RCCL®
REVIEW OF CORNEA & CONTACT LENSES
MAY/JUNE 2023

ROUNDTABLE

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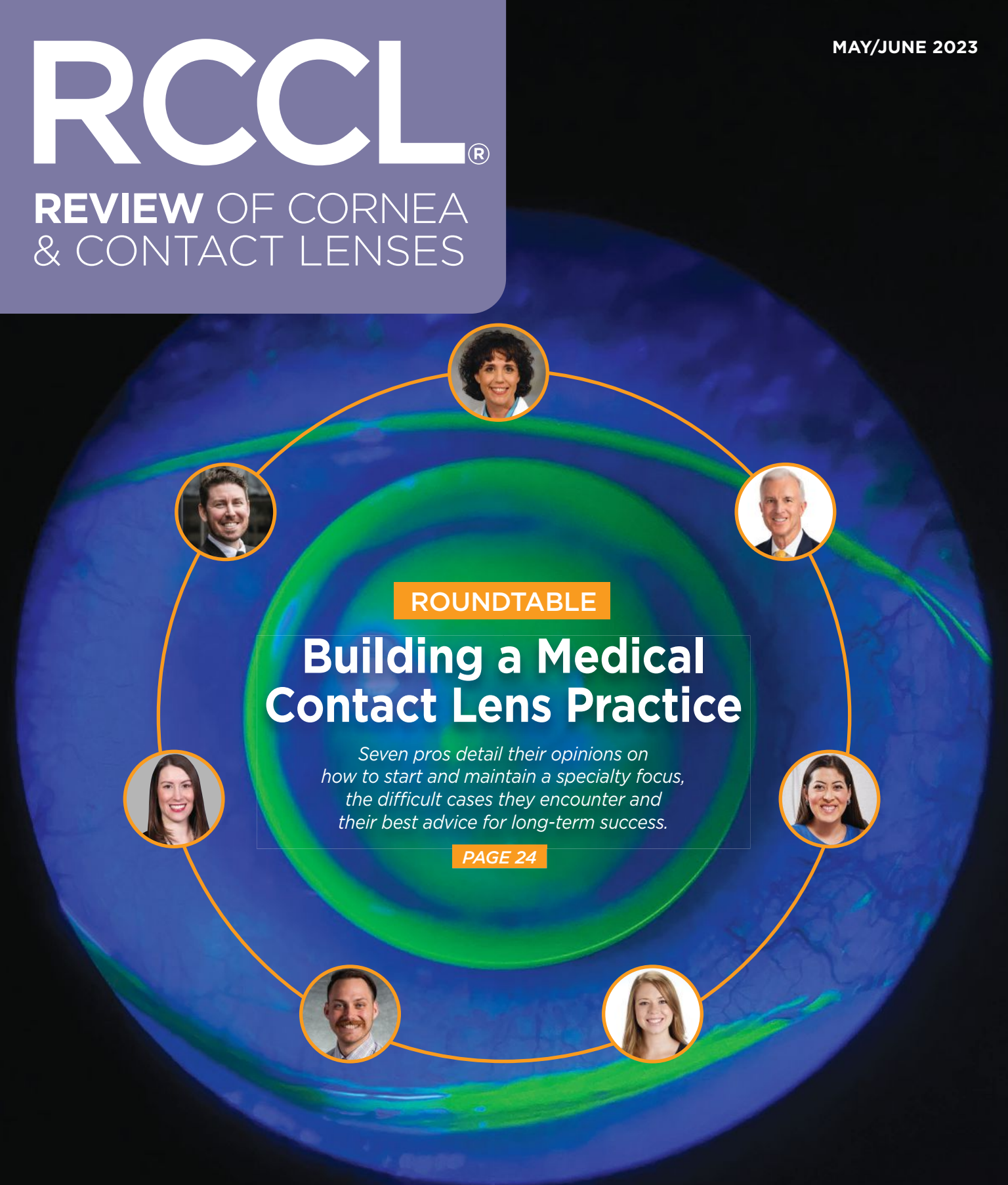
MAY/JUNE 2023



ROUNDTABLE

Building a Medical Contact Lens Practice

Seven pros detail their opinions on how to start and maintain a specialty focus, the difficult cases they encounter and their best advice for long-term success.

PAGE 24

LESSONS FROM ARVO 2023 • NOTCHED SCLERAL DESIGN TIPS • HIGH-TECH LENSES • CORNEAL SUTURE COMPLICATIONS

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Reference: 1. Data on file.

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Corneal Optics are Significantly Affected by Pterygium

Certain characteristics of this wing-shaped growth may help predict corneal changes and even recurrence.

Pterygium, a benign fibrous conjunctival growth often associated with sun exposure, distorts the cornea and induces astigmatism. According to a recent study in *Scientific Reports*, pterygium's effects on corneal characteristics are significant.

This study was among the first to compare higher-order aberrations (HOAs) in pterygium eyes with normal fellow eyes. The study included 59 patients with nasal pterygium. Here are some of its findings:

• Pterygium significantly increased WTR corneal astigmatism and corneal irregularity, inducing trefoils, horizontal coma and quatrefoils.

• Pterygium-induced corneal astigmatic/irregularity values and horizontal trefoil/quatrefoil were associated with the area of the pterygium.

• Pterygium length was an independent inducer of oblique trefoil/quatrefoil.

• Horizontal coma was independently associated with pterygium length and width.

• Pterygium grading wasn't correlated with its characteristics, except for thickness. Thickness wasn't correlated with any optical parameters.

The study authors offered a few theories for the causes of corneal distortion and flattening seen with pterygium, including tractional force of contractile elements, localized pooling of tears at the pterygium apex and stromal scarring.

"Interestingly, pterygium-induced changes in corneal optical parameters were mostly associated with the length and area of the pterygium, whereas the thickness and grading of the pterygium wasn't related to any induced corneal optical parameters," they wrote. They believe the head morphology, as opposed to the pterygium body or tail, is the key to determining factors affecting corneal distortion and flattening.

The researchers note that the following facts may support the importance of the head morphology:

•Pterygia usually exhibits firm adhesion to the anterior corneal stroma while spanning the limbal region without adherence.

• Pterygium with a flat corneal scleral transition zone induced more corneal scarring and astigmatism than pterygium with a nodular appearance.

• Traction by body or tail evoked by temporal gaze isn't an important factor in the change of astigmatism.

They add that pterygium thickness may have clinical significance as a predictor for recurrence, as greater thickness increased risk of recurrence.

"The results demonstrate that nasal pterygium significantly induces corneal astigmatism, irregularity and some HOAs," the team concluded. "These pterygium-associated changes in optical parameters could be predicted by the length, width and area of the pterygium."

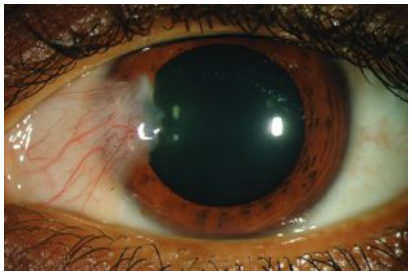

Photo: Christine Sindt, OD

Pterygium length, width and area were found to predict optical changes, while thickness may serve as a clinical indicator of eventual recurrence.

Chang H, Seol B, Choi H. Effect of pterygium on corneal astigmatism, irregularity and higher-order aberrations: a comparative study with normal fellow eyes. Sci Rep. 2023;13(1):7328.

IN BRIEF

■ Researchers recently assessed the data of 80 RCTs including 27,103 eyes to help determine **which interventions are the most effective for myopia prevention and control in children.** They found that **combined measures (in any of various pairings) were more effective in achieving axial length and refraction targets, followed by solo atropine.**

Most of the combinations prevented and controlled myopia more effectively than other forms of intervention, **with 1% atropine in combination with bifocal spectacle lenses and 0.01% atropine in combination with ortho-K being significantly more effective than progressive addition spectacle lenses**. Under-corrected single-vision spectacle lenses were less effective than other methods in slowing the increase in refraction than the other interventions.

"Atropine (1%, 0.5%, 0.1%, 0.05%, 0.01%) and ortho-K are effective in myopia prevention and control," the authors wrote. **"Progressive addition spectacle lenses, under-corrected single-vision spectacle lenses and compound tropicamide eye drops are ineffective in children."**

Zhang G, Jiang J, Qu C. Myopia prevention and control in children" a systematic review and network meta-analysis. Eye. April 27, 2023. [Epub ahead of print].

■ A recent study (n=539) found that **DMEK produced superior visual acuity outcomes to DSEK in patients with Fuchs' endothelial dystrophy.**

Graft survival at five years was **96% for both DSEK and DMEK.** Mean endothelial cell loss at five years was also similar between the two procedure types, at 57.7% in DSEK and 56.8% in DMEK eyes. **Visual improvement, however, was significantly better in DMEK eyes (20/20 DMEK vs. 20/27 DSEK).** The researchers also reported a **rebubbling rate of 7.8% in DSEK and 2.1% in DMEK.**

"There are clear differences between DSEK and DMEK, with potentially more graft manipulation to unfold the graft in DMEK surgery," the researchers concluded in their paper, published in *Cornea*.

Fu L, Hollick EJ. Comparison of long-term outcomes of DSEK and DMEK in Fuch's endothelial dystrophy. Cornea. 2023;00:1-6.

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Steroid, Antiviral Combo Best for Herpes Stromal Keratitis

When used together, the regimen can lower the risk of recurrence more than either agent separately.

Among classifications of herpes simplex keratitis, herpes stromal keratitis is a leading cause of irreversible corneal scarring, thinning, neovascularization and infectious blindness worldwide. Disease outcomes including vision loss, neovascularization and angiogenesis may progressively worsen after each recurrence. The standard treatment for herpes stromal keratitis includes antiviral medications in combination with corticosteroids, which addresses both the viral and immunomodulatory pathogenicity of the condition by reducing inflammation and inhibiting herpes simplex virus replication in the corneal stroma. Researchers recently conducted a systematic review to identify and compare interventions for treating herpes stromal keratitis and patient outcomes. They found that corticosteroids and antivirals managed the condition most effectively only when used concurrently. Results fared better than using either as monotherapy.

Two independent reviewers screened 168 records and used seven papers for data extraction. The research team examined both the conventional treatment with corticosteroids and antivirals and potential alternatives such as flurbiprofen, cyclosporine A and tacrolimus by their treatment success rate, BCVA, resolution time of successful treatment, time to failure, IOP and adverse events.

Patients with herpes stromal keratitis who received prednisolone phosphate and acyclovir showed a higher treatment success rate and significantly longer time to failure compared with patients receiving only acyclovir. No difference in resolution time was found between oral and topical acyclovir. Between groups receiving dexamethasone and flurbiprofen, resolution occurred in 93% and 67% of patients and BCVA (logMAR) improved from 1.0 to 0.30 and 0.48, respectively. BCVA improved in both cyclosporine A and its control (prednisolone) groups. A tacrolimus treatment group showed greater improvement in BCVA compared with its control (prednisolone) group.

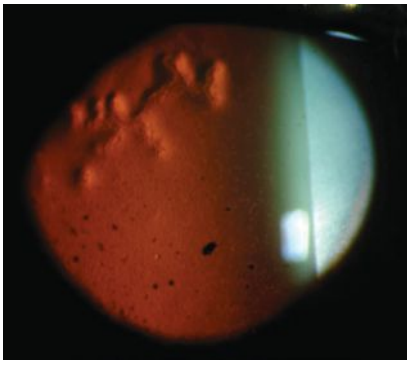

Photo: Christine Sindt, OD

When used together with an antiviral such as acyclovir, corticosteroid treatments could be more effective for herpes stromal keratitis compared with monotherapy of an antiviral or corticosteroid.

"These interventions could be potential novel approaches to the management of herpes stromal keratitis and allow health practitioners and patients—especially those who are unsuccessful with the standard treatment—to have access to alternative treatment plans that could be equally effective and potentially safer with fewer side effects," the authors wrote in their paper in *Ophthalmic Epidemiology*.

Li X, Nayeni M, Malvankar-Mehta MS. Antiviral and anti-inflammatory therapeutic interventions for treating herpes stromal keratitis: a systematic review. Ophthalmic Epidemiol. May 15, 2023. [Epub ahead of print].

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†Beyond use date is 150 days refrigerated versus 45 days frozen based on completed stability studies.
References. 1. Data on file. 2. United States Pharmacopeia <797> Pharmaceutical compounding--sterile preparations. (2022). USP-NF, Rockville, MD.

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contents

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Pigmentated iris lesion, *see p. 42.*

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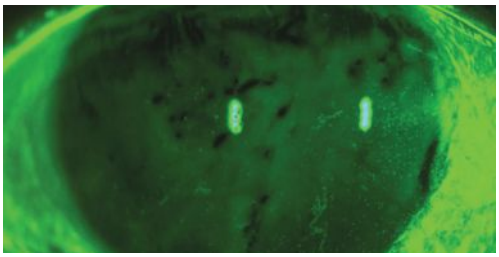

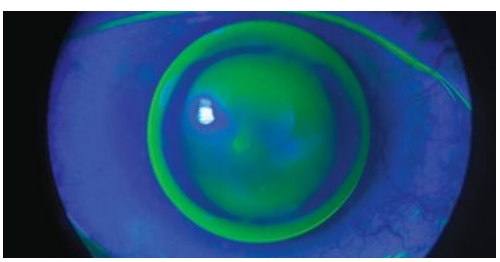

The Paradigm Shift in Keratoconus Treatment

Daniel G. Fuller, OD, FAAO Dipl, FSLS
Memphis, TN

KEY TAKEAWAYS

- Only iLink® cross-linking can slow or halt the progression of keratoconus.
- Referring progressing patients to a cornea specialist prior to vision loss is ideal.
- Slowing or halting keratoconus progression may allow patients to continue to tolerate contact lenses.

Ten years ago, there was little reason to refer a patient with keratoconus to a cornea specialist early in the course of their disease. All we could do was manage patients' vision as long as possible, hoping they didn't progress to needing a corneal transplant.

The approval of iLink® cross-linking marked a major paradigm shift in keratoconus management. Professional societies have adjusted treatment guidelines to reflect the ability of cross-linking treatment to slow or halt progression of the underlying disease. The American Academy of Ophthalmology, for example, now states in its Preferred Practice Pattern (PPP) that referral prior to vision loss is ideal, and that when keratoconus is suspected, more frequent follow-up to look for progression is warranted.[1] Any signs of progression or onset of keratoconus at a young age should lead to a prompt referral.[1]

Optometry is very good at helping patients with keratoconus see better with gas permeable (GP), hybrid, and scleral lenses. But as rewarding as it is to help the vision-impaired, we can have an even greater impact by catching this disease early and referring progressing patients for cross-linking before they lose vision, just as we refer glaucoma patients for treatment as soon as the disease is detected. For patients who are still in their peak earning and learning years, early treatment could mean 50+ years of functional vision.

Cost-effective and FDA approved

A discrete-event simulation model showed that, compared to conventional treatment, iLink cross-linking would reduce the rate of penetrating keratoplasty by 26%, and result in patients spending 28 fewer years in the advanced stages of keratoconus—all while saving money for patients, insurers, and society.[2]

The iLink procedure is an epithelium-off treatment that has undergone the scrutiny of randomized controlled clinical trials as part of the FDA approval process, demonstrating proven efficacy and safety. It is important to refer patients to doctors who use iLink, the only cross-linking procedure approved by the FDA. I believe that good science promotes good patient care and, in the case of iLink, also allows patients to use their insurance.

Vision correction post cross-linking

Slowing or halting keratoconus progression may allow patients to continue to tolerate contact lenses.[3,4] Typically, patients can resume contact lens wear within one to three months of the cross-linking procedure, although I find that corneal remodeling may continue for up to 12 months post-treatment. During this time, lens parameters may need to be adjusted. About one-third of eyes are able to continue in habitual contact lenses after cross-linking, while two-thirds require a new contact lens fit.[5]

With iLink cross-linking and modern specialty contact lenses, we have the best keratoconus management options now that I've ever seen. This represents not just a business opportunity, but the chance to have a life-changing impact on our patients. ■

Contact Lens Fitting Post Cross-Linking[5]

100% ACCEPTABLE FIT | **65%** IMPROVED SUBJECTIVE COMFORT | **20%** INCREASE IN NEAR-IDEAL FIT

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A Notch Above the Rest

Low-cost modification with power tools customizes a complex scleral lens fit.

When a patient has pingueculae or pterygia, the clinician may hesitate to fit a scleral lens, opting instead for a corneal lens where the conjunctival obstacle can be avoided altogether. If a scleral lens is necessary in a patient with pinguecula, landing zone customization, such as a toric periphery or a localized vault or notch, may be required.[1,2] Another strategy is to fit over the pinguecula by using a larger diameter scleral lens, thus compressing the lesion.[3]

CASE PRESENTATION

A 47-year-old woman with a history of phlyctenular keratoconjunctivitis and bilateral corneal scarring presented wearing scleral lenses that were three years old. Her chief complaint was blurry vision at near, OS>OD, with onset several months prior. She had not tried reading glasses over her habitual X-Cel Atlantis 15.0mm scleral lenses OU. She reported good comfort overall with the lenses and used the prescribed solutions: Clear Care (Alcon) for cleaning and disinfecting, and 0.9% preservative-free saline vials to fill the bowl of the lens prior to application. After lens removal, she often used artificial tears to improve comfort and dryness symptoms.

Her entering distance visual acuity (VA) with the habitual lenses was 20/20 OD and 20/20-3 OS. There was no over-refraction over her scleral lenses. Adequate central tear reservoir clearance was noted along with the expected transitional zone (limbal) clearance and impingement in each eye at the nasal and temporal edge landings. Her manifest refraction results were OD -6.25 -3.75x034 VA 20/20 and OS -7.00 -2.00x143 VA 20/30. Her simulated keratometry values from topography were OD 45.91/47.83@109 and OS 45.66/47.73@062.

Entrance testing was within normal limits. Slit lamp evaluation revealed temporal scarring in each eye and nasal scarring OS only. There was mild vessel encroachment OD, OS. An elevated pinguecula was present nasally and temporally OU, with the nasal area more advanced in each eye. The dilated fundus evaluation was within normal limits OD, OS.

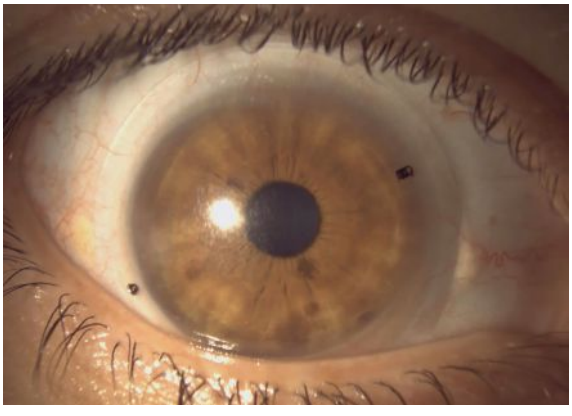

Fig. 1. The right eye initial scleral lens fit before further adjustments to landing and modification were added.

FIT ASSESSMENT

Since the patient was a previous scleral lens wearer fit in our clinic, we elected to modify the habitual lenses to fit the eye and elevated pinguecula present better (*Figure 1*). The landing zones were flattened OU for a new initial pair of lenses.

After wearing the new pair for two weeks, the patient followed up with symptoms of fogging, which subjectively worsened after a few days of wear. Upon slit lamp exam, the lenses wetted well, but there was evident tear reservoir debris OU with impingement at the end of the landing zone adjacent to each pinguecula. This impingement stained with lissamine green in each eye (*Figure 2*). New lenses were ordered with less central tear reservoir clearance OU, a steeper limbal vault and the addition of toric peripheral curves to improve the fit around each pinguecula.

Fig. 2. Left eye with initial lens removed to reveal lissamine green staining at area of conjunctival hypertrophy adjacent to nasal pinguecula.

Upon follow-up on these lenses, the patient noted improvement in lens fogging and comfort, but there was still evident impingement at the lens edge. The landing zone was flattened further, which improved the patient's symptoms. She reported being fairly comfortable in the lenses and the impingement appeared improved, but there was still persistent staining after

lens removal. Flattening the landing zone even further resulted in mild lens awareness, so the penultimate pair was notched. The final lens parameters were OD: 7.46/4187/-4.75/15.0 Atlantis Toric PC (std/double steep) and OS: 7.54/4102/-3.75/15.0 Atlantis Toric PC (std/double steep). Both lenses were Boston XO material with ice blue color.

NOTCHING PROCESS

A permanent marker was used to directly indicate the region of the scleral lens that required notching while the lens was on-eye, after a period of settling.[2] The notching procedure followed the style of that seen in an online educational video presented by Daddi Fadel, DOptom, and also that outlined in an article by Patel et al.[4,5] Care was taken to prevent sustained contact between the lens and the rotary tool to avoid excessive heat formation and lens damage or warpage (*Figure 3*). The resulting notch was then polished and rinsed prior to checking the fit on-eye. The patient was advised of where the existing markings should sit for each lens when applying it to the eye to facilitate optimal placement of the notches (though, in theory, the toric peripheral curves should help align the lens as well).

Fig. 3. Hand-notching the scleral lens in-office using a corded rotary tool. The area to be notched was marked on-eye prior to being removed for the modification.

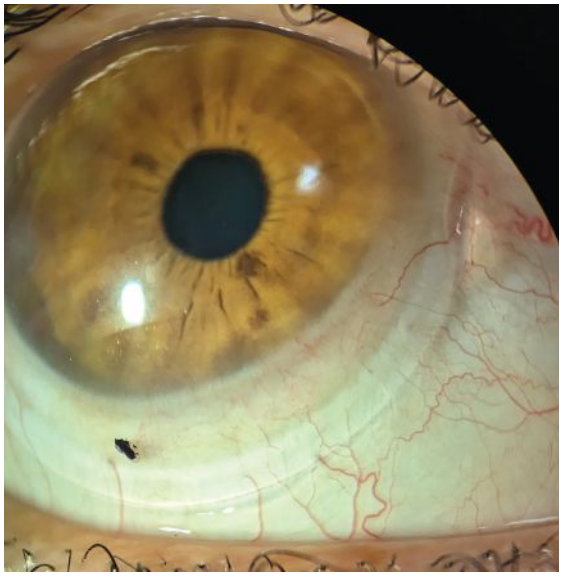

Fig. 4. Right scleral lens after completion of the notching process. Note the nasal recess allowing for less compression near the pinguecula.

CAUTIONS

It is important to ensure that when hand-notching a lens, the notches are the proper size so that the scleral lens remains sealed to prevent entry of debris and/or air bubbles (*Figure 4*).[5] The technique also has the potential to result in lens breakage or to leave rough edges behind if not properly polished. Of course, there is also the risk that the lens does break (either during notch formation or any time afterward), and then you would need to order a new lens and re-create the notch by hand again.

This technique could be especially useful for patients with an existing lens that needs adjustment, or for patients who have a budget that precludes the addition of specialized notches or vaults to a new lens. Before undertaking this technique with a patient's existing lens, I highly suggest devoting some practice time to marking and notching a few "test" lenses from those you may have otherwise discarded. This will help you get a feel for the amount of pressure needed and the way your rotary tool and accessories will behave in this use case. RCCL

Special thanks to Heather Durkee, consultant at X-Cel Specialty Contacts, for her assistance with this case.

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Sudden Pop-up of Hydrops

Are we seeing more cases today in patients with keratoconus? If so, why?

I have always been fascinated by this rare complication of keratoconus, and recently it has come up more frequently in my practice. Hydrops, a complication of corneal ectasia, presents as a sudden onset of corneal edema following a rupture of Descemet's membrane and endothelium, leading to an influx of aqueous humor into the stroma.[1] Overall, acute corneal hydrops is exceedingly rare, but do consider differentials such as infectious keratitis, uveitis, post-surgical trauma, endothelial dysfunction and acute transplant rejection episodes.[1]

Along with a history suggestive of a sudden loss of acuity, a slit lamp examination is often all that is needed to make a diagnosis. However, anterior segment OCT, *in vivo* confocal microscopy, ultrasound biomicroscopy and tomography can also help (*Figure 1*).[1,2]

The rate of acute corneal hydrops ranges from 0.2% to 2.8% in keratoconus and other non-inflammatory thinning disorders, more commonly seen in ages 20 to 40 and doubly so for males.[1-3] Risks for acute hydrops include eye rubbing, elevated IOP, steep corneas, Down syndrome and corneal variances, such as stromal thinning, hyperreflective abnormalities and absence of scarring.[1-3] Patients typically present with a spontaneous decrease in acuity as well as pain and light sensitivity precipitated by coughing, sneezing, nose blowing and other activities that can increase IOP.[2] To minimize risk, tell patients to avoid eye rubbing, treat their allergies and reduce chance of thinning and steepening in keratoconus early with crosslinking, when appropriate.

PECULIAR COMBINATION

It's simply an observation, but I have documented three new cases of acute corneal hydrops in my scleral lens wearers with keratoconus in the past seven months compared with two new cases in the past decade. I'm not suggesting scleral lens wear is causative, but with this uptick, scleral lenses are all that's changed *for me*. Still, it's interesting that my last three patients have all been neophytes younger than 40 with no previous scarring. Might these lenses in some fashion increase risk for acute hydrops in a select group?

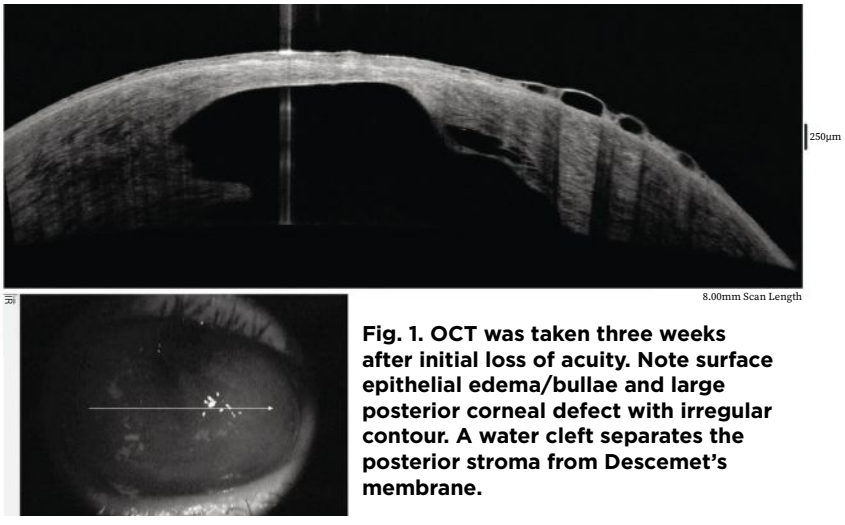

Fig. 1. OCT was taken three weeks after initial loss of acuity. Note surface epithelial edema/bullae and large posterior corneal defect with irregular contour. A water cleft separates the posterior stroma from Descemet's membrane.

In a case series, hydrops was noted in several patients who developed ectasia following penetrating keratoplasty. The authors suggested scleral lens wear played some role in that.[5] Maybe new wearers may not fully grasp how to insert and remove without inducing some trauma. Regardless, counsel patients to not rub, massage or even touch their eyes and constantly assess for any precipitating mechanisms for IOP elevation.[2] Also, emphasize caution in avoiding hard suction on lens removal.

If hydrops occurs, manage patients carefully. Its pathophysiology, time to resolution and ultimate outcome can vary widely. Topical remedies include steroids, cycloplegia, hypertonics, IOP reduction agents and antibiotic prophylaxis. Eye patching and IOP reduction is helpful with a nonperforation positive Seidel sign.[4] Surgical options include pneumatic descemetopexy for reattachment with air/gas, compression sutures to reapproximate Descemet's membrane, as well as endothelial, anterior lamellar and penetrating keratoplasties.

Am I just imagining this increase or is it truly happening? Are you seeing more hydrops now compared with years past? I'd love to hear from you. RCCL

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Today's patients are always on, all the time. Americans spend many hours a day on digital devices, with more than half using two or more devices simultaneously.[1] All that time looking at digital screens takes a toll on the eyes, as 59% of people report experiencing symptoms of digital eye strain.[1] Eye tiredness and dryness are two key symptoms associated with digital eye strain.

Patients want solutions and you play a vital role in prescribing a lens to keep up with today's lifestyles. And now you can with a groundbreaking new 1-day contact lens for all spherical wearers that provides extraordinary comfort,[2] and may help reduce eye tiredness[3] and dryness even when viewing digital devices—CooperVision MyDay Energys® contact lenses.

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In a clinical study, patients agreed that when wearing MyDay Energys®, their eyes stayed comfortable and relaxed throughout a day of frequent digital device use.[2] Wearers also agreed that MyDay Energys® made their eyes feel less tired[3], and their vision less blurry.[4]

MyDay Energys® is the first and only 1-day contact lens combining innovative aspheric design and material technology to help tiredness and dryness associated with digital eye strain. Its unique combination of features is fit for today:

DigitalBoost™ - An innovative single vision aspheric lens design that delivers a +0.3D boost of power, which helps reduce eye tiredness associated with digital eye strain.

Aquaform® Technology - An advanced material technology that hydrates contact lenses to twice their weight in water[5] for natural wettability and incredible comfort, helping eyes feel less dry, even during times of reduced blinking.

UV Blocker* - Built-in UV blocker helps protect eyes against the transmission of harmful ultraviolet rays.

MYDAY ENERGYS® COMES TO MARKET AS DEMAND FOR 1-DAY SIHY LENSES CONTINUES TO INCREASE.[6]

"Since we launched our inventive Biofinity Energys® monthly contact lenses to help eye care professionals address the challenges of digital eye strain, we've looked to provide the same advantages in a 1-day lens. Through our commitment to continuous innovation and a relentless vision to grow the value of contact lenses for fitters and patients, that day is here," said Michele Andrews, OD, Vice President, Professional and Government Affairs, Americas, CooperVision.

Dr. Michele Andrews

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MyDay Energys® is the newest addition to CooperVision's popular MyDay® family, which includes sphere, toric and multifocal contact lenses. MyDay Energys® can provide vision correction for 99.9% of spherical prescriptions.[7]

"With the high performing MyDay® portfolio, you can fit so many patients between the sphere, the expanded toric parameters, and the multifocal," said Sahil Dosaj, OD, who practices at Miller Optometry in Yucaipa, Calif. *"Now, MyDay Energys® is another option with additional benefits we can offer to all of our sphere patients. Everyone uses digital devices, so with many sphere wearers—this is the lens for them."*

Dr. Sahil Dosaj

PARAMETERS

Power Range	Base Curve	Diameter	Dk/t
+8.00D to -12.00D (0.50D steps after +5.00D and -6.00D) No Plano	8.4mm	14.2mm	100

LEARN MORE

Get ready to deliver extraordinary comfort[4] for "ALWAYS-ON" lifestyles with MyDay Energys®.

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*Warning: UV-absorbing contact lenses are not substitutes for protective UV-absorbing eyewear, such as UV-absorbing goggles or sunglasses, because they do not completely cover the eye and surrounding area. Patients should continue to use UV-absorbing eyewear as directed.

1 Vision Council 2019. The Vision Council shines light on protecting sight and health in a multiscreen era. https://thevisioncouncil.org/blog/vision-council-shines-light-protecting-sight-anhealth-multi-screen-era. Accessed 19 July 2022. **2** CVI data on file 2018. Prospective, multi-center (5 US sites), open label, bilateral wear, one week dispensing study with MyDay Energys. N=77 habitual soft CL wearers. 75% of patients slightly agree/agree/strongly agree. **3** CVI data on file 2018. Prospective, multi-center (5 US sites), open label, bilateral wear, one week dispensing study with MyDay Energys. N=77 habitual soft CL wearers. 80% of patients agreed when asked "CLs make my eyes feel less tired" (slightly agree/agree/strongly agree). **4** CVI data on file 2018. Prospective, multi-center (5 US sites), open label, bilateral wear, one week dispensing study with MyDay Energys. N=77 habitual soft CL wearers. 74% of patients agreed when asked "CLs make my vision less blurry end of day, even after a long day using digital devices" (slightly agree/agree/strongly agree). **5** CVI data on file 2022. **6** CVI data on file Q4 2022. US Industry reports and internal estimates. **7** CooperVision data on file 2020. Rx coverage database n=120,406 eyes for Rx with <0.75DC; 14 to 70 years.

COMING IN AUGUST

SECOND ANNUAL

Supplement to *Review of Optometry*

Practical Matters in Myopia Management

Proven strategies from experts to help you build confidence and improve your success rate.

As optometrists continue to embrace myopia interventions, they need concrete guidance on best practices for this new area of care. Questions of patient selection, treatment efficacy, parent "buy-in" and the practice's equipment needs can be a deterrent to enthusiasm among ODs. This supplement will guide optometrists through many of the practical challenges that might otherwise prevent them from pursuing myopia management.

Topics:

- **Myopia Management: What Does Success Look Like?**
- **All About Atropine: Do's, Don'ts and Debates**
- **Curtailing Myopia Progression with Corrective Lenses**
- **Anti-Myopia Efforts Patients and Parents Can Try Today**

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By Becky Su, OD, Marcus R. Noyes, OD, and John D. Gelles, OD

Keepin' It Simple(ish)

Here's a case in which mild irregularity allowed for soft toric multifocal success.

A 49-year-old female presented to the clinic with a history of keratoconus OD>OS. The patient had worn standard soft multifocal lenses in the past but discontinued them due to vision fluctuation and dryness. Her goal was spectacle freedom, and any glasses were unacceptable.

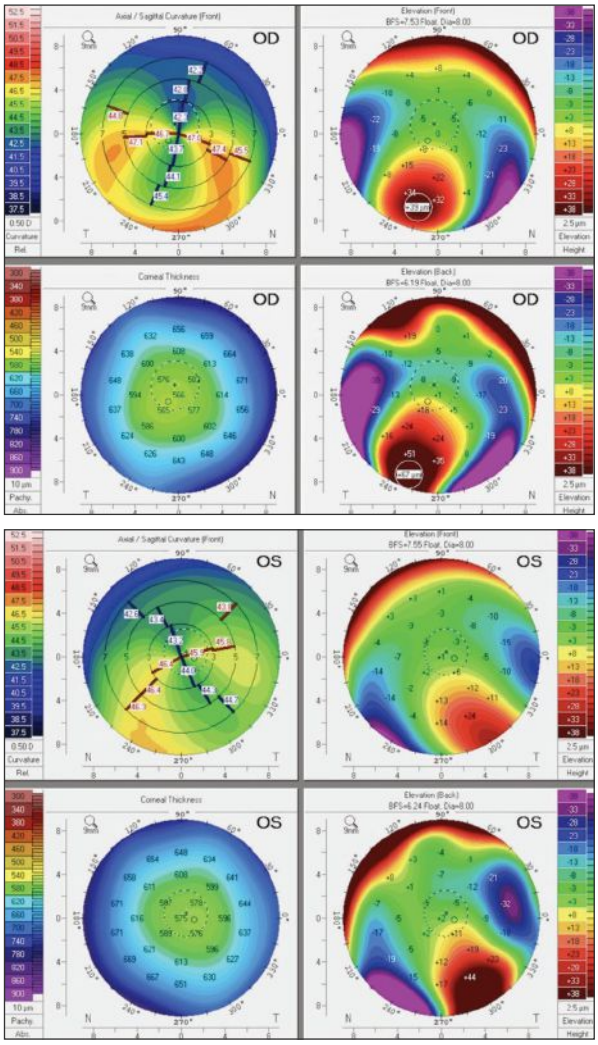
On initial presentation, uncorrected visual acuity was 20/70 OD and 20/40 OS, best-corrected to 20/20 at distance and near in each eye with a manifest refraction of +2.00 -3.75x085 OD and +1.75 -3.25x100 with a +1.00 add OS. Scheimpflug tomography (Pentacam Wave AXL, Oculus) showed an inferior-to-superior ratio of less than 5.00D in each eye and maximum keratometry readings of 48.00D and 46.90D in the right and left eyes, respectively. On slit lamp evaluation, there was no significant corneal haze, scars or thinning in either eye. The conjunctiva was white and quiet without any considerable surface elevations.

CONSIDERATIONS

Here, we highlight our thought processes and consider how each of us would proceed:

Dr. Su: In this case, the patient has a pellucid-like pattern, with a minimal inferior-to-superior ratio, correctable to 20/20 with manifest refraction. These patients are generally very successful with soft contact lenses. Unlike standardized soft lenses, custom soft lenses can be a great option as they are not limited to the constraints of the average cornea. Fit parameter customization and lens thickness manipulation that mask corneal irregularities can provide better comfort, lens stability and visual acuity. Furthermore, some custom soft contact lenses can add customized multifocal optics, which have the advantage of customized near-zone diameters for small-pupil patients or in circumstances where standard designs and optics underperform.

Since this patient has failed standard soft multifocal lenses before, it is likely the fitting relationship between the eye and lens was not ideal, and the lens optics did not align well with the patient's line of sight. Custom soft lenses with a multifocal design would be a great start since she has a low add power that may allow for easier adaptation. Another option would be continuing with a custom soft option that allows for optimal centration and comfort given her corneal shape irregularity, but with monovision optics for blended vision.



Corneal tomography of the patient's right (top) and left eyes (bottom).

Dr. Noyes: When you have a topography reading that confirms ectasia, it can be easy to slip into the "specialty lens mindset." Most of us immediately think, "RGPs! Sclerals! Hybrids! Oh my!" but this patient can be corrected to 20/20 with a manifest refraction, meaning glasses and soft lenses are still on the table. It is completely reasonable to start a patient like this with soft lenses, custom soft lenses or even spectacles. Of course, you should monitor the ectasia and corneal changes, but you can always switch to a specialty lens later if needed.

Dr. Gelles: Keep it simple. If the manifest provides 20/20 vision and soft lenses are stable and center well without edge lift or fluting, there should be a simple, ideal option. When we see any irregularity, we often jump to something more

customized and rigid; certainly, some eyes will need more complex designs, but try something simple first. Should a soft lens fail, alternatives for this patient can include corneal GP or hybrid lenses. To address the near vision demands, monovision or a multifocal should work well, especially in early presbyopia, as the disparity in monovision or induced spherical aberration in a multifocal is very small.

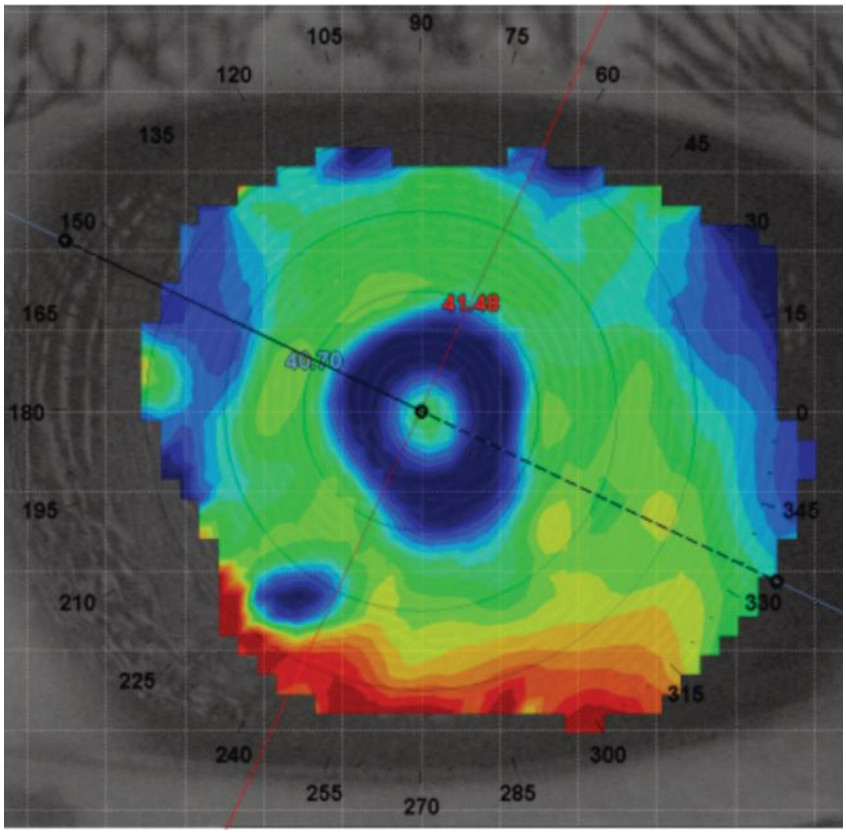
Also, a highlight of this case, pellucid topography patterns (kissing doves, crab claws, croissants and all the other cute names we like to give them) don't necessarily mean pellucid marginal degeneration (PMD). The factor that matters most when differentiating PMD from keratoconus is where the thinning is located. If it is next to the limbus, you have PMD.

Another pearl is to evaluate the pupil and the topography relationship and whether the irregularity is over the pupil. In this case, the topography over the pupil is essentially regular astigmatism, which is why the patient corrects so well. Since the pupil is small, it is unlikely that the irregularity, which is so peripheral, will contribute much to the patient's visual quality.

DISCUSSION

Most standardized multifocal soft contact lenses have a standard distance and near-zone size. These lenses do not always center perfectly on the eye, which can cause inadequate distance and near vision. With the added difficulty of fitting an irregular cornea, the decentered optics can also induce even more aberrations, further reducing visual quality.

Custom multifocal soft contact lenses can be successful with customized parameters such as diameter (OAD) and base curve (BC) to improve the fitting relationship and customized optics such as distance, intermediate and near power and optic zone size parameters—even optic zone decentration—to align the lens optics with the line of sight. The extensive power profiles and customized fitting parameters allow eyecare practitioners the complete freedom to design a lens with excellent optics at all distances for hard-to-fit presbyopic patients.



Over-lens topography of the left eye showing appropriate alignment with multifocal optics with the line of sight. Tangential map scaled to accentuate the multifocal.

RESULTS

The patient was fit with a custom multifocal toric (Revive, Bausch + Lomb) soft lens with the following lens parameters: BC 8.5mm, OAD 14.50mm, power +1.75 -3.75x085 OD; BC 8.5mm, OAD 14.50mm, power +2.00-3.25x100 OS. The add was +1.00 in a near-centered design with a 2.20mm central near-zone diameter. Her best-corrected visual acuities were 20/20 OD, 20/20 OS and 20/15 OU, and she reported clear, comfortable vision at distance, intermediate and near. RCCL

Dr. Su is the Cornea and Contact Lens Fellow at the Cornea and Laser Eye Institute (CLEI) Center for Keratoconus in Teaneck, NJ. She has no financial interests to disclose.

Lessons Learned at ARVO 2023

A review of 16 intriguing and clinically practical cornea and contact lens research papers presented at this year's meeting.

By Review of Optometry/RCCL Staff

Each year, the Association for Research in Vision and Ophthalmology (ARVO) annual meeting gifts the eyecare profession with a cornucopia of new research that lets us see where the winds are blowing clinically. Here, we've compiled research specific to cornea and contact lens care we feel may be most impactful for practicing optometrists.

This year's meeting was held in New Orleans from April 23-27. The theme of ARVO 2023 was "the beauty of diversity in science and nature." The findings summarized here are only a snippet of those presented at the meeting, of course, but show the rich expanse of insights ARVO generates each year.

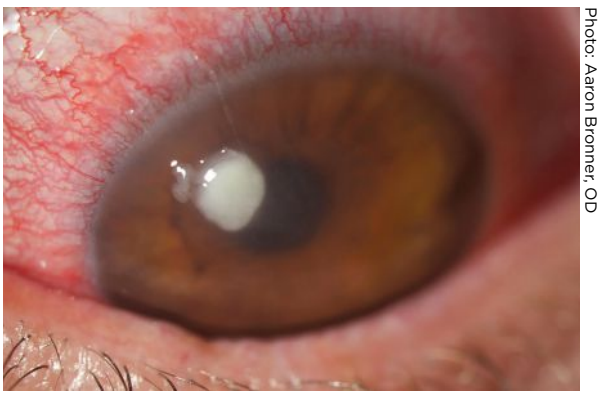


Photo: Aaron Bronner, OD

Staphylococcal infections demonstrated greater susceptibility to even some older medications in the newest ARMOR study.

CORNEA

This year's presenters highlighted a host of new and exciting research from the last 12 months focused on this part of the eye.

• ***Latest ARMOR study updates show multidrug resistance remains common.*** Treating ocular infections is hard enough as is when the drugs work as advertised, and so much the worse when the offending microorganism is resistant or only weakly susceptible to therapy. Staphylococci are known causative pathogens in ophthalmic infections, and antibiotic resistance among these bacteria is of clinical concern. The long-running Antibiotic Resistance Monitoring in Ocular micRoorganisms (ARMOR) Study, the only nationwide surveillance study of its kind, captures *in vitro* data specific to common ocular pathogens. The team's two research posters noted that, with preliminary data indicating lower resistance rates especially among *Staphylococcus aureus*, multidrug resistance was common among methicillin-resistant strains.

One analysis reported on 2022's data, when 397 isolates were collected January through October of that year.[1] *Staphylococcus aureus*, coagulase-negative staphylococci (CoNS), *Streptococcus pneumoniae*, *Pseudomonas aeruginosa* and *Haemophilus influenzae* from ocular infections were collected as part of ARMOR and submitted to a central laboratory for species confirmation and *in vitro* antibiotic susceptibility testing. Minimum inhibitory concentrations for up to 16 antibiotics (10 drug classes) were determined and interpreted.

The 142 CoNS isolates exhibited the highest resistance, with azithromycin, oxacillin/methicillin, trimethoprim, clindamycin and tetracycline resistance observed in 60%, 37%, 28%, 27% and 22% of isolates, respectively. Among the 161 *S. aureus* isolates, 46% were resistant to azithromycin, but <20% of isolates were resistant to other drugs. Multidrug resistance (poor or ineffective response to three or more drug classes) was observed in 14% of *S. aureus*, 39% of CoNS and in 59% and 88% of methicillin-resistant strains thereof, respectively.

Among the five *S. pneumoniae* isolates, 60% were resistant to azithromycin, oral penicillin and tetracycline. Although all 72 *P. aeruginosa* isolates were resistant to polymyxin B, <5% were resistant to other drugs; no resistance was found among the 17 *H. influenzae* isolates.[1]

"The clinical significance of these *in vitro* data is unclear without consideration of the ocular pharmacokinetics of tested antibiotics," the researchers concluded in their abstract.[1]

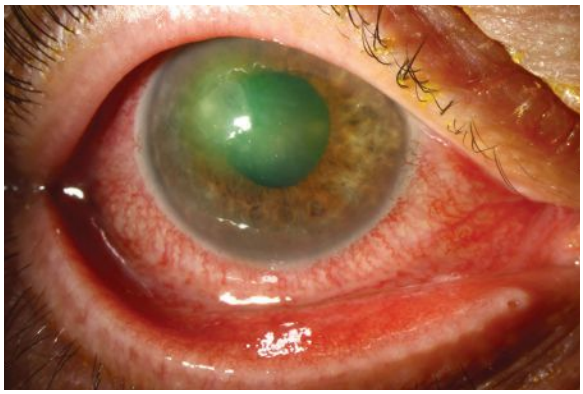


Photo: Christine Sindt, OD

Patients with treatment failure were more prone to have polymicrobial, *P. aeruginosa* (shown here) or fungal infections.

The team's other study examined resistance trends over time among staphylococcal isolates collected from 2009 through 2022 in ARMOR. A total of 2,999 *S. aureus* and 2,575 CoNS were included in their analysis.[2]

In vitro resistance decreased to methicillin/oxacillin (*S. aureus*, 39% in 2009 to 18% in 2022; CoNS, 50% in 2009 to 37% in 2022) and to ciprofloxacin (*S. aureus*, 39% in 2009 to 17% in 2022; CoNS, 46% in 2009 to 20% in 2022). Also, among *S. aureus*, resistance to azithromycin decreased (62% in 2009 to 46% and 9% in 2022), as did resistance to tobramycin (24% in 2009 to 9% in 2022); in contrast, an increase in chloramphenicol resistance was observed (7% in 2009 to 3% in 2022, peaking at 30% in 2021). Cumulative multidrug resistance (three or more antibiotic classes) was observed in 30% of *S. aureus* and 41% of CoNS and in 76% and 79% of methicillin-resistant isolates thereof, respectively.

The researchers also noted that resistance data should be considered in combination with known ocular pharmacokinetics of antibiotics. However, this time they emphasized that practitioners should also consider resistance data when selecting empirical treatment for staphylococcal eye infections in particular.[2]

• Age, smoking history, Pseudomonas among risk factors infectious keratitis treatment failure. In a retrospective study conducted at the University of Rochester, researchers examined patient demographics, systemic and ocular comorbidities and microbial data to determine which factors, if any, are associated with infectious keratitis.[3]

The study included 407 patients with infectious keratitis who had clinical follow-up documentation of at least two weeks after diagnosis. Treatment failure was defined as having no clinical improvement within two weeks of initial presentation and/or needing surgical intervention of corneal gluing, patch grafts, transplants or evisceration of the eye.

A small proportion (15.2%) of the 407 participants experienced treatment failure. However, of this group, 58.1% needed surgical intervention. After looking at the different data, researchers found higher rates of *Pseudomonas aeruginosa*, fungi and polymicrobial cultures. Other risk factors associated with treatment failure were age greater than 65, systemic immunosuppression and history of smoking.

Ocular history associated with treatment failure included previous corneal transplant, previous transplant rejection, topical steroid use, intraocular surgery history and a visual acuity of 20/250 or worse. Higher rates of prescribed fortified antibiotics were given, and more bandage contact lenses were used in patients with treatment failure during treatment.

As such, the authors noted that many different ocular and other factors put patients at risk of treatment rejection for infectious keratitis. They believe that "this study improves our understanding of infectious keratitis by identifying key prognostic indicators of treatment failure for this blinding disease," according to their ARVO abstract.

• Fuchs' questionnaire identifies modifiable lifestyle risk factors. Though it's primarily a genetic condition, Fuchs' corneal endothelial dystrophy shows some response to several lifestyle factors may also play a role in the disease onset, according to one study. Identifying potentially modifiable risk factors for severe Fuchs'—which requires corneal transplantation—may inform patient counseling for those most at risk.[4]

The researchers developed a Fuchs' dystrophy questionnaire (link available online) to assess disease-specific medical history and lifestyle risk factors such as obesity, alcohol use, smoking and sun exposure. The questionnaire was administered to a prospective cohort of patients with Fuchs' dystrophy who also had an indication for endothelial keratoplasty. These patients underwent slit lamp biomicroscopy with modified Krachmer grading to determine guttae confluence and visible corneal edema.

The questionnaire had an 82% response rate from 375 total participants. The mean age at endothelial keratoplasty was 68 years for both sexes.

No differences in corneal edema incidence were found between smokers and non-smokers or between those with frequent alcohol intake (≥two days/week) and non-frequent

drinkers. Interestingly, men were 1.42-times more likely to have corneal edema before endothelial keratoplasty than women, even though more females undergo keratoplasty.

Skin type may also be an indicator of risk. Participants who reported taking strict sun protection measures within minutes of exposure were 1.44-times more likely to have corneal edema than those with an hour or more of unprotected sun exposure. "A possible explanation of increased risk of corneal edema in participants with strict sun protection compared with those without might be that photosensitive skin types are more relevant than direct sun exposure," the researchers wrote in their abstract.

Finally, for every five-unit increase in BMI, corneal edema was 1.26-times more likely at endothelial keratoplasty but not for a higher BMI at age 21. The researchers wrote that "interventions to reduce obesity in adulthood may modify the risk of Fuchs' dystrophy severity independent of age, sex and weight in adolescence."

• ***Autoimmune disease associated with superior epithelial thinning.*** Previous studies have shown that patients with dry eye disease (DED) display thinner superior corneal epithelium compared with normal controls. Researchers recently tested their hypothesis that presence of autoantibodies has been associated with superior epithelial thinning.[5] They also assessed the link between corneal epithelial thickness and clinical findings and assessed the utility of including corneal epithelial thickness as a diagnostic tool for patients with DED.

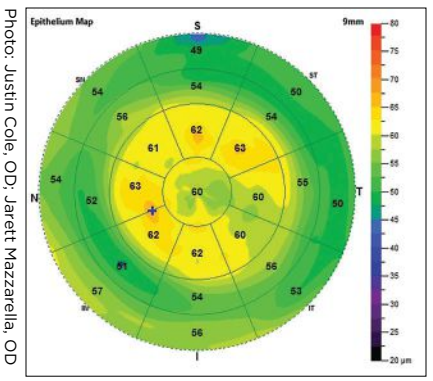


Photo: Justin Cole, OD; Jarett Mazzarella, OD

If a patient's eye has both superior corneal epithelial thickness <45µm and Schirmer's test result <10mm, they are five times more likely to have antibody-positive bloodwork and associated visual compromise.

This study included 208 patients who visited the DED clinic at University of Illinois Chicago and had bloodwork results in their medical records for autoantibodies associated with DED-related autoimmune diseases. If available, superior corneal epithelial thickness, Schirmer's 1 test and corneal higher order aberrations (HOAs) were obtained from the patient's medical records. Superior corneal epithelial thickness was determined with the RTVue XR OCT Avanti (Visionix) system, and corneal HOAs were determined using the iTrace (Tracey Technologies) system. A decision tree was used to determine feature variables and cutoffs necessary to accurately classify antibody positive and negative groups.

The researchers found that patients with antibody-positive bloodwork had a significantly thinner superior corneal epithelial thickness (47.41µm vs 49.73µm) compared with patients with antibody negative blood work (n=181 eyes).

The top two most useful clinical indicators that a patient will have antibody-positive bloodwork are a Schirmer's <15mm and an epithelial thickness <45µm. Eyes with epithelial thickness <45µm and Schirmer's <10mm (n=69 eyes) have significantly greater corneal HOAs (1.85 vs. 0.1) compared with eyes with thickness ≥45µm and/or Schirmer's ≥10mm (n=164 eyes). If a patient's eye had both superior corneal epithelial thickness <45µm and Schirmer's test results <10mm, the probability that they have autoantibody-positive bloodwork was 81.2%.

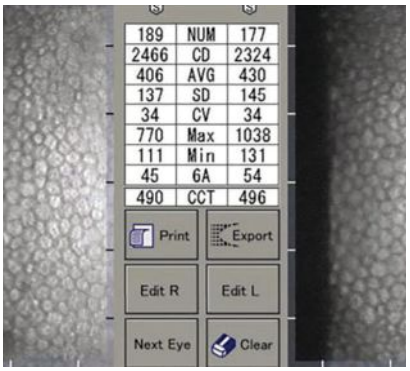


Photo: Daniel Epshtein, OD

Reduced corneal endothelial density could be expected in eyes that develop myopia, one study suggests.

"Presence of autoimmune disease must be considered in patients who have superior epithelial thinning and reduced tear production because these patients are five-times more likely to have antibody-positive bloodwork and associated visual compromise, as demonstrated by high corneal HOAs," the researchers concluded.

• ***Myopia could affect corneal endothelial morphology.*** Researchers recently observed greater polymegethism and pleomorphism in healthy eyes with wider mean anterior chamber angle.[6] This implies that the corneal endothelial quality tends to be poorer in eyes with wider anterior chamber angle. These eyes are more likely to be myopic, and myopic corneas may be more fragile and more susceptible to mechanical stress.

The study evaluated 272 eyes of 136 Caucasians. Mean age was 46.8, and 61% were men. Significant associations were shown between corneal volume, mean anterior chamber angle, white-to-white distance and age with the morphology of the corneal endothelium. Greater polymegathism was found in older individuals, and greater pleomorphism was found in adults with greater white-to-white distance.

Statistical modeling of the data revealed that mean ECD (2,673.61 cells/mm^2) was positively correlated with

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corneal volume (59.43mm^3). After adjusting for age, it was only negatively correlated with age. The coefficient of variation of cell area (28.6%) was positively correlated with mean anterior chamber angle (35.1°). After adjusting for age, the correlation was stronger. Hexagonal cell appearance ratio (67.5%) was negatively correlated with white-to-white distance (11.8mm) and mean anterior chamber angle, and after adjusting for age, this correlation remained the same.

The researchers noted that the exact mechanism by which myopia could cause corneal endothelial morphology change needs to be further studied. "Presumably, the endothelial surface area will increase as the axial length elongates and the anterior chamber deepens if the limbal dimension does not change," they proposed. "Because there is no mitotic activity in the corneal endothelium after birth, it is thus conceivable that the corneal endothelial cells will have to flatten to cover the enlarged surface. Subsequently, a reduced corneal endothelial density could be expected."

• ***Vitamin abnormalities common in neuropathic corneal pain***. The role of abnormal vitamin D and B levels in various neurological conditions has previously been established. However, to date, the relationship between vitamin levels and neuropathic corneal pain (NCP), a condition characterized by abnormal nerve function, has not been studied. Researchers explored these vitamin abnormalities as a possible underlying etiology in NCP.[7]

"Our findings indicate that vitamin abnormalities are common in patients with NCP, specifically low B2, high B6 and low vitamin D," the investigators wrote in their abstract. "High vitamin B6 levels was one of the most common findings, supporting literature that B6 toxicity may lead to neuropathy. Vitamin D deficiencies are more common in patients 18 to 30 years and in males."

The retrospective study included 84 patients with NCP. Most participants (age: 40.8 years) were female (65.5%), white (77.4%) and of non-Hispanic or Latino origin (82.1%).

At least one vitamin abnormality was found in 52.4% of patients, most common being low B2 (31.0%), high B6 (28.9%), high B12 (15.0%) and low vitamin D (15.8%). Males had higher odds than females of having a vitamin D3 deficiency (OR: 4.5). The predictive value of having a vitamin D3 deficiency decreased as age increased (OR: 0.9). Specifically, patients aged 18 to 33 had higher odds of having vitamin D3 deficiency (OR: 4.89). No category of race was at greater risk for a vitamin abnormality, and no demographic group was at greater risk for a vitamin B abnormality.

"Serology testing may help treat underlying conditions early, especially in males under 33," the team concluded. "Investigating changes in clinical findings/pain after treating abnormal levels would further illustrate the role vitamins play in NCP."

• ***Corneal hydrops found more prevalent in younger KCN patients***. A study by Cleveland-based researchers covered the lifetime prevalence of acute corneal hydrops in keratoconic eyes one-year post-treatment of corneal collagen crosslinking (CXL) or contact lenses (CLs).[8]

The retrospective study collected data from electronic health records to identify keratoconic patients and their initial treatment modality: either CXL or management with CLs. The primary outcome was acute corneal hydrops incidence after one year of treatment due to complications from continuing unstable keratoconus despite treatment.

Keratoconus was found in 32,141 patients. Of those, 12.1% chose to manage the condition with CLs, and 3.1% patients underwent CXL treatment. On average, CL patients were older, female and Black. Of those managed with CLs, 16 patients (0.4%) developed corneal hydrops one year after treatment compared with 10 CXL patients (1.0%). Though the aggregate numbers are small, this suggests a higher rate of hydrops development in this group.

The researchers determined that CXL patients possessed a higher absolute risk and likelihood of developing lifetime incidence of corneal hydrops. Along with this, the CL-managed group displayed greater event-free survival probability of hydrops over time relative to the CXL group. Additionally, the contact group had a lower hazard rate.

However, as Julie Song, OD, of SUNY College of Optometry, notes, the study's results are somewhat misleading due to the age of each subgroup population. The patients managed with CLs were on average 15 years older than those in the CXL group, with average ages of 44 and 28, respectively. Keratoconic eyes tend to stabilize around age 40, she points out, which may be why hydrops prevalence was lower in the older age group.

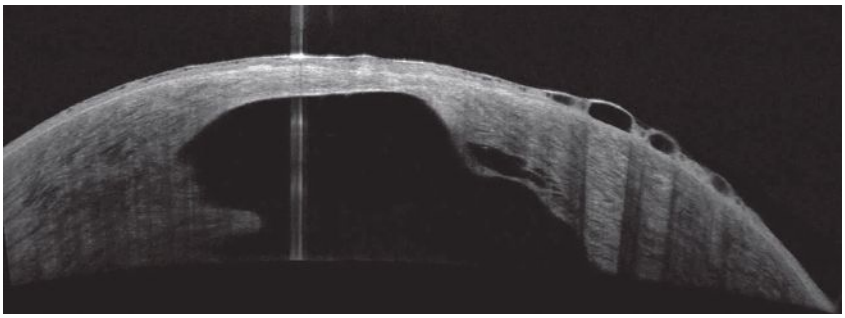

Photo: Joseph Shovlin, OD

One study investigated higher rates of corneal hydrops development in keratoconus, finding it more prevalent in younger patients.

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The younger CXL group was "in the age range of patients who are still susceptible to natural keratoconic progression," which is likely a contributing factor to greater hydrops incidence, Dr. Song says. She adds that "patients who tend to undergo CXL are often patients who are already identified as having progression in their keratoconus, which is why they were referred to undergo the procedure to begin with."

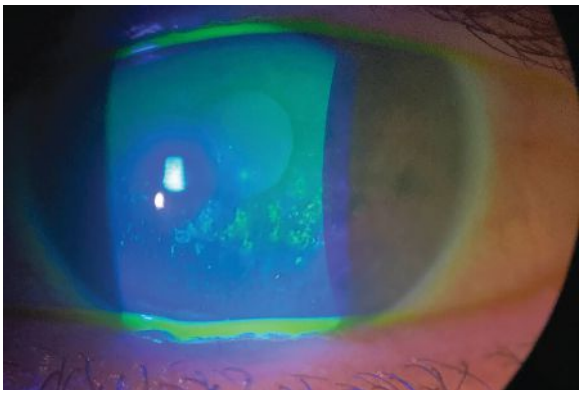


Photo: Pam Theriot, OD

The tear film may be disrupted by skin oils, which can lead to a faulty tear film and dry, irritated eyes.

Although acute corneal hydrops is displayed here as a rare complication in both groups, the authors relay that "clinical significance remains unclear, as acute corneal hydrops represents a rare lifetime complication in both cohorts, and patients managed with CXL may be at higher risk for complications in general."

The authors also noted that several factors must be considered when managing keratoconus, as Dr. Song echoes, and that corneal hydrops typically spontaneously resolves within two to four months along with conservative management.

OCULAR SURFACE

Several groups of researchers presented findings of the latest studies on the treatment and management of the most common patient-reported ocular surface complaint: dry eye.

• Use of several systemic meds associated with worse DED. Many systemic medications have been reported to be associated with DED, yet their associations with the severity of DED are not well studied.[9] Researchers recently evaluated whether various classes of systemic medications are associated with the severity of DED signs and symptoms via secondary analysis of data from the Dry Eye Assessment and Management (DREAM) study, a large multicenter, randomized, placebo-controlled clinical trial of patients with moderate to severe DED.

A total of 535 patients with moderate to severe DED self-reported their current use of systemic medications. At baseline, six and 12 months, DED symptoms were assessed using the Ocular Surface Disease Index, and DED signs were evaluated through use of tear breakup time (TBUT), Schirmer's test, corneal fluorescein staining, conjunctival lissamine green staining, meibomian gland dysfunction (MGD) and tear osmolarity.

Systemic medications were categorized into the following classes: statin, proton pump inhibitor, aspirin, vitamin D3, nonsteroidal anti-inflammatory drugs, steroids, diuretics and medications for treating hypothyroidism, diabetes, hypertension, seizure and migraine. Generalized linear models compared the scores of DED signs and symptoms between users and non-users of each of these medication classes, with adjustment factors that were previously found to be associated with severity of DED in the DREAM study.

Below are some notable findings among dry eye patients taking various meds compared with non-users:

- Aspirin users had lower TBUT.
- Steroid users had lower TBUT, lower Schirmer's test scores and higher tear osmolarity.
- Seizure medication users had higher composite dry eye severity scores.
- Vitamin D3 users had lower TBUT and greater meibomian gland abnormality.
- Migraine medication users had lower Schirmer's test scores.
- Diuretic users had less meibomian gland abnormality.
- None of the meds for systemic conditions (*e.g.*, diabetes, hypertension) was associated with symptom severity.

The team concluded in their abstract that "use of aspirin, steroids, vitamin D3 and medications for seizure and migraine was associated with worse DED severity, while the use of diuretics was associated with less meibomian gland abnormality. No systemic medications were associated with DED symptom severity."

• Oily skin increases risk of dry eye. It's been proposed that meibomian lipids on the lid margin form a barrier that prevents skin lipids from entering the eye and disrupting tear film stability.[10] What happens, then, when MGD upsets this balance by reducing eyelid lipid release? Optometrist Jim Kokkinakis from Sydney described his recent investigation of the interaction. Using three volunteer subjects, Dr. Kokkinakis found that applying facial lipid samples to the ocular surface caused tear film disruption, pain, fluorescein staining of the corneal surface and meibomian gland activity. According to the author, this is the first study showing the effects of skin lipid contamination of the ocular surface.

First, the side of each participant's nose was swabbed to collect lipids found on the skin. Next, the corneal surface, eyelid margin, eyelash base or lacrimal lake were touched with either a cleaned (control) or loaded thread. Acetic acid was used as the control for low pH. Effects on the tear film were visualized using fluorescein

or TearView, a new device that shows tear film formation and stability in real time.

Both TearView and fluorescein assessment showed that minimal amounts of skin lipid applied to the cornea, eyelid margin or lacrimal lake spread and destroyed the tear film's integrity, which was not restored for several blinks. The contamination of the eye with the skin lipid sample also caused pain and staining of the corneal surface. TearView showed that introducing the skin lipid triggered meibomian lipid secretion that displaced the substance, presumably giving protection. In the control subjects, acetic acid—emulating skin pH—destroyed the tear film but did not spread from the site of touch. It caused corneal staining, and the tear film recovered with one blink. Neutral control lipids did not cause any discomfort or destroy the tear film but smeared across it during blinking. In contrast, free fatty acids had similar effects to the skin swab substance.

Tear film disruption is most likely due to fatty acids and low pH, which supports the proposed barrier function of meibum on the eyelid margin, the author explained. "This barrier would be compromised by diminished meibomian lipid secretion or excess of skin lipid secretion, which would overwhelm the lid margin barrier. Therefore, skin lipid contamination of the ocular surface might be a common factor for the cause of dry eye in various types of blepharitis, ocular rosacea and MGD," Dr. Kokkinakis concluded in his abstract.

• Dry eye emerges as side effect of endocrine therapy for breast cancer. Side effects such as fatigue, joint pain and stiffness are common in endocrine therapy to treat breast cancer.[11] Researchers evaluated another possible side effect of this treatment: dry eye.

A total of 88 women were included in the study—56 undergoing aromatase inhibitor treatment and 32 undergoing selective estrogen receptor modulator treatment. Their ages, BMIs, treatment situations and ocular symptoms were recorded. A Comprehensive Eye Surface Detector was applied to detect patients' ocular surface condition and evaluate for signs of dry eye. The Self-Rating Anxiety Scale and Hamilton Anxiety Scale was administered to evaluate patients' anxiety and depression, and levels of blood lipid and sex hormone were also examined.

Seventy-seven, or 87.5%, of the breast cancer patients had dry eye. Among this group, 11.4% received selective estrogen receptor modulator treatment and 76.1% received aromatase inhibitors. The frequencies of the clinical subtypes of dry eye were evaporative dry eye (59.7%), aqueous-deficient dry eye (23.4%) and mixed dry eye (16.9%).

Among aromatase inhibitor-treated patients with dry eye, patients under the age of 50 had significantly more prevalent subjective symptoms and objective exam results of dry eye than those of patients older than 50. All breast cancer patients had different degrees of anxiety and depression, the prevalence of which were significantly higher than patients without dry eye. The degree of anxiety and depression was related to the severity of dry eye; the higher the degree of dry eye, the greater the anxiety and depression. Age, BMI, lipid profile and sex hormone level were found to not be significantly associated with dry eye.

"Taking measures to intervene in the occurrence and development of dry eye at the initial stage of endocrine treatment for breast cancer patients may greatly improve the patients' quality of life," the authors concluded in their abstract.

• Dry eye more likely in geriatric patients with depression, anxiety. A group of researchers recently revealed an association between dry eye and the following factors: gender, age, race, geography, anxiety and depression.[12] The strongest association was noted in patients with both psychiatric disorders.

The team analyzed data of 21,059 patients with clinically significant dry eye (defined as two or more dry eye claims submitted in one calendar year) from a 5% random sample of 2011 Medicare beneficiaries in the US (average age: 75). To calculate odds ratios (ORs) between dry eye and anxiety and depression, the team used logistic regression models controlled for demographical covariates.

Compared with men, women in the cohort were 2.03-times more likely to have dry eye. Patients of Asian (OR: 1.85) or Native American race (OR: 1.51) were more likely to have a diagnosis of dry eye than their white counterparts, and Black patients were even less likely to have dry eye (OR: 0.83).

Geographic residence and age also both affected ORs for dry eye; compared with patients in the Northeast, those residing in the West were more likely to have dry eye (OR: 1.38), while patients

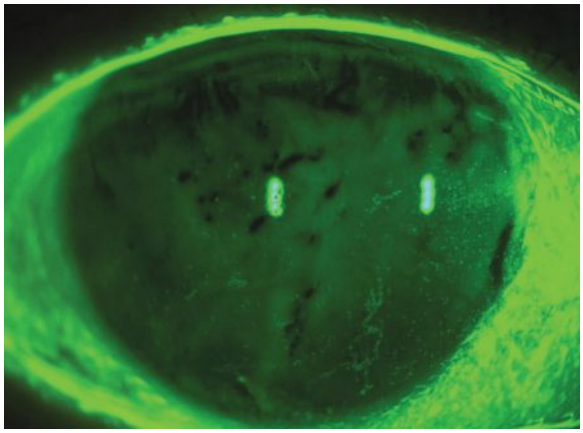


Photo: Luis Rojas, OD

Patients with anxiety and depression may be more likely to also develop dry eye.

in the Northwest were less likely (OR: 0.58). Patients aged 75 and older were also more likely to have dry eye than those aged 65 to 74 (ORs: age 75 to 84, 1.49; age 85+, 1.54).

Regarding the association between depression and anxiety and dry eye, the researchers pointed out in their abstract that "having both depression and anxiety was more highly associated with dry eye (OR: 2.38) compared with having depression (OR: 1.95) or anxiety (OR: 2.22) alone." The team concluded that "longitudinal studies evaluating the temporal relationship between dry eye and psychiatric disease are warranted."

• ***DREAM study researchers again challenge omega-3 efficacy in DED treatment.*** Several studies have investigated the potential benefit of omega-3 fatty acid supplementation in the treatment of DED. However, to date, such literature—including the widely reported DREAM study—has not provided convincing evidence that omega-3 fatty acids are effective in controlling DED symptoms or progression; rather, the pills showed results similar to the placebo.[13]

While the original DREAM study only followed patients for 12 months, researchers—again led by study chair Penny Asbell, MD—recently obtained an additional year of data from moderate to severe DED patients who had been initially randomized to receive omega-3 pills the first year. During the second year, these participants (n=43) were re-randomized to either continue with omega-3 (n=22) or switch to placebo (n=21). The team evaluated the progression of DED symptoms and signs over the two years with follow-ups at baseline, three, six, 12, 18 and 24 months.

The data showed that at three months, DED patients taking omega-3 showed significant improvements in Ocular Surface Disease Index and Brief Ocular Discomfort Index scores and less use of artificial tears or gel; however, after this period (an additional six to 24 months), DED symptoms and treatments remained stable. There were also no significant changes over two years in corneal staining, TBUT, Schirmer's test, MGD, tear osmolarity or noninvasive keratography measures in patients treated with omega-3. The only DED metric that did show a significant change in the treatment group over two years was conjunctival staining score.

The researchers explained in their abstract that the significant improvement in subjective DED symptoms in the first three months of omega-3 treatment could be chalked up to a placebo effect or regression to the mean. Due to this observation, they noted that "future clinical trials of DED should consider the short-term placebo effect of treatments on DED symptoms."

The results of this randomized follow-up study on the DREAM cohort suggest that omega-3 supplementation and observation promote comparable treatment outcomes over two years in DED patients. Additionally, the researchers concluded in their abstract that "these results do not support progression of DED over the two years of observation."

CONTACT LENSES

Let's take a closer look at some of the studies presented on this ever-evolving area of eye care.

• ***Myopia control with soft multifocals benefits all progression rates.*** Two presentations evaluated reports from the BLINK (Bifocal Lenses in Nearsighted Kids) study on multifocal CL myopia control. The first one compared myopia progression and axial elongation in children wearing +2.50D add multifocal vs. single-vision CLs to find out whether the treatment effect of optical myopia control is better for fast progressors, and results suggest that children receive a similar amount of treatment benefit from myopia control regardless of their underlying rate of progression.[14]

The BLINK study randomized 294 children between the ages of seven and 11 to wear Biofinity soft CLs for three years in either a D-design with a +2.50D add, +1.50D add (not analyzed in this study) or single-vision CLs. Cycloplegic refractive error was between -0.75D to -5.00D (sphere, inclusive) at baseline with less than 1.00D of astigmatism. Three-year myopia progression and axial elongation for single vision (n=96) and +2.50D add (n=95) groups were plotted against their cumulative frequency Z-scores with slopes estimated by linear regression.

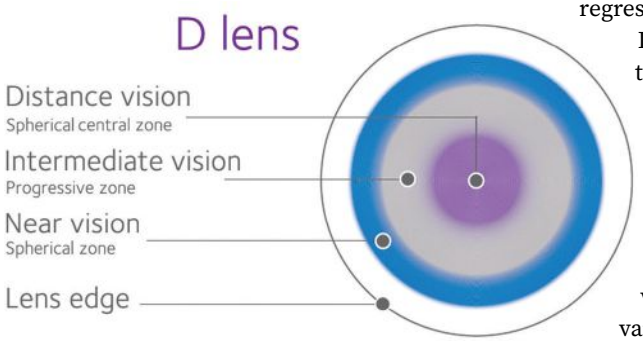


Photo: CooperVision

Results from the BLINK study suggest that treatment effect for myopia control is similar for all progression rates in children and that soft multifocal CLs don't affect comfort, focus or how well the two eyes work together.

Differences between treated and control groups only varied by ±0.11D across two standard deviations of myopia progression with no significant variation across the range of axial elongation. The variations were not large enough to create meaningful differences between the treated and control groups over three years. "A uniform treatment benefit suggests

that all children should be considered candidates for optical myopia control rather than prioritizing those at risk for fast progression," the authors concluded in their abstract.

The second presentation compared Convergence Insufficiency Symptom Survey findings, phoria and accommodative lag between single-vision and multifocal CL wearers with +1.50D add and +2.50D add over three years and found that myopia control with soft multifocal CLs does not negatively affect how well the two eyes work together, how accurately they focus on a near target or the comfort of the eyes.[15]

The accommodative lag was less than baseline at all visits for the three groups, except the lag was similar between baseline and two weeks for +2.50D add. The only differences observed were between single vision and +2.50D add at two weeks and one year and between single vision and +1.50D at two weeks. The maximum difference between groups in average accommodative lag was never more than 0.33D. Near phoria was statistically significantly more exophoric after baseline for both add powers but never became more than 2.40 prism diopters more exophoric over the three years. The +2.50D add group was more exophoric than the single-vision group at all visits after baseline but never more than 2.00 prism diopters more exophoric on average over three years.

• ***Take note of subjective vision with teens in myopia control contacts***. The optics of myopia control soft CLs slow myopia progression, but they can also reduce vision quality vs. conventional optical designs. Myopia control soft CLs are often evaluated in younger children (≤12), but meaningful myopia progression can occur during their teen years. Researchers at Johnson & Johnson Vision performed a post-hoc analysis of a prospective clinical study in myopic children (ages seven to 17) that assessed subjective vision with myopia control soft CLs using a patient-reported outcomes questionnaire.[16] They found that older children were more judgmental of their vision experience during early wear.

The team conducted a multi-site, single-masked, 3x3 crossover study with a run-in period. Healthy myopic children aged seven to 17 years old were recruited, balancing the number of children seven to 12 with those 13 to 17. Subjects initially used a daily disposable soft CL with conventional optics for one week, then lens wear sequence was randomized and subjects were fit with one of three myopia control soft CLs for three two-week periods. There were two senofilcon A prototype myopia control soft lenses with noncoaxial ring-focus designs (for enhancing efficacy and enhancing vision) and one omafilcon A dual-focus design. Subjective vision was assessed using the Pediatric Myopia Control Questionnaire at the two-week follow-up. An overall vision item was analyzed using the Pearson chi-square test to assess differences in top two box score proportions between the two age groups (excellent and very good) for each lens type separately.

The intent-to-treat population included 75 participants, with 38 aged seven to 12 (mean age: 10.6) and 37 aged 13 to 17 (mean age: 14.7). The researchers detected a significant difference in top two box score proportions by age for enhancing efficacy and approach for dual focus, but there was no significant difference for conventional optics or enhancing vision.

"A different balance of vision quality and myopia control efficacy may be prudent in older children to better fit their more critical assessment of vision quality and decrease the average annual myopia progression rate," the researchers concluded in their abstract.

These informative findings will help ODs devise new ways to help their patients. Check out ARVO's full listing of abstracts and posters to see for yourself the latest advances in eye and vision care. RCCL

1. Sanfilippo CM, DeCory H, Asbell PA. Antibiotic resistance among ocular pathogens – an update from the 2022 ARMOR Study. ARVO 2023 annual meeting.

2. Asbell PA, Sanfilippo CM, DeCory H. Longitudinal analysis of in vitro antibiotic resistance rates among ocular staphylococci collected in the ARMOR Study. ARVO 2023 annual meeting.

3. Maretz C, Atlas J, Shah S, Wozniak R. Infectious keratitis treatment failure—a study of patient and microbial characteristics in Rochester, NY. ARVO 2023 annual meeting.

4. Lieberum J, Zander D, Reinhard T, et al. Lifestyle risk factors across Fuch's endothelial corneal dystrophy severity. ARVO 2023 annual meeting.

5. Bernal A, Yang Y, Surenkhuu B, et al. Corneal epithelial thickness in dry eye disease (DED) patients: association with autoimmunity. ARVO 2023 annual meeting.

6. Chalkiadaki E, Tsiripidis K, Gartaganis P, et al. Correlations of corneal endothelial morphology with anterior segment parameters in healthy adults. ARVO 2023 annual meeting.

7. Bogen CS, Cox S, Hamrah P. Role of vitamin abnormalities as possible underlying etiology in patients with neuropathic corneal pain. ARVO 2023 annual meeting.

8. Nguyen C, Siso D, Truong N, et al. Lifetime incidence of corneal hydrops in keratoconic eyes post corneal collagen crosslinking vs. contact lens management. ARVO 2023 annual meeting.

9. Guo M, Patel C, Yu Y, et al. Association between systemic medication use and severity of dry eye symptoms and signs in the DREAM study. ARVO 2023 annual meeting.

10. Kokkinakis J. In vivo evidence that skin lipids may be a cause of dry eye in humans. ARVO 2023 annual meeting.

11. Ma N, Zhang C, Zhao H. Dry eye, its clinical subtypes and associated factors in breast cancer patients undergoing endocrine therapy: a cross-sectional study. ARVO 2023 annual meeting.

12. Li G, Vargas CG, Klawe J, et al. Association of dry eye with demographic characteristics, geography, and psychiatric comorbidity in the geriatric population. ARVO 2023 annual meeting.

13. Daniel Lee D, Yu Y, Bunya VY, et al. Two-year progression of dry eye disease in the dry eye assessment and management (DREAM) study. ARVO 2023 annual meeting.

14. Mutti DO, Sinnott LT, Berntsen DA, et al. Uniformity of treatment benefit in multifocal contact lens myopia control. ARVO 2023 annual meeting.

15. Walline JJ, Tomiyama E, Sinnott LT, et al. Phoria, accommodative lag and symptoms of soft multifocal contact lens myopia control. ARVO 2023 annual meeting.

16. Nixon A, Xu J, Brennan NA, et al. Subjective vision differences with soft contact lenses for myopia control in children and teenagers. ARVO 2023 annual meeting.

Building a Medical Contact Lens Practice

Seven pros detail their opinions on how to start and maintain a specialty focus, the difficult cases they encounter and their best advice for long-term success.

Participants: Christine Sindt, OD, Tom Arnold, OD, Stephanie L. Woo, OD, Heidi Miller, OD, Marcus R. Noyes, OD, Tiffany Andrzejewski, OD, John D. Gelles, OD

Edited by Mark De Leon, Senior Associate Editor

Building a practice around GP, scleral and other specialty lenses requires dedication and an ongoing need to remain up-to-date and proficient. This persistence will be necessary when you come across fitting challenges and busy scheduling. *Review of Cornea and Contact Lenses* hosted a roundtable discussion among several experts and moderated by Christine Sindt, OD, to help novice practitioners who are serious about medical lens management gain confidence. The pros also discuss what continues to be a thorn in their side and what priorities they maintain as their practices and expertise evolve.

This conversation has been edited for length and clarity.

PART I: DECLARING A FOCUS IN MEDICAL CONTACT LENSES

Dr. Sindt: I tried to pull a group of people in different types of practice settings with different perspectives about medical contact lenses. We'll talk about why they're in their particular practice setting, their view of the role of medical contact lenses, how each participant got going and what motivates and inspires them.

When you're in private practice, you must recruit or market a little bit more by going out and talking to other practices about recruiting to get those patients in the door vs. when you're in a university practice like I am. There are days when I feel like, "Whoa, somebody turn off the spigot of these medical contact lenses."

What led you to medical contact lenses? Tom, why don't we start with you? To you, what is a medical contact lens, and how did you get there?

Dr. Arnold: I got started by my cornea specialist, who I had a relationship with since I graduated. He started his medical practice; I started my optometric practice. I fitted the standard lenses, the little mini cones and some hybrids. I knew about sclerals, but I

Photo: Jeffrey Sterling, OD

Remind patients to be gentle with the DMV inserter.

didn't really pursue them. I had a busy practice. I was going, "I don't have time for this stuff." But I had sent my cornea specialist a couple of people I thought needed penetrating keratoplasties (PKs), and he said, "No, you need to fit them in sclerals."

And I didn't know anything back then. Soon, here comes the fitting set and my next cone patient. I said, "Well, I have a new lens. I don't know much about it, but it's supposed to be good. Would you like to try?" And I was just very lucky that after I put those first lenses on the patient, she just went, "This is amazing. Best thing I've ever done." I was off to the races.

Dr. Sindt: **What kind of commitment do you think people need to make, and how do you get to that point where you're going to make that commitment?**

Dr. Woo: When I completed my contact lens residency and had just started in private practice, similar to Tom, where I was seeing everything except for specialty lenses. I didn't do anything at first. We started slowly integrating specialty lenses into a large private practice setting, and then over the years we grew and grew. By the end of it when I sold the three practices, I think about 25% of all of our income was from specialty lenses.

At some point, I had a come-to-Jesus moment where I was trying to come up with my ideal day. And I said, "Well, I'm happiest on the days where I just see specialty patients or I see a majority of specialty lens patients—whether it's new consults, fittings, troubleshooting. I love it all." So, then I thought, "Well, maybe I just want to do specialty lenses. Is that even possible? If I want to do that, then I've got to move to a bigger city."

And that's how Las Vegas came into play. I said to myself, "Oh, there's no one fitting EyePrint here," so that's a huge opportunity. "Oh, there's no fellows of the Scleral Lens Society in town," that's another huge opportunity. "No one has a scleral topographer in all of Nevada!" I know a lot of doctors were fitting sclerals out here, but I don't think anybody was doing it at a very high level, and that's where I took the plunge and opened up a practice just dedicated to specialty lenses.

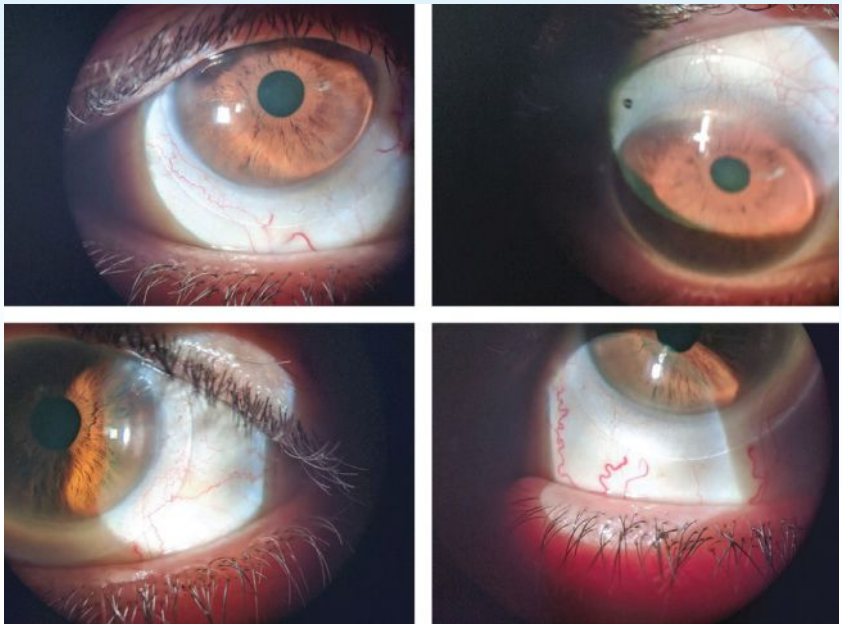


Photo: Christopher Lopez, OD

Scleral lenses fitted on a patient with post-refractive surgery ectasia.

Yes, it takes a lot of guts, and you do need to have a lot of patience and a lot of tolerance for risk, I would say. I had access to a lot of resources to get that started. Past webinars from the Scleral Lens Education Society and also joining social media groups such as Scleral Lens Practitioners and Business of Scleral Lenses were very useful. Also attending meetings such as Global Specialty Lens Symposium and the scleral lens tracks from Vision Expo helped greatly.

I'm always happy to share if somebody does want to go down that path, to advise them on what needs to happen or how to slowly integrate it in. You know, I'm happy to talk about both sides of it.

Dr. Sindt: **I talk to doctors who say, "Oh, I do maybe one or two specialty lens fits a day." Do you think it's easier to integrate it into a bigger practice, or the more you do the easier it becomes? And I guess this leads into the dabbler question—is it possible to be proficient but only see a small number of cases?**

Dr. Woo: I think the more experience you have with something, you just naturally become an expert in it. As far as the dabbler question, I'd love to hear from the group, too. But I used to be on the side of believing, "Anybody can do sclerals, and in fact everybody *should* do them. You know, you might have one patient a year, but that patient's going to be excited to have access to you."

Now I'm totally in the other camp, where I feel that if you don't love doing it and you're not doing it routinely, send it to someone else. I follow that same protocol. I don't like to do regular eye exams with kids, so I send them to my friends who love doing them. I'm not good at vision therapy or low vision, so I send them to people who enjoy doing those things and are very good at it. So I've switched camps.

Dr. Miller: I'm with you, Steph. One and done is fine in some situations if that's the most realistic way to serve the patient's needs, but are we causing more of a problem with some practitioners not being well-versed in fitting lenses or understanding the pathology behind what they're fitting.

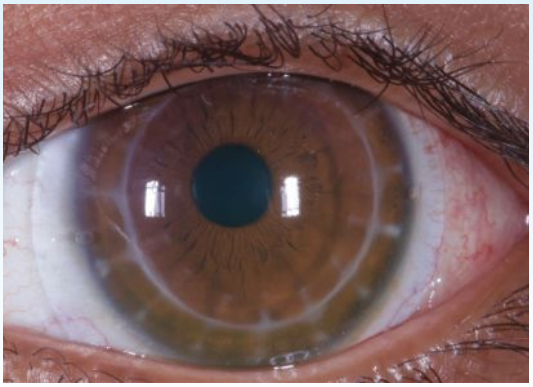
I am totally in the camp of advocating that practitioners need to know the field well and commit to continued learning. Products are constantly evolving, ways that we manage disease are constantly evolving. You need to be well-versed with both of those situations if you're going to be doing sclerals.

Dr. Arnold: That is so true, Heidi. What has energized me is that there is always something new to learn, always something evolving.

Chris was helping me with an EyePrint, and it was very difficult. Great patient but very challenging case. I'd done pretty much everything I thought I could do, and I called Chris. We went through the case, and she said, "You know, some patients are just hard." I've never forgotten that.

Dr. Noyes: When sclerals first came out, many people reacted by saying, in effect, "Oh, here's a new keratoconus lens." But as we all know, the breadth of what we use sclerals for has just exploded: graft-vs.-host disease, severe dry eye, scars, all sorts of stuff. I think that all these people who wanted to get into sclerals were originally thinking, "Sure, I can do this new GP lens," and then they didn't really realize the much more broad range of uses, the side effects, warning signs to look for, the differing fitting philosophies—all the nuances of the craft.

Photo: Tom Arnold, OD



A well-fit scleral lens over an eye that has undergone a corneal transplant.

Dr. Woo: This might be a stretch of an analogy, but would you go to a doctor who does heart surgery once a year? Do you want that doctor doing your heart surgery? I personally would want to go to a doctor who's well-versed and sees these types of patients every day because I know that they've seen basically all the things that can happen and they would know how to manage my case in the best way.

Dr. Miller: I feel like most of my referrals come from a patient who had tried a scleral or a corneal GP lens and felt they weren't a good candidate because the result was subpar. That's unfortunate because I feel we have to start over from square one. You don't want to throw your colleagues under the bus. I end up treating these cases as if they've never worn a lens before: "Let's start back to basics. We're going to train you from beginning to end."

So, I wish people didn't dabble because it also puts you in a tough situation, though I do understand the challenge on their end—you've got to start somewhere.

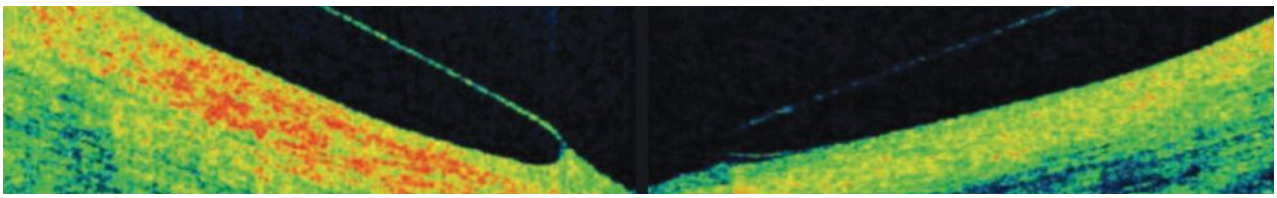
Dr. Andrzejewski: I remember a patient a few years ago. He came in saying, "Sclerals are the worst thing ever. I like those hybrids that you fit me in years ago." Now, this was before his disease progressed and before he had Intacs. I examined him and said, "Yeah, you need sclerals." He pushed back, "Those things are terrible." I had to explain that a good-fitting scleral lens should be quite comfortable, that if it's not, something is not right.

It goes back to knowing what you're doing because otherwise it sours a patient on the modality. I just had a young guy yesterday who was here for a first-time appointment. His attitude at the start was, "I've heard those hard lenses are terrible, I want a scleral." After I showed him what a scleral was, his knee-jerk reaction was, "I don't want that, that's too big." But we tried it on and within 15 minutes, he was adapting well and ready to try it.

Sometimes patients develop preconceived notions about specialty lenses because of what they've read online, what they've heard from friends or other patients or doctors.

I say, tell fellow OD colleagues and students who are interested in specialty contact lenses and want to incorporate this into their practice: "You can learn, with some dedication, how to fit scleral lenses and be proficient at it. It takes time and patience. The more you start fitting sclerals and specialty lenses, the other challenge is integrating it into practice; the challenging

Photo: Chandra Mickles, OD



AS-OCT shows a scleral lens edge with slight impingement into the conjunctiva (left) and an edge that lifts away from the conjunctiva (right).

thing is the patient flow, checking the insurance and getting all the logistics worked out so that patients can have a smooth experience."

If you're dabbling, you may not get to master these things, and there's no consistency to your method. It would mess up your day to have a full general book and then, all of a sudden, you've got this scleral lens fit in the middle of it. So, I think the challenge of dabbling has to do as much with how you run your clinic as acquiring the technical skills.

Dr. Sindt: **How do you all feel about GP lenses and where you're placing them in your practice at this point? Are you all-in for sclerals? Do you feel like there's a place for GP lenses? Do you feel like you're using GP lenses more or less now?**

Dr. Woo: All of us love corneal GP lenses, and if you ask some people that are dabblers, like Heidi was saying, they're never going to fit a GP lens. But all of us love GP lenses because we know where they fit in.

Dr. Andrzejewski: I explain to my fourth-year interns that, if there's mild keratoconus and/or there's a nice central cone and it's not too steep, then I can fit a corneal GP so much faster than a scleral. Chair time is a valuable thing in practice.

Dr. Arnold: I agree. I think getting really into sclerals energized my GP practice. It made me bolder. For patients coming in with a custom toric or wanting a custom soft toric, I often say, "Look, I've analyzed this, I've looked at all this data—you would be great in a GP." I love fitting GPs. In many cases, patients see better with them.

Dr. Noyes: I'll take the contradictory side. Although I do a lot of GPs, I usually lean a little bit more on sclerals. The main things that will take me to a GP: (1) they're a little more affordable and (2) if the patient doesn't qualify for sclerals. But I will lean a little bit more on sclerals than GPs mainly just for patient comfort. Also, we do a lot of EyePrint lenses, and those are just perfect every time, so that makes it a little easier, too.

Dr. Sindt: **When approaching medical contact lens fitting, we manage a lot of things in our practices. So I'd like to hear from you guys about other things that you have to manage besides just the contact lens.**

Dr. Woo: That's like what Heidi was saying—fitting lenses is the easy part. It's managing the disease and the patient's emotions and personality and expectations, that's what's hard about specialty lens fitting.

Dr. Sindt: **What steps did you take to build a medical contact lens practice?**

Dr. Arnold: I made a packet that included my CV, a little about the clinic, a little about scleral lenses, some medical billing type information and I visited other practices with that. (See "Resources for Scleral Lens Wearers" and Scleral/EyePrintPro Prospects") I targeted anterior segment surgeons, the cornea people, and I would set up appointments. I would go talk, myself. I did not send staff. It's important that you go yourself. And I reached out to all the ODs in my area.

You keep reaching out and make sure you touch base with them. That's how I built it. It takes work. It was maybe three years of pounding the pavement consistently.

Photo: Tiffany Andrzejewski, OD

Scleral lens application can be a challenge for some patients, leading to bubbles and eye irritation if the patient isn't aware of their presence.

Dr. Andrzejewski: I work with ophthalmology, and cornea specialists in particular. In the Chicago area, while some patients may come to the practice to see a cornea specialist, they stay because of us optometrists. I found that what really helped grow my practice within the system is, when I'm seeing a patient referred by an outside ophthalmologist or any other outside eyecare practitioner, I send back a letter saying, "I saw your patient, here's an update of what's going on with them. I'll continue seeing them for their specialty lens needs,

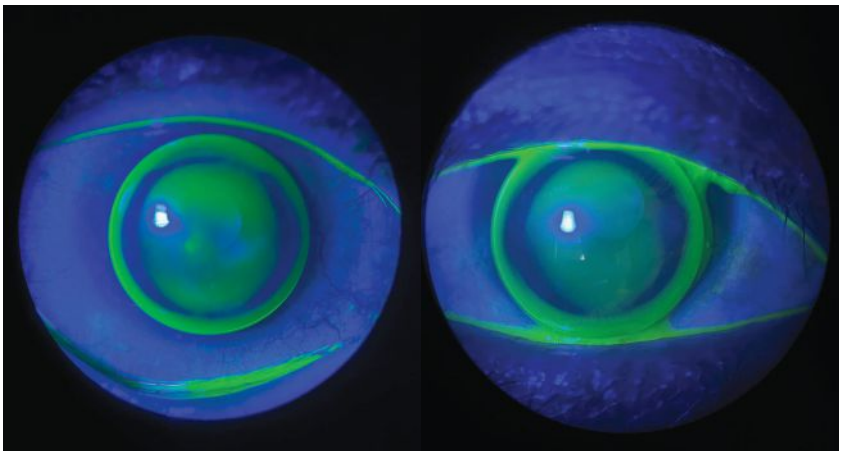


Photo: Heidi Miller, OD

Scleral lens for a keratoconus patient with corneal Intacs.

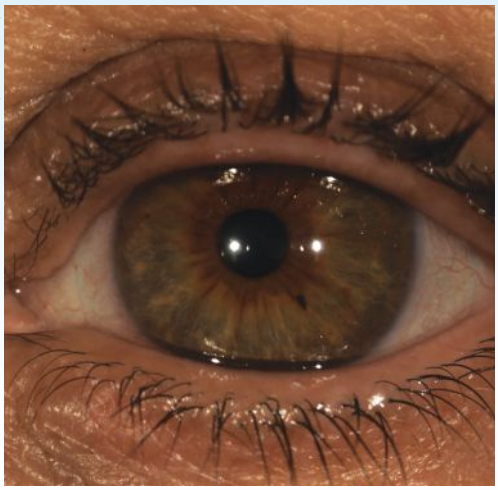


Photo: Stephanie L. Woo, OD

A patient wearing a custom scleral lens called the Latitude (Visionary Optics).

but I will refer them back for their other eyecare needs."

That led to those other doctors, especially from outside our practice, now referring to me because they can entrust me with their patients' contact lens and vision needs and they're not afraid of losing a patient.

I have found that this has helped grow my practice within the practice and that I get more referrals from not only outside ODs but also outside ophthalmologists.

Dr. Miller: The common theme I'm hearing from everybody here is to create your practice with a lot of openness so that referring doctors feel that there's communication and won't feel threatened that it's a power play of taking the patients. The focus stays on what is in the best interest of the patient, and communicating back and forth keeps that best interest going forward.

PART II: MEDICAL LENS FITTING ISSUES, COMPLICATIONS AND PATIENT COMPLIANCE

Dr. Sindt: **How do you decide between fitting a GP vs. scleral lens? What's your decision tree?**

Dr. Miller: I'm paying attention to the person themselves. When I'm having a conversation and giving instructions, what is their feedback? Because there's a lot of maintenance in sclerals, and there's a lot of things you need to follow. Are they well-suited to it?

And because I'm comanaging really closely with our cornea service, a lot of times I get information on the transplants or what their corneal endothelium status is, things like that. So, I might do a corneal GP because I don't think they're going to be a great scleral lens candidate based on the likelihood of edema or complications in that regard.

Dr. Sindt: **Let's discuss scleral complications. I generally feel that typically a complication from a GP lens is, "Oh, it popped out," or, "Oh, gosh, you're dry." The worst complications are things like diffuse lamellar keratitis, corneal abrasion, vascularized limbal keratitis or something along those lines. Fortunately, they're rare.**

Dr. Woo: I am not proud of it, but I've had a few corneal transplant rejections. We did everything we could initially to identify the patient as a good candidate.

Usually with transplants, I try to put them in a GP if I can just because they're safer for the eye long-term. But let's say they tried GP lenses or their corneal transplant is so irregular no GP lens is going to stay on, it just immediately pops off. There's a variety of reasons. But we've taken all the measurements, checked their endothelial cell count, looked at the transplant and talked with the surgeon; everything seems like it's a go, but their transplant just doesn't like it and starts rejecting.

What I've learned from that is you've got to monitor transplant patients very carefully, even if you think they're the best candidate, have done all the testing and even if the surgeon referred them directly to you for a scleral lens. You still have to be very upfront with the patient in letting them know the risks and benefits.

So, I am very upfront, and everything is written down. I go through all the things that we've done to determine that they are a good candidate, but I articulate the risks. I go through everything that could happen, and I think it's important that they're aware of all that, because they've already been through so much with this transplant situation. If it seems like the benefits outweigh the risks, then they go ahead and we go for it, and we just have to monitor them carefully.

Dr. Sindt: **What I'm hearing you say is that it's not about how to fit the plastic, it's more about how to manage the problems.**

Dr. Woo: Right. It's not about fitting the patient; that's easy. It's everything that comes after that; the dispensing visit, the training, all the follow-up care, managing the health of the eye, monitoring the underlying issue, managing the personality, the emotions.

You're right, Chris, it's all of this stuff that happens after the initial fitting.

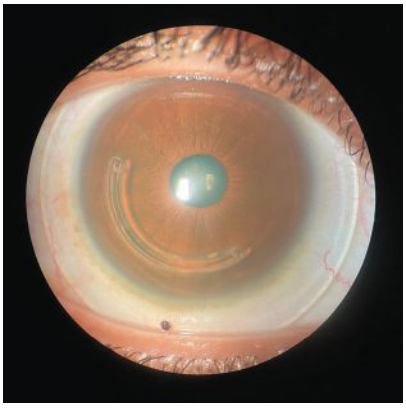


Photo: Heidi Miller, OD

Corneal GP lens on mild keratoconus patient.

UNDERSTANDING THE 3-ZONE PROGRESSIVE DESIGN

Jill Saxon, OD
Executive Director, Professional Strategy at Bausch + Lomb Vision Care

Kristen Hovinga, MS
Director, Lens Design R&D, at Bausch + Lomb Vision Care

THE IMPACT OF OPTICAL DESIGN

Understanding multifocal optical design is paramount to satisfying the visual needs of presbyopes. In addition to dryness, poor vision remains one of the leading reasons for contact lens discontinuation among the growing presbyopic population.[1,2,3] It's clear that optical design can be an important component of successful multifocal lens fittings. In a typical day, the modern presbyope may need to switch between a variety of dynamic vision tasks involving digital devices, driving, reading in low light, reading menus, or work. Bausch + Lomb's lens design team has developed a modern, multifaceted approach to multifocal optics, engineered to provide visual clarity across distances, accommodate transitions between zones, and enhance the presbyopic lens-wearing experience.[4]

VISUALIZING POWER

Bausch + Lomb's multifocal contact lenses incorporate the 3-Zone Progressive™ Design **(Figure 1)**. To evaluate the 3-Zone Progressive Design, multifocal contact lenses were measured with a high-resolution Shack-Hartmann wavefront sensor that took over 6000 unique measurements of their power profiles. The generated power profiles illustrated changes in lens power from the center of the optic zone to the periphery. The 3-Zone Progressive Design features three zones of consistent power in its profile, with seamless transitions across all distances. The power profiles were optimized across the three zones, including the slopes of the power profile within each zone along with transitions between the zones for near, intermediate and distance vision.

RESEARCH-BASED DESIGN

Conventional considerations in optical design development, such as refractive error and/or pupil size, have been incorporated in previous design options. During the development of the 3-Zone Progressive Design used in Bausch + Lomb Multifocal contact lenses, pupil size was just one of many dynamic components within a more complex system that also includes higher-order aberrations.

Bausch + Lomb developed the 3-Zone Progressive Design to go beyond pupil size. Taking refraction, higher-order aberrations, anterior chamber depth, axial length, corneal curvature, and residual accommodation across 9 distances into consideration, the design accounts for individual contact lens wearer variability.[5] As part of their extensive research on multifocal lenses, computer-generated models based on data from individual patients' eyes were were used to predict logMAR visual acuity scores.[4,5] The 3-Zone Progressive Design was further optimized with finite element modeling to predict how contact lenses conform to corneas and to gain insight into the effects of decentration and rotation on optical performance.[4]

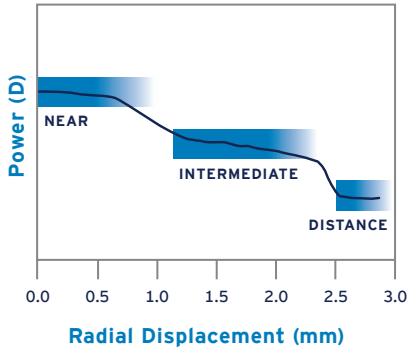
COMFORT & CONSISTENCY

Consistency of measured powers across the available prescription range helps achieve a successful fit with lenses that incorporate the 3-Zone Progressive Design. Eyecare practitioners who followed the fitting guide for 3-Zone Progressive Design lenses reported the lenses were easy to successfully fit during the first visit.[6]

Bausch + Lomb has developed a one-day multifocal contact lens with this proven 3-Zone Progressive Design. Bausch + Lomb INFUSE® Multifocal lenses are built on a next-generation silicone hydrogel material (kalifilcon A), which has high moisture and oxygen permeability with a low modulus. The material is also infused with breakthrough ProBalance Technology®–a proprietary combination of osmoprotectants, electrolytes, and moisturizers–to help minimize contact lens dryness. Given that contact lens dryness and discomfort is the primary cause of discontinuation among presbyopic contact lens wearers,[3] a lens with the material properties of INFUSE® may be especially well suited to help deliver a comfortable wearing experience in this patient population.

It can be daunting for eyecare practitioners to differentiate between the assortment of multifocal contact lens options available to them. Bausch + Lomb's 3-Zone Progressive Design can be characterized by its optical design that was developed and optimized using computer modeling. The delivery of accurate power at every power with smooth transitions across distances–combined with a material designed to help minimize contact lens dryness means exceptional performance for wearers.

CONSISTENT POWER IN EACH ZONE FOR AN EXCEPTIONAL VISUAL EXPERIENCE[5]



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BAUSCH + LOMB

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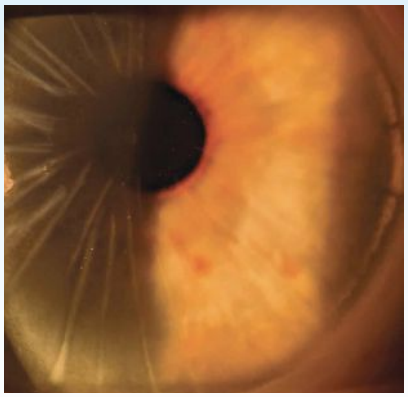
Photo: Marcus Noyes, OD



Most often, scleral lenses are used for post-RK corneas because the extreme flatness and irregular astigmatism may be difficult to fit with a corneal lens.

Dr. Miller: I've had a few patients I'm convinced were self-induced hydrops. Maybe the lens was too tight or they weren't putting the plunger down at the end, resulting in suction forces. But then they disappear, and all of a sudden, they're back in your chair and they have hydrops. And I'm convinced it had to have been some sort of mechanical thing that caused it.

Dr. Arnold: Handling is so important. I had a very large man—a big, strong guy—and he was just brutal with his lenses. Once he came in and he had popped all the vessels in the perilimbal loops, and he had just blood up into his cornea. It wasn't in his visual axis, but it was in the cornea. It wasn't hyphema, but it was pretty ugly. I said, "Look, you've got to learn to be gentle."

Dr. Sindt: **So, let's talk about that perilimbal area there for a second. Because again, that's an area that no other type of contact lens affects. You're not going to get that with a soft lens or a GP.**

Dr. Andrzejewski: For limbal stem cell deficiency, you don't want to touch the limbus, so it makes sense to fit the patient in a scleral. But when things go wrong with a scleral, then you sit there and think, "Oh, now what do I do?" That's the toughest thing in the book. Sclerals can be wonderful, and I've seen it reverse limbal stem cell deficiency in my own patients, but you're right—if you're not careful, it can cause it or other complications.

Sometimes it's very easy to blame the plastic when in fact it's the disease, the eye, the underlying pathology, autoimmune conditions or, yes, the patient's own compliance. It's very easy for people to turn around and say, "Oh, it's your fit that went wrong, it's the lens," but everything looks absolutely great at the slit lamp. It's challenging.

Dr. Sindt: I struggle with this idea of the tear exchange. I'm glad you brought that up. I've been fitting scleral lenses for 25 years or more, and so I'll tell you the early fits were just really bad.

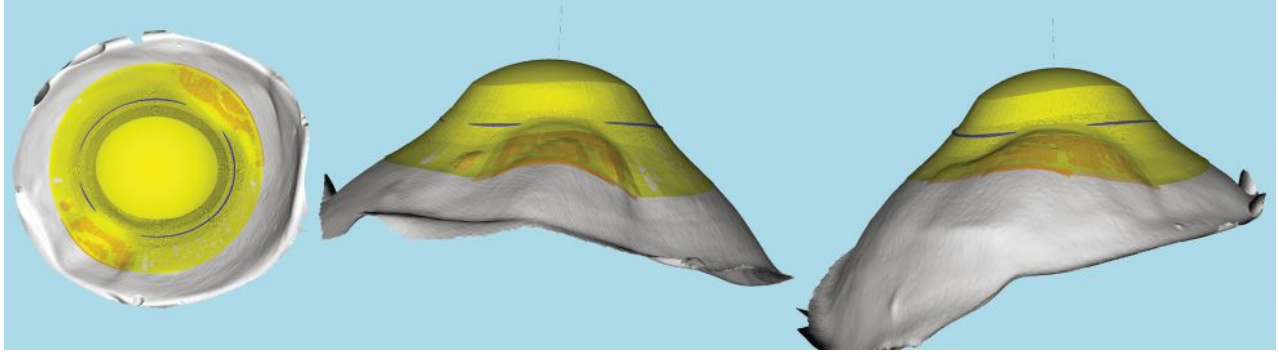
We had no way of even cutting toric peripheral curves. The patient would blink, the lens would move and fluid would go in under. However, we rarely saw limbal complications. You never saw the complications that I see now. And I think a lot of it was tear exchange—they had good tear exchange underneath the lenses.

So, I wonder what the group thinks about tear exchange. In online discussions these days, I hear a lot of people say, "Put fluorescein over the lens, and if you have leakage under the lens you have to tighten up that area of the contact lens." Unless they're getting massive amounts of mid-day fogging, I don't necessarily want it to be 100% perfectly sealed because I think that negative pressure underneath the lens that is trapping inflammatory products causes probably most of the limbal stem cell deficiency that I see. We used to call it the toxic swamp, what's underneath the contact lens.

Many of our colleagues talk about tightening the periphery to reduce mid-day fogging. Where do you stand on that?

Dr. Arnold: We all know the pros have been fitting very large lenses with very high clearance for a long time on the most complicated cases. Having said that, I try to adhere to good practices, but as long as a lens clears and it's reasonable, I'm not going to fit a lens and be satisfied with 500µm of clearance, but I don't sit and have an ideal clearance for any one lens. I do agree I want some tear exchange.

Photo: Marcus Noyes, OD



This is a 3D representation of an elevation-specific freeform impression-based EyePrint lens.

We monitored that in our office during follow-up visits; the patient would come in, the tech would check their vision, and they would dab some fluorescein on the bulbar conjunctiva before they took them back. They would do an OCT, and then I would see them. I would expect to see some fluorescein coming through in the fluid reservoir after 15 or 20 minutes. So, I don't fit super tight, and I don't lose sleep at night trying to get some ideal clearance.

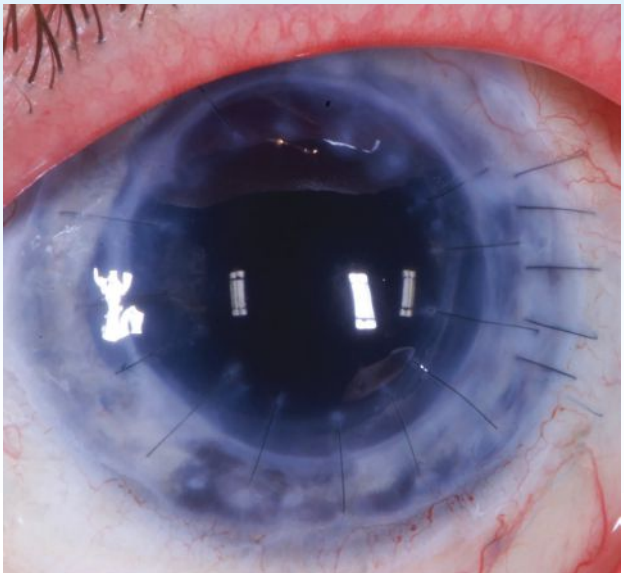


Photo: Tom Arnold, OD

In PKs, monitor for edema and consider a larger lens.

Dr. Gelles: It all depends on the physiologic response and what the patient's wearing the lens for. In some, a little trickle can be good. Some individuals that are just type-A.

Dr. Sindt: He does practice on the east coast.

Dr. Gelles: For me, I'm apt to just tighten it down in the area of misalignment to eliminate their worries, if it's not going to cause a health concern. But it depends on how long it's going to take for that fluorescein to get under the edge. If I paint it on the front of the lens and they take one blink and the whole chamber is filled with fluorescein, I know it's just a bad fit.

Dr. Woo: I think too many doctors chase the fit to perfection, and I think I did that in my residency, too—calling the consultant constantly and making a thousand changes on each patient. Then, 20 lenses later, I realize lens number three was probably just fine for them. Now, if I see a tiny imperfection in the fit, I take it in stride. If the patient's doing well and their eye is healthy, they're seeing great, let them go. Stop making these tiny little changes and wasting your time, wasting the patient's time.

Dr. Andrzejewski: And wasting lab resources.

Dr. Gelles: I want to throw one interjection into that, though. The vast majority of the patients who come in to see me have seen somebody else already, and usually they've had complications with their fit.

Yesterday I had a case of neovascularization like I had never seen before. I asked her about a history of viral infections or any inflammatory or autoimmune diseases that might be in play. Not one. I looked at the notes from five years ago, and the fit reportedly did look good then.

So, the issue is, how perfect do you want to be or should a fit be? For me, I don't let the patient out of the office until I know that even if they showed up five years down the line, I'm not going to have a train wreck on my hands. This is especially on my mind coming on the heels of COVID. That patient never made it back to the original practice during all that time.

Dr. Sindt: What did the lenses look like?

Dr. Gelles: They were small and resting on the limbus. I used to think that the Boston Foundation for Sight recommendation of a big and loose fit was a little silly. I can get success with a 15mm or a 16mm, what does it matter? Nearly every single lens that I fit back in the day in the range of 14.8mm or 15.5mm has ended up with problems. Breakdown at the limbus, deep trenching impression rings, all sorts of issues. Lo and behold, "large and loose" is where I ended up.

Every single lens I fit right now is 18mm to 20mm, every single one. Most lenses I see that are 15mm to 16mm in diameter leave a giant impression ring and generate a lot of patient complaints: "When I take my lenses off, my eyes are red and irritated."

They all have staining around their limbus. It's just inherent to it: not enough haptic surface area to spread the lens force over so the lens sinks into the conjunctiva, thus the impression ring forms and limbal clearance is lost. You may think you can remedy that with ease when you see them at follow-up—"Oh, I'm just going to raise your limbal clearance a little bit more"—and then you do that again the next year and the next year. A few years in, you look and say, "Gosh, my haptic is really heel down and I keep having to bring the limbus up."

Dr. Arnold: Elbow, yes.

Dr. Gelles: There have been very small things that early on I'd let go that, three years later, are a problem. Conjunctival hypertrophy, for instance—maybe it starts as just a couple fine vessels being compressed at very small, like less than a millimeter area at the lens edge.

No big deal, right? I'll see them back every six months for routine follow-up, but three years later, "Wow, that gigantic granuloma wasn't there before." Some things smolder and then become a problem.

Dr. Sindt: **Do you think it's hard to see your own problems?**

Dr. Gelles: Not really. I would put it this way since I've seen many patients and thus patients with problems induced by lenses, both fit by me and others, even from doctors who I really respect and know are skilled. Over time, seemingly little things can become big issues, so mitigate them when they are small. Be diligent about follow-up and early to react.

It can be a challenge, though; some patients disappear during the fitting and fall into the "I'm comfy and can see. I'm done!" mentality and come back as a train wreck, or worse end up at another practitioner's office and they go, "Gosh, what the hell was he doing?"

We all want these eyes to remain healthy. That's the biggest thing. "Is this lens that I'm creating for this individual going to harm them?" That's more of what I've evolved into my fitting philosophy.

Dr. Sindt: Well, I think that's a key thing with medical contact lenses—we could harm people with them.

Dr. Gelles: Yeah. Double-edged sword for sure, you have to know what is going on with the eye.

Dr. Woo: And maybe that goes back to the topic of the dabblers. Doctors with less experience have good intentions, but if you don't know what you're looking for, you don't know proper follow-up care, especially for some of these very diseased corneas or people who are at risk, you could really harm someone.

Dr. Gelles: I cannot count the number of times that I've gotten a patient who comes into our office when just the basics of a scleral lens fit are not even close to being followed.

Dr. Miller: I still encounter some ODs who say they are doing scleral lenses, and they don't own any sort of topographer. I find that to be wild. Who is telling you that this is okay? Because you're clearly not managing disease processes, just the plastic itself, unless maybe you're doing some very active comanagement system.

There's no way you're at the depth of knowledge that you should be if you don't have a topographer but you're fitting sclerals.

Dr. Arnold: Or a practitioner who only uses one lens all the time. One lens on everybody.

Dr. Andrzejewski: Here's the one thing that I think is always interesting about scleral lenses. I very much try to fit scleral lenses responsibly, in the sense of looking for reasons to maybe not fit a scleral on some patients.

Sure, it's very easy to put sclerals on everybody, because they're comfortable and you get that wow factor. But if you can get by with something else, why not? Is two weeks of GP adaptation really that bad? For some patients, yes. Others will take the time to adapt, usually for the sake of better vision. The vision with GPs can be very motivating.

If a corneal GP lens bothers a patient, what does that patient do? They usually stop wearing it. However, if a patient's having a problem with a scleral lens, what do they do? They keep wearing it, thinking it's going to get better. And they can rationalize it to themselves: "Oh, it just hurts when I take it off," probably because it's touching the cornea or squeezing the limbus. They just keep wearing it and wearing it. Then, once they're really miserable, they come into your office. It's so much worse because they didn't stop wearing it. The lens size is sometimes too forgiving and doesn't give patients the immediate feedback they sometimes need.

It's especially hard because we know how often patients are lost to follow-up. I saw a 40-something-year-old GP wearer recently who hadn't had an eye exam in 12 years. He had gone to another practitioner during COVID, but they didn't fit GPs. He then came to see me asking for sclerals, telling me how he wants things easy and doesn't want to deal with anything complicated and time-consuming. I had to have an honest discussion with the patient, telling him, "Sir, scleral lenses are definitely more complicated than corneal GPs."

I was thinking to myself, "You haven't had an eye exam in 12 years and were forced to finally because you went and bought lenses online that you've had for seven months now, and your eyes feel miserable. That's what it took for you to come in. What are you going to do with scleral lenses? You're going to take these lenses and run, and you might not even let me finish completing the fit because we all know it's rarely one lens and done. Why am I going to put you in a scleral? You don't seem trustworthy to return for follow-up."

This anecdote underscores the importance of looking at the whole package, anatomy and psychology.

Dr. Noyes: Excellent point, Tiffany. Clearly agree with everything, just one

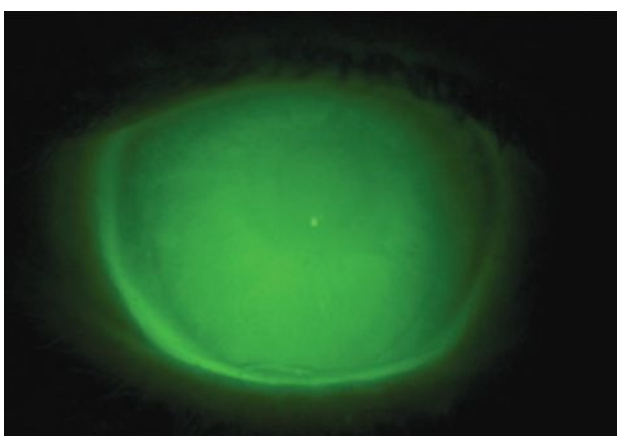


Photo: Brooke Messner, OD

Prioritize proper clearance and fit over leakage when using sodium fluorescein.

thing that I would add is that as uses for scleral lenses, or even GPs, do tend to increase, there's more and more stuff we've got to figure out. Talking to people in the field and sharing ideas in a forum like this is also a huge help. You've got to try and stay on top of it however you can.

Dr. Arnold: The people who have been doing this a long time, they're so humble and talk about all their failures and how sometimes even they are confused. Like Chris told me, "Sometimes, it's just hard." We're always learning, we're always evolving—it's an amazing time, it's the best time in the world to be an optometrist. But challenges never go away; others just take their place.

PART III: PEARLS FOR POST-OP LENSES

Dr. Sindt: **I thought this was a great conversation. Thank you, everyone. Maybe we can end with a quick look at different corneal surgeries and the approach to specialty lens choices for each, be it old radial keratotomy (RK) eyes, LASIK patients, PK vs. a lamellar graft or eyes with tube shunts. Do these factor into your approach?**

Dr. Gelles: In PKs, you're looking for swelling, you need to monitor for edema. Whether that means that you're looking for microcysts or, more appropriately, using corneal tomography to look at your global pachymetry, you're monitoring what their cornea is doing in response to the lens over time.

For RK, it's all about making sure that your lens vault is up and over everything, and you're not allowing things to be compressed or cause problems. Compression leads to neovascularization of those incisions. With tube shunts, ultimately, the answer is always EyePrint. The lens has to go over the tube shunt, and it has to not touch or compress it. If you touch or compress it, you end up with breakdown to the overlaying tissue and erosion of the tube. This can open the patient up to really, really bad things like endophthalmitis.

Dr. Arnold: One thing, going back to small vs. larger lenses, I think it's a rule of thumb that when you're trying to do RK, PK, all these things, you need to go to the larger lens. It's very difficult to get up and over, and then come down. I think those particular post-surgical cases need a larger lens.

Dr. Sindt: I start at the eyelid. Are they over-bioburdened, inflammatory, are the lids positioned right and properly mobile? Am I going to be battling somebody's rosacea on top of everything else? Do their eyelids even touch their globe or are they flapping in the breeze?

Next, I go to the cornea. Do I have a weird shape that I'm dealing with, do I have an epithelial problem, a stromal problem, an endothelial problem? Do I have pingueculae, conjunctivochalasis, granulomas, all those kinds of things?

Every one of those things is going to make me think, "How annoyed am I going to be by that?" And if I'm annoyed, that helps me decide which lens. Do I want to go big and get over it, do I want to go small and avoid it? It doesn't matter what the surgical state of the eye is. What matters is the health situation of every single layer of that eye. Am I going to drive inflammation? And if I am, do I have to manage the inflammation first?

Dr. Gelles: Two other things. First, do you have a collaborative care team? Do you have a team in place if it goes south? And second,

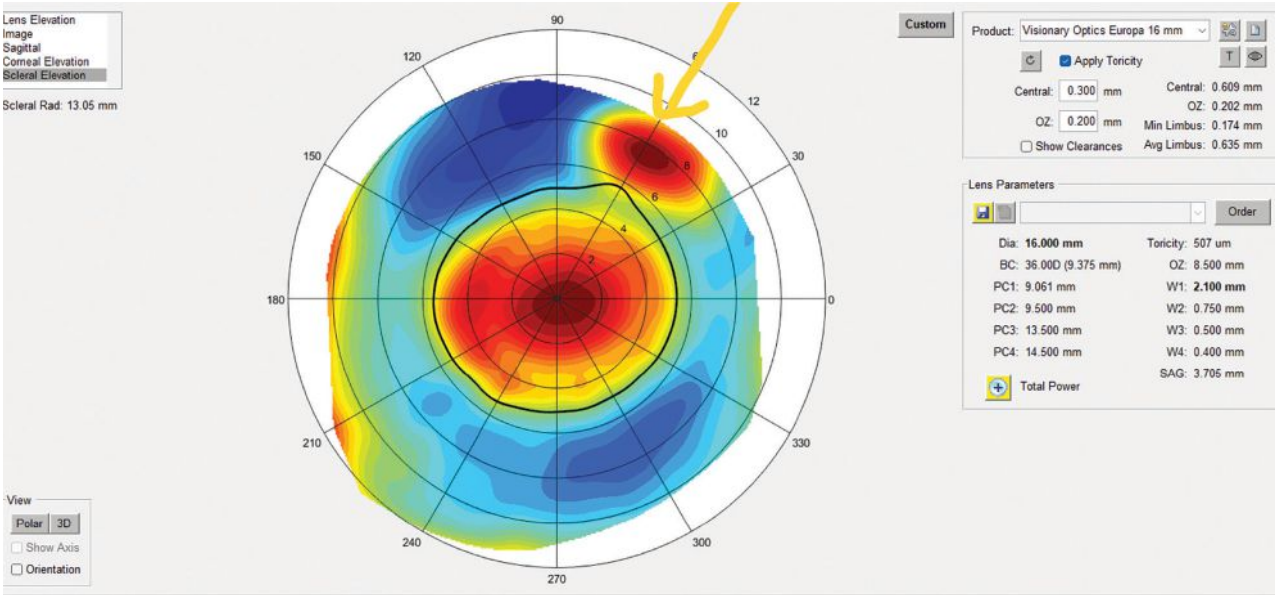


Photo: Stephanie L. Woo, OD

Using scleral profilometry can help clinicians create a well-designed lens that works best for the patient.

Resources for New Scleral Lens Wearers

Provided by Tom Arnold, OD

Give this list of resources to patients at the initial evaluation so they can get familiar with scleral lenses—not only with indications and usage but also training videos and access to solutions.

YouTube Videos:

1. youtu.be/hOdI2P6qyZU - Scleral Lens Insertion and Removal (Scleral Lens Education Society)
2. youtu.be/xHRTuDXqV7E - Patient removal—plunger method (Blanchard Contact Lenses)
3. youtu.be/K12S7Q7tol0 - Patient removal—pop out method (Blanchard Contact Lenses)
4. youtu.be/gBbrY19GpsY - Custom Stable Care and Handling (Valley Contax)
5. www.youtu.be/MKPu8cSAxII - Introduction to Scleral Lenses (Mayo Clinic)

Websites:

www.onefitlenses.com/handling-onefit

www.sclerallens.org

www.allaboutvision.com/contacts/scleral-lenses.htm

www.contactlenses.org

www.sclerallens.org/for-patients-2/patient-faqs

Caring for Your Lenses:

Evening Care Regimen:

1. Clean with daily cleaner—Optimum.
2. Rinse with LacriPure Saline.
3. Soak in Unique pH overnight.
4. Use Progent Bi-Weekly Cleaner once every two weeks (when directed by your doctor).

A daily cleaner and Progent are not required with lenses treated with Hydra-PEG.

Morning Care Regimen:

1. Rinse with LacriPure saline (DO NOT rinse with tap water!).
2. Completely fill lenses with LacriPure Saline (no substitutions!).
3. Insert lenses.

Solution Vendors:

www.myeyesupply.com (scleral lens kits, rubber plungers, Unique pH, Progent and others)

www.meniconamerica.com (LacriPure Saline)

For Additional Lubrication:

In bowl—Oasis Tears Plus

Over lenses—Refresh Optive nonpreservative, Systane nonpreservative or Blink Contacts

Photocopy the form to the right or download it from the online version of this article. The contact lens coordinator should complete this internal screening form as they vet the new patient prior to the initial appointment.

Provided by Tom Arnold, OD

there's a ton of different lenses out there. Remember that a scleral lens is not the right answer all the time. Be creative, find the right solution for the patient and go from there.

Dr. Miller: Pingueculae can especially drive me crazy. I'm just thinking of this patient right now—they were big, I was ambitious, and I probably should have just gone smaller on this person and avoided the pingueculae altogether. So, yes, I would agree with everything you said, Chris. That is the approach to take when considering sclerals vs. GPs.

Dr. Sindt: What it really comes down to is how annoying is the fit going to be to me. How much work do I have to put into it, how much follow-up care, what are the possible complications? I just want everything to work, and I can control at least some of that at the outset with the choices I make.

Dr. Arnold: You can't rule out the patient's personality, expectations and demands.

Dr. Gelles: I have one last pearl that I want to put in there that's very important for your patients after crosslinking. You can put them back into their scleral lens two to four weeks post-op, right? Many have heard these absurd recommendations, like suspension of lens wear for three months. It's not the case. We've been doing it for years without an issue.

Focusing on medical lenses in your practice is an investment. Managing complex scleral fits and specialty lens complications can be practiced by motivated eyecare practitioners. But don't expect it to be easy. RCCL

Scleral/EyePrintPro Prospects

Patient Info

Date: _____ Name: _____ DOB: _____

Phone: _____ Email: _____

Address: _____

Referred by: _____ Appt: _____

Insurance

Vision Plan: _____ DX: _____

Member ID#: _____ Group #: _____ Phone: _____

Medical Plan: _____

Member ID#: _____ Group #: _____ Phone: _____

History

Type of current correction?: _____

Correction used in the past? Member ID#: _____

Eye surgeries?: _____

Eye injuries?: _____

Patient packet _____ Emailed _____ Mailed _____

A Closer Look at HIGH-TECH Contact Lenses

These cutting-edge technologies are now becoming a reality, but where do they currently stand?

By Catlin Nalley, Contributing Editor

With ongoing advancements, we have seen growing interest in the area of smart contact lenses and drug-eluting lenses. While there's still much to discover, the potential implications of these technologies paint an exciting future for eye care.

"Many years and decades of discussion are now becoming actuality with the new Acuvue Theravision lens with ketotifen that was recently released," by Johnson & Johnson says Rebecca Rojas, OD, of Columbia University, Harkness Eye Institute. She notes that this "opens the door for other drug-eluting lenses and smart lens trials to follow."

This article will delve into current research and development efforts, as well as associated challenges and hopes for the future of smart contact lenses and drug-eluting technology.

WHERE WE STAND

Both drug-eluting lenses and smart contacts have seen increasing momentum in recent years, and efforts to capture the potential of these technologies are in full force.

Drug-eluting lenses. The concept of contact lenses as ocular drug-delivery systems is not new; however, with ongoing advances, it is now becoming a reality. There are a number of ways to develop therapeutic contact lenses, according to Melissa Barnett, OD, of the University of California, Davis Eye Center. These include the soaking method, molecular imprinting, colloidal nanoparticle-laden lenses and using vitamin E.

"Drug-eluting contact lenses are unique, given each pharmaceutical formulation presents different challenges with regard to demonstrating safety and efficacy for the respective indication," notes Jerry Legerton, OD, co-founder and chief clinical and regulatory officer of Innovega. "In some cases, the pharmaceutical must be reformulated and diluted for constant presence during the continuous elution.

"Other challenges include management of shelf life of the drug-loaded contact lenses, and their respective efficacy gradients may be impacted by aging over time. This in turn impacts the labeled shelf life," he explains. "There are multiple strategies for making drug-eluting contact lenses, including, but not limited to, surface printing, nanoparticles, polymer structure to accommodate molecule size and shape and microfluidics."

In March 2022, Johnson & Johnson's Acuvue Theravision (etafilcon A drug-eluting contact lens with ketotifen) was the first drug-eluting contact lens to receive FDA approval. Each daily disposable lens contains 19mcg of ketotifen and is indicated for the prevention of ocular itching due to allergic conjunctivitis. Phase III clinical trial findings showed a meaningful reduction in itchy eyes with allergies as quickly as three minutes after lens insertion and lasting up to 12 hours.[1]

John Gelles, OD, director of the Specialty Contact Lens Division at the Cornea and Laser Eye Institute (CLEI) and the CLEI Center for Keratoconus in New Jersey, says that he's heard this therapeutic contact lens has a "good effect for individuals who have mild allergies." While this approach so far appears to be less effective for patients with more moderate to severe allergies, he notes that this is a "big win for those with mild cases."

This approval—and others like it in the future—helps address a significant issue associated with eye drops: patient compliance. "This is a huge driver in these efforts," says Dr. Gelles, who is also a clinical assistant professor at Rutgers New Jersey Medical School, Department of Ophthalmology and Visual Science. "No one who needs correction is going to go without correction throughout the day. However,

that same person will skip their drops because they're inconvenient. So, if we can put their medication into lenses that they absolutely need, this can be very effective."

Another area where drug-eluting contact lenses are being explored is glaucoma. The SIGHT (Sustained Innovative Glaucoma and ocular Hypertension Treatment) clinical program aims to treat mild to moderate glaucoma and ocular hypertension. The phase IIa SIGHT-1 trial evaluated LLT-BMT1 (MediPrint Ophthalmics), a drug-eluting lens that uses bimatoprost.

"The study demonstrated strong safety signals with 100% tolerability and no significant adverse events," according to Dr. Barnett, who discussed drug-eluting lenses in a previous *Review of Optometry* article. "The researchers also found that the incidence of hyperemia among study participants was lower than what is observed for bimatoprost drops—a standard of care approach for this condition."[2]

Based on these findings, in November 2022, the company announced the initiation of SIGHT-2, a dose-finding phase IIb study. There are also plans to continue exploring the potential of LLT-BMT1 in phase III clinical trials.

Contact lenses could also prove to be an effective vehicle for latanoprost—an FDA-approved agent for the treatment of elevated intraocular pressure (IOP) in glaucoma patients. Preclinical data has shown that continued delivery of latanoprost via contact lenses is at least as effective as daily latanoprost ophthalmic solution, according to Dr. Barnett.[2] A phase I study is currently underway, aiming to explore the safety, tolerability, comfort and feasibility of lowering IOP in glaucoma patients using latanoprost-eluting contact lenses (NCT04500574).

There are a number of other avenues currently under investigation, including lenses that deliver anti-inflammatory, antibiotic and pain-reducing drugs. This could be beneficial for patients undergoing ocular surgery as well as those with corneal abrasions. Another area where drug-eluting lenses could have a significant impact is in the treatment of ocular inflammation. A dexamethasone-releasing contact lens has shown promise in animal models. "While more research is needed, dexamethasone-eluting lenses could prove to be an effective treatment for ocular inflammation and a promising drug-delivery system," says Dr. Barnett.[2]

Photo: Melissa Barnett, OD

The mainstays of drug delivery—bottles and droppers—can make instillation challenging for patients. So far, there's one drug-eluting contact lens available, Johnson & Johnson's Acuvue Theravision, and others are anticipated.

"Drug-releasing contact lenses may be beneficial for certain patients who have difficulty with compliance when drops are required multiple times a day," says Dr. Rojas. "For others, instillation of eye drops also poses a challenge.

"For age-related conditions that affect the same population, insertion and removal of contact lenses may still be just as difficult due to dexterity issues or poor vision," she adds. "Taking those considerations into account, it is evolving to where lens use may not be needed daily but for lesser wear time with extended-release capabilities up to several days after one day of wear."

Smart contact lenses. The field of smart contact lenses is an exciting one that could have an array of implications for eye care; however, we are still in the early stages of innovation. "Smart contact lens development is very difficult and has consumed as much as $1 billion in research and development to-date," notes Dr. Legerton.

"Two of the big four contact lens companies invested heavily for the better part of a decade in smart contact lens development and solved many of the important pieces required for placing electronics and micro-electro-mechanical-systems in contact lens materials," he says. He adds that the lenses advanced through phase II clinical investigations and stopped short of the phase III pivotal investigations needed for market clearance or approval.

"Generally speaking, they established efficacy for the indications they were pursuing in accommodating contact lenses and sensing of constituents in the tear film that are indicators of ocular or systemic health status," says Dr. Legerton. "Why did they not take the next steps to market clearance or approval?"

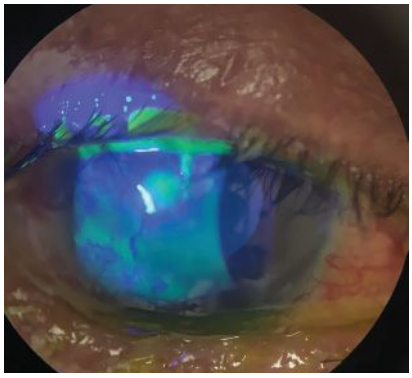


Photo: Melissa Barnett, OD

Antibiotics in the bowl of a scleral could help heal persistent epithelial defects and neurotrophic keratitis, as seen in this eye.

While the reasons for this are likely multifaceted, a necessary component of any commercialized product is that it must be both useful and usable. "When we describe a smart contact lens, we place a great emphasis on its usefulness or purpose. We envision what it does, its purpose and benefit to humankind and the problem it solves," says Dr. Legerton. "At the same time, the final product must be usable."

This holds true for smart contact lenses, as well. Just as these innovations need to address a problem and/or enhance quality of life, they must also not disturb vision. They need to be easy to handle, apply and remove. Additionally, the care product regimen must be convenient and usual, notes Dr. Legerton, and it must have an acceptable cost-to-benefit ratio.

Ongoing innovation is paving the way for the development of useful—and usable—smart contact lenses, and a variety of new directions are currently being explored. For instance, researchers have developed a smart contact lens that continually monitors an individual's blood sugar—a device that could have significant clinical implications if successfully brought to market.

"Smart contact lenses for continuous glucose monitoring have great potential for huge clinical impact. To date, their development has been limited by challenges in accurate detection of glucose without hysteresis for tear glucose monitoring to track the blood glucose levels," the researchers note in a recent *Advanced Materials* paper.[3]

Long-term continuous glucose monitoring was conducted in preclinical models using bimetallic nanocatalysts immobilized in nanoporous hydrogels in smart contact lenses, according to one study. "After redox reaction of glucose oxidase, the nanocatalysts facilitate rapid decomposition of hydrogen peroxide and nanoparticle-mediated charge transfer with drastically improved diffusion via rapid swelling of nanoporous hydrogels."

Another team of investigators developed a smart contact lens that can monitor and control IOP by combining an IOP sensor and a flexible drug-delivery system. Recently published findings showed that their theranostic smart contact lens enabled both IOP measurements in real-time and the appropriate amount of drug release to match the degree of IOP among rabbits with glaucoma.[4]

The concept of not only measuring but also controlling IOP via one system is exciting, Dr. Gelles notes. However, it also raises important questions, particularly in regard to extended wear. "We know the risks that are associated with extended contact lens wear, and we are going to have to find ways to mitigate those risks."

Innovega's iOptik smart contact lens is another example of where the field is headed. "The iOptik lens represents what we call eyeborne optics that enable the eye to see the real world and to view a near eye display without any other optics between the eye and the display," explains Dr. Legerton.

This technology is the first to reduce the bulk and weight in the display eyewear, according to Dr. Legerton. He notes that "all VR headsets and most AR glasses employ optics between the display and the eye. The iOptik lens allows for removal of those optics and direct viewing of the display while still seeing the real world with corrected vision."

Previously released findings from a phase II clinical trial "demonstrated positive results with normally sighted subjects fit with iOptik smart contact lenses when tested both with and without the display eyewear," according to the company.[5]

Another study of the eMacula system—which pairs the iOptik smart contact lenses with display eyewear—showed its potential for helping partially sighted individuals with their daily tasks, including reading, smartphone use and distance.[6]

Results showed that visual acuity was improved in each eye tested with the device. "Study participants also rated the comfort of the smart contact lenses at an average of 7.1 on a scale of one (poor) to 10 (excellent)," according to findings released by the company. "Three-quarters of subjects felt the device would likely improve performance on tasks of daily living and increase their independence."

These are just a handful of the various areas currently being explored and developed; the potential implications of smart contact lenses have just started to be fully realized. However, Dr. Rojas believes they could be particularly impactful for certain patients.

"It's especially exciting for low vision patients to implement the most up-to-date technology to not only improve their vision but also their quality of life," she says. She reiterates the benefits of other smart lenses, including "the ability to self-monitor and track IOP or glucose and/or provide extended-release drug-delivery options, which are beneficial in diagnosis and treatment plans."

OTHER CHALLENGES & CONSIDERATIONS

While the innovation behind these contact lenses is exciting and holds promise for the future of eye care, the

developmental process isn't without its hurdles, some that will certainly prove more challenging to navigate than others.

An example is Mojo Vision's recent pivot away from smart contact lenses. The company attempted to develop a scleral contact lens that included electronic components for projecting display light through the eye to the retina, explains Dr. Legerton. "The scleral contact lens form factor was, of necessity to house the electronics, approximately 2mm thick, or six-times the average scleral contact lens design."

This underscores the importance of usefulness and usability. "While the vision and mission of Mojo Vision was exciting, the practical element of using an ultra-thick scleral contact lens as the form factor was a show-stopper from the start with regard to the otherwise useful technology to be usable," says Dr. Legerton. He notes that the hope for success from the start depended on miniaturization.

"It is noteworthy that miniaturization is a major factor in the failure of smart glasses for extended reality to be accepted," he adds. "The headsets and glasses are simply too bulky, too heavy and consume too much power. The industry calls this 'SWAP,' or size, weight and power."

Does the display contact lens still have potential? As a self-described futurist, Dr. Legerton says, yes. "That said, futurists see mountain tops and have more difficulty estimating the length of the valleys between the mountain ranges," he notes. He also emphasizes that "electronics of all types have the potential to be components in a contact lens."

"The electronics industry has enjoyed miniaturization at an accelerated pace over the last six decades," Dr. Legerton says. "Mojo Vision made a pivot to exit the contact lens development and become a leader in the miniaturization that is required."

As hurdles are overcome and advances continue, optometrists will be on the frontlines of integrating new lenses, such as Johnson & Johnson's Theravision, into clinical practice. This comes with its own set of challenges and considerations, including issues of non-compliance, poor lens hygiene and overwear, according to Dr. Rojas.

"These can lead to further complications of irritation, inflammation, infections or risks to eye health," she notes. "Just like any medical device placed on any organ of the body, there need to be proper follow-ups to maintain the integrity and health of the eye and prevent any potential complications."

Optometrists, as they always do, will play a key role in patient education and support. "It is important for both the patient and the doctor to make sure patients are properly informed of the risks associated with improper lens care and wear," Dr. Rojas says.

"Any type of contact lens can pose a risk to eye health if not properly cared for or not fitted properly," she emphasizes. "Just like any other medical device, we need to make sure the patient's health is the priority and whatever device used has benefits that outweigh the risk."

ON THE HORIZON

What comes next? With ongoing advances and a growing interest in smart contact lenses, the path forward will certainly including multiple directions. And while it likely will be a long road with many twists and turns along the way, smart contact lenses could one day have a significant impact on eye care.

For Dr. Legerton, his personal vision and mission is to "invent and develop technologies that enhance the health, wellness and quality of life for humankind while respecting the value of optometry in the delivery of the technologies."

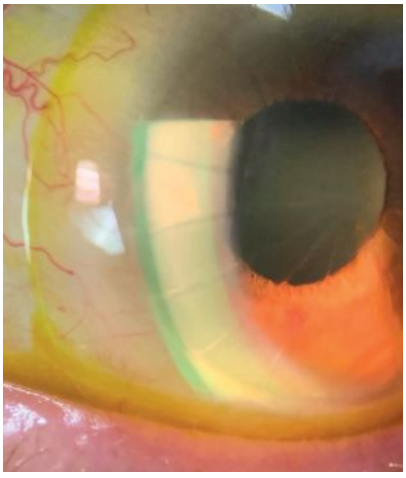


Photo: Melissa Barnett, OD

A scleral with sodium fluorescein on an eye with radial keratectomy, lipid keratitis and neovascularization.

While Dr. Rojas isn't sure smart contact lenses will become mainstream any time soon, as safety and affordability are still important factors to consider, she can see the benefit and initial growth for a specific patient base. "It is exciting to see how far technology has come and the potential it offers to improve patients' lives," she says. RCCL

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2. Barnett M. The Coming Rise of Drug-delivery Contact Lenses. Review of Optometry. 2021; https://www.reviewofoptometry.com/article/the-coming-rise-of-drugdelivery-contact-lenses.

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4. Kim TY, Mok JW, Hong SH, et al. Wireless theranostic smart contact lens for monitoring and control of intraocular pressure in glaucoma. Nature Communications. 2022; https://doi.org/10.1038/s41467-022-34597-8.

5. Positive Visual Performance Reported with Innovega's iOptik Contact Lens. https://www.prnewswire.com/news-releases/positive-visual-performance-reported-with-innovegas-ioptik-contact-lens-301421115.html.

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A Stitch in Time

Learning the common corneal complications of sutures will help you manage patients when symptoms present.

A 60-year-old male presented complaining of decreased vision of his left eye in his scleral contact lens. He reported that his vision was hazier than usual even wearing glasses. His ocular history was significant for a failed corneal transplant OD resulting in light perception vision and a penetrating keratoplasty (PKP) OS one year prior. He had a history of wearing a custom scleral lens OS. His drop regimen at the time was Durezol (difluprednate) every other day OD, Pred Forte (prednisolone) and Celluvisc (Refresh) OS.

Entering corrected acuity was 20/600 OS, pinhole to 20/400, and IOP was 16mm Hg. On exam, his palpebral conjunctiva was 2+ injected; he had slight edema on his PKP near a broken suture at 10 o'clock with a small epithelial defect and a small stromal infiltrate. The anterior chamber had a grade 1 cell, his pupil was round and reactive and he had grade 1 nuclear sclerosis.

DIAGNOSIS

The patient was diagnosed with a broken PKP suture OS with a small corneal infiltrate. The suture was removed in-office and the patient was instructed to discontinue lens wear. An assumption was made that the keratitis was likely bacterial in origin due to his contact lens use. He was instructed to continue Pred Forte BID and start moxifloxacin every waking hour.

He returned after a long weekend with his vision and IOP unchanged. The edema had improved, the epithelial defect was resolving and the small stromal infiltrate was receding. He was instructed to switch his moxifloxacin every two hours.

An example of a suture abscess, localized near the suture.

Five days later he returned and reported significant improvement. Entering acuity with glasses correction was 20/300, IOP was 19mm Hg, trace edema was seen, the epithelial defect had resolved and the infiltrate was gone. The patient was tapered to moxifloxacin four times a day.

One week later, vision had improved to 20/150 with correction, IOP remained normal, the PKP was clear, no edema was present and a small scar at 10 o'clock had formed. The patient was told to continue moxifloxacin for four more days and then discontinue. He was told he could restart lens wear in one week. At his two-week follow-up visit, his vision was back to its baseline of 20/70 in his scleral contact lens.

WHAT'S THE STITCH?

In this case, the patient was post-PKP; however, a suture complication can occur days to years after any suture placement, whether due to cataract extraction, laceration repair, glaucoma surgery and more.

When a patient has a suture in their eye, the possibility of a suture-related problem is present. As surgeons, ophthalmologists must make the decision of which type of suture material to use (nylon vs. Mersilene), which technique to use (continuous vs. interrupted) and when to remove the suture. The primary purpose of the suture placement at the time of surgery is proper apposition of the wound edges and aiding in the healing process.[1]

As optometrists, we play a vital role in recognizing the proper material, technique and use of these sutures at the same time as managing any complications they cause. Corneal sutures can lead to eye irritation, inflammation and increased risk of infection. Suture-related problems can involve excess tightness, loosening, breakage, infiltrates, giant papillary conjunctivitis, neovascularization and more.

The quickest way to access a suture is using topical sodium fluorescein (NaFl). If the suture is appropriately covered by epithelium, there should not be staining of the NaFl under blue light. If NaFl staining is seen, a thorough exploration for a broken, loose or eroded suture must be conducted.

COMPLICATIONS

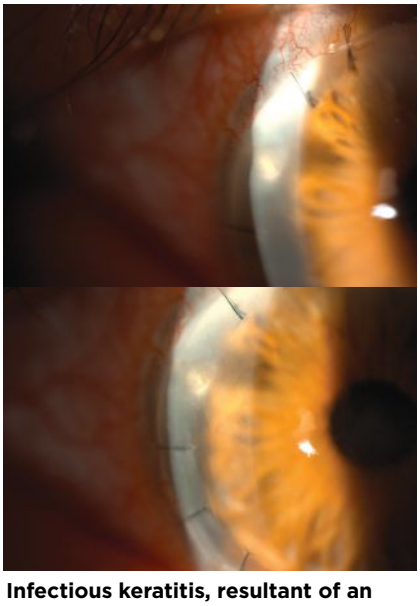
There are different kinds of suture complications, as detailed below:

Excessive tightness. Tightening can occur after a suture is placed and ultimately lead to irregular astigmatism. This can be followed by retinoscopy, refraction and corneal

topography. Often the decision to remove a suture is made to decrease induced astigmatism.

Suture loosening. Wound contraction is the usual cause of any loosened sutures, suture breaking, biodegradation of the suture material or suture cheese wiring with time. In a five-year retrospective PKP study in *Cornea*, the occurrence of loose sutures that would cause imminent wound separation needing surgical repair was 8.3%.

Broken, continuous suture. This does not aid in controlling wound stability and is why it has to be removed as soon as possible. Symptoms of postoperative suture breakage may be one or more of the following: foreign body sensation, irritation, redness, photophobia, epiphora and visual acuity alteration. Signs of postoperative suture breakage consist of the suture end which may be visible, discharge, injection, cells and flare, mucus filaments, conjunctival hyperemia, wound leak and more.



Infectious keratitis, resultant of an ulcerative epithelial defect.

An infectious abscess. These are usually localized around or near a broken, loose or exposed suture. Patients often complain of foreign body sensations, irritation, redness, photophobia, epiphora and visual changes. In the same five-year study, the occurrence of suture erosions was 10.8%, and in these cases, fluorescein-stained epithelial defects over one or more sutures were seen. Some patients were symptomatic while some were asymptomatic. Infectious keratitis, which is an ulcerative epithelial defect with stromal infiltrate, was observed to be 3.3% when adjacent to a broken or loose suture. Almost all cases presented with a hypopyon in the anterior chamber. These patients complained of foreign body sensations, discomfort and visual symptoms.

Noninfectious suture infiltrates. These present as small, non-progressive subepithelial suture infiltrates and were noted to be 0.4%. Subepithelial, suture-related immune infiltrates are common at the entry into the corneal stroma and often present in the early postoperative period. They can be seen on either side of the PKP; however, they are more often seen in the recipient's cornea. A small portion of these patients had mild foreign body sensations, while the majority were asymptomatic with no visual symptoms, and the complications were observed on a routine follow-up. When cultures were performed on this population they were often inconclusive.[2]

Giant papillary conjunctivitis. This condition is rare; however, it can be caused by exposed knots or broken suture due to a corneal or scleral suture. Often surgeons can rotate the suture so the knot is no longer exposed.

Vascularization. This effect can be seen along suture tracks, indicating that the wound is adequately healed in that area and the suture could be removed safely. It is important to remember that vascularized sutures are also at a high risk of loosening and can increase the risk of graft rejection.

MANAGEMENT

The first step is checking the suture's integrity and ruling out wound dehiscence and/or identifying an infection. There is no consensus regarding suture removal timing for adults, and often different approaches are used based on surgeon experience.

Non-pharmacological intervention of a loose or broken suture should be exercised with caution. Sterile instruments must be used, and the wound should be checked for leakage after removal. Povidone-iodine solutions are used prior to removal and a topical anesthetic may be necessary to aid in the removal. Prophylactic broad-spectrum topical antibiotic drops are often given until the epithelial defect is closed after removal, especially in cases where there is a likelihood of infection.

Prevention of suture-related complications is related to frequent monitoring and timely intervention. It is important to reiterate to patients the most common signs and symptoms so prompt care can be given. RCCL

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3. Henry CR, Flynn HW Jr., Miller D, et al. Delayed-onset endophthalmitis associated with corneal suture infections. J Ophthalmic Inflamm Infect. 2013;3(1):51.

By Christine W. Sindt, OD

Looks Can Be Deceiving

Pigmented iris lesions need not always be cause for concern.

A 58-year-old male presented to our clinic for evaluation of an iris lesion, identified after his wife noticed an irregular pupil in the left eye. He had no history of ocular surgery or trauma. His last eye exam, performed elsewhere, occurred at least 10 years prior. Despite the otherwise unremarkable history, he did, however, report a long history of iris heterochromia.

Upon examination, his visual acuity was 20/15 bilaterally without correction. Intraocular pressure was 20mm Hg OD and 16mm Hg OS. Pupillary, motility and confrontation visual field testing were all within normal limits bilaterally. Slit lamp examination revealed clear corneas and normal anterior chambers. The right iris had an yellowish coloration superonasally near the pupil. Additionally scattered throughout the iris were yellowish "fleshy" spots that likely represent a variant of normal anatomy. There were some prominent and dilated normal iris stromal vessels. The left iris had even more prominent stromal vessels. There was a yellowish nodule at 12 o'clock on the pupillary margin.

Inferiorly, there was marked ectropion uvea. At 6 to 7 o'clock, there was an amelanotic nodule with central excavation. No frank neovascularization was noted, though there was some increased vascularity nasal to the lesion. Gonioscopy revealed an open angle ciliary body 360 degrees in both eyes. There were no peripheral anterior synechiae, nor a neovascularization of the angle, noted.

Dilated fundus examination showed healthy optic nerves bilaterally with 0.1 cup-to-disc ratios. The retinal vasculature and periphery were normal, including no ciliary body or pars plana masses on the scleral indentation exam.

An ultrasound was obtained, which revealed a cystic-looking irregular structure from 5 to 7 o'clock on the inferior left iris. There was no evidence of ciliary body or posterior masses by ultrasound. A diagnosis was made of congenital iris lesion vs. occult trauma. The lesion was photodocumented and will be followed in six months for change. RCCL

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-Dr. Bradley Barnett, MD

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