satisfactory visual outcome.

The fitting technique is a four-step process, from the inside out:

1. ***Determine the central base curve.*** Use the supplied initial lens selection table that recommends the base curve/fitting curve combination based on average Ks (or Sim Ks if using topography) for the central 3mm to 4mm zone. This test lens is applied, filled with high molecular weight fluorescein, and evaluated to achieve an acceptable lens that demonstrates neither excessive bearing over the cone nor excessive apical clearance *(figure 4)*.

2. ***Determine lens thickness (IT factor).*** Use the lowest IT factor that produces regular mires verified by over-keratometry or topography. If irregularity is observed, switch to a higher IT factor. (Smaller, central

Photo: Alden Optical



4. Fitting evaluation of NovaKone using high molecular weight sodium fluorescein.

cones usually can be treated successfully with lower IT factors, while larger, decentered cones will often require much higher IT factors.)

3. ***Determine the total lens power needed.*** Compensate for vertex distance, as well as rotation, when adding the SCOR to your spherical test lens.

4. ***Determine the para-central fitting curve.*** Typical soft lens fitting characteristics should be observed. Excessive lens movement or edge lift requires use of a steeper fitting curve, while little to no movement or edge impingement requires a change to a flatter fitting curve.

Kerasoft IC

The Kerasoft IC is distributed through Bausch + Lomb and several authorized manufacturing labs, such as ABB Concise, Art Optical and Metro Optics. These lenses are used for all stages of keratoconus, pellucid marginal degeneration, post-LASIK ectasia and other irregular astigmatic conditions.

Practitioners who want to fit either the NovaKone or Kerasoft IC must first complete the online certification process.

The aspheric Kerasoft IC lens is made from Definitive silicone hydrogel material (74% water, 60Dk) that is designed for quarterly replacement. Fitting employs an eight-lens diagnostic set, with standard 14.5mm diameter (others available), plano power and a range of base curves (7.80mm to 8.60mm, with others available). Most lenses in the set have a standard periphery, but the flatter base curves also include lenses with flat and steep peripheries for unusual fitting circumstances. It is a lean set, but one that is very useful in its intelligent design. Powers are available from +20.00D to -20.00D, with cylinder from 0.50D to 12.00D in 0.25D increments at any axis *(figures 5 and 6)*.

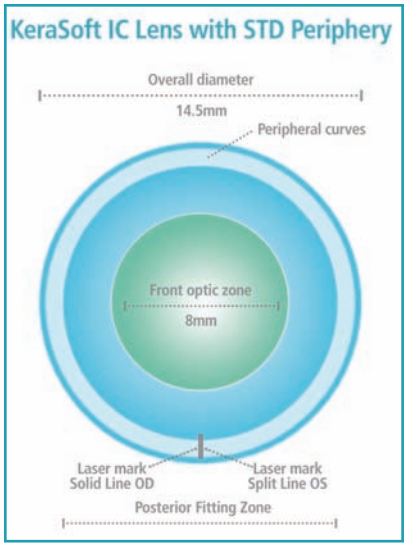


Photo: Bausch + Lomb

5. Kerasoft IC lens.

The fitting process with the Kerasoft IC follows a rigid protocol, known as the MoRoCCo VA system. Initial lens design for keratoconus involves first looking at the patient's corneal shape, which can vary from steep central cones to low, decentered cones that require different base curves—depending on the severity of the cone. Pellucid corneas often need flatter base curves, and may require additional peripheral modification of the flat superior and steep inferior zones. Post-surgical corneas will need steeper peripheries. Use of the "corneal shape recognition" and "profile" charts can help select an initial lens for evaluation.

The MoRoCCo VA system is then employed for the fitting assessment, as follows:

- ***Mo*** (Movement) is evaluated, and up to 2mm of movement is acceptable as long as the patient is comfortable. Change the base curve radius if movement is greater than 2mm or less than 1mm, or if the patient is uncomfortable. (Be prepared to see more movement with soft keratoconic lenses than you would otherwise observe with conventional soft lenses. Increased patient comfort comes with adaptation, so patient education is important here.)
- ***Ro*** (Rotation) is assessed using the vertical laser mark, which should be at six o'clock, stable, with up to 10º of acceptable rotation. Rotation will need to be compensated. A slightly flatter base curve may improve the stability, but unstable rotation is caused by a flat fit.

FDA-Approved Definitive SiHy Lenses

Israel-based Soflex has been granted FDA marketing approval for the following lenses based on the Definitive silicone hydrogel material. These lenses are not currently available through US distributors.

- **Eni-Eye Soft K:** daily wear lens for keratoconus and irregular corneas.
- **Eni-Eye Soft K Toric:** daily wear lens for keratoconus and irregular corneas.
- **Eni-Eye SH Soft K:** three-month replacement silicone hydrogel lens for keratoconus and irregular corneas. According to the manufacturers, the base curve geometry has a spherical optic zone with an aspheric periphery. The front curve has a reinforced optic zone, a special lenticular zone for structural stability and a very comfortable edge. A special system incorporates pressure-balancing holes to equalize the pressure between the front and back of the lens.
- **Eni-Eye SH Soft K Toric:** a back toric prism ballasted lens design, marked with an engraved dot at 270º.

Photo: Bausch + Lomb

Standard Diagnostic Fitting Set Parameters			
Base Curve	**Diameter**	**Periphery**	**Power**
7.80mm	14.5mm	STD	Plano
8.00mm	14.5mm	STD	Plano
8.20mm	14.5mm	STD	Plano
8.40mm	14.5mm	STD	Plano
8.60mm	14.5mm	STD	Plano
8.80mm	14.5mm	STD	Plano
8.20mm	14.5mm	FLT2	Plano
8.60mm	14.5mm	STP2	Plano

MATERIAL	Benz G4X 54%, Hioxifilcon D
DIAMETER	15.0 as standard, others available in 0.1 mm steps
BASE CURVE (central)	5.4 and 5.8, 6.2, 6.6, 7.0, 7.4, 7.8, 8.2, 8.6 as standard, others available in 0.1 mm steps
FITTING CURVE (para-central)	8.2, 8.4, 8.6 as standard, others available in 0.1 mm steps
SPHERE POWER	+30.00 to -30.00 in 0.25D steps
CYLINDER POWER	up to -10.00 in 0.25D steps
AXIS	1° to 180° in 1° steps
IT FACTOR* (increased thickness)	0 = standard thickness 1, 2, 3, 4 incrementally thicker for higher levels of irregularity

*I.T. Factor is used to increase the lens thickness when irregularity is observed.

6. Eight-lens Kerasoft IC fitting set.

Stable but greater than 10° rotation implies a tight fit and the base curve should then be flattened.

• *C* (Centration) should be good, but a minimal amount of decentration is acceptable if acuity is stable and clear. If vision improves immediately after the blink, then there is a tight fit. Lateral decentration with a drop on up-gaze indicates a flat fit.

• *Co* (Comfort) should be good, but if persistent edge awareness exists, try a steeper base curve. If there is discomfort and the lens is stationary, the lens likely is tight.

• *VA* (Visual Acuity) should be stable, without fluctuation between blinks. If the vision is worse after the blink, it is likely due to a flat fit. If it is clearer after the blink, a steep fit is likely. If acuity cannot be achieved after the above adjustments, this may be due to a very flat peripheral cornea. Peripheral modification may be needed, or the lens design discontinued in favor of other lens options.

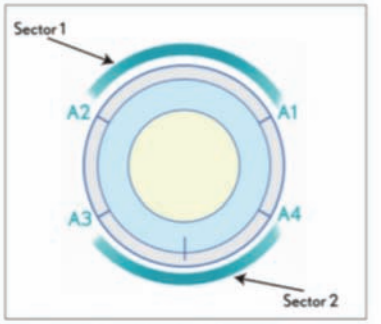
The periphery of the Kerasoft IC is unique in that it can be steepened or flattened, independent of the base curve. This customizable process is known as sector management control (SMC). Up to two sectors in the periphery can be modified when necessary, such as with post-graft corneas that require flatter base curves but need peripheral steepening. Also, low cones and PMD corneas may require SMC steepening of the inferior sector and possibly flattening of the superior sector. Lens sector angles (quadrants) are designated and specified as either STD or STP 1-4 or FLT 1-4 *(figure 7)*.

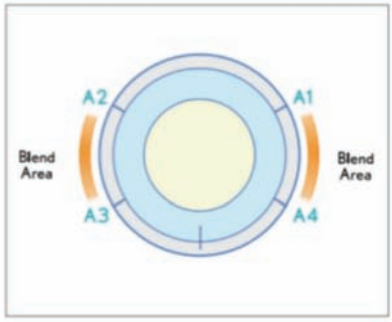
The use of these new, specialized soft lens designs for keratoconus can be very rewarding. They give practitioners the ability to improve visual acuity for patients with irregular astigmatism or irregular corneal profiles that is on par with GP lenses, but with improved comfort. Good lens movement and the use of silicone hydrogel materials provide these corneas with improved metabolism, free of the risks of vascularization sometimes seen with tighter hybrid designs.

Whether using these new soft lens modalities or using scleral lenses (which also provide good acuity and comfort), the clinician now has powerful tools that can better serve these patients. Considerable time is needed to work with these patients, so schedule your appointments accordingly. And, remember to fit each lens individually, per eye. RCCL

Photo: Bausch + Lomb

For more irregular corneas, up to two sectors of the periphery can be modified independently of the base curve and customized to the specification of the practitioner (indicated in less than 10% of KeraSoft IC fits).





How to define the SMC Sector Angles

Record angles counter-clockwise around the lens circumference as A1,A2,A3 and A4.
A1 and A2 define beginning and end of the first sector.
A3 and A4 define beginning and end of the second sector.

Each sector can be ordered as either STD, STP 1-4 or FLT 1-4.
Blend areas are automatically set once sector angles are defined.
There must be a minimum of 30° between each sector.

7. Kerasoft IC sector management control (SMC).

Scleral Lenses: An Overlooked Fix for Dry Eye?

In addition to treating corneal irregularities, the scleral lens's tear reservoir may also effectively relieve dry eye.

By Greg DeNaeyer, OD

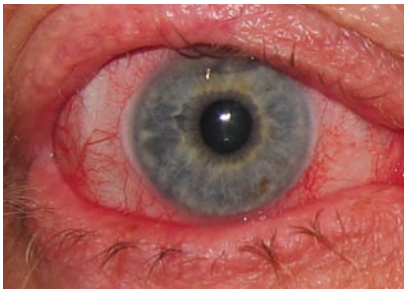
With an estimated 4.91 million Americans over the age of 50 suffering from dry eye, eye care practitioners are perpetually on the lookout for better treatment options.[1] What about scleral lenses? We commonly associate scleral lens fittings with corneal irregularities, since the lenses hold a liquid reservoir that allows them to mask the irregularity and return patients to near normal visual function. However, the liquid reservoir these lenses hold can also aid in effectively managing and providing relief for patients with dry eye. This article offers advice for using scleral lenses to treat moderate to severe dry eye.

Understanding Dry Eye

Evaporative dry eye has been strongly linked to meibomian gland dysfunction (MGD), whereas aqueous-deficient dry eye is often secondary to systemic disease—such as Sjögren's syndrome and chronic graft vs. host disease (cGVHD).[2]

The best approach to managing dry eye is based upon its etiology and severity. Scleral lenses are typically reserved for helping to manage moderate to severe dry eye disease. In 2007, the International Dry Eye Workshop recommended that contact lenses be considered for Grade 3 level of severity.[3] Grade 3 patients have chronic dry eye that affects

Dr. DeNaeyer is the clinical director for Arena Eye Surgeons in Columbus, Ohio, and a consultant to Visionary Optics, Bausch + Lomb and Aciont. You can contact him at gdenaeyer@arenaeyesurgeons.com.



1. Severe lid disease in a patient with cGVHD.

their comfort and vision, which can potentially limit their activity. These patients often present with lid disease *(figure 1)*, central corneal staining *(figure 2)*, filamentary keratitis, mucus clumping and increased tear debris. This results in severe discomfort and decreased visual acuity.

Treating Dry Eye

Recent literature reports success in managing moderate to severe dry eye disease with scleral lenses. In 2012, researchers used mini-scleral contact lenses for moderate to severe dry eye patients previously unsuccessful in conventional therapy. They found that four of the seven patients fitted in scleral lenses reported reduced discomfort and dry eye symptoms, decreased use of artificial tears and improved visual acuity.[4]

A retrospective case series of five patients (10 eyes) who were successfully fit with Jupiter scleral lenses was analyzed in a 2008 study to better understand the use of scleral lenses in the management of chronic graft vs. host disease.[5] All patients reported improved comfort, and seven of the 10 eyes demonstrated improved best-corrected visual acuity.

A 2007 study on the use of scleral lenses to manage severe dry eye related to cGVHD followed 33 patients with severe dry eye secondary to cGVHD and had previously failed conventional treatment. Study patients were fit with the Boston scleral lens prosthetic device (BSLPD); the results showed that management with the BSLPD produced an improvement in pain, photophobia and general quality of life for nearly all patients.[6]

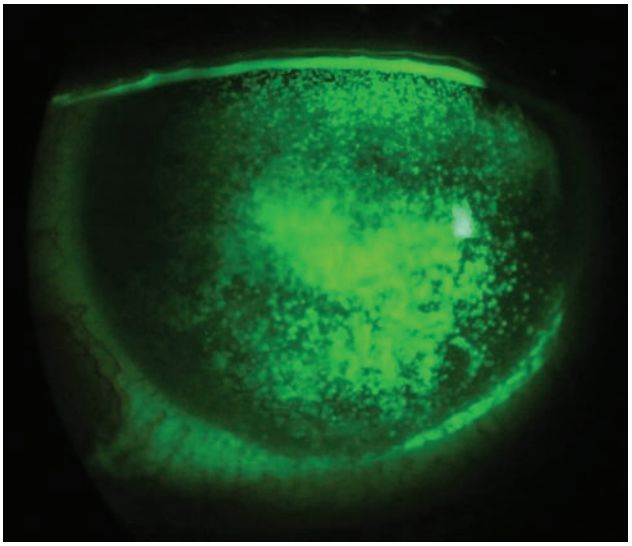
Fitting Scleral Lenses

When fitting scleral lenses, the objective is to achieve complete lens clearance of the cornea, evenly distributed haptic bearing that doesn't excessively compress the bulbar conjunctiva and a semi-seal fit. However, there are some special factors to consider when fitting a scleral lens specifically to manage dry eye.

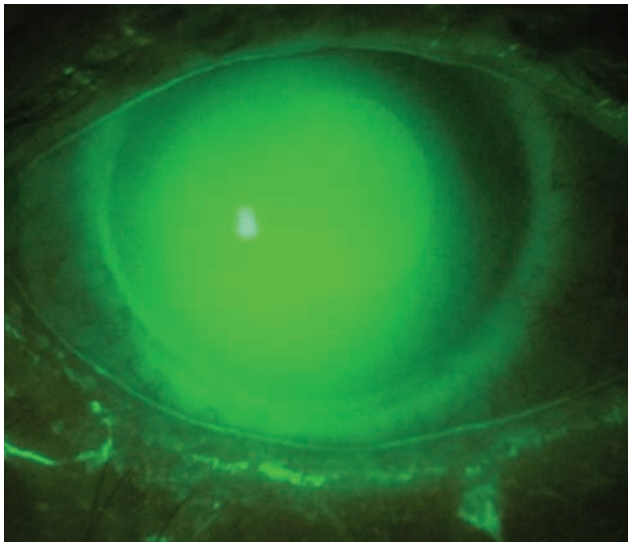
• ***In dry eye patients, avoid using smaller corneo-scleral lenses (12.5mm to 15mm in diameter) because they are more likely to exhibit some shared bearing between the cornea and the sclera.*** It's important that the scleral lens completely vaults the cornea to avoid mechanical injury, especially when the cornea is already compromised due to dryness. Mini-scleral lenses (15mm to 18mm) or full scleral lenses (18mm to 24mm) are a better choice for managing dry eye because they provide increased vaulting capability *(figure 3)*.

Although the ideal vaulting range for mini-scleral or full scleral lenses varies between 100µm to 300µm, it's best to err on the side of more vault to ensure that you have enough liquid reservoir across the entire cornea, including the limbus.

• ***Inform your patients in advance that scleral lenses may require extra care due to possible complications.*** Patients who have



2. Corneal staining of a patient with cGVHD.



3. A 18mm scleral fit for a patient with cGVHD.

moderate to severe dry eye produce significantly more mucus and usually exhibit excessive tear debris. Unfortunately this excessive debris gets pumped underneath the lens and builds up during wear time *(figure 4)*. Reservoir debris does not diminish comfort, but it can negatively affect vision by causing the patient's visual field to appear cloudy. In this case, a symptomatic patient will have to remove lenses for rinsing and refilling.

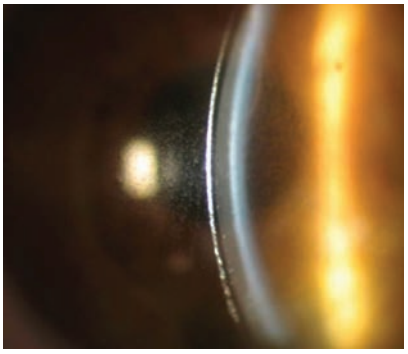
Your patients are less likely to be discouraged with scleral lens wear if they have been previously educated on these potential scenarios. Minimize the impact by fitting the haptic as evenly as possible to the scleral conjunctiva. Small areas of haptic edge lift can be an entrance port for debris, which can result in increased accumulation in the reservoir of the lens. Fitting the patient in a back surface toric or quadrant specific back surface design can minimize or eliminate edge lift.

Special Considerations

• ***Don't forget about the eyelids.*** Chronic blepharitis or MGD can be a contributing factor for moderate or severe dry eye disease. Habitual use of lid scrubs and warm compresses can help improve the patient's tear film. Consider oral or topical pharmaceuticals for severe lid disease or to treat patients who are unsuccessful with lid scrubs and warm compresses.

• ***Pick the right solution.*** Prescribing the appropriate solution is an important step in successfully managing dry eye with scleral lenses. Have the patient use a hydrogen peroxide care system for cleaning and disinfection. This will ensure that no residual preservatives get trapped underneath the bowl, which could later become toxic to the anterior ocular surface. Prescribe the off-label use of 0.9% saline (single-use ampules to avoid toxic exposure to preservatives or buffers in bottled saline solutions). Consider having the patient use an extra-strength cleaner periodically if they are prone to deposits and build-up of debris.

• ***Redefine the role of eye drops.*** Patients referred for severe dry eye secondary to a systemic issue (e.g., cGVHD) will probably be on numerous topical medicines, including steroids, autologous serum and antibiotics. If the scleral lenses are successful, often the dosage can decreased or eliminated altogether. Comanage any medication changes with all other professionals involved in the patient's care. The patient may continue to use artificial tears during lens wear to keep the surface lubricated; topical lubricating gels may be used at night after lens removal.



4. A scleral lens with significant reservoir debris.

Moderate to severe dry eye is a disabling condition that can limit a patient's activity and decrease their quality of life. The use of scleral lenses for dry eye patients who have been unsuccessful with conventional therapy can significantly improve comfort and vision. RCCL

Dr. DeNaeyer is the designer of the Europa scleral lens (Visionary Optics).

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A Case Study

A 41-year-old white male with a history of cGVHD was referred for a scleral contact lens fitting by his corneal specialist. The patient complained of decreased vision, dry eye and photophobia. He was using bacitracin/polymyxin QID OU and Muro 128 QID OU. His best-corrected visual acuity was 20/80 OD and 20/60 OS. Slit lamp exam showed moderate corneal staining OU and scattered Salzmann's patches on both corneas.

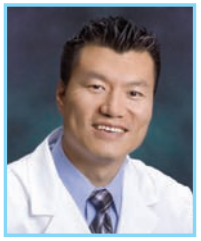
The patient was diagnostically fit with Europa Scleral (Visionary-Optics) 18mm diameter lenses, which were dispensed two weeks later. After application of the lenses, the patient's visual acuity improved to 20/25 OD and 20/20 OS. The scleral lenses adequately vaulted the cornea and evenly fit the sclera.

The patient was prescribed Clear Care (Alcon) for cleaning/disinfection and off-label 0.9% sodium chloride solution for filling the lens pre-application. At his three-week follow-up, he reported improved vision and comfort with the scleral lenses. He has discontinued using the Polysporin and Muro 128 drops and rarely uses artificial tears.

Advertorial

Meeting the Goal of Clear, Crisp Vision in CL Patients with Astigmatism

It's all about vision



By Scott Han, OD, FAAO

For virtually every patient who walks into my office, it's all about vision. This personal perception was very much brought home to me as a major finding of the Needs, Symptoms, Incidence, Global Eye Health Trends (NSIGHT) study.[1] This large global survey of vision-corrected individuals found that patients want the best vision possible from us as eye care professionals. That means not only visual acuity as measured on the Snellen eye chart but also quality of vision. So I go into every exam thinking about how I can make that patient's quality of vision better. I'd like to share with you my own experience in meeting the challenges of providing consistent, crisp vision in my contact lens patients with astigmatism.

Halos and glare are a familiar concern in spectacle and contact lens patients alike. In spectacle patients, we are quick to offer anti-reflective coatings but what about the contact lens patient with astigmatism? The PureVision®2 for Astigmatism lens is designed to reduce positive spherical aberration in both the spherical and cylinder meridians, across the entire power range. In addition, the large optic zone of PureVision®2 for Astigmatism maximizes the optical benefit from this aberration reduction, most notably in low light conditions when the pupil is large.

My patients consistently comment about their improved quality of vision, especially at night. I'm reminded of a young male patient who I found walking around in the office parking lot shortly after I had fit him with a new PureVision®2 for Astigmatism lens. He was looking up into the surrounding lights, commenting on how great his new lenses would be for playing softball at night because of the reduced glare compared to his previous contacts.

Another issue contact lens patients with astigmatism experience is the tendency of the lenses to rotate, resulting in hazy, blurry or inconsistent vision. The Auto Align Design of PureVision®2 for Astigmatism uses thick and thin zones to stabilize the lens on the eye, in essence incorporating a hybrid design with the stability characteristics of a prism ballast and two peri-ballast areas (Figure 1). The large lens diameter (14.5 mm) along with the 8.9 mm base curve also helps in maintaining centration and stability.

When I first tried out this lens it worked extremely well for me and for the patient. As it happens, I put the lens in but instead of having the patient go out into the waiting room we began talking, with her still in the chair. Suddenly the patient simply exclaimed that her vision felt good, she was able to see right away. Indeed, under slit lamp examination I could see that the lens was orienting almost immediately. For the next patient, as a test I placed the lens exactly 180 degrees opposite to where it should be. By the time I was able to get into position and look into the slit lamp the lens had already settled – in less than a minute. So not only does it have the quality of vision but it also has stability of vision,

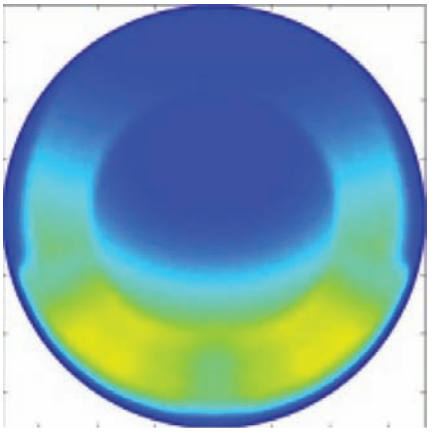


Figure1. *The Auto Align Design, a hybrid ballasting system, keeps the lens from rotating out of position. Yellow color indicates the thickest portions of the lens and the blue color represents the thinnest portions of the lens.*

quickly providing very consistent, crisp vision for the patient. Patients want to see well but they want comfort at the same time. PureVision®2 for Astigmatism incorporates two key features to improve comfort: a thin edge profile that is also rounded to provide a natural feel throughout the day, and a moisture rich packaging solution so that it's comfortable on insertion. One of my patients told me he couldn't feel any difference between the spherical lens and the toric lens. For the first time he was able to tolerate wearing contacts and was excited to have an option other than spectacle lenses.

Comfort, quality of vision and stability of vision – these are the things I'm looking for in an astigmatism correcting contact lens. And with the expanded parameters, there's the ability to offer increased myopic and hyperopic correction. As a result, PureVision®2 for Astigmatism has become the "go to" lens that I use to provide clear, consistent and comfortable vision to my contact lens wearing patients with astigmatism.

Dr. Han is Director of Optometry and a partner in a multispecialty, multidisciplinary, private practice with five locations in three counties in Florida.

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Bending the Curve: How to Improve Toric Lens Success

Despite an abundance of options on the market, it is becoming increasingly difficult to find the right fit for your astigmatic patient.

By Ed Bennett, OD, MSEd

Today's contact lens practitioner has an increasing number of astigmatic options in the toolbox. Yet, it can be difficult to decide whether to pick the gas-permeable (GP) or the soft lens option. In many situations, this is a case-by-case decision. This article offers eight representative cases—some with two different scenarios—to help guide practitioners as they make similar decisions in their daily practice.

Case Study #1: Low Refractive Cylinder (0.75D to 1D)

Patient A: spherical soft lens wearer; Patient B: spectacle lens wearer.

Practitioners worldwide have routinely bypassed the correction of low levels of refractive astigmatism (≥ 0.75D).[1] In fact, the number of individuals who are fit into astigmatic-correcting lenses is approximately only half of those who could potentially benefit from such a lens.[2-4] This is often the result of the perceived complexity, time, and expense of soft toric lenses.

These low refractive patients are often good candidates for soft toric lenses, especially if they have been wearing spherical soft lenses or even spectacles. Several studies in which low astigmatic patients were fit in both spherical and toric soft lenses found that toric lenses resulted in a significant improvement in vision.[4,5]

The best recommended method is to provide a "Coke-Pepsi" test: Allow your patient to try both modalities, or at least test their vision with and without astigmatic correction in the phoropter, before making the final decision.

Case Study #2: Significant Residual Cylinder

Patient A: -3.50, -1.00x180, 43/45; Patient B: -3.50, -2.25x180, 43/44.

Patients exhibiting ≥ 0.75D of residual astigmatism—i.e., not corrected with a spherical GP lens—often benefit from soft torics, especially if their

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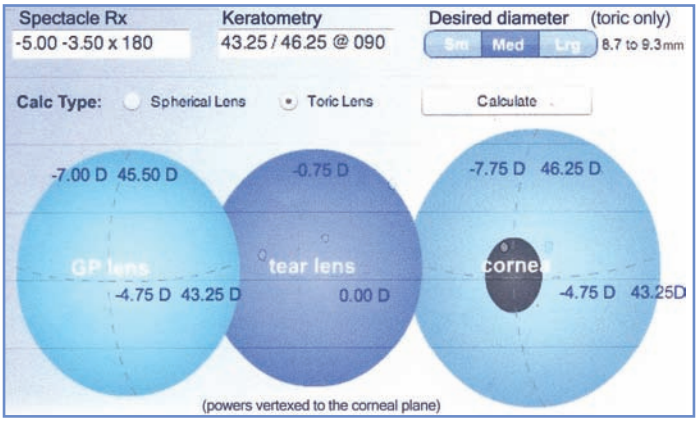
refractive cylinder is in the customary range of standard designs (0.75D to 2.50D).[6] In particular, silicone-hydrogel frequent replacement and disposable toric lenses are recommended; there are currently at least 12 such designs.[7] These designs all meet the corneal oxygen requirements under open-eye conditions and also dehydrate at a slower rate than their hydrogel counterparts.[8,9]



1. The GPLI Toric and Spherical Lens Calculator: Bitoric Design.

Historically, front surface toric rigid GP lenses have been used in many of these cases; however, problems of decentration, vision instability and reduced comfort often occur. This is, in part, due to the greater thickness of these prism-ballasted lenses.

In the case of Patient B, a bitoric GP lens design is an alternative if a soft toric lens rotates excessively and results in unsatisfactory vision.

Case Study #3: Critical Vision Demands

Patient A: soft toric lens wearer; Patient B: new lens wearer.

Consider GP lenses for all individuals who have critical distance vision requirements. This is because GP lenses can mold the front surface of the eye, thereby eliminating anterior corneal astigmatism. They can also provide outstanding optical quality, which has resulted in better visual performance as compared to soft lenses.[10-12]

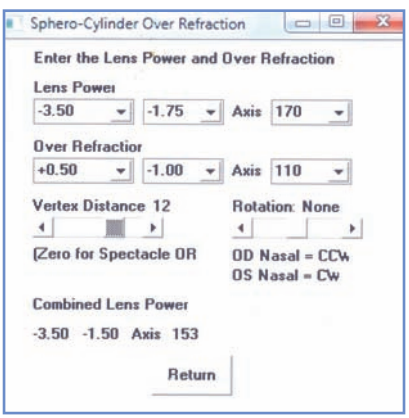
Initial comfort can be improved by a positive, proactive presentation, the use of a topical anesthetic immediately prior to initial lens application, and by ordering the lenses empirically so that the patient's initial experience is visually encouraging.[13,14]

Secondary options include either a hybrid or a semi-scleral design; the latter has recently been found to result in wear and comfort comparable to soft torics, yet offers better subjective quality of vision.[15]

Case Study #4: Low Spherical Error/High Cylinder

Patient: -0.75, -2.75x180

These individuals often benefit from a bitoric GP lens design, particularly if their corneal cylinder is at least 2.50D.[6] These designs are not complicated, plus there are several easy-to-use empirical guides and calculators available, such as the Mandell-Moore Guide, the GPLI Toric and Spherical Lens Calculator *(figure 1)* and Newman's GP Toric Guide. All of these resources are available online at the GP Lens Institute (www.gpli.info).



2. The AOA cross cylinder calculator recommendation based on a sphero-cylindrical over-refraction over a soft toric lens.

Empirical fitting of bitoric lenses has been found to be as successful as diagnostic fitting, and has resulted in greater patient satisfaction when compared to soft toric lenses.[10,16] A recent study found that 14 out of 19, or 74% of high astigmatic subjects who wore both soft toric and back surface GP toric lenses preferred the vision of the GP lenses and preferred to stay in them, even though most of the subjects entered the study wearing soft toric lenses.[10,11,14,19] The researchers concluded that GP toric lenses should be considered as an option for all high astigmatic patients as they are preferable in day-to-day critical vision activities, notably reading and computer use.

The biggest challenge presented with soft toric lenses is not only the high cylindrical component of the refraction, but also that the cylindrical component is predominant. For an individual with -3.00D of cylinder, 5˚ of rotation results in approximately 0.50D of over-refractive cylinder, and this increases approximately 0.50D for every additional 5˚ of rotation (i.e., -1.00D at 10˚, -2.00D at 20˚, etc.).[17] This is also significant at lower cylinder levels, as 10˚ of rotation results in an over-refractive cylinder of 0.75D with a patient exhibiting -2.25D of refractive cylinder and 0.92D if they exhibit -2.75D of cylinder.[18]

Several calculators are available to assist in determining the soft toric cylinder amount and axis if a sphero-cylindrical over-refraction results from lens rotation on the eye *(figure 2)*.[19] Custom soft toric lenses are an option if GP lenses are not successful

or desired. The fact that these lathe-cut designs can be manufactured in a 60Dk silicone-hydrogel material (e.g., Definitive from Contamac; available from Art Optical, ABB Concise, Metro Optics and Unilens) with up to 5.00D of cylinder correction and any axis is beneficial. The downside is that these lenses are more expensive than their hydrogel counterparts, and are only replaced quarterly.[20]

Case Study #5: Against-the-Rule Cylinder

Patient: 44.25/43 @ 090/-5.00 -1.50x090

Individuals exhibiting against-the-rule (ATR) astigmatism often benefit from a soft toric lens design. Upon blinking, GP lenses tend to follow the steeper corneal meridian on the eye; therefore, they tend to move laterally on an ATR cornea, which can result in fluctuating or blurry vision. Either one of the several newly introduced semi-scleral lens designs for healthy eyes or a hybrid design are recommended when a soft toric lens is not successful.

Case Study #6: Oblique Cylinder

Patient A: refractive axis; Patient B: over-refraction with soft toric lenses

Individuals with oblique cylinder axes benefit visually from a GP lens design. Patients with healthy corneas who exhibit an oblique cylindrical correction or those with irregular astigmatism (i.e., keratoconus or post-surgical etiology) are both ideal candidates. The latter patients benefit from the ability of a GP lens to mold the front surface of the cornea into a sphere, which greatly reduces the irregularity and improves the quality of vision.

Also keep in mind that oblique axes incorporated into soft toric lens designs often result in rotation-induced reduced vision due to complex lid-lens interactions.[21,22] If GP lenses are not successful, a second option is to fit the patient in either a hybrid or a semi-scleral design.

How Do Daily Disposable Torics Impact Prescribing Habits?

The increasing marketplace availability of daily disposable hydrogel toric lenses, and the forthcoming introduction of silicone hydrogel materials in this modality, should affect how we prescribe contact lenses to the astigmatic patient.

Daily disposable torics should be considered the lens of choice if your astigmatic patient's prescription falls within the current limited range of availability: ≤ 9.00D of spherical power, ≤ 1.75D cylinder with axes within 20° of 90 and 180.[23] These include Focus Dailies Toric (Alcon), Soflens Daily Disposable for Astigmatism (Bausch + Lomb), and Clearsight 1 Day Toric (CooperVision). One exception is 1-Day Acuvue Moist for Astigmatism (Vistakon), which is available in 10° steps from 10 to 180 and in -2.25D of cylinder with limited axes.

In particular, daily disposable torics work best for:

- Individuals seeking occasional lens wear.
- Athletes who plan to wear lenses only during their events.
- Non-compliant individuals who do not properly care for the lenses nor discard them at prescribed intervals.
- Individuals with a solution or material sensitivity or toxicity.

Case Study #7: Occasional Wear

Daily disposable toric lenses are the obvious option for astigmatic individuals who plan to wear their lenses only on occasion. Although the parameter range is limited and these lenses are not currently available as silicone hydrogels, they are a noteworthy alternative for the astigmatic athlete or individual with low refractive error who wears lenses only for critical distance vision tasks, such as night-time driving *(see "How Do Daily Disposable Torics Impact Prescribing Habits?" above)*.

Remember to avoid the temptation to prescribe the spherical equivalent power in a spherical daily disposable lens. It is also important to note that daily disposable lenses, along with GPs and daily wear soft lenses, have the lowest incidence of infection.[24]

Case Study #8: Young Progressive Myope

Patient A: low cylinder (1.00D); Patient B: high cylinder (2.00D)

Several recent studies have found that the design of overnight orthokeratology lenses is responsible for slowing down myopia progression and also exhibits a significant effect on axial length growth.[25-28] This appears to be consistent with recent research that the peripheral retina plays an important role in myopia progression, and designs that do not result in peripheral retinal hyperopia appear to essentially serve as a "stop sign" for eye growth.[29]

Spectacles, soft lenses and conventional GP lenses appear to exhibit little to no effect on myopia progression.[25,26,30] In fact, some of these lens designs actually encourage myopia, particularly if they have increased minus power in the periphery of the lens.[31]

For higher astigmatic patients, the use of meridional differences in elevation (e.g., Paragon CRT Dual Axis, Paragon Vision Sciences) can result in reducing the astigmatism in the central treatment zone.[32] Alternatively, spherical GP lenses or soft toric designs can be used with these patients to increase self-esteem and quality of life, relative to only spectacle wear.[33]

CONTACT LENS CORRECTION OF ASTIGMATIC PATIENT SELECTION GUIDE	
Patient Type	**Recommended Contact Lens Option(s)**
1. Low cylinder power (0.75D – 1.00D) (e.g., spherical soft lens wearer; spectacle lens wearer motivated for soft lens wear)	1. Soft toric
2. Residual cylinder ≥ 0.75D (e.g., SRx: -3.50 –2.25 x 180; K's: 43/44 SRx: -3.50 –1.00 x 180; K's: 43/45)	1. Soft toric
3. Critical vision demands	1. GP lens design 2a. Hybrid, or 2b. Semi-scleral (if sensitive)
4. Low sphere/high cylinder power (e.g., -0.75 –2.75 x 180)	1a. Bitoric GP (if corneal cyl ≥ 2.5D) 1b. Spherical GP (if corneal cyl < 2.5D) 2. Custom SiHy soft toric if GPs not successful or desired
5. Against-the-rule cylinder (-5.00 – 1.50 x 090; 44.25/43 @ 090)	1. Soft Toric 2a. Hybrid or 2b. Semi-scleral
6. Oblique cylinder (e.g., cylinder axis: -1.25 x 060; OR axis: -1.00 x 150)	1. GP lens design 2a. Hybrid or 2b. Semi-scleral
7. Occasional wear (e.g., athlete)	1. Daily disposable soft toric
8. Young myope [e.g., 42/43 (OOK); 42/44 (dual axis OOK)]	1a. Overnight orthokeratology (OOK) 1b. OOK (dual axis) 2a. GP lens design or 2b. Soft toric

It is clear that we have many options when fitting even our astigmatic patients. Picking the right lens can help achieve the ideal patient vision and overall satisfaction. The good news is that both GP and soft lens options are readily available, are increasing in parameters and are an easy fit. RCCL

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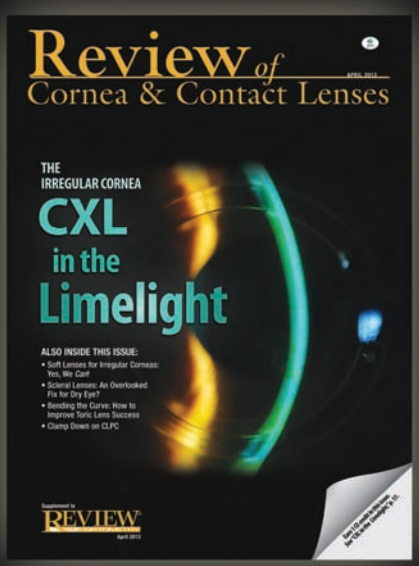

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Review of Cornea & Contact Lenses

Clamp Down on CLPC

When patients complain of recent-onset lens discomfort, lift their lids to check for this surprisingly persistent menace.

By Ernie Bowling, OD

Dr. Bowling runs a solo private optometric practice in Gadsden, Ala. He is also a diplomate in the Primary Care Section of the American Academy of Optometry.

Those of us with sufficient experience in contact lens practice recall that papillary conjunctivitis was an all-too-common side effect of lens wear in the early years of the modality. Such were the limitations of the first-generation materials, which allowed excessive protein build-up on the lenses to trigger an inflammatory response. "Planned replacement" lenses were heralded for their ability to reduce the incidence of contact lens-induced papillary conjunctivitis (CLPC)—and indeed they did. Yet it persists. Let's try to understand why, and what can be done about it.

What is CLPC?

The chronic inflammatory condition we know as giant papillary conjunctivitis (GPC) predates contact lens wear, as ocular prostheses and exposed sutures have long been known to cause the condition through mechanical irritation of the ocular surfaces.[1] Constant use of soft or gas-permeable (GP) contact lenses can increase the incidence of it, especially in individuals already experiencing other allergy episodes. For greater specificity, the term CLPC is used to describe cases in which contact lens wear is the primary culprit.

CLPC is prevalent in approximately 20% of hydrogel lens and 5% of RGP lens wearers.[2]

CLPC is not a true form of allergic conjunctivitis, but rather a non-IgE mediated inflammation of external ocular surfaces. As such, it can exist with other forms of ocular allergy.[1] There is no increase in IgE or histamine in the tears of CLPC patients.[3] CLPC symptoms can increase during allergy and dry eye season.

Case in point: A 17-year-old male presents complaining of red, itchy eyes and contact lens intolerance during the past month. He has a four-year history of successful daily wear of contact lenses. He has been using an OTC medication without relief. On exam, a papillary reaction was noted on the superior palpebral conjunctiva bilaterally (*figure 1*).

Signs and Symptoms

Patients with CLPC complain of itching, foreign body sensation, decreased contact lens wearing time, blurry vision due to lens decentration, and a white, ropy discharge. These patients may report replacing their contact lenses more frequently than they have in the past. Note: Always suspect CLPC when a patient presents complaining of recent-onset lens discomfort in a lens that has previously been worn comfortably.

Frequent use of contact lenses causes repetitive physical trauma to the upper tarsal conjunctiva, which produces a papillary hypertrophy—often seen as abnormally large "cobblestone" papillae readily apparent on lid eversion.

The appearance and location of the papillary reaction can vary depending on the type of contact lens worn.[4] In hydrogel and GP lens wearers,

the CLPC tends to be bilateral and uniform across the tarsal plate, while the papillae tend to be more asymmetric in silicone hydrogel lens wearers.

Remember, to see the papillae you have to evert the lids. Any contact lens patient who complains of discomfort or irritation with contact lens wear, or ptosis, should have their lids everted to examine for CLPC. Rigid lens-related GPC has a localized response, with raised fibrotic white apices generally found closer to the lash region.

The frequency of the patient's soft contact lens replacement schedule is a major factor in the development of CLPC. A retrospective study of 47 soft contact lens patients showed that patients replacing their lenses at four weeks or longer had a 36% incidence of CLPC, while patients replacing their lenses at less than four weeks had only a 4% to 5% incidence of CLPC. No patients wearing two-week replacement or daily disposable contact lenses developed CLPC in that study.[5]

CLPC stems from debris buildup on the lens surface, which leads to inflammation that produces even more lens deposits, thus continuing the cycle.[6] Complications of CLPC come from immune reactions to the accumulated residue deposited on the contact lens, which may contain cellular debris, contact lens solution preservative deposits and mucus.[7]

Treatment

Treatment of CLPC is two-fold. The first step is to decrease or eliminate the antigenic load and mechanical irritation from the contact lens itself. The next step is to balance the inflammatory response.

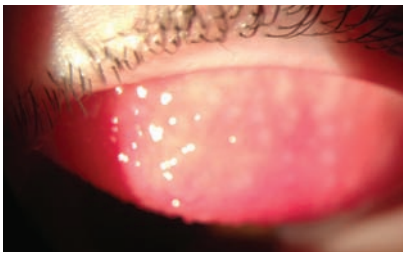
Decreasing contact lens coatings entails improving lens cleaning, decreasing wear time, shortening the lens replacement interval or changing the lens material or design.[7] Medications that can temper the inflammation include topical steroids, topical non-steroidal anti-inflammatory agents and mast-cell stabilizers.[4]

I always strongly recommend the patient temporarily discontinue contact lens wear for several weeks to decrease the antigenic load and remove the mechanical stimulus that produced the CLPC in the first place. However, convincing patients to discontinue contact lens wear, even for a relatively short period of time, can prove difficult.

If the patient has a mild to moderate case of CLPC, I prescribe a "soft" steroid—usually Lotemax (loteprednol 0.5%, Bausch + Lomb) two to four times daily, depending on the severity of the symptoms and CLPC presentation. It should be instilled 10 minutes prior to contact lens insertion and twice in the evening after contact lens removal for two weeks.[8]

I also recommend a combination antihistamine/mast cell stabilizer—usually Pataday (olopatadine 0.2%, Alcon) one drop in each eye BID. A recent Japanese study confirmed that this agent was found to be generally safe, well tolerated and effective when dispensed in this BID dosage.[9] Keep in mind that while olopatadine 0.2% drops are designed and labeled for once-daily dosing, olopatadine and other members of its class—e.g., Elestat (epinastine 0.5%, Allergan), Zaditor (ketotifen, Novartis), Alaway (ketotifen, Bausch + Lomb) and Optivar (azelastine 0.05%, Meda Pharmaceuticals)—are very safe and can be used more often if necessary.[10] The combination of olopatadine and a soft steroid was found effective in treating CLPC.[11]

Have the patient return for follow-up in two weeks to monitor papillary reaction and intraocular pressure. Depending on the presentation, I may taper the steroid to twice daily for another two weeks or discontinue use altogether.



1. Papillary reaction in CLPC.

Once the steroid is discontinued, the patient remains on the antihistamine/mast-cell stabilizer long-term. Mast cell stabilizers have been shown to be effective for CLPC, with one study reporting a 70% success rate in patients who had experienced a return of symptoms.[12]

Finally, the patient's contact lens and disinfection system should be addressed. If the patient is averse to temporarily discontinuing contact lens wear, then advise switching to a more frequent replacement schedule, daily disposable lenses being the best option. Increasing replacement frequency or transitioning to a daily disposable lens has a success rate of more than 90%, according to one study.[13] Also consider recommending a hydrogen peroxide disinfection care system, which is known to be an effective protein remover. Lastly, advise the patient to reduce their contact lens wearing time during periods of allergic activity.

Once diagnosed, patients need to be educated about the chronic nature of CLPC and its symptoms, and reminded to present for care should symptoms reappear. The case mentioned above resolved nicely by temporarily discontinuing the patient's contact lens wear and prescribing a short course of topical steroids and combination mast cell stabilizer. RCCL

References available at www.reviewofcontactlenses.com.

By Gary Gerber, OD

Will Contacts Go the Way of Kodak Film?

By taking the time to properly define your business, you can better adjust your practice to adapt to changing market trends.

There is a lot we can learn from Kodak's unfortunate demise.

For decades, the orange and yellow box was an American icon, and trust in the brand was unparalleled. Think back to the pre-digital era: Would you even think of taking your kid's kindergarten graduation photos with any brand of film but Kodak? As a photographer myself, I felt saddened when Kodak declared bankruptcy. It felt as if a small part of our national identity was lost.

In the post-Kodak world, much has already been written about why the company eventually went under. We can attribute some of the decline to today's digital revolution and the continually diminishing price of digital images. But how could a former Fortune 500 company that was savvy enough to lead the market in high-quality photographic film production and introduce various cutting-edge imaging products not have forecasted the coming digital revolution and prepared for it?

The answer is simple: Of course, they saw it coming. In fact, I'd bet that Kodak's own top executives likely had cell phones with cameras before any front-line factory workers. The photographers Kodak hired to publish the company's annual reports probably shot the images digitally.

So, why then, did Kodak close its doors?

Kodak Moments

There were two fundamental lessons that we can take away from the Kodak story.

- ***Define your business.*** Kodak failed to have a clear understanding of what its business entailed. The company believed they were in the film business. However, if they restructured their identity with a broader core mission—to capture and store memories—they might still be around today.
- ***Adjust your business model.*** Making a huge fundamental shift in your company's DNA is certainly not easy. After you define the business you are in, you have to have the courage and fortitude to make the requisite changes. In the case of Kodak, simply saying they were in the business of capturing and archiving memories wouldn't save the company unless they were able to muster the resources to actually make that change happen.

Applying These Lessons

So, what business are you in? Most of our readers would likely say they are in the business of fitting contact lenses. If that is how you responded, think ahead: When Google Glass goes beyond spectacles and launches its new contact lenses, will you still say you are in the same business? These questions aren't meant to scare you about your potential obsolescence, but rather, to emphasize that even multi-billion dollar corporations, with vast research and marketing brain-power, can be at risk of extinction if they don't take the proper steps to prevent their demise.

So, if you're not specifically in the business of fitting and prescribing contact lenses, then what exactly do you do? The answers may vary. For example, we have heard people say that they are in the business of "making people see better" or that they "allow people to experience the complete spectrum of their visual world." The truth is that there is no one-size-fits-all answer, and there doesn't have to be. Remember, just getting to that answer alone is not enough to ensure your long-term survival.

So, take this line of thought a little further. If you're in the business of making people see better, how would you prepare your practice for a future contact lens that can be worn continuously for one year and only costs the patient $1? Or, what if corneal reshaping becomes an in-office procedure and the results last three years? Use your imagination and think of any future scenario that today may be considered unlikely. Why would someone who is coming to your practice now continue to visit you one, three or 10 years from now when one of the aforementioned scenarios is available? Because you've positioned yourself *now* to be the place where "We make people see better."

Thinking about the long run, and acting on it now, will allow you to stay on the forefront of market trends and help you proactively introduce new technology into your practice. More importantly, it will add an important layer of thick insulation against changes you might not even be aware are coming. RCCL

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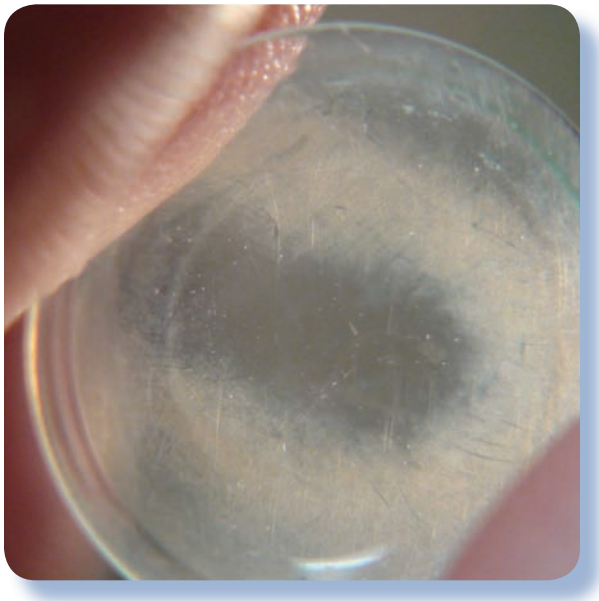
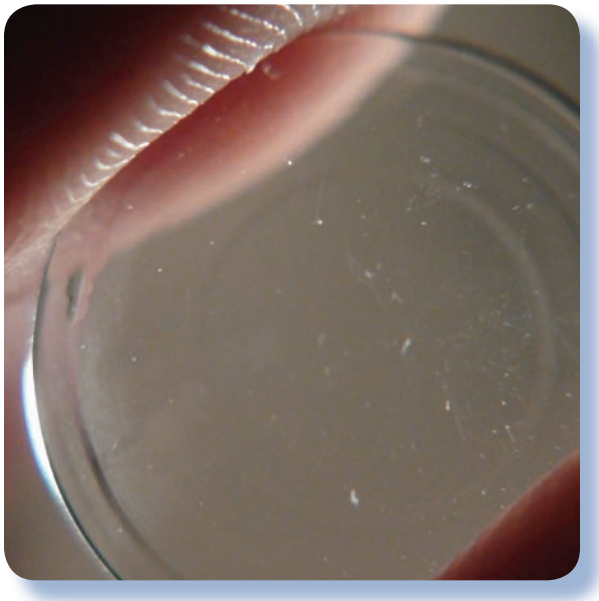


Before



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Before and after photos courtesy of Stephen P. Bynes, OD, Londonderry, NH. 16.5mm diameter FSA lens with a Dk of 141.

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