

# RCCL®

## REVIEW OF CORNEA & CONTACT LENSES

JUNE 2014

# 20

## BRIGHT IDEAS TO ILLUMINATE AND INSPIRE

These thought-provoking abstracts from ARVO will likely help define best practices in the near future.

### ALSO IN THIS ISSUE:

- Uncovering VLK
- The Case for Custom Lenses
- Altering the Landscape of Keratoconus with CXL

Supplement to

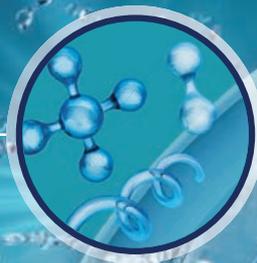
**REVIEW**  
OF OPTOMETRY



EARN 1 CE CREDIT: DECODING THE GENETICS OF CORNEAL DISEASE, BY THOMAS JOHN, MD

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Reference: 1. Wolffsohn J, Hunt O, Chowdhury A. Objective clinical performance of 'comfort-enhanced' daily disposable soft contact lenses. *Cont Lens Anterior Eye*. 2010;33(2):88-92.

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# contents

Review of Cornea & Contact Lenses | June 2014

## departments

### 4 News Review

Grafts from Older Donors More Suitable for DMEK; Is a Topical Drug for Presbyopia on the Horizon?

### 6 My Perspective

The Eluding Nature of the Eluting Lens  
By Joseph P. Shovlin, OD

### 7 Lens Care Insights

Out With the Old  
By Christine W. Sindt, OD

### 8 The GP Expert

Scleral Lenses to the Rescue!  
By Stephanie L. Woo, OD

### 30 Corneal Consult

The Missing Link?  
By James Thimons, OD

### 32 Derail Dropouts

Relieving the Fear for Those Who Can't See Near  
By Mile Brujic, OD, and Jason R. Miller, OD, MBA

### 34 Out of the Box

What's UPP, Doc?  
By Gary Gerber, OD

## features

# 10

### 20 Bright Ideas to Illuminate and Inspire

*These thought-provoking abstracts from ARVO will likely help define best practices in the near future.*

By Joseph P. Shovlin, OD

# 16

### Finding the Perfect Fit

*High-tech tools may improve contact lens manufacturing efficiency—and patient vision and comfort.*

By Jerome A. Legerton, OD, MS, MBA

# 20

### Uncovering VLK

*Don't be caught off guard by this rare complication of contact lens wear.*

By S. Barry Eiden, OD, FAAO, Jane M. Trimberger, OD, and Paul Velting, OD

# 24



### CE — Decoding the Genetics of Corneal Disease

*Using a variety of novel tests and treatments, we can better detect and correct these hereditary conditions.*

By Thomas John, MD



## IN BRIEF

• **Anterior chamber washout and amniotic membrane transplantation** combined with **topical corticosteroids** appears to be an effective treatment option for **severe peripheral ulcerative keratitis** with endothelial exudates, according to a study published in the June 2014 *Cornea*. Twelve eyes of 12 patients with severe corneal ulceration were included in the study. A surgical procedure to remove the corneal ulcer was performed on each patient. Following surgery, an amniotic membrane was placed on the corneal lesions. Each patient then received topical corticosteroid drops and systemic anti-inflammatory medication.

Patients were followed up for three to 15 months. All corneal ulcers were healed by one to two weeks following the surgical procedure and all patients achieved a stable ocular surface. Additionally, no recurrence of ulceration was exhibited during the follow-up period.

Yanni J, Hua G, Suxia L, et al. Combined anterior chamber washout, amniotic membrane transplantation and topical use of corticosteroids for severe peripheral ulcerative keratitis. *Cornea*. 2014 Jun;22(6):559-564.

• Members of the **FDA** met with experts in contact lens care to discuss updating **premarket guidelines** for daily contact lens wear and contact lens care products. Since the last premarket guidelines were established nearly 20 years ago, lens and solution materials have changed, leading to potential lens/solution incompatibilities. As a result, new silicone hydrophilic lenses will be added to the previously established testing guidelines. Additionally, the number of lens types tested has increased from four to nine, categorized by their water content and ionicity.

## Grafts from Older Donors More Suitable for DMEK

**D**onor age and endothelial cell density influence the properties of Descemet's membrane endothelial keratoplasty (DMEK) grafts, and as a result, influence the duration of the surgical procedure, according to a study published in the June 2014 *Cornea*.

Researchers correlated donor characteristics to the width of DMEK grafts and to the duration of graft unfolding and postoperative endothelial cell loss, to determine whether the surgical technique may be simplified by donor selection. Two separate studies were conducted: an experimental series investigating storage and preparation of DMEK grafts, and a clinical series examining the unfolding time of DMEK grafts.

In the experimental series, 28 DMEK grafts were prepared *in vitro* and each graft roll width was measured. The rolls were then compared to a number of donor characteristics, including donor age, total storage time, storage deswelling time, preoperative endothelial cell count, time from death to corneoscleral excision and width of DMEK graft. Each graft was prepared in a standardized way and stored at the same temperature (34°C).

Following the experimental series of 28 graft preparations, the researchers found that both donor age and endothelial cell density had a statistically significant influence on the width of the DMEK graft ( $p < 0.001$  and  $p < 0.05$ ,

respectively). Older donors and grafts with a higher endothelial cell count resulted in broader rolls formed spontaneously by Descemet's membrane when placed into a buffered saline solution.

In the clinical series, 31 DMEK surgeries were performed under general anesthesia by three corneal surgeons at Albert-Ludwigs-University of Freiburg. Researchers measured the time interval from when the graft was placed into the anterior chamber to the point when it was first attached to the posterior stroma of the host (i.e., the unfolding time). Also included in this measure is the time it takes to center the graft after it has been unfolded and before it is attached to the posterior stroma.

Donor age had a statistically significant influence on the unfolding time of the graft ( $p < 0.01$ ). Grafts from younger donors took longer to unfold in the anterior chamber than those of older individuals. Additionally, the investigators correlated the difference between pre-op and early post-op endothelial cell density (the latter measured a mean 104 days after surgery). There was a statistically significant positive correlation between the relatively early postoperative endothelial cell loss and the unfolding time.

Based on the results of this study, the researchers suggest that grafts from older donors with high endothelial cell counts are the most suitable for DMEK.

Heinzelmann S, Hüther S, Böhringer D, et al. Influence of donor characteristics on descemet membrane endothelial keratoplasty. *Cornea*. 2014 Jun;33(6):644-8.

**JOBSON PROFESSIONAL PUBLICATIONS GROUP**

11 Campus Blvd., Suite 100  
 Newtown Square, PA 19073  
 Telephone (610) 492-1000  
 Fax (610) 492-1049

Editorial inquiries (610) 492-1003  
 Advertising inquiries (610) 492-1011  
 E-mail rccl@jobson.com

**EDITORIAL STAFF**

**EDITOR-IN-CHIEF**

Jack Persico [jpersico@jobson.com](mailto:jpersico@jobson.com)

**ASSOCIATE EDITOR**

Frank Auletto [fauletto@jobson.com](mailto:fauletto@jobson.com)

**CLINICAL EDITOR**

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**CONSULTING EDITOR**

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**GRAPHIC DESIGNER**

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**AD PRODUCTION MANAGER**

Scott Tobin [stobin@jhihealth.com](mailto:stobin@jhihealth.com)

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# Is a Topical Treatment for Presbyopia on the Horizon?

Correcting presbyopia may eventually be as simple as instilling a daily eye drop, according to a presentation during the New Technologies symposium at this year's ASCRS Annual Meeting in Boston. The investigational eye drop, which is currently known as "Liquid Vision, the Reading Eye Drop," induces a miotic effect on the pupil that lasts approximately eight hours after instillation, its developers say. By constricting the pupil and creating a pinhole effect, the drops help to improve near-vision performance.

According to [eyewiretoday.com](http://eyewiretoday.com), researchers introduced a video of an optometrist who described his personal experience with the drops. The 55-year-old subject in question stated that he wore a +2.00D monovision contact lens and had difficulty reading up close without this lens.

Upon instillation of the drop, the report states, his pupil contracted from 4mm in ambient light to just 1.6mm. Thirty minutes after instilling the drop, he demonstrated the ability to read a document typed in 10-point font at a distance of 12 inches. Prior to use, he struggled to read the same document at arm's length. Additionally, he mentioned his ability to drive, read electronic medical records and see his dash-

board better when using the eye drops.

"On the positive side, clinical evidence shows an improvement of acuity with changes in pupil size as demonstrated by pinhole effects," says Joseph P. Shovlin, OD. However, he cautions that "one concern might be the limitations with a pupil that's too small for some patients," adding that clinicians will need to fully understand the intricacies of the new pharmaceutical agent, if it should come to market.

Corneal inlays that induce a pinhole effect correct near vision in a similar manner, but require an elective surgical procedure. This eye drop would likely offer a more affordable and reversible option, though one that requires patient compliance with the regimen to maintain efficacy.

While the drops are still in development, Dr. Shovlin looks forward to the potential future application of such a treatment. "It's exciting to think about an option that's reversible, doesn't permanently alter the lens or cornea through surgical means, and apparently has fewer aberration-causing distortions except for possible diffraction effects," he says. Comparisons with corrective lens options for presbyopia would also be eagerly anticipated by eye care practitioners.

**Advertiser Index**

Alcon Laboratories ..... Cover 2, Cover 4  
 CooperVision ..... Cover 3  
 Bausch + Lomb ..... Page 15, Page 23



# The Eluding Nature of the Eluting Lens

Novel drug delivery methods were on display at this year's annual ARVO meeting.

For many years, researchers have dreamed of a magical lens that can deliver drugs to the eye consistently in a sustained-release manner. For decades, manufacturers have tried to bring this dream to reality by developing ingenious ways to mitigate the many limitations in contact lens delivery systems. Are we any closer to a perfectly effective drug delivery system using a lens in tandem with enhanced technology? Or will an entirely new delivery system take over?

This year at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), a number of fascinating abstracts addressed the topic of drug delivery and novel ways to deliver drugs to the eye. The systems/devices for ocular drug delivery range from therapeutic agents formulated in nanoparticles to devices that release a drug upon irradiation with low (safe) levels of UV light to drug-eluting intraocular lenses that bypass the ocular surface entirely.

## DRUG DELIVERY SYSTEMS OF THE FUTURE?

Below are thumbnail sketches of a few of the promising studies in drug delivery from this year's ARVO:

- The UV-induced nanoparticle platform has the potential to deliver a wide range of molecules (e.g., hydrophobic drugs and proteins) for at least 12 weeks post-injection.

*Poster D0061, Shining a Light on Drug Delivery: On-Demand Light-triggered Release of Payload to the Eye, Nguyen Huu VA, Luo J, Zhu J, et al.*

- Further research in developing intraocular lenses that release

one- and two-layer films to function as intraocular delivery systems seems likely, following an initial pilot report this year. Development of films based on organic polymers and dexamethasone for direct delivery via intraocular lenses may be feasible.

*Poster D0062: First Steps Towards a Drug Eluting Intraocular Lens, Lamprogiannis L, Karamitsos A, Logothetidis S, et al.*

- Another novel device—using a conjunctival ring—designed for drug delivery to the eye was evaluated. No remarkable side effects were observed in animal experiments and delivery of antibiotics and steroids appears to be feasible even to posterior eye tissues.

*Poster D0101, Safety Evaluation of Novel Drug Delivery Device, the Conjunctival Ring, Kinoshita S, Noda K, et al.*

- Punctal plugs may be another novel way to deliver drugs to the anterior eye. Corticosteroids were released from punctal plugs on the basis of aqueous solubility in another abstract. The studies demonstrate that plugs containing a high dose of a given steroid will release the same amount per day and will release drug over a longer period of time.

*Poster D0091, In Vivo Drug Release of Low Solubility Drugs from Biodegradable Hydrogel Punctal Plugs, McGrath M, Blizzard C, Desai A, et al.*

- Because only about 15% of drug doses applied to the eye stay long enough to be effective, drug carriers for prolonged retention make sense. Adherence time was found to be greatly increased using DNA-based nanoparticles that have a high affinity for the cornea. Ideally, a lower concentration of drug may reduce side effects and improve compliance.

*Poster D0087, DNA-Based Nanoparticles as a Potential Drug Carrier for the Treatment of Anterior Segment Diseases, Schnichels S, Willem J, Strudel L, et al.*

- Increasing contact time and/or drug adherence to the surface of the eye has several benefits. Phenylboronic acid (PBA), a synthetic ligand, may be useful in enhancing muco-adhesion that improves drug delivery to the eye by enhancing site-specific targets and improving bioavailability. PBA was successfully incorporated into pHEMA, PVP and pDMA hydrogels, and demonstrated good muco-adhesion and drug release with good binding potential.

*Poster D0074, Development of Phenylboronic Acid Containing Mucoadhesive Hydrogel Materials for Ophthalmic Drug Delivery Applications, Liu L, Sheardown H.*

- Micro-engineered delivery systems have the potential to administer a precise concentration—in a sustained fashion—of a drug with a single injection to the ocular surface. This abstract highlights a system that encapsulates a drug within a polymer delivery system using a process that produces monolithic encapsulates. These drug containing microparticles may be a feasible concept for replacement of eye drops delivered multiple times each day.

*Poster D0075, Single Administration Sustained Release Formats for Administration of Ophthalmic Medications to the Ocular Surface, Cornea and Anterior Chamber, Barman S, Barman K, Ward K.*

Perhaps we have moved past the thought of delivering a consistent dose of drug(s) over time by using a contact lens. These abstracts, at the very least, will spark additional studies. And, who knows—some of these technologies may be ready for prime time in the near future. **RCCL**



# Out With the Old

The FDA has completely revised its contact lens solution testing—a dramatic step forward in ensuring patient safety.

**D**espite the continual advances in contact lens materials and cleaning solutions we have enjoyed in recent years, the Food and Drug Administration guidelines for lens/solution compatibility testing have not changed in 20 years. The current guidelines cover the following:

- (1) *lens compatibility*—does the solution alter the lens parameters?
- (2) *cleaning effectiveness*, determined through the use of Critical Micelle Concentration
- (3) *microbial testing*, with the use of predetermined microbes
- (4) *toxicology testing*, to determine cytotoxicity, systemic toxicity and ocular irritation
- (5) *clinical testing*, with a minimum of 60 subjects over one month

These seemingly well-designed guidelines failed to keep the public entirely safe. A number of factors raised questions about whether the old guidelines were still applicable for today's lenses, including the outbreaks of *Fusarium* (in 2006) and *Acanthamoeba* (in 2007).

Beginning in 2008, the FDA met with a number of leaders in the field and initiated a series of research projects to determine what flaws existed in the current system. The results were published in the November 2012 *Eye & Contact Lens*.

The FDA met on May 13, 2014 to establish new guidelines for future solution testing. So, what changes will be made?

## OVERHAULING THE PROGRAM

In this column and several to follow, we'll look at each of the five

**Table 1. Conventional Hydrophilic Material Group Description**

Hydrophilic Group	Water Specification	Ionicity*
I	Low Water Content (<50%)	Nonionic
II	High Water Content (>50%)	Nonionic
III	Low Water Content (<50%)	Ionic
IV	High Water Content (>50%)	Ionic

**Table 2. Silicone Hydrophilic Material Group Description**

Silicone Hydrophilic Group	Water Specification	Ionicity*	Surface Properties
V-A	No Water Specification	Ionic	
V-B	High Water Content (>50%)	Nonionic	
V-C	Low Water Content (<50%)	Nonionic	Hydrophilic Monomer only
V-Cm	Low Water Content (<50%)	Nonionic	Surface Treated (ST)
V-Cr	Low Water Content (<50%)	Nonionic	Non-ST, Semi-interpenetrating network

FDA testing categories and discuss what is being updated, beginning this month with lens compatibility.

Lens materials were far less complex in the past than they are today. The four testing groups (*Table 1*) were based on water content and ionicity of the lens. This grouping was devised to make solution testing more affordable; instead of testing every solution with every lens, just one lens from each group had to be tested with the proposed solution. However, new silicone materials have varying surface properties and different patterns of uptake and release of chemicals than hydrogel lenses.

As such, a new series of testing groups was devised to address silicone hydrogels. The new standards will account for the variation in silicone hydrogel lens properties and will add five new categories to the existing material group descriptions (*Table 2*). Dimensional stability and tolerance of silicone hydrogel lenses

will be added to the testing.

The adsorption and release of preservative is another problem addressed by the new guidelines, as it has demonstrated toxicity to the epithelium. In addition, by removing available biocide from the solution, microbes have been allowed to grow in the depleted solution. The new guidelines will ensure representative lenses do not decrease the concentration of preservatives below a specified range.

There will be further discussion about testing under noncompliant situations and ways to include information about lens/solution incompatibility on the product label.

The new FDA solution testing guidelines are a giant step forward in ensuring the safety of our patients. Stay tuned for further discussion on solution testing and any changes you and your patients will see in the future. **RCCL**

# Scleral Lenses to the Rescue!

This modality can be used to treat a number of corneal conditions—including many you might not expect.

**D**o you have a patient whose superficial punctate keratitis (SPK) persists no matter how many eye drops and gels they use? How about a patient with dry eye symptoms who gets no relief from lid hygiene, artificial tears, Restasis—i.e., the works? Have you seen someone present with a recurrent corneal erosion that just won't go away?

I'm sure the answer to each of those questions is yes. But I'll bet you never imagined GP contacts could help with these conditions.

Traditionally, scleral contact lenses are reserved for irregular corneas; however, many doctors began taking advantage of the superior tear chamber clearance offered by the modality to help manage certain corneal problems (Figure 1). In fact, a number of conditions—depending on the cause—can be treated with a scleral contact lens:

- Acute or chronic SPK
- Filamentary keratitis

- Recurrent corneal erosion
- Large corneal abrasion
- Many forms of dry eye (e.g., evaporative, Sjögren's, post-surgical), especially in patients unresponsive to palliative therapy.

- Incomplete blinkers
- Bell's palsy
- Graft-vs.-host disease

## NOT JUST FOR IRREGULAR CORNEAS

Many of the patients who present with the aforementioned conditions are at the end of their rope. They are often extremely uncomfortable and experience poor quality of life. Despite our best efforts to treat our patients with severe dry eye, every practitioner sees a few of these patients who just never seem to find long-lasting relief from their symptoms. A study published in the December 2007 *Cornea* involving 33 chronic graft-vs.-host disease patients with severe dry eye found that the Boston prosthesis (a type of scleral contact lens) resulted in the highest possible improve-

ment in pain symptoms (52% of patients), photophobia (63%) and quality of life (73%).<sup>1</sup> Scleral lenses had a tremendous impact on these patients!

So, how exactly can scleral lenses help these patients? The bowl of the scleral lens is usually filled with non-preserved saline and then placed on the eye with the patient's chin tucked into their chest and facing the floor (Figure 2). Upon successful insertion, a layer of liquid rests between the anterior portion of the cornea and the posterior surface of the contact lens. This keeps the cornea moisturized by bathing it all day.

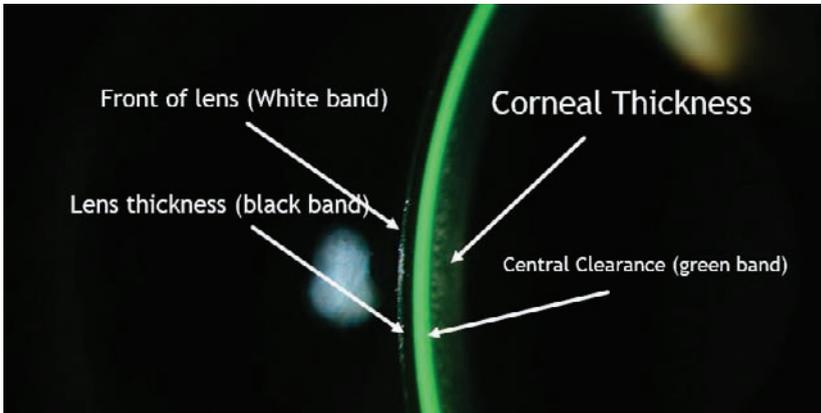
The scleral lens also prevents the eyelids from making contact with the cornea, which prevents disruption of the corneal epithelium. Because the scleral lens covers the entire corneal surface, even if the tear layer evaporates off the contact lens surface (e.g., as in evaporative dry eye patients, incomplete blinkers, etc.), the cornea remains unaffected.

**Table 1. Predicted Central Oxygen Transmissibility\* in Scleral Lenses With a Dk of 150**

		Clearance (µm)						
		100	150	200	250	300	350	400
Lens thickness (in µm)	250	34.3	28.2	24.0	20.9	18.6	16.6	15.0
	300	30.8	25.8	22.2	19.5	17.4	15.7	14.3
	350	27.9	23.7	20.7	18.3	16.4	14.9	13.6
	400	25.5	22.0	19.3	17.2	15.6	14.2	13.1
	450	23.5	20.5	18.2	16.2	14.8	13.5	12.5
	500	21.8	19.2	17.1	15.5	14.1	12.0	12.0

\* Expressed in Fatt Dk/t units

■ : Satisfies HM criteria  
 ■ : Satisfies both HM and HB criteria



**Fig. 1. The superior tear chamber clearance offered by scleral lenses allows practitioners to prescribe the modality to treat a number of corneal conditions.**

### EXTENDED SCLERAL LENS WEAR

The key to delivering the highest amount of oxygen to the cornea is a high oxygen permeable material combined with a small amount of central clearance (*Table 1*).<sup>2</sup> Research shows that the cornea does not receive much



**Fig. 2. The proper scleral lens insertion technique.**

oxygen during scleral lens wear, and the modality is best suited to a daily-wear schedule—not worn on an extended basis.<sup>2</sup> Patients with extreme dry eye or severe epithelial defects are the exception to this rule, however.<sup>1,3-4</sup>

One noteworthy study evaluat-

ing scleral lens extended wear in patients with persistent epithelial defects such as Stevens-Johnson syndrome found it effective in promoting the healing of persistent corneal epithelial defects in some eyes that failed to heal following other therapeutic measures.<sup>3,4</sup> The healing response was attributed to a combination of oxygenation, moisture and protection of the corneal epithelium. Despite the positive healing effects, however, there was a significant risk of microbial keratitis; it was observed in 30% of the eyes wearing extended wear scleral lenses.

Although extended wear of scleral lenses is not the typical wearing schedule, in some cases it is necessary. Patients requiring extended wear should be monitored very closely, and prophylactic antibiotic drops may be considered.

Scleral lenses offer hope to patients with extreme dry eye symptoms who have seemingly

### Clinical Pearl

Having your patients fill their scleral contact lenses with a “cocktail” of half non-preserved saline and half Celluvisc (a non-preserved, but more viscous, artificial tear) can also be a great option for those patients who are in need of even more lubrication.

reached a dead end with other treatment options. Several case reports and some solid evidence demonstrate that corneas can be healed and treated with scleral lenses. Personally, I have successfully used scleral lenses to treat several patients who had corneal damage. Many of these patients were referred to me because their doctor had explored every other treatment option, yet the patient was still in pain and the cornea was left unhealed.

Scleral contacts can truly change someone’s life. Hopefully, in the future, they may be considered as one of our first treatment options to prevent needless suffering and wasteful trial-and-error attempts that ultimately lead to the same solution. **RCCL**

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# 20 BRIGHT IDEAS

In a profession so deluged with data, another torrent is hardly welcome—and yet absolutely essential. The protocols and practices of eye care are continually remade by new ideas; without them, stagnation and decline are inevitable.

A very talented group of researchers, including the world's best vision scientists and clinicians, assembled in Orlando last month to present their most recent findings on a multitude of topics at the annual ARVO conference. While no single report can encapsulate the thousands of papers presented, here we present 20 intriguing findings involving corneal infections and lid pathology that have especially keen clinical relevance. The selected abstracts will hopefully help clinicians in general practice, and in particular contact lens practice, better serve our patients.

## 1. Keratitis and *Pseudomonas aeruginosa* positivity increase in the summer.

Researchers from SUNY Ophthalmology in Brooklyn analyzed seasonal variations in the incidence of infectious keratitis, as well as seasonal changes in its etiologies, risk factors and clinical outcomes. There is a higher frequency of infectious keratitis and *P. aeruginosa* positivity during the summer months. Possible contributing factors include warmer temperatures and higher humidity levels.

There should be a heightened awareness to the possibility of

corneal infection during warmer seasons—especially in any contact lens wearers.

*Program #1507. Seasonal variation as a risk factor for infectious keratitis. ARVO 2014.*

## 2. There is a potential link between corneal innervation and endothelial cell homeostasis.

Boston-based researchers from Harvard's Massachusetts Eye and Ear Infirmary and the Schepens Eye Research Institute used *in vivo* confocal microscopy (IVCM) to analyze bilateral corneal endothelial cell density as correlated to sub-basal nerve changes in patients with unilateral stromal scarring due to HSV keratitis. Patients with unilateral HSV keratitis exhibit a significant decrease in corneal endothelial cell density in both the affected eye and the unaffected eye.

Corneal endothelial cell density is correlated with a decrease in corneal sub-basal nerves. As such, the researchers hypothesize a link between corneal innervation and endothelial cell homeostasis.

*Program #1471. In vivo confocal microscopy demonstrates bilateral loss of corneal endothelial cells in unilateral herpes simplex. ARVO 2014.*

## 3. AST can regenerate sub-basal nerves.

Another Mass Eye and Ear study evaluated the use of 20% autologous serum tears (AST) in patients with chronic debilitating corneal pain unresponsive to conventional therapy. Using IVCM, underlying alterations of the sub-basal nerve plexus was identified in patients suffering from debilitating corneal neuralgia. AST—rich in neurotrophic factors—lead to corneal

sub-basal nerve regeneration and significant improvement in corneal pain in patients with corneal neuropathy. Nerve beading and presence of neuromas decreased significantly from 37.5% and 75% of all points to 6.25% and 68.75%, respectively.

*Program #1468. Efficacy of autologous serum tears for treatment of severe corneal pain in patients with corneal neuropathy: an in vivo confocal microscopy study. ARVO 2014.*

## 4. Bacteria found in contact lens cases could potentially adhere to lenses in the presence of tears.

The degree of contact lens case contamination during use depends on the type of multipurpose disinfecting solution (MPDS) used; certain solutions are associated with high levels of gram-negatives in cases.

Researchers at the School of Optometry and Vision Science at the University of New South Wales, Australia compared adhesion of microbes isolated from these MPDS/lens cases with and without organic soil.

Results indicated that bacteria found in contact lens cases could adhere to contact lenses in relatively high numbers in the presence of organic soil. This might indicate that a similar phenomenon can

### ABOUT THE AUTHOR

Dr. Shovlin is a board certified optometrist and a Fellow of the American Academy of Optometry. He practices at Northeastern Eye Institute in the Clarks Summit and Scranton offices. He is the Clinical Editor of Review of Cornea & Contact Lenses and Associate Clinical Editor of Review of Optometry.



# to illuminate and Inspire

These thought-provoking abstracts from ARVO will likely help define best practices in the near future.

By Joseph P. Shovlin, OD

occur in the presence of tears. This might encourage bacterial transfer from the lens to the cornea and the production of corneal infiltrates.

These particular “bugs” (i.e., *Stenotrophomonas maltophilia*, *Delftia acidovorans* and *Achromobacter xylosoxidans*) have been found in abundance in cases of patients who experience diffuse infiltrative responses while wearing contacts.

Program #4646. Adhesion of *stenotrophomonas maltophilia*, *delftia acidovorans* and *achromobacter xylosoxidans* to contact lenses in the presence of organic soil. ARVO 2014.

## 5. Peptide melamine-coated contact lenses exhibit high antimicrobial properties.

Investigators at the School of Optometry and Vision Science at the University of New South Wales studied the performance of melamine-coated contact lenses in a human clinical trial. Antimicrobial peptide melamine, applied by covalent bonding onto contact lenses, can produce a broad-spectrum antimicrobial lens.

This study is the first to provide evidence that humans can wear antimicrobial peptide-coated lenses safely. The melamine-coated lens wear was uneventful, with the exception of its association with higher corneal staining in extent and depth. Following wear, the lenses retained their high antimicrobial activity.

Program #4647. Biocompatibility and retention of activity of melamine antimicrobial contact lenses in a human clinical trial. ARVO 2014.

## 6. Subtherapeutic dosing of prophylactic antibiotics may increase the likelihood of antibiotic resistance.

Researchers at UPMC, Pittsburgh studied the surveillance cultures of bandage contact lenses (BCL) in patients with a clinical history of requiring a BCL. In analyzing surveillance cultures of BCLs, 84% were culture positive; of these, 24% grew organisms that were resistant to antibiotic treatment.

In 89% of patients, cultures were used to support therapy changes, suggesting that BCL cultures provide useful information for effective prophylaxis—and for guiding treatment if infectious complications arise. Dosing with subtherapeutic prophylactic antibiotic does not seem to lead to increased risk of infection of culture-resistant organisms. However, subtherapeutic dosing may increase the likelihood for an organism becoming resistant to an antibiotic. For this reason it is not recommended that patients with chronic ocular disease use sublethal dosing of prophylactic antibiotics—especially in a population with chronic ocular disease.

Program #4661. Contact lens surveillance cultures in patients wearing bandage contact lenses. ARVO 2014.

## 7. IL-17A response after infection with *Acanthamoeba* plays an important role in protecting the host from invading parasites.

In *Acanthamoeba* keratitis, the relative contribution of a proinflammatory cytokine, IL-17A—which promotes migration, activation and function of neutrophils in the cornea—is poorly defined. The role of adaptive immune response, particularly the contribution of CD4+ T cell subsets such as Th17 and Tregs in AK is yet to be understood.

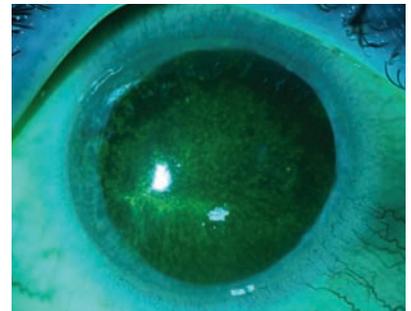


Photo: Christine Sindi, OD

## A better understanding of pro-inflammatory cytokine activity in *Acanthamoeba* keratitis might lead to improved care protocols.

*Acanthamoeba* corneal infection induces both T effector and Treg response, which responds to microbial antigens in the cornea. In contrast to other corneal infections, such as herpes and *P. aeruginosa* keratitis, where IL-17A exacerbates corneal pathology and inflammation, this study's findings indicate the IL-17A response after infection with *Acanthamoeba* plays an important role in protecting the host from invading parasites.

Perhaps this strategy of antisense therapy will aid in developing more effective treatment options for this dreaded disease process in contact lens wearers.

Program #1689. IL-17A-mediated protection against *acanthamoeba* keratitis. ARVO 2014.

## 8. Reservoirs for *Acanthamoeba* hosts may be more common than we previously thought.

Researchers at Bascom Palmer Eye Institute in Miami investigated the ecological diversity of *Acanthamoeba* host and associated microbial communities. The team compared clinical isolates from the corneas and contact lenses of patients with

## 20 BRIGHT IDEAS TO ILLUMINATE AND INSPIRE

*Acanthamoeba* to associated communities from seven environmental hosts: shower heads, marine waters, swimming pools, ice machines, drinking fountains and eyewash stations.

*Acanthamoeba* was recovered from all environmental sources and ranged from 11% (pools) to 40% (drinking fountains). Eyewash stations (15.9%) and showerheads (17%) were more frequently associated with *Pseudomonas* and *Mycobacterium* species. Reservoirs and transmission niches for *Acanthamoeba* hosts and associated microbial communities may be more common than previously recognized. Additionally, human colonization and pets may be unrecognized sources.

Program #6260. Ecological diversity of *acanthamoeba* and associated microbial communities. ARVO 2014.

### 9. Several bacterial isolates are demonstrating increased anti-bacterial resistance rates.

The ARMOR (Antibiotic Resistance Monitoring in Ocular Microorganisms) surveillance study was initiated in 2009, monitoring resistance trends of bacterial pathogens of ocular significance. A report of the study results to date for 2013, compared to results from 2012, was presented at this year's ARVO meeting.

Ciprofloxacin and imipenem non-susceptibility rates for *P. aeruginosa* more than doubled to 14% and 21%, respectively. No resistance was found in *H. influenzae* isolates. The rate of 6% for non-susceptibility to penicillin remained steady among *S. pneumoniae*. Azithromycin and imipenem non-susceptibility rates decreased to 29% and 6%, respectively. Slight increases over the previous year were found in isolates of *S. aureus* and coagulase-negative staphylococci

isolates (CoNS) to oxacillin/methicillin (43-59%), ciprofloxacin (33-43%), clindamycin (21%) and azithromycin (60-63%). Multi-drug resistance stayed prevalent in *S. aureus* and CoNS (38-39%) from 2013, especially among methicillin-resistant staphylococci (60-81%).

The 2014 ARMOR surveillance data show increased levels of resistance among previously problematic staphylococci and *P. aeruginosa* isolates. These results point to judicious use of antibiotics in the treatment of ocular infections, and the need for ongoing studies and surveillance of ocular pathogens.

Program #6281. Antibiotic resistance profile of ocular pathogens — an update from the 2013 us armor surveillance study. ARVO 2014.

### 10. The antimicrobial activity of tear fluid under a hydrogel contact lens degrades over time.

Contact lens-related corneal infection is common with soft contact lenses, and the risk increases with use of extended wear modalities. This could be due to the lack of tear exchange under soft lenses—tear fluid contains antimicrobial factors. Researchers from UC Berkeley tested the hypothesis that tear fluid between the corneal surface and the contact lens during wear loses the ability to suppress growth of *P. aeruginosa* over time.

Results of this study show that tear fluid under a hydrogel lens can lose antimicrobial activity with time; packaging solutions can counteract this. It is not clear whether antimicrobial activity is reduced because critical tear components are degraded, excluded or reduced in production. Further study is needed to determine if the effect of packaging solution occurs directly to bacteria or whether it acts indirectly

by impacting tear fluid chemistry and physiochemistry.

Program #859. Impact of contact lens wear on post-lens tear fluid antimicrobial activity. ARVO 2014.

### 11. There may be an indirect link between *Demodex folliculorum* and chalazia.

Researchers at NYIT College of Osteopathic Medicine, New York Eye and Ear Infirmary and Hofstra Jewish School of Medicine examined the association of *Demodex folliculorum* and *Demodex brevis* with chalazia and sought to identify associated histopathologic changes. There was a significantly greater mean number of *Demodex folliculorum* in biopsies with chalazia when compared to biopsies without chalazia, but causality cannot be established between *Demodex* and chalazia. Their findings suggest that *Demodex folliculorum* may be indirectly involved in the pathogenesis of chalazia via its effect on the anterior eyelid margin.

Program #6250. *Demodex* and its association with chalazia: a histopathic study. ARVO 2014.



Collarettes around the lashes, a predictable sign of *Demodex*.

### 12. *Demodex* mites may be associated with dry eye symptoms.

In a study conducted by researchers in private practice in Minnesota and California, patients were examined and asked to fill out four questionnaires: Ocular Surface Disease Index (OSDI), the

Photo: Christine Sindt, OD

Subjective Evaluation of Symptom of Dryness (SESoD), the Subjective Evaluation of Frequency of Itch (SEFoI) and the Total Ocular Surface Score (TOSS). The patients were then examined for the presence of *Demodex* mites. If any were present, the patient was included in the study.

Average number of mites per patient was 7.93, and 36.1% scored 13 or greater on OSDI and were classified as symptomatic for dry eye. In the SESoD section, 23.6% scored higher than one, indicating clinically significant dryness. In the SEFoI section, 20.8% scored higher than one, which signifies clinically significant itching. Finally, in the TOSS score, 27.7% scored higher than 13, a mark that indicates clinically significant itching.

In all three subsections, the majority of patients presented without symptoms or with minimal symptoms associated with dry eye or allergy. This may help to explain why this condition is often overlooked for treatment.

*Program #1996. Symptoms associated with the presence of demodex folliculorum. ARVO 2014.*

### **13.** *Oral azithromycin seems to be an excellent alternative to oral doxycycline in patients with meibomian gland dysfunction.*

Investigators at the Nouvel Hospital Civil De Strasbourg in France studied the clinical efficacy and safety of oral azithromycin vs. oral doxycycline in subjects being treated for MGD. They were also able to evaluate rosacea prevalence in the trial population. Patients with moderate to severe MGD received either oral azithromycin 500mg three times a week tapered for three months or oral doxycycline 100mg daily for three months. Palpebral and dermatologic signs of rosacea were

primary outcomes. Secondary measures were quality of life, tear film break-up time, corneal staining, tolerance and compliance.

There was a statistically significant non-inferiority for all endpoints for azithromycin compared to doxycycline. Only a 5% occurrence of side effects was observed for both groups.

*Program #1481. Oral azithromycin versus doxycycline for the treatment of moderate to severe meibomian gland dysfunction (MGD): a randomized prospective non-inferiority study. ARVO 2014.*

### **14.** *Tearing may help differentiate dry eye from conjunctivochalasis.*

Conjunctivochalasis (CCh) causes precorneal tear film instability, increases the mechanical friction during blinking and decreases tear flow in the lower meniscus. Subjective symptoms of CCh vary greatly. Researchers at the Kyoto Prefectural University of Medicine in Kyoto, Japan evaluated the differences in subjective symptoms between CCh and dry eye.

The study involved 87 eyes of 87 dry eye patients. The subjective symptoms—dry eye sensation, difficulty in opening the eye, foreign body sensation, pain, redness, tearing, discharge, itchiness, blurred vision, sensitivity to light, heavy eyelids and eye fatigue—were evaluated by use of the visual analogue scale (VAS). Findings of this study show that CCh exhibits subjective symptoms similar to dry eye.

The symptom of tearing may help differentiate the diagnosis of dry eye from that of CCh; tearing is stronger in CCh secondary to decreased tear flow at the lower tear meniscus due the redundancy of the conjunctiva.

*Program #1991. Comparison of subjective symptoms between conjunctivochalasis and dry eye patients. ARVO 2014.*

### **15.** *Intense pulsed light therapy (IPL) for ocular rosacea can improve dry eye symptoms.*

Researchers at the Mayo Clinic in Scottsdale and Arizona College of Medicine in Phoenix conducted a retrospective study to describe the early treatment outcomes for meibomian gland dysfunction and ocular rosacea in dry eye patients with IPL therapy. Medical records of 19 dry eye patients treated monthly with IPL and MG expression were retrospectively examined for outcomes. Demographics, ocular histories, SPEED2 scores, slit-lamp exam and meibomian gland evaluation were reviewed at baseline and after IPL treatment.

The average number of IPL treatments was three. Out of the 19 patients, seven were good responders ( $\geq 40\%$  decrease in SPEED2), six were mild responders (1% to 39% decrease in SPEED2), five were non-responders or adverse responders (i.e., no change or decrease in SPEED2) and one was intolerant of pain of gland expression. A number of patients noticed transient symptom improvement after the first treatment, including 85.7% of good responders, 66.7% of mild responders and 40% of adverse or non-responders. Additionally, 65.8% of eyes demonstrated improved MGE scores. There were no pathologic changes on slit lamp after therapy.

In this study, 68% of patients had a positive response to IPL. Anecdotal improvement in symptoms after one treatment can be a prognostic indicator of a patient's responsiveness to IPL. Further work is needed, as this is a small sample and a retrospective study.

*Program #2018. Early treatment outcomes in dry eye patients treated with intense pulsed light therapy. ARVO 2014.*

### **16.** *Androgen treatments significantly influence gene expression in human meibomian gland (HMG) cells and conjunctival epithelial cells.*

## 20 BRIGHT IDEAS TO ILLUMINATE AND INSPIRE

Androgen insufficiency is considered a significant risk factor for development of MGD. To better understand why this is so, researchers at Australia's University of New South Wales and the Houston College of Optometry sought to determine the effect of two androgens—testosterone and dehydroepiandrosterone—on HMG cell proliferation and lipid production.

Androgens increased cell proliferation and lipid production for up to 24 hours in HMG cells, but the long-term effect of androgen on cell proliferation and lipid production needs further study. The findings of this study may be useful in the development of androgen based topical therapy for MGD treatment.

*Program #18 Poster Board #A0006. The effect of androgens on human meibomian gland epithelial cells. ARVO 2014.*

### **17.** *Microorganisms in cataract patients with MGD may contaminate the incision.*

In a study conducted at the Beijing University Third Hospital, the influence of meibomian gland excreta on cataract surgery was evaluated. Sixty cataract patients with dry eye were treated with meibomian gland massage and the secretions were collected for bacterial culture, fungal culture and antibiotic drug sensitivity test. Among the 60 eyes for bacterial culture were 48 positive results, in which 46 were gram-positive and two were gram-negative. There was a 3% positive result for fungal culture.

The conclusions drawn from this study suggest there is microorganism growth in meibomian glands of some cataract patients who have MGD, which has a chance to contaminate the surgical incision. Researchers consider the intraocular surgery incision as a type-11 incision. The orifice of the meibo-

mian gland should be completely wrapped to better prevent intra- or postoperative infection.

*Program #48 Poster Board #A0036. Detection of microorganisms in meibomian glands of cataract surgical patients. ARVO 2014.*

### **18.** *Obstructive sleep apnea-hypopnea syndrome (OSAHS) is associated with a number of conditions.*

Floppy eyelid syndrome (FES) is a subset of lax eyelid conditions characterized by an extreme laxity of the upper eyelids. This causes eversion upon minimal mechanical manipulation. FES is known to be associated with ocular and systemic disease, including OSAHS. Researchers at Loyola University of Chicago conducted a study to determine the association of OSAHS with various ocular and systemic diseases.

A data mining study for ocular and systemic disease was performed using the electronic database of 562,585 patients. The study demonstrates a positive association between OSAHS and several ocular diseases: FES, dry eye, rosacea conjunctivitis and keratoconus. Systemic associations include obesity, hypertension, rosacea and diabetes mellitus type 1 and 2. The association between FES and ASOHS is significant, but the researcher's data suggests it is underdiagnosed at this medical center compared to control values in the literature.

*Program #1465 Poster Board #C0104. The association of systemic and ocular disease and the underdiagnosis of floppy eyelid syndrome in patients with OSA. ARVO 2014*

### **19.** *Glaucoma drugs have a negative effect on both meibomian gland morphology and function.*

Researchers from Pamplona, Spain sought to determine the impact of topical glaucoma meds on the meibomian glands. This was a cross-sectional, observational study of 45 patients treated with glaucoma

drops and 20 without any topical therapy. Those treated underwent therapy for more than one year. Researchers quantified the number of treatments used, eye drops instilled per day and medications that contained benzalkonium chloride.

The following tests were performed: Schirmer test, tear break-up time test, slit-lamp biomicroscopy analysis of the ocular surface and non-contact meibography of the upper eyelid. The results suggest that topical glaucoma treatments affect the meibomian gland morphology (specifically, tortuosity and length) and function. They also decrease the total area of meibomian glands in the upper eyelid.

*Program #1487 Poster Board #C0126. Evaluation of meibomian gland morphology and function in patients treated with anti-glaucomatous eye drops. ARVO 2014.*

### **20.** *Contact lens wear is associated with long-term negative changes to both the tear film and meibomian gland function.*

In another study out of the University of New South Wales, researchers investigated the characteristics of the meibomian glands (MG) and tear film in current and former contact lens wearers compared to non-wearers.

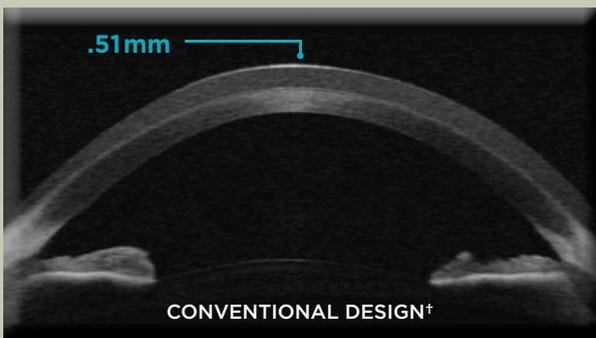
This was an ongoing, cross-sectional study with 74 participants. Procedures were conducted to investigate symptoms of dry eye, function of MGs and tear film, lipid layer thickness, phenol red thread, tear meniscus cross-sectional area, tear osmolarity, tear evaporation rate and lid wiper staining, and morphology of MGs.

The study showed that contact lens wear is associated with negative changes to the tear film (e.g., osmolarity and tear break-up time), as well as MG function and morphology. Even after discontinuing lens wear for six months, the changes appear to persist for some. **RCCL**

# Two approaches to treating irregular corneas with custom soft lenses.

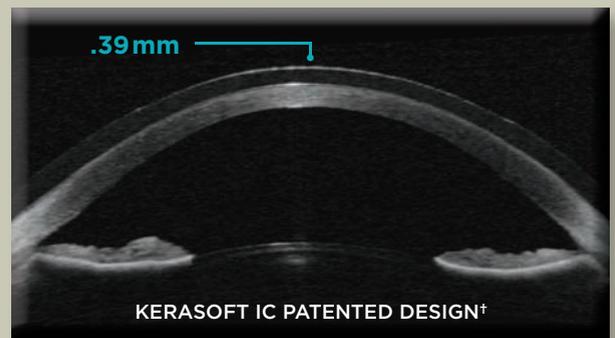
## In its time

Thickness of material



## In its prime

Anterior aspheric optics



†Images represent horizontal scan of -3.00D lenses. KeraSoft® IC uses prism ballasting.

## KeraSoft® IC. The prime time approach.

When treating irregular corneas with a soft lens, there was a time when “thickness of material” was thought to be the best approach. Today, there is KeraSoft® IC. Its patented design “drapes” over the cornea to correct the vision rather than simply “mask” the irregularity. This enables KeraSoft® IC to have a thinner optical center than in traditional designs, while still providing excellent visual acuity – a significant factor to consider when choosing a lens that meets your patient’s needs. And for comfort, KeraSoft® IC is made of a quarterly replacement silicone hydrogel\*.

\*Definitive Material.

When fitting the KeraSoft® IC soft contact lens, the MoRoCo VA App can help. Visit [kerasoftic.com](http://kerasoftic.com) for details.

**KERASOFT® IC**  
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Don't mask the problem.

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# FINDING THE PERFECT FIT

High-tech tools may improve contact lens manufacturing efficiency—and patient vision and comfort.

By Jerome A. Legerton, OD, MS, MBA

**F**ifty years ago, nearly all contact lenses were made to order. Today, however, it is estimated that less than 10% of contact lenses are. The balance are mass produced, low-cost, cast-molded soft lenses. In a 2002 study, Andre et al. demonstrated the value of customized lenses through the distribution of the sagittal depth in a population of human eyes, owing to variations in corneal curvature and corneal diameter. They forecast that as many as 50% of patients would benefit from customized diameters alone.<sup>1</sup>

At the same time, the industry is experiencing less than 2% annual net growth. Even though more than four million new patients are dispensed their first contact lenses each year, we seem to be taking one step back for each step forward, as a nearly equal number of existing wearers discontinue.

## Do Poor Fits Lead to Dropouts?

One must wonder if there is some correlation between the low made-to-order market share and the high dropout rate.

Making millions of one product design is a manufacturer's dream; making one of a million is their nightmare. Most would agree that the major cast-molded soft lens manufacturers have executed with

excellence in their material and surface modification science, low stock-keeping unit design strategies and low-cost manufacturing. They have also made it incredibly easy for eye care practitioners to prescribe their lenses. The manufacturers provide in-office inventories that enable same-day dispensing, and they use direct-to-consumer advertising to raise awareness of contact lenses generally and their brands in particular. Despite these excellent marketing and manufacturing techniques, the industry's lackluster growth leaves much to be desired.

Add to this phenomenological overview the reality that third-party reimbursement entities structure fees for contact lens evaluations and lenses by category and pricing. It appears that these entities treat all lenses the same—as though they are all low-cost, cast-molded lenses. Additionally, they treat customized soft lenses as though they carry the same chair time and lens cost basis as low-cost, cast-molded lenses to both the practitioner and patient alike.

Patient fees for customized lenses are greater than those for production lenses purchased through fulfillment businesses. The fees from practitioners for customized lenses are also significantly greater than what is paid to them by third-party plans.

These disparities create issues for patients and practitioners.

Lack of patient knowledge about customized lens alternatives requires eye care practitioners to spend extra time in consultation and patient education. For the busy practitioner, this can be painful chair time. The innocent naïveté of consumers constrains our opportunity to better serve them with customized soft lenses. These market forces discourage practitioners from providing their patients with the best possible solution when patients could benefit from customized lenses.

Practice patterns must respect market forces. As a result, the customized lens opportunity must be orchestrated through efforts to drive unnecessary cost out of the delivery. The three tenets of supply chain management for customized lenses are:

## ABOUT THE AUTHOR

Dr. Legerton is an author, lecturer, inventor and consultant to the ophthalmic industry. He is a cofounder of SynergEyes, Innovega, and Vico and has 40 issued U.S. patents for contact lens technology, including SynergEyes, Paragon CRT, NormalEyes minisclerals, myopia progression control, presbyopic laser refractive surgery, and novel multifocal and aberration-correcting contact lenses.



Dr. Legerton has direct financial interest in Vico and is a consultant to Paragon Vision Sciences.

- (1) greater efficiency in manufacturing
- (2) technology-driven prescribing
- (3) delegation of information gathering and task completion to ancillary personnel

A number of factors are allowing customized lens manufacturers to produce quarterly replacement lenses, and in some cases, monthly replacement lenses on a competitive basis: numerically controlled lathes, auto-loading robotics, and low-cost latheable conventional hydrogel, silicone hydrogel and base curve molded buttons. It is hoped and forecast that manufacturers will continue to drive down the costs. Economies of scale may also result in lower cost of lenses, as the segment of customized soft lenses expands to its potential to serve the percentage of wearers who are expected to need them.

### Moving from Art to Science

One attribute of our rapidly transforming profession is the addition of imaging, sensing and automated measuring devices. Many practitioners have enjoyed the adoption of corneal topography to assist their rigid lens parameter selection. Topography software for contact lenses—which is compatible with many brands of topographers—has been distributed for customized lenses. For example, the Paragon CRT soft-

ware suggests the starting lens for corneal refractive therapy and has demonstrated final lens accuracy of about 80%.<sup>2</sup>

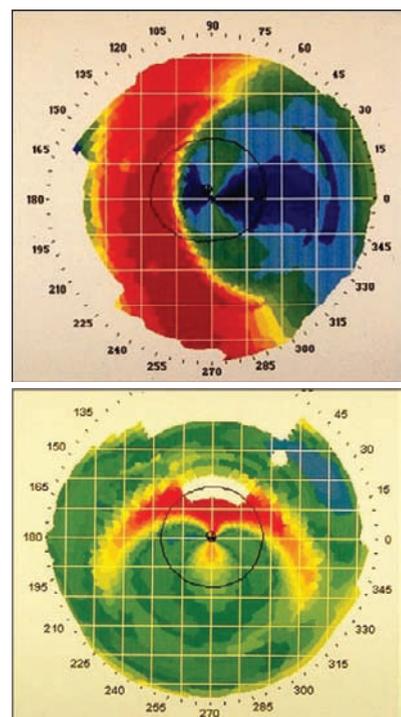
Following lens fitting, videokeratographic images are useful in identifying a well or poorly fit lens (*Figure 1*).

Customized soft lens fitting can also be enhanced by technology. The advent of anterior segment OCT software, and now what is referred to as “fringe topography,” where a fringe pattern is projected onto the ocular surface after instillation of sodium fluorescein. This technology is used with the Eye Surface Profiler (Eaglet Eye), or ESP for short, which provides a means of understanding full ocular contour out to a chord diameter of 20mm. These data provide a means of correlating soft lens design with known ocular contour.

For instance, using a fringe topographer to gather a normal distribution of contours circumferentially in a population of normal eyes, *Figure 2* demonstrates six standard deviations of the measures of the horizontal meridian of all right eyes. These data illustrate the significant difference in the sagittal depth of eyes at the chord where soft lenses make scleral contact.

An initial reaction to these data is one of amazement that a production lens of one diameter and one base curve could fit the majority of the normal population. Is

it possible that the production lenses are not the best option in a significant percentage of cases? In fact, Alonso-Caneiro et al. discovered corneal morphology changes after wearing soft lenses daily.<sup>3</sup> This finding may support the notion of improper lens fitting and may reveal the role of fit as a possible ingredient in end-of-day discomfort or low-grade inflammatory response.



**Fig. 1. Two topographic images showing post treatment corneas with overnight reshaping lenses which were not centered.**

Kollbaum et al. reported the optical power differences of soft lenses when on the eye and when off the eye.<sup>4</sup> Their conclusions support the existence of soft lens deformation on-eye. This stands to reason, as the mean flat keratometry value of human eyes is about 7.8mm while the mean soft lens base curve is about 8.3mm. Additionally, the power of soft lenses is not adjusted for a tear lens power. In other words, the

Table 1. Clinical Metrics for Empirical Ordering of Custom Soft Lenses	
Clinical Metric	Lens Parameter
Manifest Refraction	Power
Keratometry	Base Curve Radius
Corneal Diameter	Overall Lens Diameter
Sag of Eye at Key Chord for Design	Landing Zone Angle

## FINDING THE PERFECT FIT

soft lens is known to “drape” or conform (deform) to the shape of the underlying cornea. At the same time, a moncurve lens, which also has a base curve of about 8.3mm, extends onto the sclera, which has a radius of about 12.5mm, and appears to conform (deform) to a compatible lens-eye relationship.

Figure 3 displays an OCT image of a soft lens that is not fully conforming to the scleral sagittal depth and volume and is impinging. Vicoh team observations of ocular contours matched with successfully fit soft lenses reveal that the majority of soft lenses are about 200µm deeper than the eye

for the convex toward-the-eye (or posteriorly convex) landing zone used in some scleral lens design philosophies, such as that of the NormalEyes 15.5 (Paragon Vision Sciences).<sup>5</sup>

There is an opportunity to use ocular contour mapping for soft lens design to reduce corneoscleral morphology changes and lens deformation. The design rationale would use clinical markers or metrics to determine the parameter values. One example is a soft lens design produced for independent laboratories by Vicoh. Four clinical metrics are used to determine four parameter values (Table 1). Manifest re-

and confounds precision optics for peak clarity and optimum simultaneous vision optics needed for multifocal lenses. The second objective is to produce the best possible corneoscleral lens-eye relationship to reduce morphology changes and any adverse response from excessive localized mechanical interaction. The third objective is to improve the extension of lenses onto the sclera for consistency of fit over the population distributions of corneal diameter.

These three distinct objectives are met in a number of ways: the first by matching the soft lens radius more closely to the corneal radius; the second by matching the landing zone angle more closely to the corneoscleral contour; and the third by selecting an overall diameter that is responsive of the corneal diameter.

### Information Delegation

The beauty of technology-driven prescribing is the relative independence of instrument accuracy and repeatability from the operator. For example, it doesn't matter who operates a corneal topographer or the ESP—the results will be the same regardless. As such, ancillary personnel can gather the data needed for a custom soft lens order.

The measures of flat keratometry and corneal diameter can be accomplished with most modern corneal topographers. Ocular contour can be measured with an OCT or an ESP. Anticipated future advancements in OCT software will provide more nuanced measurements of corneoscleral geometry to help us better determine the appropriate landing zone angle of the lenses discussed earlier. These same data can be used for toric soft lens design. Added measurements of lid position allow for

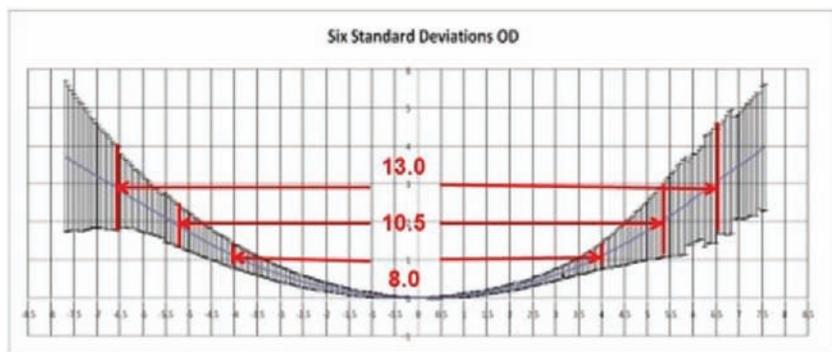


Fig. 2. Ocular contour plot in a single meridian of normal eyes showing geometric diversity to six standard deviations.

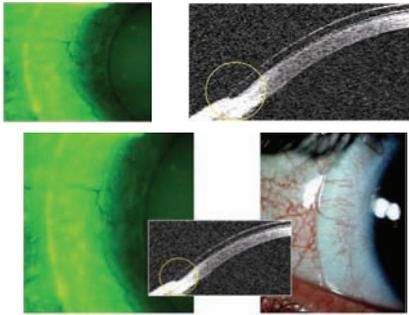
to which they are fit.

Another observation from fringe topography of human eyes reveals a zone that extends out from the limbus, which is concave away from the eye when mapped and measured at 60µm steps. Consider that most soft lenses have concave toward the eye ocular surfaces. This means a concave toward the eye ocular lens surface is mated to a concave away from the eye scleral contour. This represents a mismatch to the eyes in the normal distribution and an angle of incidence of the lens periphery that would suggest impingement. This concave away from the eye ocular contour is the rationale

fraction determines lens power; flat keratometry establishes base curve; corneal diameter (horizontal visible iris diameter) provides overall lens diameter; and OCT or ESP reveals the landing zone angle.

Alternatively, a diagnostic set with base curve radii, overall diameter and landing zone angle increments can be used to select the landing zone angle by observation. The greatest chair time efficiency is achieved with clinical measurements alone rather than with diagnostic lens observations.

The first objective in ocular contour-driven soft lens design is to reduce lens deformation, which induces higher-order aberrations



**Fig. 3. OCT image of a soft lens with conventional curvature incident on the bulbar conjunctiva.**

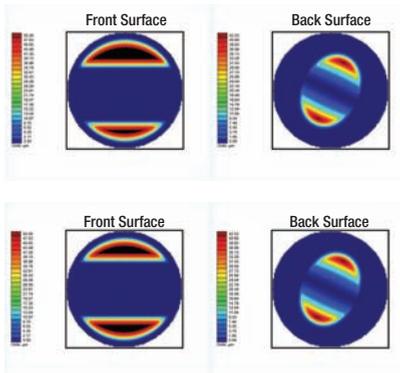
custom superior and inferior slab off dimensions (Figure 4).

Technology-driven prescribing can also help to resolve the enigma of presbyopia correction with soft lenses. It is well understood that the visual axis is nasal to the geometric center of the pupil, while the most common soft lens displacement is temporal. Chateau et al. observed a mean deviation of the geometric center of soft lenses to be more than 0.4mm temporal to the pupil center and a near equal amount inferior to the pupil center.<sup>6</sup> These data suggest that the optical center of the average lens could approach 1.0mm from the visual axis. As such, there is a need for a visual axis-aligned multifocal that would be fit with the same precision as progressive addition spectacle lenses.

Pupil size and reactivity also have a population distribution and play an important role in selecting segment sizes and optics to improve simultaneous vision designs in presbyopia correction. These can also be measured clinically through a number of methods.

Customized spherical aberration correction can be used to improve the vision of the largest contact lens wearers demographic (i.e., patients between the ages of 18 and 34). The eyes of younger wearers are inclined to manifest larger

pupil sizes, resulting in differences between their daytime small-pupil refraction and nighttime larger-pupil refraction due to spherical aberration. This age group also typically enjoys a greater frequency of nighttime spectator activities and greater nighttime driving hours per week. Wavefront aberrometry over



**Fig. 4. Two toric lenses with different slab-off dimensions to conform to two different eyes with different upper/lower lid positions.**

the full natural pupil under scotopic conditions will demonstrate the spherical aberration of each eye. Customized lenses can be made with two or more spherical aberration levels for each lens power.<sup>7</sup>

Finally, a thin soft lens for keratoconus may also be designed using population distribution of ectasia. Schwiegerling et al. measured eyes with keratoconus that were not deformed by rigid contact lens wear. He found a population distribution that could be described by the displacement of the apex of the cone, the width of the cone and the sagittal height of the ectasia from a reference sphere.<sup>8</sup> These data were used to design a series of soft lenses with posterior divots, which can be selected by use of corneal topography.<sup>9</sup> The peripheral landing zone angles and overall diameters can also be selected in the same manner as soft lenses using OCT or

ESP as previously described.

I believe there is a clear opportunity to expand customized lens use beyond its current confines to provide better vision, comfort and health for a significant percentage of patients who are candidates for soft lenses. The most significant missing piece has been the knowledge of ocular contour, as Otto Wichterle—the person credited with inventing the soft lens—himself believed.<sup>10</sup> The hypothesis that a significant number of soft lens wearers drop out due to inadequacies that would be overcome by customized lenses is worth researching.

Customized lens laboratories are making great strides in their adoption of more precise manufacturing and metrology technology. Material suppliers are increasing their efficiency in button production and advancements, including base curve molded buttons. They are also supporting the laboratories by enabling technologies that include specialized surface treatments and lens tinting. In-office instrument technology can now link the eye care practitioner directly to the sophisticated apparatus of industry. [RECL](#)

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# UNCOVERING

**B**ecause mechanical irritation and altered tear film dynamics have long been associated with rigid contact lens wear, it is perhaps surprising that vascularized limbal keratitis (VLK) was first identified somewhat recently. In 1989, Grohe and Lebow described VLK as an entity clinically distinct from other forms of peripheral keratitis and corneal anomalies.<sup>1</sup> The condition manifests as a focal limbal hypertrophic lesion located along the horizontal meridian (at approximately three or nine o'clock). In some cases, there may also be an associated localized hyperemia of the conjunctival vessels proximal to the lesion. The lesion will show superficial staining, and can progress to localized infiltration with a frank overlying epithelial defect with associated limbal staining and associated non-wetting surrounding the lesion.

In more advanced and longer-standing cases, superficial and deep peripheral corneal vascularization localized to the lesion can also form. Subjectively, patients sometimes experience a significant decrease in lens wearing comfort, a decrease in contact lens wearing time and significant awareness of the presence of the VLK lesion.

VLK is often associated with gas permeable contact lens wear, in many cases, patients have a long history of GP use.<sup>1,2</sup> The lenses that tend to trigger VLK are frequently large or steep. Additionally, lenses with low edge lift have been thought to trigger VLK. Furthermore, the lenses tend to sit centrally and have poor movement. These lens characteristics

can lead to poor tear film fluid dynamics, desiccation and resulting VLK.<sup>1</sup> Previously common PMMA contact lenses were also thought to trigger VLK if lens crazing occurred.<sup>3</sup> Anecdotal evidence further suggests that the use of a continuous positive airway pressure machine for sleep apnea may also trigger the condition, due to dryness from air leaking into the eyes or air passing from the nose into the eyes via the nasolacrimal duct.<sup>4</sup>

## STAGING OF VLK

VLK progresses through four stages, and patients can present in any of the four. As such, the symptoms reported by patients depend on which stage of the disease they are experiencing. Patients often

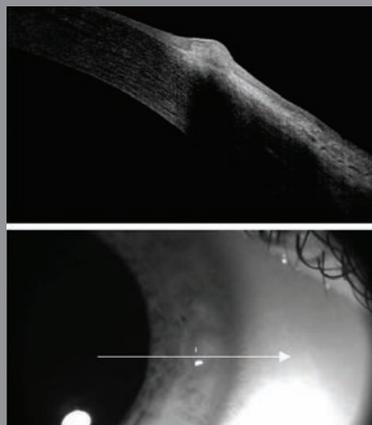
report lens discomfort, lens awareness and decreased wear time. Furthermore, they may have light sensitivity, tearing and awareness of a white spot on their eye.<sup>1</sup>

Just as the symptoms of VLK depend on the stage of the condition, so too do its signs. Stage I is characterized by a lack of symptoms, superficial punctate keratitis and epithelial hyperplasia, the latter caused by poor fluid dynamics and resulting corneal desiccation. Stage II is comprised of two phases. First, the conjunctiva becomes hyperemic. This is then followed by the possible formation of corneal infiltrates. During stage II, the patient may experience mild lens awareness and superficial punctate keratitis with staining.

Once vascularization is noted,

## CASE EXAMPLE

A 42-year-old white female recently presented with common signs and symptoms of VLK. She complained of ocular irritation OD when wearing her gas permeable contact lenses and the presence of a small white spot on the colored part of her eye. Her pain resolved when her contact lenses were removed. She reported previously using Zylet eye drops (loteprednol etabonate 0.5% and tobramycin 0.3%, Bausch + Lomb) for similar occurrences in the past.



**Fig. 1.** VLK OD active anterior segment OCT image.

Upon exam, vascularization and associated scarring were noted at the three and nine o'clock positions in both corneas. Additionally, a raised, circular and opaque area was seen nasally in the right eye. Fluorescein showed 3+ staining on the elevated area OD and trace superficial punctate keratitis nasally and temporally OS.

The contact lens OD was seen to abut against the elevated area. An anterior segment OCT revealed significant epithelial and stromal hypertrophy nasally OD (*Figure 1*) and mild stromal hypertrophy nasally and temporally OS.

# VLK

## Don't be caught off guard by this rare complication of contact lens wear.

By S. Barry Eiden, OD, FAAO  
Jane M. Trimberger, OD  
Paul Velting, OD

VLK is classified as stage III. At this stage, both deep and superficial vascularization can occur, and signs of hyperemia and staining persist. Patient symptoms increase during this stage, resulting in decreased lens wearing time. Stage IV is marked by erosion of the hyperplastic area and a sharp increase in symptoms. Patients often have photophobia, pain when the lens abuts the area of elevated epithelium, and lens intolerance. Furthermore, the hyperplastic epithelium often becomes visible to the naked eye.<sup>1</sup>

### DIFFERENTIAL DIAGNOSIS

When VLK is suspected, it is important to first rule out other conditions, such as corneal neovascularization, dellen, phlycten-

nulosis and pseudopterygium.<sup>1</sup> Corneal neovascularization can be confused with stage III or IV VLK, as those are accompanied by vascularization. In corneal neovascularization, hypoxia often triggers limbal hyperemia. If the hyperemia is left untreated, it can progress to superficial neovascularization and possibly deep stromal neovascularization.

Corneal neovascularization is a rare complication of gas permeable lens wear. However, if it does occur, it often regresses with contact lens removal—leaving behind ghost vessels.<sup>9</sup> Unlike VLK, there is no change in corneal topography and there are usually no corneal opacities. Additionally, VLK responds to treatment quicker than corneal neovascularization.<sup>1</sup>

As a result, this condition can be easily distinguished from VLK.

Much like corneal neovascularization, dellen is easily differentiated from VLK. Dellen do not have any fluorescein staining, but will pool fluorescein. Additionally, topography reveals a corneal depression instead of the staining elevation seen in VLK.<sup>1</sup>

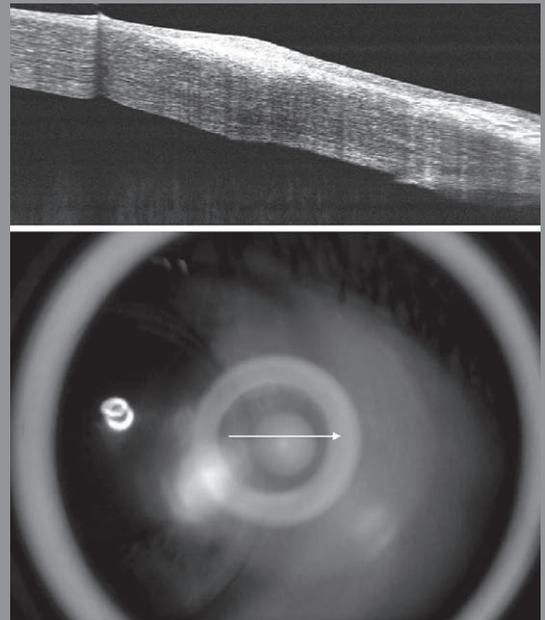
Phlyctenulosis is another differential diagnosis to consider. Patients will often present with symptoms similar to those of VLK, and both conditions may present with a white nodule and hyperemia.<sup>10,11</sup> VLK can be differentiated from phlyctenulosis by how quickly it regresses. VLK can regress in a few days with proper treatment; phlyctenulosis can persist for up to two weeks.<sup>1</sup>

The patient's right eye was classified as stage IV VLK, as an eroded area of epithelial hyperplasia was noted. Surprisingly, the patient was not sensitive to light and could tolerate a small amount of lens wear. The patient's left eye was classified as stage III VLK, as vascularization was noted without corneal erosion. In this eye, the patient still tolerated the lens very well. Treatment to stop the VLK flare-up and eliminate future problems included decreasing the contact lens diameter OU from 9.2mm to 8.7mm along with an increase in axial edge lift of the lenses.

The diameter reduction and increase in edge lift prevented further corneal irritation of the affected areas. She was also prescribed Zylet QID OD for five to seven days to reduce the

inflammation. At the follow-up visit, anterior segment OCT revealed a significant reduction in the stromal hypertrophy OD (*Figure 2*). The patient reported that the pain in her right eye had subsided and the new lenses were comfortable.

Upon slit-lamp observation, the new, smaller diameter lens edge did not touch the previously affected three and nine o'clock positions of the cornea. Furthermore, the elevated nasal opacity in the right eye had dissipated and no longer showed any fluorescein staining.



**Fig. 2. Resolution of VLK following medical management and contact lens design modification.**

## UNCOVERING VLK

Additionally, unlike VLK, phlyctenules can migrate throughout the cornea and have an infectious etiology.<sup>10</sup>

Pseudopterygia can also be confused with VLK. Similar to VLK, it can develop as a result of gas permeable lenses drying and altering the tear film at the three and nine o'clock positions of the cornea. These signs, along with superficial punctate keratitis, can lead to vascularization extending from the limbus and eventual subepithelial opacification of the affected area.<sup>12</sup>

There are a few ways to differentiate pseudopterygia from VLK. First, a pseudopterygium only has superficial vascularization; VLK has both superficial and deep vascularization. Also, superficial punctate keratitis is found at the leading edge of the pseudopterygia, but has a diffuse presentation in VLK. Finally, pseudopterygia are more likely to leave a permanent subepithelial opacity than VLK.<sup>1</sup>

### TREATMENT

Developing a treatment regimen for VLK depends primarily on the stage of the condition. However, changes in lens parameters enacted at any stage will help prevent future flare-ups.

Treating stage I VLK should begin by reducing lens wear time. Additionally, it may be necessary to flatten the peripheral curve to help prevent progression to further stages. In stages II-IV, it is recommended that patients discontinue lens wear entirely.<sup>1</sup> Lenses should not be worn again until elevation and vessels have receded.<sup>2</sup> To prevent peripheral corneal damage and improve tear dynamics, flatten the base and peripheral curves, and reduce lens diameter before the patient resumes lens wear.<sup>1,5</sup> If the patient is wearing lenses made of silicone acrylate, it is

recommended to switch to fluoro-silicone acrylate material.<sup>6</sup>

Educating patients on thorough lens cleaning techniques will also help to ensure improved wettability and tear movement.<sup>7</sup> Alternatively, switching to a lens that vaults the cornea (e.g., prosthetic replacement of the ocular surface system or a scleral lens), will help to eliminate further corneal irritation.<sup>8</sup> Additionally, refitting VLK patients in a soft or hybrid lens will also typically address the problem. Failure to change the lens design will likely result in a rebound of the condition.<sup>1</sup> Upon resuming lens wear, extended wear should be eliminated.<sup>2</sup>

Along with changes in lens parameters, it is important to treat any flare-ups with the appropriate topical therapy. It is recommended to treat patients presenting with stage I or II VLK with lubricating drops. Stage III patients (and recurrences of stage II) should be treated with corticosteroids to address vascularization. Finally, due to the erosion of the cornea, it is recommended that stage IV VLK is treated with antibiotic steroid combinations.<sup>1</sup> When treated this way, the elevated area should recede after about five days.<sup>2</sup> If etiology is uncertain, a tissue scraping or culture may be considered in later stages.<sup>1</sup>

VLK is a relatively uncommon complication of rigid corneal contact lens wear. It typically is due to peripheral desiccation and secondary inflammation that results in a localized area of limbal hypertrophy with potential corneal infiltration, vascularization and epithelial erosion. Management includes changes to contact lens design or modality along with appropriate medical therapy. The case presented documents the appearance and resolution of VLK using anterior segment OCT. 

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### ABOUT THE AUTHORS



Dr. Eiden is president and medical director of North Suburban Vision Consultants, Ltd., a private group practice specializing in primary eye care, complex contact lens management, treatment of eye diseases, and refractive surgery.



Dr. Trimberger will soon be starting a residency at the Illinois College of Optometry, specializing in primary care and ocular disease.

Dr. Velting is currently a student at Indiana University School of Optometry.

# Seeing Eye to “i”

## Meeting the new visual demands of today’s digital devices with a frequent replacement lens



BY KERRY A. GIEDD,  
OD, MS, FAAO

Digital devices have led to a recalibration of our patients’ visual expectations, raising the bar for eye care professionals and the products we prescribe. Patients expect to read large amounts of type in very small fonts on their smartphones, and want to see every blade of grass or the individual whiskers on a man’s face on their HDTVs at home. Once upon a time we were impressed with cameras that had resolutions of a few megapixels but today’s digital cameras have resolutions many times that. Patients are expecting to see more and – like all of us – never appear to log off or tune out.

In contrast, we have not had a newcomer to the world of frequent replacement lenses – our biggest contact lens category – in seven years. I’d like to share with you some recent study findings on the performance of Bausch + Lomb ULTRA™ contact lenses, and why it has become my “go to” lens in meeting patient expectations for clarity and comfort in today’s digital world.

The Bausch + Lomb ULTRA lens has the breathability we’ve come to expect from silicone hydrogel lenses but offers some important improvements. These include a low modulus, high water content and a thin edge design for comfort, and aspheric optics and resistance to dehydration for visual clarity. The level of patient satisfaction with this combination of features was evaluated in a recent prospective multi-center study.<sup>1</sup> Successful wearers (n=327) of leading brands of frequent replacement contact lenses were refit into Bausch + Lomb ULTRA contact lenses and asked to complete a questionnaire after seven days of wear. They rated their lens wearing experience with the Bausch + Lomb ULTRA lenses compared to their habitual contact lenses.

Overall, the Bausch + Lomb ULTRA lens was preferred ( $p < 0.05$ ) over the leading silicone hydrogel lenses for comfort and vision, and demonstrated high levels of satisfaction across a variety of lens wearing situations.<sup>1</sup> More patients agreed, for example, that the Bausch + Lomb ULTRA lens provided better overall comfort (3 to 1) and end-of-day comfort (2.6 to 1) vs. Acuvue Oasys, Air Optix Aqua, and Biofinity lenses, including better comfort while using digital devices (3 to 1).

Similarly, the Bausch + Lomb ULTRA lens provided superior vision for digital device users.<sup>1</sup> More patients (81%) agreed that the Bausch + Lomb ULTRA lens provided clear end-of-day vision over the leading brands of silicone hydrogel lenses, including clear vision after long hours at a computer (83%) vs. Acuvue Oasys, Air Optix Aqua, and Biofinity lenses.<sup>1</sup>

What’s striking about these results is that they involve typical patients – successful wearers of well-recognized products introduced over the last decade – who prefer the Bausch + Lomb ULTRA lens as an advance over what they had been wearing. The patient base in my practice consists of young professionals who typically spend many hours a day on a computer or other digital devices. These patients enjoy hearing about a new product and, after being given the chance to try the Bausch + Lomb ULTRA lens, appreciate the comfort and clarity it delivers.

In my own practice I like to be able to offer my patients the most modern and innovative technology and products, always telling them about new products that have come to market and giving them a “risk free” trial opportunity to experience what’s new and see for themselves how it performs. This adds tremendous value to the exam and to the patient’s experience, and, ultimately, builds loyalty to my practice. The Bausch + Lomb ULTRA contact lens marks an exciting addition to our armamentarium – one that I think addresses some of the rapidly changing visual demands of today’s digital devices in a modality where we have not had anything new to offer our patients for quite some time. ■

Reference: 1. Merchea MM, Steffen R, Hook DJ. Clinical performance of a novel silicone hydrogel contact lens with optimized chemical and physical attributes. Poster presented at the Global Specialty Lens Symposium, Las Vegas, NV, January 2014.

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# DECODING THE GENETICS of Corneal Disease

Using a variety of novel tests and treatments, we can better detect and correct these hereditary conditions.

By Thomas John, MD

One of the most interesting recent developments regarding corneal dystrophies has been the linkage

of genetics to these conditions as potential agents in their manifestation (*Table 1*).<sup>1</sup> As such, it is vital to explore the clinical relevance of genetics, in-office testing and gene therapy for these diseases.

When dealing with a clinical diagnosis of a corneal dystrophy, genetic testing needs to be on the radar of both primary eye care providers and cornea specialists alike.<sup>1-5</sup> When used appropriately, genetic testing can allow clinicians to put into motion management efforts that reduce the risk of disease occurrence; these tests also provide significant and useful information to children and other family members of those presenting with a corneal dystrophy.

Additionally, genetic testing can help identify the mutation that is causing the disorder and may help clinch the diagnosis. This may shed light on the likelihood of possible future deterioration in vision, a knowledge that could aid in career choices or help in directional changes in one's career and other life goals.

With the results of genetic testing in hand, we can provide our patients with more individually tailored counseling, and also potentially confirm or rule out the presence of a disease entity that is present in a given family. The downside to use of a genetic test is its untoward psychological effect in an otherwise asymptomatic individual when the results are positive. However, on balance, molecular genetic testing is valuable. It can aid in accurate diagnosis and shed light upon inheritance patterns. Genetic testing can also help patients make an informed decision about the choice of a board-certified medical geneticist or genetic counselor.

This article will focus on various corneal dystrophies and provide an overview of some of the issues and advances in the field of genetic testing and the current status of gene therapy.

## CLASSIFICATIONS

The phrase *corneal dystrophy* refers to a group of rare, non-inflammatory, inherited, bilateral corneal diseases with accumulation of abnormal substances that is limited to the cornea.<sup>1-5</sup> They often begin early in life, but may not manifest

clinically until much later; as such, they often display a pattern of slow progression. The anatomic classification of corneal dystrophies based on the levels of corneal involvement is shown in *Table 1*.

## GENETIC TESTING

A genetic test involves a clinical or laboratory investigation that offers information as to whether or not a person is affected with a heritable disease. It provides an analysis of chromosomes (DNA), proteins and some metabolites in an attempt to identify heritable disease-related genotypes, phenotypes, karyotypes or mutations for clinical purposes.<sup>6</sup> Thus, the genetic diagnosis provided by these tests can be used to determine a patient's susceptibility to inherited diseases. Additionally, genetic tests can provide informa-

## ABOUT THE AUTHOR

Dr. John is Clinical Associate Professor at Loyola University in Chicago, and is in private practice in Oak Brook, Tinley Park, and Oak Lawn, Illinois. He can be reached at 708-429-2223; fax: 708-429-2226; e-mail: tjcornea@gmail.com. He has no financial interest in any aspect of this article.



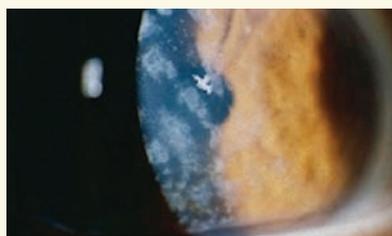
tion that can be used to establish an individual's ancestry or a child's parentage. The various types of testing include newborn screening, diagnostic testing, carrier testing, preimplantation genetic diagnosis, predictive and presymptomatic testing, prenatal diagnosis and pharmacogenomics.

The first genetic test for Avellino corneal dystrophy (granular corneal dystrophy type II) emerged in 2013 when Avellino Lab USA launched the Avellino-Gene Detection System (AGDS) in the United States. The company claims the test, which involves a mouth swab that is sent to the company for analysis, is 100% accurate in its ability to determine the presence or absence of the biomarker; results are available within 24 hours. The AGDS is especially useful prior to refractive surgery, as patients with Avellino corneal dystrophy who undergo any type of refractive surgery are at an elevated risk of vision loss. This is because LASIK surgical stimulus to the cornea can accelerate the condition with worsening of the density of corneal clouding that can result in potentially significant visual loss. The company now has a second test for another genetic mutation; namely, granular corneal dystrophy type 1. It is now called Avellino DNA Dual Test for LASIK Safety. It is worth mentioning that there is currently no curative treatment for these corneal dystrophies.

Other genetic tests include the Asper Biotech corneal dystrophy test, which can be used to screen for 333 mutations in the following 13 different genes: COL8A2, TGFBI, VSX1, CHST6, KRT3, KRT12, GSN, TACSTD2, CYP4V2, SOD1, TCF8/ZEB1, SLC4A11 and UBIAD1. Genetic variations in these genes are associated with multiple corneal dystrophies that may affect the corneal epithelium, stroma or

the endothelium (Table 1). A number of direct-to-consumer testing options are also available, which allow patients to perform a type of genetic test at home, thus bypassing the interpretation and guidance of a health care professional entirely.

The practicing eye care provider needs to be aware that specific genetic testing is now available for various inherited ophthalmic diseases, including corneal dystrophies. These tests are especially useful whenever one is dealing with monogenic diseases. Practitioners should be particularly suspicious of a corneal dystrophy in the event of a patient presenting with bilateral corneal opacities that are somewhat similar in morphology in otherwise non-inflamed eyes without any sys-



**Avellino, a variant of granular dystrophy. It has multiple superficial focal opacities and stromal deposits.**

temic findings. In cases such as this, it would be beneficial to consider genetic testing.

The eye care provider should discuss with the patient the potential value—and limitations—of genetic testing. One has the option to take

an active role in the testing and reporting process or refer the patient to a physician or counselor who is considered an expert in the field of genetic testing. Additionally, genetic counseling becomes an integral part of this process, so the patient should be directed to a trained, board-certified medical geneticist or genetic counselor for further assistance. The recommendations of the American Academy of Ophthalmology Task Force on Genetic Testing are a valuable resource for every practicing eye care provider in the US. Web-accessible resources include NIH Genetic Testing Registry ([www.ncbi.nlm.nih.gov/gtr/](http://www.ncbi.nlm.nih.gov/gtr/)), American College of Medical Genetics ([www.acmg.net](http://www.acmg.net)), American Board of Genetic Counseling ([www.abgs.net](http://www.abgs.net)) and the National Society of Genetic Counselors ([www.nsgc.org](http://www.nsgc.org)).

The Genetic Information Nondiscrimination Act protects individuals in the US by prohibiting health insurers from denying patients coverage based on genetic predisposition to future development of a disease. Additionally, this legislation prohibits employers from detrimentally using a patient's genetic information with regard to employment issues.

## MONOGENIC VS. COMPLEX GENETIC DISEASES

Numerous monogenic diseases and their molecular bases have been detected via human genetic stud-

**Release Date:** June 2014

**Expiration Date:** June 1, 2017

**Goal Statement:** Genetic testing can help identify the mutations responsible for numerous corneal dystrophies. This course will review a number of these dystrophies, their genetic associations, and currently available genetic testing and treatment options.

**Faculty/Editorial Board:**  
Thomas John, MD

**Credit Statement:** COPE approval for 1 hour of CE credit is pending for this course. Check with your state licensing board to see if this counts toward your CE requirements for relicensure.

**Joint-Sponsorship Statement:** This continuing education course is joint-sponsored by the Pennsylvania College of Optometry.

**Disclosure Statement:** The author has no financial relationships to disclose.



**Table 1. Corneal Dystrophies and Genetic Association**

Corneal dystrophy	Inheritance Mode	Gene	Gene Locus	Location*
Epithelial recurrent erosion dystrophy (Recurrent hereditary corneal erosions)	Autosomal dominant	Unknown	Unknown	A
Meesmann corneal dystrophy (Stocker-Holt dystrophy)	Autosomal dominant	KRT3, KRT12	12q13, 17q12	A
Lisch epithelial corneal dystrophy (band-shaped and whorled microcystic dystrophy of corneal epithelium)	X-linked recessive	Unknown	Xp22.3	A
Gelatinous drop-like corneal dystrophy (Subepithelial amyloidosis, primary familial amyloidosis)	Autosomal recessive	TACSTD2	1p32	A
Subepithelial mucinous corneal dystrophy	Autosomal dominant	Unknown	Unknown	A
Reis-Buckler corneal dystrophy (Corneal dystrophy of Bowman's layer type I)	Autosomal dominant	TGFBI	5q31	A
Thiel-Behnke corneal dystrophy (Corneal dystrophy of Bowman's layer type II, honeycomb corneal dystrophy)	Autosomal dominant	TGFBI	5q31	A
Granular corneal dystrophy type I (Corneal dystrophy Groenouw type I)	Autosomal dominant	TGFBI	5q31	S
Granular corneal dystrophy type II (Avellino corneal dystrophy, combined lattice-granular dystrophy)	Autosomal dominant	TGFBI	5q31	S
Lattice corneal dystrophy type I	Autosomal dominant	TGFBI	5q31	S
Lattice corneal dystrophy type II (Biber-Haab-Dimmer dystrophy)	Autosomal dominant	GSN	9Q34	S
Macular corneal dystrophy (Corneal dystrophy Groenouw type II)	Autosomal recessive	CHST6	16Q22	S
Gelatinous droplike corneal dystrophy	Autosomal recessive	TACSTD2	1p32	S
Schnyder crystalline corneal dystrophy	Autosomal dominant	UBIAD1	1p34.1-p36	S
Fleck corneal dystrophy (Francois-Neetens speckled corneal dystrophy)	Autosomal dominant	PIP5K3	2q35	S
Congenital stromal corneal dystrophy (Congenital hereditary stromal dystrophy)	Autosomal dominant	DCN	12q13.2	S
Posterior amorphous corneal dystrophy	Autosomal dominant	Unknown	Unknown	S
Fuchs' endothelial corneal dystrophy	Autosomal dominant	COL8A	1p34.3	P
Posterior polymorphous corneal dystrophy (PPMD)	Autosomal dominant	TCF8	10p11.2	P
Congenital hereditary endothelial corneal dystrophy (CHED) type I	Autosomal dominant	Unknown	20p11.2-q11.2	P
Congenital hereditary endothelial corneal dystrophy (CHED) type II	Autosomal recessive - Linked to SLC4A11 gene mutation linked to mutations in SLC4A11 gene			P
X-linked endothelial corneal dystrophy	X-linked recessive	Unknown	Unknown	P

\*Location Key: A: Anterior or Superficial; S: Stromal; P: Posterior

ies. However, these studies have been far less successful in detecting the association of phenotype to genotype in complex, multigenic conditions. The phrase *monogenic diseases* refers to mutations that occur in a single gene that is responsible for the disease. Detecting these mutations can unravel the possibility of developing the disease with a relatively high level of precision. Examples of monogenic disorders include TGFBI-related corneal dystrophies (Table 1).

Unlike monogenic diseases, complex disorders (e.g., AMD and glaucoma) are more common in the general population. It is important to note that detection of any one of the disease-associated genetic abnormalities alone is not usually predictive of disease development in the future. Hence, in these complex diseases, clinical evaluation and diagnosis play a vital role and genetic testing is less relevant. As such, routine genetic testing for complex disorders should be avoided.

## GENE THERAPY FOR CORNEAL DISEASES

In most developing countries, corneal diseases represent the second leading cause of blindness; worldwide, corneal diseases are recognized as the third leading cause of blindness.<sup>7,8</sup> The application of gene therapy would be well suited to limiting corneal blindness due to the accessibility and immune-privileged nature of the cornea, ease of vector administration and visual monitoring, and ability to perform frequent noninvasive corneal assessment.<sup>8</sup>

Advances in gene-based corneal interventions to combat inherited corneal disorders include the use of numerous effective vectors and improved delivery techniques during the last decade. These methods should bring us closer to achieving the goal of efficacious therapy with

## GLOSSARY

**Genotype:** The genetic makeup of an organism or group of organisms with reference to a single trait, set of traits, or an entire complex of traits. (Dictionary.reference.com).

**Phenotype:** The appearance of an organism resulting from the interaction of the genotype and the environment. (Dictionary.reference.com).

**Karyotype:** A karyotype (Greek karyon = kernel, seed or nucleus) is the number and appearance of chromosomes in the nucleus of a eukaryotic cell. (wikipedia.org).

**Monogenic diseases:** Monogenic diseases result from modifications in a single gene occurring in all cells of the body. (www.who.int/genomics/public/geneticdiseases/en/index2.html).

prolonged therapeutic gene expression in target corneal cells that has a high safety index and low tissue toxicity.

Gene therapy is also being explored in possibly improving the quality of donor corneas for corneal transplantation in an attempt to decrease graft rejection; both adenovirus and lentivirus have been tested to deliver genes to corneal endothelial cells.<sup>9,10</sup> Additionally, in a culture setting, cryopreservation shows retention of phenotypic properties of corneal endothelial cells. The ability for lentiviral-mediated genetic modification of human cultured endothelial cells can potentially afford future therapeutic application for treatment of corneal endothelial disorders.<sup>11</sup>

Apart from viral vectors, the use of nanoparticles as carriers is another novel approach for the delivery of therapeutic materials to target ocular tissues in the treatment of various diseases.<sup>12</sup>

There have been tremendous advances in our understanding of genetic eye diseases—and, in particular, their impact on the human cornea. With commercial testing for a number of these diseases cur-

rently available, genetic testing has reached a significant milestone. It is important that every eye care provider become familiar with these genetic testing options as they pertain to the eye. Additionally, we must be cognizant of the importance of referring these individuals to a trained geneticist or genetic counselor for their genetic counseling.

Despite the notable strides we've made in understanding various genetic eye diseases and facilities for appropriate counseling, gene therapy for corneal disorders has not yet arrived for use in clinical practice. However, ongoing research efforts in this arena of corneal genetic disorders appear very promising, and the future certainly looks bright for our patients and their families! **ACCU**

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## The Missing Link?

Collagen crosslinking offers clinicians the potential to forever alter the impact of keratoconus on our patients.

**K**eratoconus is a condition for which treatment has been limited to palliative intervention during the early phases of the disease, and surgical intervention in the late-presenting cases. This has created a challenge to clinicians and patients alike, in that doctors' best efforts frequently were just good enough to allow the patient to function visually.

Collagen crosslinking (CXL) brings a new option to keratoconus therapy, and opens the door to a remarkable future for clinicians and patients.

The underlying principles behind crosslinking involve the use of riboflavin in a special mixture that generates increased penetration, along with highly focused ultraviolet light at 370nm. The combination of these elements in the corneal stroma creates a reactive oxide, which structurally enhances the collagen matrix and strengthens the stroma, ceasing the progression of thinning and forward coning of the corneal surface.

The procedure can be applied in a multitude of ways. There has been some controversy over whether epithelial removal ("epi-off" crosslinking) improves riboflavin penetration compared to the "epi-on" technique of leaving it intact. This has been addressed in numerous clinical trials, and is currently under review in the Avedro CXL USA trials. Data shows both interventions to be efficacious, with the difference

in outcomes based primarily on the management of the epithelial wound healing in epi-off patients and the relatively small, but real, risk of complications related to wound healing delay and the potential for infectious disease.

CXL is best applied to the keratoconic patient in the earlier phases of the disease state. Typically, the corneal thickness should be greater than 400 microns. Additionally, minimal scarring, if any at all, is preferable, although not preclusive. Based on the European protocols, patients undergoing crosslinking should be over 10 years old.

There are other factors that enter into the decision-making process, including previous surgical interventions such as RK, PK, LASIK and PRK. In patients who have had previous PRK or LASIK and become ectatic, the procedure has been very effective in halting the progression and allowing clinicians to better manage the visual rehabilitation of the patient.

The procedure has been less successful in patients with previous RK surgery. As the wounds are frequently unstable, crosslinking does not have the same impact that it typically produces in a normal keratoconic patient. Some centers outside of the United States will treat both the keratoconus with CXL and the current refractive error using topo-guided wavefront laser systems and PRK treatments to simultaneously allow for both visual rehabilitation and stabilization.

### CXL IN THE CLINIC

The procedure is relatively straightforward: if the patient is epi-on, the riboflavin is administered every two minutes until there is full corneal saturation and riboflavin "flare" in the anterior chamber is achieved upon physical slit-lamp assessment by the clinician. In most patients, this is typically achieved in 30 to 40 minutes; however, it may take longer in younger individuals because the corneal epithelial matrix is more difficult for the riboflavin to penetrate. The epi-off method uses the same procedure, but 30 minutes is typically sufficient in most cases to provide full saturation before initiation of treatment. Most riboflavin CXL applications are done one eye at a time, but some newer technologies offer simultaneous bilateral treatment.

The postoperative course of the patient is predicated on which of the two interventions is selected for the individual. Epi-off patients are typically placed in a bandage contact lens (BCL), and topical antibiotics and steroids are used QID for one week—much like post-PRK management. Once epithelial closure has been achieved, the antibiotic is stopped and the steroid is tapered over three additional weeks. In my experience, the wound healing is slightly slower than we typically see in a PRK treatment, and may last up to seven days or longer post-intervention.

Epi-on patients also receive a BCL plus topical antibiotics and steroids; the anti-inflammatory is



then tapered over several weeks. The antibiotic is typically stopped in three days, once the epithelium has completely healed.

During epi-on treatment, patients usually experience some discomfort in the first 24 hours due to the toxicity from the numerous drops applied during the procedure and the UV light. This discomfort usually dissipates by the next morning. Additionally, to blunt the discomfort, I typically use homatropine 5% preoperatively and postoperatively along with a topical NSAID. In my experience with epi-on, the BCL can be removed the following day, and the patient can return to normal activities at that time.

In most cases, because the vision is not optimal with correction prior to the procedure, acuity is only marginally affected and not a noticeable part of the postoperative course. Epi-on patients will have minimal, if any, complications beyond the noticeable corneal haze in some patients.

### POST-OP COMPLICATIONS AND LENS WEAR

Predominantly observed in the epi-off treatment protocol, these can involve delays in wound healing, microbial keratitis and stromal haze development.

I have observed several epi-off patients who present with wound healing delays and increased discomfort. Oftentimes, these complications resolve within seven days, but it is not unusual—even with continued use of a BCL—that a defect may remain for a

more prolonged period. In cases such as this, I have had excellent success with pressure patching and the use of a steroid antibiotic unguent (e.g., Tobradex) for one or two days.

Most epi-on patients can return to contact lens wear within one week, if wearing soft lenses or combination, piggyback fits, but we would recommend 10 to 14 days for hybrid lenses and more complex interventions. In patients who have undergone the epi-off procedure and plan to resume lens wear, for soft lenses my recommendation is seven to 14 days; for hard lens wear, approximately three to four weeks; and for complex lens wear, a four- to six-week period. This is due in part to the experiences that I have had with the epithelial remodeling after the procedure, and the potential for a recurrent erosion-like presentation if the cornea is manipulated significantly in the early postoperative course.

It is important to remember that the crosslinking process can continue for up to six months in most patients, which can produce a relative flattening and thinning of the cornea that may affect lens design. Typically, this will be accompanied by a light haze that indicates active crosslinking.

Corneal collagen crosslinking will (literally) alter the landscape of keratoconus once it's approved in the US. Its potential to produce a cessation of disease progression, and to improve the visual welfare of the treated individual, is unrivaled.

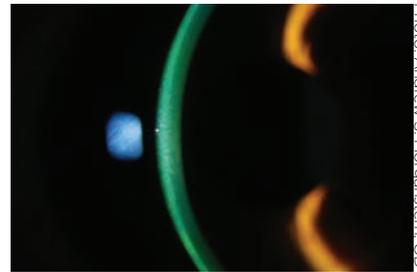


Photo: Andrew S. Morra, MD

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

Because the procedure is best for patients who show true progression of their keratoconus, it should be limited to these individuals. As such, the minimum age for the procedure is 10; the maximum age typically tails out at 40 to 45 years, as the body crosslinks naturally secondary to ultraviolet light exposure and the body's own blood sugar levels. This accounts for the often-noted cessation of progression in a keratoconic patient as they enter their fourth to fifth decade of life. While this is true of the vast majority of cases, I have seen several individuals older than 45 with progressive disease—typically resulting from trauma.

CXL typically provides a change in the refractive error in a significant percentage of patients. Most will show a mild decrease in myopia, astigmatism or both over the first three to six months while the crosslinking process is completed. As the science surrounding the treatment has grown both internationally and in US clinical trials, corneal collagen crosslinking has the potential to forever alter the impact of keratoconus globally. **RCCL**

# Relieving the Fear for Those Who Can't See Near

A number of barriers can prevent presbyopes from experiencing comfortable lens wear. Fortunately, some new lens options may be able to change that.

**T**he guiding principle of long-term contact lens success is that patients who experience the most comfort in their lenses are much less likely to drop out of contact lens wear. Unfortunately, that isn't always the case. Despite having access to highly advanced technologies to help our patients achieve ever-increasing levels of comfort, current contact lens wearers exhibit a dropout rate of 16% to 23%.<sup>1,2</sup>

This prompts the question, "What are the barriers to providing our patients with the best possible wearing experience?" The answer to this question, while important to the success of all of our contact lens wearers, is absolutely critical for our presby-

opes as a critical component to success. Additionally, these patients tend to have the most challenging prescriptions to fit—requiring both distance and near correction. Adding to the complexity, their visual needs and ideal correction will change often as presbyopia advances.

Fortunately, several new daily disposable lens options for our presbyopic patients have recently hit the market. The advanced designs of these new lens options offer a comfortable wearing experience and the opportunity to improve both distance and near vision. As with other daily disposables, they also provide our patients the convenience of a new lens every day.

This month's column will

review some of the new daily disposable options for presbyopes and how they might help dissuade them from discontinuing lens wear. In addition to keeping current wearers in their contact

lenses, they can provide presbyopes who are new to refractive correction the option of comfortable, convenient lens wear.

## FOCUSING ON NEW LENS OPTIONS

The *Proclear 1 Day Multifocal* (CooperVision) is made of omailcon A and contains phosphorylcholine, a coating designed to optimize the surface characteristics of the lens, leading to comfortable wear throughout the day. The lens is available in powers ranging from +6.00D to -10.00D in 0.25D steps up to -6.00D and then in 0.50D steps above -6.00D.<sup>3</sup>

What makes this lens unique is the availability of just one add power, which simplifies the fitting process. For patients with an add power up to +1.00D, the lens is fit by simply selecting their best-corrected distance vision power after being vertexed. For add powers between +1.25D to +1.75D, a "near boost" is recommended by adding +0.75D to the distance power of the non-dominant eye.

For those who require add powers between +2.00D to +2.50D, a near boost is also recommended, but it should be slightly stronger than the aforementioned approach; in these patients, it is recommended to add between +0.75D to +1.00D to the distance power of the lens. It is important to note that the dominant eye power is not

**“OUR PRESBYOPES TEND TO LIVE VERY BUSY LIFESTYLES THAT REQUIRE CONVENIENCE AS A CRITICAL COMPONENT TO SUCCESS.”**

opic patients. This cohort faces the challenge of a deteriorating tear film, which can significantly impede comfortable lens wear. Our presbyopes also tend to live very busy lifestyles that require

review some of the new daily disposable options for presbyopes and how they might help dissuade them from discontinuing lens wear. In addition to keeping current wearers in their contact



modified as the patient progresses through presbyopia.<sup>3</sup>

The *Dailies AquaComfort Plus Multifocal* (Alcon) daily disposable lens, made of nelfilcon A, has a 69% water content; this is the same material found in Alcon's Dailies AquaComfort Plus spherical lens. The blister pack contains both polyethylene glycol and hydroxypropyl methylcellulose, which helps to provide comfort upon initial insertion of the lens.<sup>4</sup> Additionally, the lens contains polyvinyl alcohol, which is designed to slowly release upon blinking, providing the lens with what the company refers to as "blink-activated moisture."

The multifocal possesses a center-near design that progresses to the distance power in the periphery—the very same design found in its monthly replacement predecessor, the Air Optix Aqua Multifocal. It is available in three add powers: Lo (for patients with an add up to +1.25D), Med (for patients with an add between +1.50D and +2.00D) and Hi (for patients with an add between +2.25D and +2.50D).<sup>5</sup> Because the fitting guideline is the same as the Air Optix Aqua Multifocal, success found with the monthly replacement option should translate well to the new daily disposable lens.

The *Clariti 1day Multifocal* (Sauflon), the first daily disposable silicone hydrogel multifocal lens, is composed of somofilcon A and has a 56% water content. Its base curve is 8.6mm and diameter is 14.1mm.<sup>6</sup> The lens uses a

## A Multifocal Solution

A 44-year-old female came to our office for an eye exam as a new patient. At that time, her medical history was unremarkable and she denied any allergies. Her chief complaint was an increasingly difficult time focusing at her computer, tablet and smart phone. Additionally, her ocular health was unremarkable. Her refraction was as follows:

OD +0.75 20/20  
OS +0.75 20/20  
+1.00 add 20/20 OU

We discussed the advantages and disadvantages of the various options available to correct her vision. We fit her with a simultaneous vision daily disposable contact lens with the following parameters:

OD +0.75 / Lo / 8.7 / 14.0  
OS +0.75 / Lo / 8.7 / 14.0

The patient's visual acuity was 20/20 OU at distance with the lenses and 20/25 OU at near. She was pleasantly surprised by the quality of both her distance and near vision with the lenses. No over-refraction was needed to improve her vision. She purchased a 30-day supply of the lenses and was seen again for follow-up 20 days after the initial fitting. At that time she reported comfortable lens wear and functional vision without the need for reading glasses. She then proceeded with a year supply of contact lenses.

simultaneous vision design—its near optics are located in the center of the lens and progress to the distance power in the periphery of the lens. It is available in two add powers: Low (for patients with an add up to +2.25D) and High (for patients with an add between +2.25 and +3.00D).<sup>7</sup>

Because it is a silicone hydrogel lens, it offers a high level of oxygen permeability; at -3.00D, the Dk/t is 86. Currently, the lens is available in distance powers ranging from +5.00D to -6.00D in increments of 0.25D.<sup>7</sup>

It is important that we keep abreast of the newest multifocal options and understand how they might prevent our presbyopes from dropping out of lens wear. It is equally important to provide

the opportunity for comfortable contact lens wear to new patients in this demographic who require refractive correction. With so many new options emerging in the presbyopic market, patients and practitioners alike are sure to find an appropriate solution for this often frustrating condition. **RCCL**

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## What's UPP, Doc?

Taking advantage of this new policy may provide much-needed growth for the contact lens industry—and your bottom line.

**T**he biggest developments in contact lenses also tend to be the least well known and least understood. A simple three-letter acronym could create a renaissance in contact lenses—and it's unrelated to clinical advances, polymers, dk/T or expanded parameters.

The acronym I'm referring to is UPP, or “unilateral pricing policy.” For those doctors who understand and embrace the philosophy of UPP, it has the ability to fundamentally change how they manage their contact lens practices—for the better.

### BALANCING THE COMPETITION

This unilateral pricing policy—employed by some manufacturers—dictates the minimum price you can charge for contact lenses. Doctors are allowed to charge more than the mandated price, but not less. Because this policy is “unilateral,” the manufacturers enact it without agreement from the reseller. To enforce this, manufacturers can cut off practices they catch selling lenses for less than the mandated price.

The policy applies to anyone selling the lenses, regardless of mode of practice or amount of lenses they buy from the manufacturer. For example, Dr. Small, who buys three boxes per year from Company X, and Dr. Large, who buys 1,000 boxes per year from the same company, are both required to sell the lenses for the same minimum price.

One of the biggest benefits to practitioners of UPP is that it instantly creates a perfectly level play-

ing field; volume discounts for large practices and online retailers go away. While this may create friction with buying groups, the benefits outweigh any ancillary issues. More importantly, however, it forces practices to focus on something other than price to keep prescriptions in their office—if all “retailers” sell the lenses for the same price, the method and environment under which they are sold will be the factors that determine where a patient decides to purchase their lenses.

For example, if a practice prices lenses at the required minimum UPP, and a patient buys their lenses elsewhere, the practitioner need only look in the mirror to determine why the patient did not buy the lenses in their office. Once they can pinpoint why (e.g., poor service, unfriendly staff, etc.), they can get busy addressing those issues. With pricing nearly neutralized (but not completely neutralized, as a practice can charge more than the required UPP) across all practices, the loss of a contact lens order can no longer be attributed to price competition.

Manufacturers also benefit from UPP because retail price erosion can be stopped. With a “race to the bottom” from aggressive price cutting eliminated, motivations to fit a particular lens increase; this has the ability to support and protect brand equity. Outside of the contact lens industry, companies such as Apple and Bose have used UPP for a long time.

Because practitioners can no longer set their own fees for lenses, some will point to the perceived loss of entrepreneurial independence.

While this is true, it's my opinion that the benefits listed above far outweigh this one possible negative.

### UPP, UP AND AWAY

Manufacturers employing UPP have the ability to “cut off” a doctor who does not abide by their pricing policy. Some practitioners question the ability and willingness of manufacturers to enforce these rules. To date, I'm aware of several instances where a manufacturer with a UPP has prohibited an online vendor from selling below the UPP. The hope is that all manufacturers with UPP lenses will follow suit, should other resellers not play by the rules.

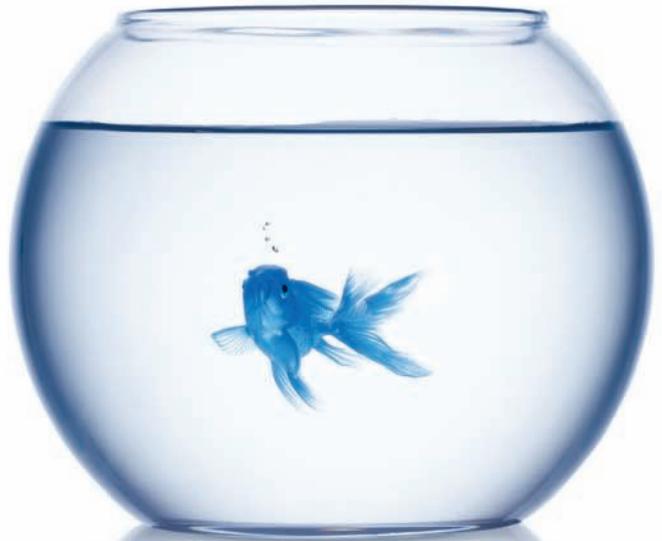
Finally, the actual price mandated by UPP has so far been higher than lenses that do not have a UPP. This has afforded higher profit margins and created a new sense of excitement surrounding contact lenses.

All things being clinically equal (which of course they rarely are), savvy practitioners will give serious thought to prescribing UPP lenses. For example, if you have a patient with astigmatism and they can wear a UPP lens, and a non-UPP lens is clinically equivalent, a smart doctor will choose the UPP option.

It's great for your practice and the industry. And ultimately, if the industry continues to thrive, it's also great for patients. Yes, they may pay more as a result, but UPP has the potential to put the brakes on significantly declining profit margins that were already anemic to begin with. Doctors who say, “contact lenses aren't profitable” may need to reexamine that statement in the context of newer UPP lenses. **RCCL**



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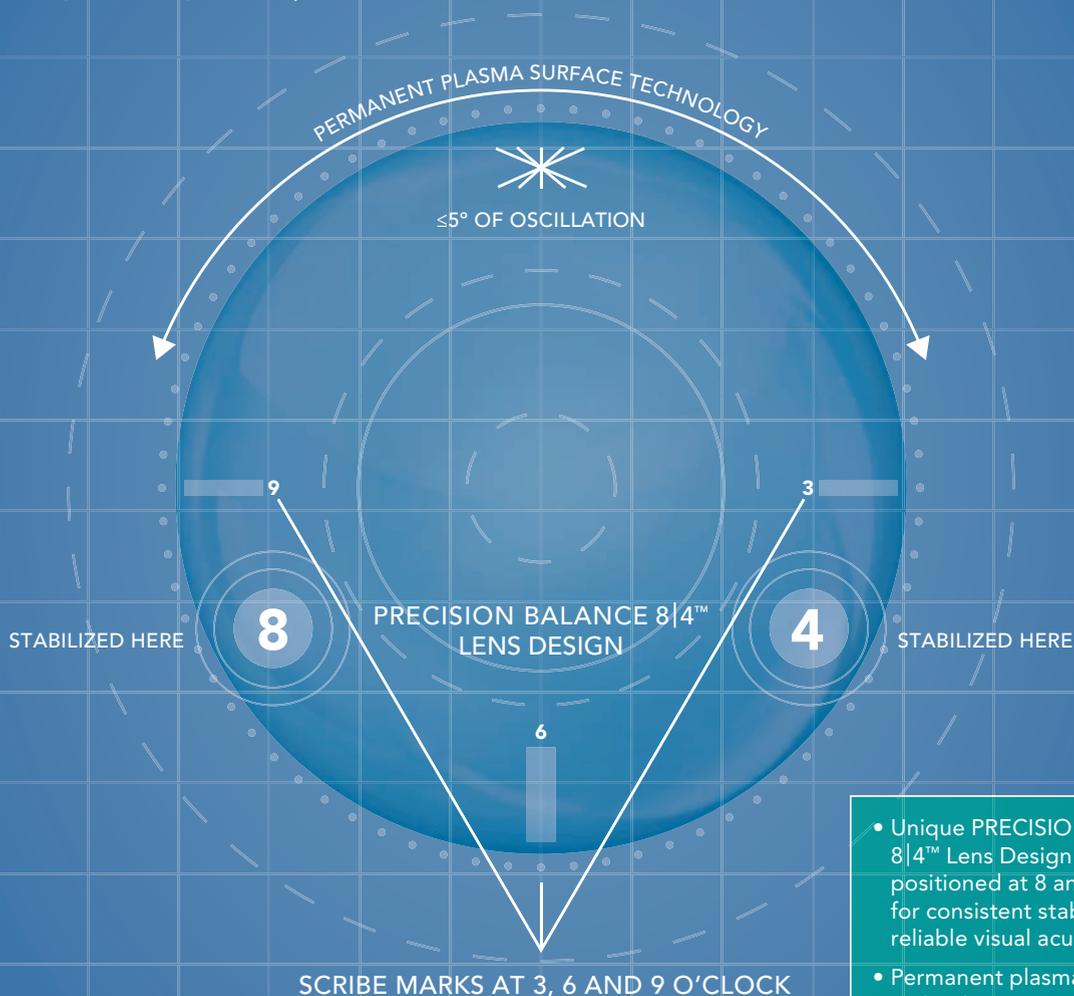
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