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## REVIEW OF CORNEA & CONTACT LENSES



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SEPTEMBER/OCTOBER 2020

### RIGID LENS SUCCESS

*When only strength will do, here's  
how to build a lasting solution  
for your patients' visual needs.*

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1. CVI Data on file 2018. Non-dispensing, subject masked, randomized, bilateral, cross-over short-term clinical evaluation. 27 astigmatic, presbyopic soft CL wearers at 2 sites (UK & US) fitted using CVI fit guide  
2. CVI data on file 2019. Based on total number of prescription option combinations manufactured (for sphere, cylinder, axis and add – including D & N combinations). 3. For nearly 100% claim: CVI data on file 2020; Rx coverage database; 42 to 70 years  $\geq 0.75$ DC 4. CVI data on file, 2019. US industry reports and internal estimates. ©2020 CooperVision. 8823 04/20

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# BLINK Results Support Multifocals for Myopia

The long-awaited BLINK study results are out, and the data adds more weight to the growing body of evidence that soft multifocal contact lenses are viable treatment options for children with myopia.

The study included 294 children between the ages of seven and 11 with  $-0.75D$  to  $-5.00D$  of myopia and less than  $1.00D$  of astigmatism. The researchers, led by Jeffrey J. Walline, OD, PhD, of the Ohio State University College of Optometry, randomized patients to wear high add power, medium add power or single-vision contact lenses. The patients wore their lenses for a mean of 11.0 hours per day. At three years, the team evaluated the change in cycloplegic spherical equivalent autorefractometry and other secondary end points such as eye growth.

The study found the adjusted myopia progression after three years of treatment was  $-0.60D$  for those wearing high add power lenses,  $-0.89D$  for patients wearing medium add power and  $-1.05D$  for single-vision contact lens wearers. The researchers also noted the difference in progression was  $0.46D$  for high add power compared with single-vision,  $0.30D$  for high add power compared with medium add power and  $0.16D$  for medium add power compared with single-vision. The researchers added that longer wearing times did not seem to improve the  $+2.50D$  add power effects.

As for eye growth, patients wearing high add power lenses experienced the least growth, a mean of  $0.42mm$ , compared with those wearing medium add power ( $0.58mm$ ) or single-vision lenses ( $0.66mm$ ).

“Among children with myopia, treatment with high add power multifocal contact lenses significantly reduced the rate of myopia progression over three years compared with medium add power multifocal and single-vision contact lenses,” the researchers concluded in their paper.

Walline JJ, Walker MK, Mutti DO, et al. Effect of high add power, medium add power, or single-vision contact lenses on myopia progression in children: The BLINK randomized clinical trial. JAMA. August 11, 2020. [Epub ahead of print].

## GENETIC RISK FACTORS FOR MYOPIA IDENTIFIED

Researchers have linked two single-nucleotide polymorphisms (SNPs) to moderate and high myopia, while four other SNPs confer risk to excessive axial length in children.

In 3,300 children aged five to 10 years old, a team selected 13 SNPs in 13 genes/loci for genotyping and analyzed the associations between each with myopia severities and ocular traits.

The researchers found three SNPs nominally associated with myopia, while two others exhibited stronger associations with moderate and high myopia. Another SNP had a stronger association with mild myopia and showed a difference between emmetropia and hyperopia.

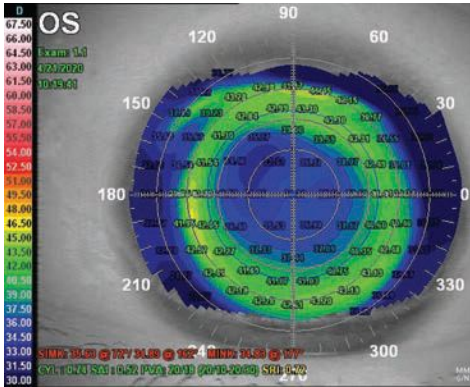
Three SNPs were correlated with both myopic spherical equivalent and axial length elongation, another correlated with both axial length and corneal radius and three more correlated with the axial length-corneal radius ratio.

Li FF, Lu SY, Tang SM, et al. Genetic associations of myopia severities and endophenotypes in children. Br J Ophthalmol. August 14, 2020. [Epub ahead of print].



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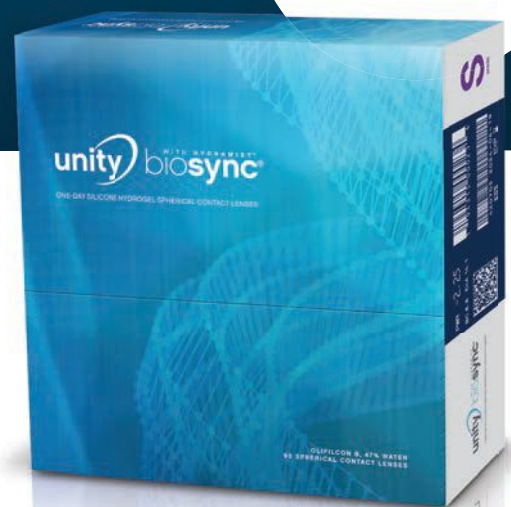
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# The FTC's One-Two Punch

Patient safety and prescriber sanity were not priorities of the recent rule change.

**T**he Contact Lens Rule, in effect since 2004, imposes obligations on both prescribers and sellers of contact lenses.

By all measures, we have complied admirably, with very few complaints made to the Federal Trade Commission (FTC). Unfortunately, the same can't be said about sellers, whose passive verification efforts are riddled with abuses. And now the final, amended Contact Lens Rule tips the scales further against prescribers and our patients. What on earth is the FTC thinking?

## HIT US WITH MORE PAPERWORK...

Instead of zeroing in on the seller's blatant infractions and disregard for the Rule's objectives, the FTC chose to place additional burdens on prescribers, requiring us to release all prescriptions and maintain documentation for three years. Unfortunately, the Final Rule does a poor job at modernizing the prescription verification process, especially the irksome computer-generated robocalls.<sup>1</sup>

The Final Rule's new hassles are made even more stressful by the COVID-19 pandemic. The cost of these new measures is estimated at \$18,000/year for every practice. This could easily be addressed through more modern and less intrusive means.<sup>1</sup>

The House Financial Services and General Government Subcommittee inserted language admonishing the FTC and directed the commission to delay implementation.<sup>1</sup> If it goes forward in October as planned, the FTC amendment gives us five options for documenting Rx release:

- Ask the patient to acknowledge

their receipt of the contact lens Rx by signing a separate document.

- Ask them to instead acknowledge this by signing a copy of the Rx that contains a statement confirming the patient received it.
- Add a statement about Rx release to the sales receipt for the exam and ask the patient to sign a copy.
- Provide the patient with a digital copy of the Rx in a way that is verifiable after the fact.

In addition, patients can request an additional copy of their prescriptions for within 40 business hours.

## ...AND LET SELLERS SLIDE

The Final Rule, although "prohibiting prescription alteration," includes modifications designed to purportedly reduce illegal sales by sellers. It allows substitution for private label lens prescriptions "when they are identical lenses made by the same manufacturer."<sup>2</sup> This modification is extremely troubling in light of the push by some sellers to make all prescriptions suitable for substitution with a generic version, if they so desire. It appears that we're only a small step away from that debacle.

Secondly, by not addressing the abuses that take place due to passive verification, the FTC has placed retail over health and safety. The FTC has definitely missed an opportunity to address safety concerns. There is a high rate of invalid prescriptions presented for passive verification.

More than half (52.8%) of all passive verification fax requests in a recent study were found to be invalid.<sup>3</sup> The majority of the prescriptions were expired, some contained incorrect specifications or no record of prescription by the provider. The au-

thors concluded, "the current mechanism of passive verification, with the burden on the provider for denial within a short time window, makes it likely that such prescriptions would be filled, potentially putting patient comfort and safety at risk."<sup>3</sup>

Should you witness any retailer's abuses, please report them to: [www.aoa.org/stopillegalcls](http://www.aoa.org/stopillegalcls). We need to support legislation (HR 3975) in Congress that addresses robocall abuses.

If I had the opportunity, I would ask the FTC bureaucrats: (1) why the imposition and additional encumbrance and (2) why now, when we're struggling to deal with the ravages to our practices placed upon us by the COVID-19 pandemic? The last thing we need is additional paperwork as things just begin to get back to near-normal.

**W**here do we go from here? If you're not happy and feel you want to continue the cause, write to your legislators now. A special thank you to the American Optometric Association, the Health Care Alliance for Patient Safety, the manufacturers who responded to date and all the rest of the folks who worked tirelessly to stop this unnecessary burden. Regardless of the final outcome, they should be acknowledged for their tenacious effort to halt the Final Rule. **RCCL**

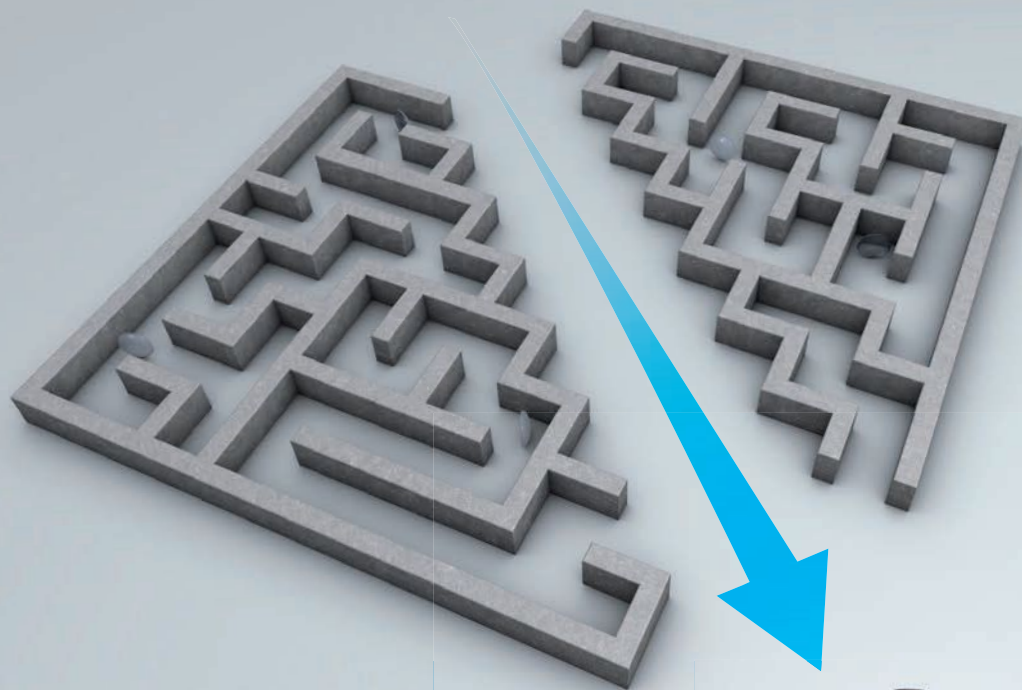
1. American Optometric Association. Action Changes Things. July 2020.

2. Federal Trade Commission. FTC Announces Final Amendments to the Agency's Contact Lens Rule. [www.ftc.gov/news-events/press-releases/2020/06/ftc-announces-final-amendments-agencys-contact-lens-rule](http://www.ftc.gov/news-events/press-releases/2020/06/ftc-announces-final-amendments-agencys-contact-lens-rule). June 23, 2020. Accessed July 30, 2020.

3. Yupari RJ, Steinemann TL: Passive verification: A flawed system putting patient's sight at risk. *Eye Contact Lens*. 2020;46(4):197-200.



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## Evidence-based Resources Amid COVID-19

Select advice can be useful in the clinic for patient education, while other information may contain background reading to educate yourself on best practices during the pandemic.

**H**aving recently put together myriad virtual learning resources for my students on all things cornea and contact lenses amidst the COVID-19 pandemic, I was reminded of several key resources for online education. Many have compiled extensive information regarding COVID-19 and how it affects contact lens wearers as well as best practices for safe contact lens wear.

In light of the pandemic, some of the resources around disinfection and safety have become more crucial than ever for you and your patients to know. Included here are some that will help propel you forward during this uncertain time. It is worth noting that several of these sites also have contact lens education (webinars, continuing education, articles) specific to gas permeable (GP) and soft contact lenses in addition to the information related to the pandemic.

### THE AOA

The American Optometric Association (AOA) put together a website of coronavirus/COVID-19 crisis response resources for optometrists and their patients during the pandemic ([www.aoa.org/coronavirus](http://www.aoa.org/coronavirus)). One of the AOA's popular offerings is a series of AskAOA webinars for practitioners to help navigate the pandemic in their offices, including special topics such as billing and coding for telehealth-based care and navigating Paycheck Protection Program loans. There are practice resources, including advice on what to do if



**A patient adds artificial tears to the bowl of a scleral lens while observing the in-office masking protocol. Patients receive an email before in-office appointments containing video training on application and removal of their particular lens type.**

someone in the office tests positive for COVID-19, as well as financial relief and support resources.

The AOA's patient-facing COVID-19 resources include advice on proper handwashing before every contact lens insertion and removal.

The AOA's site for contact lens health ([www.aoa.org/contactlenshealth](http://www.aoa.org/contactlenshealth)) contains information that was previously housed on [contactlenssafety.org](http://contactlenssafety.org). Whether for my patients, coworkers or my students, I often turn to this resource to provide the citations behind the recommendations we make daily. There are four sections that I reference the most, collected together at the top of the sidebar: contact lens case care, lens care, purchasing and environments. Further contact lens fitting and training advice pertinent to the

pandemic can be found at [www.aoa.org/contact-lens-fitting-and-training-during-covid-toolkit](http://www.aoa.org/contact-lens-fitting-and-training-during-covid-toolkit).

### THE AAO

The American Academy of Optometry (AAO) has a new resource right on its homepage called My COVID-Hub ([www.aaopt.org/my-covid-hub](http://www.aaopt.org/my-covid-hub)), which is an up-to-date repository of clinical information related to the COVID-19 pandemic. The AAO appointed a COVID-19 task force early in the pandemic and has worked to assemble an extensive list of resources. There is a video series covering the most up-to-date information, including a donning and doffing of personal protective equipment (PPE) video, a clinical update and information on how COVID-19 can affect the eye.

The Academy's COVID-19 Hub features over 25 "synopsis" documents that provide a research summary of relevant COVID-19 literature. There are also patient-facing resources that assist in identifying COVID-19-associated pink eye and provide patient education on what to do if someone thinks they have ocular sequelae.

Of note, the Hub also contain a printable version of the newest flow chart for in-office disinfection of multi-patient use contact lens. For GP lenses, the recommendation is to clean the lens with daily cleaner and then disinfect it for three or more hours in 3% ophthalmic-grade hydrogen peroxide in a non-neutralizing case. After the soak, the lens is rinsed with multipurpose solution, patted dry and stored.



## THE CDC

The Centers for Disease Control and Prevention (CDC) offer numerous resources, updated daily, regarding COVID-19 at ([www.cdc.gov/coronavirus/2019-ncov/index.html](http://www.cdc.gov/coronavirus/2019-ncov/index.html)). Regarding handwashing, there are several useful things here: [www.cdc.gov/handwashing/when-how-handwashing.html](http://www.cdc.gov/handwashing/when-how-handwashing.html). Specifically, the CDC's "Clean Hands Count" campaign encourages healthcare providers to make hand hygiene a priority. On these pages, you can find downloadable posters, factsheets, brochures and other assets to help promote handwashing in your practice and on social media using the hashtag, #CleanHandsCount.

## THE CORE

A recent peer-reviewed paper from the Centre for Ocular Research and Education (CORE) published in *Contact Lens and Anterior Eye* draws attention to considerations for contact lens practitioners during the COVID-19 pandemic. The paper urges eye care practitioners to review optimal contact lens care behaviors and practices with patients, including: appropriate handwashing before both contact lens application and removal, appropriate daily cleaning and case care practices, avoidance of contact lens wear altogether if unwell (particularly with any cold or flu-like symptoms) and reminders about the option of moving to daily disposable lenses where applicable/appropriate.<sup>1</sup>

CORE's top tips for contact lens patients during the pandemic, summarized in a one-minute video,

at [core.uwaterloo.ca/covid-19/](http://core.uwaterloo.ca/covid-19/) include:

1. You can keep wearing contact lenses.
2. Good hygiene habits are critical.
3. Regular eyeglasses/spectacles do not provide adequate protection.
4. Keep unwashed hands away from your face.
5. If you are ill, temporarily stop wearing your contacts and use your glasses instead.

The *Contact Lens Update* website ([contactlensupdate.com](http://contactlensupdate.com)) is also produced by CORE. The site's COVID-19 Special Edition Issue, published in March 2020, contains insight regarding the pandemic for both practitioners and patients.

One special resource available there is a set of four printable brochures that eye care practitioners can download and distribute to patients.

## THE BCLA


The June issue of *Contact Lens and Anterior Eye*, the journal of the British Contact Lens Association (BCLA), contains an article titled "Contact Lens Practice in the Time of COVID-19."<sup>2</sup>

Other useful resources on the BCLA site ([bcla.org.uk/public/public/consumer/contact-lens-wear-and-coronavirus-guidance.aspx](http://bcla.org.uk/public/public/consumer/contact-lens-wear-and-coronavirus-guidance.aspx)) include advice on returning to practice and wearing gloves during a contact lens evaluation as well as two issued statements on contact lens wear: one geared toward eye care practitioners and the other toward consumers.

## THE GPLI

During the pandemic, extra webinars at the Gas Permeable Lens Institute (GPLI) were added on specialty GP lens fitting and maintaining best practices for contact lens safety during COVID-19 ([www.gpli.info/](http://www.gpli.info/)). The most informative offering specifically related to the pandemic is a 90-minute special COVID-19 webinar titled "Today's Contact Lens Challenges Bring Tomorrow's Practice Advantages," that features its executive director, Ed Bennett, OD, as moderator and panelists Jeffrey Sonsino, OD, and Susan Resnick, OD.

The GPLI has also gathered links to various contact lens practice-related and keratoconus-specific COVID-19 resources on its COVID-19 Resource Center: What to Know About Contact Lenses and Practice Reopening page at [www.gpli.info/coronavirus/](http://www.gpli.info/coronavirus/).

Across the Internet, there are many resources on COVID-19, but only select ones contain trusted information that can educate yourself, your staff and your patients. In a fast-changing situation like this global pandemic, it is prudent to ensure you are keeping up-to-date with the most current advice for soft lenses and GPs and seeking out that information from credible and professional regulatory bodies and government sources. Stay healthy! 

1. Jones L, Walsh K, Willcox M, et al. The COVID-19 pandemic: important considerations for contact lens practitioners. *Cont Lens Anterior Eye*. 2020;43(3):196-203.

2. Zeri F, Naroo SA. Contact lens practice in the time of COVID-19. *Cont Lens Anterior Eye*. 2020;43(3):193-5.

# Bad Fit, Big Opportunity

A decentered lens compromised vision and induced corneal reshaping.

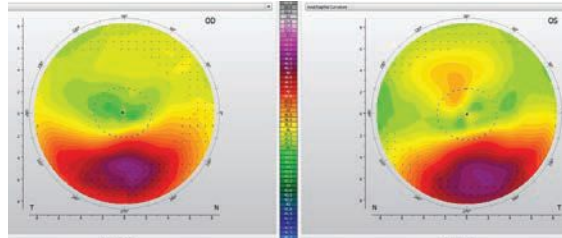
**W**hen properly fit, corneal gas permeable (GP) multifocal lenses can provide a clear, comfortable and healthy contact lens option. Fortunately, these lenses are generally simple to fit and follow the same basic fitting strategies as other GPs. An ideal fit consists of a centered lens, a slightly steep central and mid-peripheral fluorescein pattern, approximately 1mm of edge lift and 1mm to 2mm of movement. This case highlights the importance of a properly fit lens in achieving visual success and demonstrates the impact that poorly fit corneal GP lenses can have on the anterior corneal surface.

## THE CASE

A 59-year-old female presented for a contact lens fitting. She had been wearing corneal GP lenses for more than 30 years. During the past five, she had moved from distance vision to multifocal lenses. During this period, she struggled to achieve the near vision she needed to be functional in her occupation as an accountant. Also, the distance vision she was able to achieve with her glasses was not clear on the days she had worn her lenses. She presented to our office for a second opinion, as she had grown frustrated with her current lenses.

## DIAGNOSTIC TESTING

Entering distance visual acuity (DVA) with her current lenses was 20/30 OD, 20/30 OS and 20/30 OU. Near visual acuity (NVA) was 20/50 OU. The fit assessment in both eyes showed a superiorly decentered lens, a flat central fitting relationship and



**Fig. 1. The patient's eyes had a large degree of asymmetry between the superior and inferior cornea with significant inferior steepening.**

high edge lift. The lens was essentially immobile, requiring manual manipulation to create any movement. Parameters of the patient's habitual lenses were unavailable, though the overall diameter (OAD) was measured at 9.3mm OD and OS.

Upon removal of the patient's lenses, I performed topography. Both eyes demonstrated a large degree of asymmetry between the superior and inferior cornea with significant inferior steepening (*Figure 1*).

Slit-lamp exam of the cornea was relatively unremarkable with an intact epithelium and a clear stroma. There was no evidence of ectasia.

I then conducted refraction. Her habitual glasses yielded -7.75 -0.25x033 with a DVA of 20/80 and an NVA of 20/50 OD and -8.75 with a DVA of 20/50 OS and an add of +2.25D OU. Her manifest refraction was -5.25 -0.50x140 with a DVA of 20/25 and an NVA of 20/25 OD and -7.50 -0.25x050 with a DVA of 20/25 OS and an add of +2.00D OU.

Based on the fit assessment and topography, I identified corneal molding (i.e., corneal reshaping as a result of the interaction between the cornea and contact lens). The superior decentration and flat fit of the patient's habitual lenses had resulted in superior flattening and

inferior steepening of the anterior corneal surface. This was further suggested by the patient's complaint of spectacle blur, a potential result of flat-fitting corneal GP lenses. In comparing the manifest refraction after lens removal to the patient's habitual glasses, there was clearly a hyperopic refractive shift created by the

central corneal pressure exerted by her habitual lenses.

I reviewed this with the patient and advised a refit. Although I would have preferred she discontinue lens wear for one to two weeks before a refit, the patient noted she was unable to function in her current glasses. As such, I performed an initial fitting with the expectation that additional alterations would be required based on the expected changes in her corneal shape following the discontinuation of her current lenses. Her glasses Rx would be finalized following the contact lens refit.

## INITIAL FITTING

I used a spherical corneal GP lens to perform a diagnostic fitting and a larger-diameter corneal lens to better center the lens. We trialed lenses until achieving a uniformly aligned fit OU.

Consistent with the patient's corneal topography, the lenses tended to decenter inferiorly, centering over the steepest portion of the cornea. I accepted this outcome because of her current corneal shape and assumed the decentration would correct itself as the cornea returned to a more symmetrical pattern.

The diagnostic lenses that displayed the best fitting relationship were -3.00D/46.50D/10.00mm



OAD/0.12mm axial edge lift (AEL) with an over-refraction of -4.00D and a DVA of 20/20 OD and -3.00D/46.50D/10.00mm OAD/0.12mm AEL with an over-refraction of -5.50D and a DVA of 20/20 OS.

While the central relationship was adequate, the lenses displayed excess edge lift. I compensated for this by decreasing the AEL to 0.08mm in both eyes. I selected a center-distance aspheric multifocal design and calculated the add by using lens design guidelines and adding 0.25D to the spectacle add.

I ordered the following lenses: -6.75D/+2.25D add/ 46.50D/10.00mm OAD/0.08mm AEL OD and -8.25D/+2.25D add/46.50D/10.00mm OAD/0.08mm AEL OS.

### LENS DISPENSING

At this visit, the lenses showed a fairly uniform alignment pattern, were minimally decentered inferiorly and an improved edge lift compared with the diagnostic lenses. The patient's distance and near vision was 20/30 OU. I dispensed the lenses and asked the patient to return in one week.

### FOLLOW-UP

The entering distance vision was 20/30 OU and near vision was 20/20 OU. She reported improved vision compared with her habitual lenses at near but said her distance vision was not as clear as she would like. She noted good comfort with the lenses and no difficulty removing them.

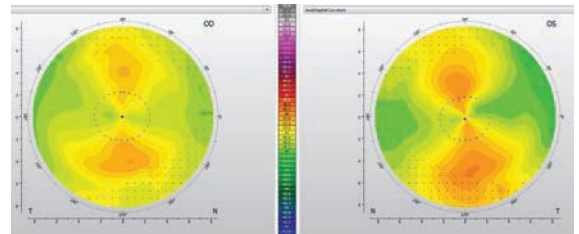
The lens fit had significantly changed since dispensing. The lens centration had gone from inferior OU to well-centered OD and mildly superiorly decentered OS.

The fluorescein pattern now displayed a with-the-rule astigmatism pattern with alignment along the horizontal meridian and mild clearance along the vertical meridian.

The right eye had adequate edge lift 360° around the lens, while the left eye showed excess superior and inferior edge lift. I presumed this high vertical edge lift was causing the mild superior decentration in the left eye. The fit was optimal in the right eye. I used a toric edge design in the left eye to steepen the vertical meridian's edge and improve centration.

A -0.50 OU distance over-refraction improved distance acuity to 20/20 while preserving near acuity of 20/20. I ordered new lenses with these parameters: -7.25D/+2.25D add/46.50D/10.00mm OAD/0.08mm AEL OD and -8.75D/+2.25D add/46.50D/10.00mm OAD/0.08mm AEL OS. These lenses yielded a distance and near visual acuity of 20/20 OU. As expected, the new left lens was centered and displayed a more uniform edge lift pattern with the toric peripheral curves.

The patient returned two weeks later and reported excellent distance and near vision. Her distance and near visual acuity was still 20/20 OU. The fit remained unchanged with centered lenses, a with-the-rule central fitting relationship, uniform edge lift and 1mm of movement. After removing the lenses, I performed topography. Both eyes displayed a regular, with-the-rule corneal astigmatism pattern (Figure 2). I finalized the contact lens Rx.



**Fig. 2. A regular, with-the-rule corneal astigmatism pattern was visible in both eyes.**

I then repeated manifest refraction. As anticipated, the results were significantly different with the refit. The new manifest correlated well with the changes in topography. It measured -8.25 -1.25x180 with a DVA of 20/20 and an NVA of 20/20 OD and -9.00 -2.25x015 with a DVA of 20/20 OS and an add of +2.00D OU.

I issued a new glasses prescription. The patient has since reported an easier transition from contact lenses to glasses upon lens removal.

### DISCUSSION

I needed to correct two issues when refitting this patient. First and foremost, I was tasked with improving distance and near vision in contact lenses. Secondarily, I had to address her spectacle blur. Both issues were the result of poor-fitting habitual lenses. The flat-fitting original lenses were decentered superiorly, placing the patient's visual axis within the mid-periphery of the lens and resulting in subpar visual performance at both distance and near. The fit was also causing the corneal molding responsible for the spectacle blur.

To improve centration, we pursued a larger lens design and a central alignment fit. The patient was able to achieve clear distance and near vision while easily transitioning from contact lenses to glasses. **RCL**

# Let's Talk About Labs

**Ask yourself if your current relationship with your labs meets your needs.**

By Suzanne Sherman, OD, and Pratik Patel, OD

**T**echnology and resources for specialty contact lenses are rapidly expanding, and practitioners are now surrounded by a variety of evolving lens labs. The two of us got together to discuss how we evaluate labs and how our relationships have evolved as we have become more experienced.

The key questions in this discussion revolve around how to choose one lab vs. another and how to determine if a lab is good for them. It became evident that four key lab qualities helped answer those questions. The qualities that we focus on here include the product(s) offered, the people we interact with, the location/size and the lab policies. Our conversation further delves into the intricacies of these four qualities.

## PRODUCT

*Is it more important for a lab to offer variety or specificity?*

**Dr. Sherman:** Many labs offer a variety of products from soft lenses to sclerals. Sometimes, these larger companies act as distributors and provide various products from nu-

merous brands. Whereas other labs solely focus on a specific product and possibly are well-known in that niche. Each option is great, and choosing the best for you often depends on the modalities offered and your practice's patient population.

A lab that offers a variety of products can be a good resource for a practice that wants to provide specialty contact lens services but is just starting out or sees a lower volume of patients. Ordering from this lab is a centralized way to access different types of contacts from a single location. In addition, it can be easier for backend payment purposes.

However, a lab that specializes in one product can also be quite valuable. For example, a lab that only makes scleral lenses may provide more unique customization and consultation options that larger labs may not offer. The extra focus on one product may make the lab the top in the industry.

For example, both of us work in a large medical center and co-manage a lot of anterior segment pathology. So having access to the best products and customization

to treat and manage complex cases is crucial. This will reduce lens remakes and patient satisfaction. So for me, the expertise of labs with specificity is more sought after.

*Does the lab need to offer the latest technologies?*

**Dr. Patel:** Advanced technologies became increasingly important to me when I started to expand my specialty lens service. The days of seeing straightforward keratoconus patients had passed, and I needed

## ABOUT THE AUTHORS



Dr. Sherman is an assistant professor of optometric sciences (in ophthalmology) and the director of optometry at Columbia University Medical Center. She specializes in complex and medically necessary contact lens fittings and ocular disease. She is a fellow of the American Academy of Optometry.



Dr. Patel is currently a clinical instructor at Weill Cornell Medicine Ophthalmology in New York City, where his focus is anterior segment management and specialty contact lens fitting. He is a fellow of the American Academy of Optometry.

ways to accommodate more challenging cases. I quickly realized that if I had a patient in a lens that couldn't be modified, I would have to start the process from scratch with a different lens.

While I don't use advanced technologies such as microvaults, decentered optics, channels or multifocals on all my patients, working with a lab that provides these options when I need them has become crucial to my practice. I can troubleshoot areas of concern quicker, and I can apply them to my initial fits more often. These customization options have elevated my specialty practice and set me apart from practitioners who do not feel comfortable using these advanced technologies.

## PEOPLE

### *Is the lab's team important?*

**Dr. Patel:** A lab is made up of numerous people, from the team members who take the order to the customer service staff on the phone. The longer I work with a lab, the more I get to know many of them. Building a relationship with a lab can go a long way towards maintaining happy patients, who deserve the best available. This may occur over the phone with customer service or by chatting with a sales representative at a conference exhibit hall. We have all had fittings that do not go as expected or have ordered lenses with the wrong fit or prescription changes. A reassuring call with a friendly, understanding customer service member can resolve these worries and ease any added stress.

A lab that emphasizes their commitment to working along with practices can result in a long relationship, trust and loyalty.

### *How important is the consultant-practitioner relationship?*



**Ensure that your labs deliver your orders in a timely fashion, so that they are ready for dispensing.**

**Dr. Sherman:** Your relationship with your lab should be a partnership. While you are loyal to them and bring them business, they also need to know that you will need to lean on them from time to time.

Time is everything. My practice is part of a large academic hospital center in the middle of New York City, where efficiency and effectiveness are crucial. I have learned that I need one consultant from each lab that I trust thoroughly, and I need the quickest and easiest way to reach them.

At the beginning of my career, talking to a consultant on the telephone gave me the support I needed; however, I would grow frustrated if they kept me on hold for long periods of time. As I became more knowledgeable about each specific lens, I found I didn't need the consultant to the same degree. I adapted my communication to only sending a quick email to someone I trusted who was fast and efficient.

More recently, some labs have their own web portal where you can see graphs and images of lens

manipulations. This is a great tool for a more seasoned clinician. First, I feel more in control and, second, I can show students and residents exactly what I am thinking. I have also often used these visuals in grand round presentations to teach my ophthalmology colleagues more about custom lens fittings.

In the end, my relationship with each lab consultant is different, but the theme is the same: I want a consultant or lab representative with a wide depth of knowledge, the ability to think outside of the box and the availability to be easily reached. If I don't find this right off the bat, I often will shift away from that lab.

## LOCATION AND SIZE

### *Where is the lab delivering goods from?*

**Dr. Sherman:** Even though we are healthcare professionals, if you fit lenses, you still deal with customer service. We all have patients who want their lens the same day they come in for their first visit, or they are moving to another country tomorrow and immediately need a new lens.

Whether the lab is in the United States or not, in your current state or across the country, matters in terms of shipping time. For my practice patient demographic, this is crucial to maintaining the patient. I frequently have patients come from around the world for a short period of time to see me and a few other specialists in the area. This constraint demands expedited shipping as well as quick and accurate delivery methods. If a lab consistently takes longer than promised, I will often reassess my relationship with them and try to find someone who makes a comparable product and can deliver in a timelier manner.

We all have had a patient who

## LET'S TALK ABOUT LABS



**A lab that offers a variety of products can be a good resource for a practice that wants to provide specialty contact lens services.**



**A lab that only makes scleral lenses may provide more unique customization and consultation options that larger labs may not offer.**

is fully dependent on their lenses call the practice saying they lost or broke a lens. How quickly we can achieve adequate patient satisfaction affects our patient's general thoughts about our services and our practice.

### *Does lab size matter?*

**Dr. Patel:** In recent years, we have seen small labs bought by larger companies who then integrate them into a family of products. This creates a one-stop shop for practitioners. This can be advantageous in numerous ways. It can streamline ordering a variety of lenses at once and also reduce costs such as shipping.

In addition, larger labs have greater outreach to practitioners. This may allow a practice to have access to products that may not have been otherwise accessible due to logistical reasons. Larger labs may also offer resources such as patient education material and marketing assistance.

In comparison, smaller labs provide their own unique experience. Practices that use smaller labs can become familiar with lab personnel

and speak with the same consultant each day, compared with a call center with many customer service representatives at a large lab. The familiarity and understanding between the consultant and practitioner can reduce ordering time and lessen the chance for a remake. Once a larger company takes over, the consultation services may become combined with several products and the experience may differ.

Larger labs or distributors can offer your practice many products and services, but remember that small labs can provide unparalleled personalized knowledge and service.

### **POLICIES**

#### *How's the warranty and flexibility of the lab?*

**Dr. Sherman:** I think of my contact lens lab warranties and return policies the same way as I think of any retailer: they must keep up with the market. When I was a new fitter, I relied heavily on being able to do multiple remakes, and, now as a more experienced practitioner,

I know my patients are relieved to know we have the time to get the fit correct. I often send them away with their initial pair for a month before seeing them back, which then allows me to troubleshoot more long-term complications at the second visit.

Therefore, if a lab isn't giving you the same or greater warranty time and flexibility as other labs, then you have to consider if they offer something that no one else has. Otherwise, it is time to move on.

In time, you will figure out how accommodating the lab is to your needs, whether it's breaking a lens accidentally or missing the warranty by a day. This has been especially important during the current COVID-19 pandemic since many patients are reluctant to schedule a follow-up visit.

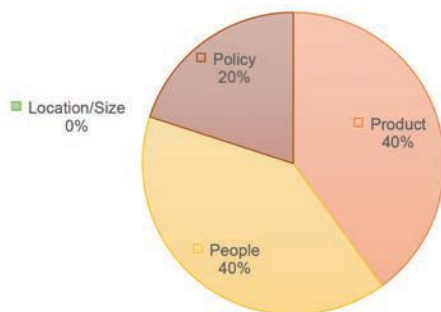
Lastly, a financial assistance program can be the icing on top of the cake. A lab with a good product that also assists you in helping others is smart business for you both. The extra benefit allows you to help those who might not



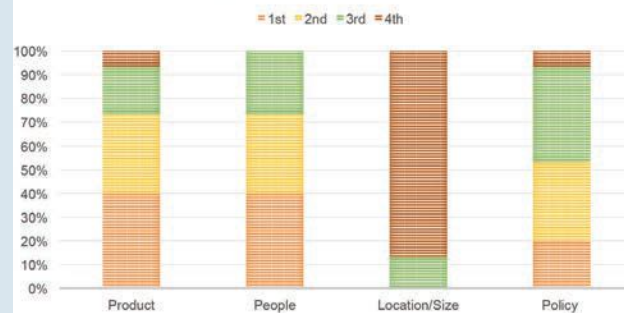
## Practice What You Preach

Choosing a lab is subjective, with no exact formula. So the two of us thought it would be a good idea to gather various opinions of specialty contact lens practitioners from around the country. We asked them to rank the four lab qualities we devised (product, people, location/size and policy) in order of importance to them. We polled 15 colleagues with an almost even split between private practice (solo or group) and academic (optometry school or medical centers) modalities. The figures below show the distribution. Product and people were the two most important factors, and location/size the least. An interesting finding between private practices vs. academic practitioners was that private practitioners place slightly more importance on policies. Although this was not a scientific poll, the information shows that there is not just one specific factor that practitioners consider when working with a lab.

### MOST IMPORTANT LAB QUALITY



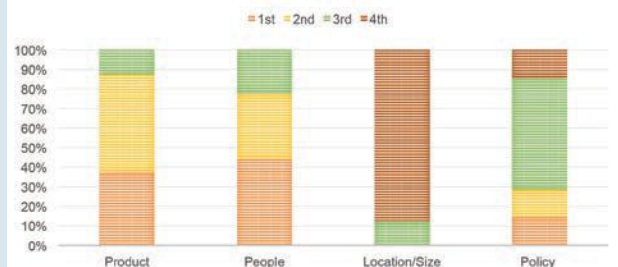
### LAB QUALITIES RANKING



### LAB QUALITIES RANKING PRIVATE PRACTICE



### LAB QUALITIES RANKING ACADEMIC



ordinarily be able to be fit in any kind of special lens, and these cases make you more well-rounded as a practitioner.

#### What about billing?

**Dr. Patel:** Often, we think about the cost and the warranty policy, so billing might not initially come to mind. Billing and payment may be the least of a practitioner's concern when fitting lenses but should be a crucial practice management consideration.

Depending on the practice's structure, always check with your staff member who deals with invoices and payment. The way the

lab structures and sends invoices may not be the ideal format and could provide challenges for the office payment staff. This can be more evident in larger practice settings with multiple providers and departments. The last thing a busy specialty lens practice wants to see is a hold on an account. Communication is essential between the practitioner, office payment staff and lab billing staff.

Choosing a lab is a personal decision, with right or wrong answer. Take a step back and prioritize what aspects are most

important to you and your practice, then review your current lab relationships. Do they share the same values and goals as you? Do you feel that you are in a partnership with them, even if they are a large company? If the answer is yes, then you know you are in a strong place. If not, then it is time to reassess.

Lastly, always keep your eye on new opportunities when you see them at conferences, journals and CE sessions. Even if you are content and doing well, it is prudent to keep a pulse on where the industry is going. **RCCL**

# When to Consider Piggybacks and Hybrids

**Get the best of both worlds when mastering the techniques for these options.**

By Ryan O. McKinnis, OD

**W**hat was once one of the more popular methods of mitigating contact lens–related discomfort is now often relegated to an afterthought. Piggyback fitting, which involves placing a soft lens beneath a corneal rigid gas permeable (GP) lens, was once the primary tool practitioners employed to reduce discomfort in those who relied on the vision provided by their rigid lenses.

Previous generations of hydrogel contact lenses failed to provide sufficient oxygen transmissibility and tear exchange to preserve corneal physiology. Newer silicone hydrogel soft lenses, in conjunction with improved rigid GP technology, have rectified many of these concerns.<sup>1</sup> With the explosion of scleral lens technology, the art of piggyback fitting is not often discussed. However, it remains a valuable tool that practitioners would be wise to use.<sup>2</sup>

## SETTING IT UP

The beauty of piggyback fitting lies in its simplicity. The practitioner

first fits the desired rigid GP lens and achieves the best lens-to-cornea fitting relationship possible. When the corneal GP is ready to be dispensed, the practitioner places the soft lens on the eye prior to inserting the corneal rigid lens. This helps achieve a cushioning effect, whereas the corneal rigid lens is no longer resting directly on the cornea.

The goal of such a fitting relationship is to maintain the optics of the GP lens while improving overall comfort and avoiding corneal insult.<sup>3</sup> This is achieved by ensuring that the soft lens portion of the system achieves some movement along with the rigid lens.

The optics of such a system are remarkably simple as well. The soft contact lens only contributes 20% of its listed power to the overall refractive system.<sup>4</sup> Thus, if a nominally powered soft lens is used, the power of the soft contact lens can effectively be ignored when calculating the final power of the corneal rigid lens.

Some practitioners will use a moderately high-plus soft lens, such as a +3.00DS lens, if the location of the

cone is low. In these instances, the soft lens may contribute a visually significant amount of refractive power into the system and would require neutralization by a corresponding change in the power of the corneal GP lens.

There is some debate surrounding whether it is best to use a nominal-powered soft contact lens vs. a plus-powered contact lens. The flatter front curvature noted with minus-powered and plano lenses may allow for a more appropriate fitting relationship when the steepest portion of the cornea is central or in the mid-periphery.<sup>5</sup> The flatter curvature of the soft contact lens provides some degree of normalization, upon which the rigid GP portion sets; in other words, the flatter

## ABOUT THE AUTHOR



Dr. McKinnis practices at the Cleveland Eye Clinic in Avon, OH. He is a Fellow of the American Academy of Optometry as well as a Fellow of the Scleral Lens Education Society.



**This poorly wetting scleral surface could benefit from adding a soft lens.**

front curvature of the soft lens may help to offset the steeper, underlying corneal curvature.

If the practitioner is fitting a regular cornea, then the GP can often be ordered empirically by providing the spectacle prescription and keratometry values. Occasionally, the lab may request corneal eccentricity data.

In the case of an irregular cornea, trial lens fitting is necessary to ascertain the best possible fitting relationship. Ordering these lenses is likewise straightforward; the practitioner will be asked to provide the trial lens base curve, power and over-refraction as well as any changes that are indicated. If a piggyback system is used, the laboratory consultant can calculate any changes to the GP power that may be necessary. The practitioner may also simply provide the final lens data requested if they prefer to work out the calculations on their own.

#### **CLEANING A PIGGYBACK**

One of the drawbacks related to a piggyback system is having the patient maintain different cleaning regimens for each lens. Traditionally, the soft lens would be manufac-

tured from a silicone hydrogel material to promote maximum available oxygen to the corneal structures. In years gone by, this would have uniformly meant that a monthly replacement soft lens was necessary. However, with the increased availability of single use contact lenses, a piggyback system no longer needs be complicated. These daily lenses may also be manufactured in silicone hydrogel materials, thus allowing practitioners and patients alike to benefit from simplicity while maintaining the corneal physiology.

#### **WHERE DO SCLERALS FIT?**

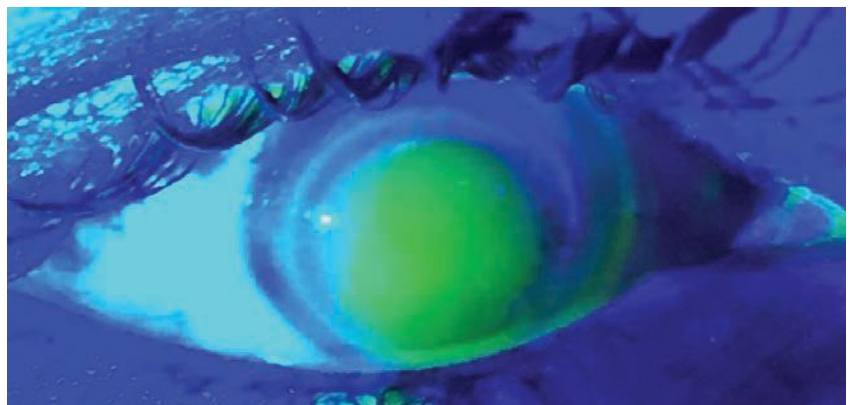
Scleral lenses have largely become the favored lenses of practitioners who fit irregular cornea patients. These devices are remarkably customizable and allow visual correction of patients with myriad corneal profiles. The practitioner can achieve comfort by avoiding corneal touch and allowing for the weight of the lens to be borne entirely by the conjunctiva and the underlying sclera. But is there a situation where a piggyback arrangement may be beneficial while also employing sclerals?

In short, using a scleral lens as part of a traditional piggyback system would indeed be rare. Back

when base curve alteration was one of the only means possible to adjust sagittal depth, there was some thought that using a soft lens beneath the scleral lens could alleviate mechanical trauma while optimizing the fit in other areas. There are also reports of successful piggyback systems when a soft contact lens is combined with a corneo-scleral lens.<sup>6</sup> However, given the array of options available today that allow for extreme customization of an ocular device, the use of a soft contact lens beneath a scleral is no longer in vogue. The physiologic concerns that stem from oxygen availability as well as the cumbersome nature of such a system would steer most practitioners away from such an arrangement.

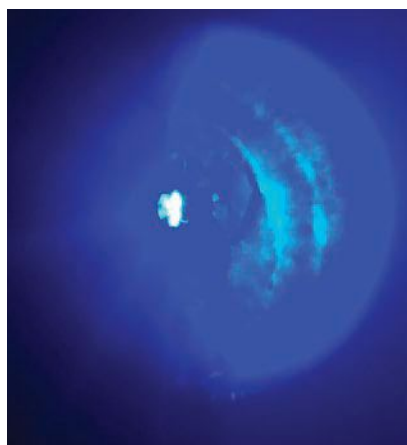
One niche use of soft contact lenses in conjunction with a scleral lens involves dealing with a poorly wetting scleral lens surface. A non-wetting scleral lens results in a poor visual experience as well as a substandard outcome, since the practitioner is unable to determine a proper refractive endpoint. While you could remove the scleral lens to rehabilitate the surface in a timely manner, this situation is often unwieldy and time-consuming.

Instead, a Dailies Total1 lens (Alcon) may be placed directly on the front surface of the scleral lens.



**This steep-fitting hybrid lens has a corresponding NaFl pattern.**

## WHEN TO CONSIDER PIGGYBACK SYSTEMS AND HYBRIDS



**Corneal molding and staining with a tight-fitting hybrid lens.**

When allowed to sit for 10 to 15 minutes, the lens surface will regain its wettability and the soft lens may be removed due to the unique phospholipid properties inherent in the Dailies Total1 lens. Upon removal of the soft lens, the scleral surface should now wet more appropriately.

Another iteration of a “reverse piggyback” may be beneficial in allowing the patient to “test-drive” a scleral lens while in the office. In a situation where the patient may be hesitant and doubts whether they will be able to appreciate the improved visual performance, place a daily lens mirroring the over-refraction on the front surface of the scleral lens. This would allow the patient to experience true visual potential in a controlled environment. Of course, you may also use a handheld lens to demonstrate to the patient their true visual potential. These uncommon situations may not present on a regular basis, but the available tools may aid the patient and practitioner in achieving a satisfactory result.

### HISTORY OF HYBRIDS

A more recent option that combines the visual benefits of a rigid GP lens with the improved comfort of a soft contact lens is hybrid contact lenses. First patented in 1977 by Charles E.

Erickson and Amar N. Neogi, the first commercially available hybrid lens was launched in 1984 under the trade name Saturn II.<sup>7</sup> Due to stresses placed on the soft hydrogel material during manufacturing, this iteration of hybrid lens suffered from the soft skirt tearing as well as corneal adherence and edema.

The original design underwent significant modifications and was re-released under the tradename SoftPerm. While material improvements allowed for an increase in successful fits as compared with the Saturn II lens, issues related to tight lenses, corneal staining and overall discomfort remained a barrier.

A third generation of hybrid lenses received market clearance in 2005. Manufactured and distributed by SynergEyes, four versions of hybrid lenses were initially available. The lenses were marketed as the SynergEyes A (for high astigmatism), SynergEyes KC (keratoconus), SynergEyes PS (post-surgical) and SynergEyes MF (multifocal). The lenses consisted of a GP portion with a dK value of 100 and a HEMA skirt with a dK value of approximately 17.

Due to improvements in manufacturing technology, separation of the skirt from the GP portion became nearly impossible. However, the lenses still exhibited tight-fitting characteristics. Such complications often included corneal staining, corneal molding and lens awareness.

### STRIVING FOR CORNEAL COMFORT

It was not until the fourth generation of hybrid contact lens technology that significant patient comfort was achieved. With the introduction of the Duette family of lenses (for normal corneas) and the UltraHealth family (for irregular corneas), it was finally possible to provide maximal oxygen availability

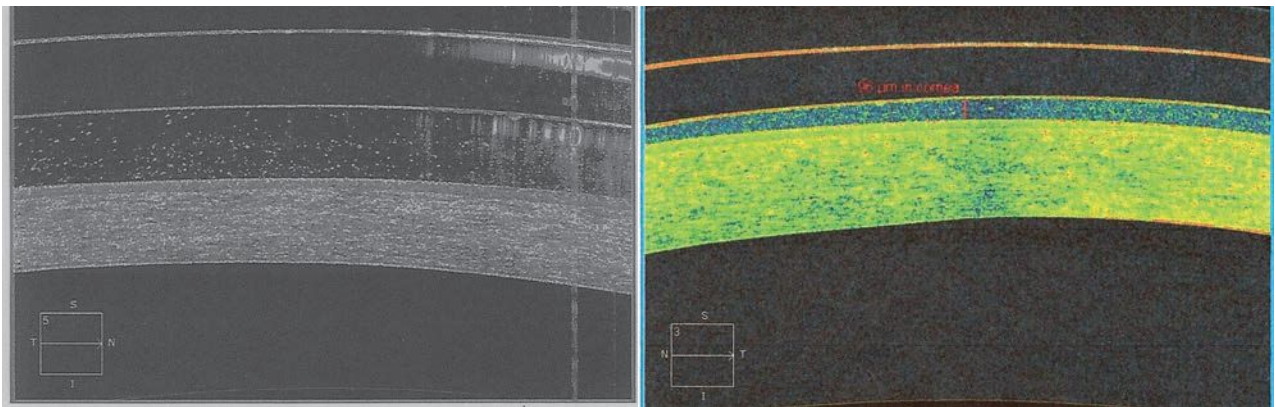
while maintaining proper corneal physiology. Both the Duette and UltraHealth consist of a hyper-dK rigid GP portion with a measured dK value of 130. The soft skirt is manufactured from a silicone hydrogel material with a dK value of 85.

With the transition away from HEMA materials, the overall fitting characteristics of the lens also required modification. With earlier versions of hybrid lenses, the HEMA skirt possessed sufficient strength to raise the overall clearance of the lens by altering the skirt profile. Silicone hydrogel skirts, however, do not possess this characteristic.<sup>8</sup>

Practitioners who had become accustomed to steepening the skirt profile to elevate the hybrid lens were now instructed to choose a lens with an overall deeper sagittal depth. The sole role of the soft skirt was to improve centration of the lens. This resulted in far fewer adjustments of the soft skirt profile when compared with the fitting philosophies employed with earlier hybrid lens iterations.

Practitioners may order the Duette family of lenses empirically by providing a member of the SynergEyes consultation team keratometry values, the spectacle prescription and the horizontal visible iris diameter (if available). A calculator is also available on the company’s website if the practitioner prefers to order the lens virtually ([synergieyes.com/professional/duette/fitting-calculator/](https://synergieyes.com/professional/duette/fitting-calculator/)).

If a multifocal lens is desired, the patient’s spectacle add power and pupil size are also necessary. Duette Progressive lenses are available in both center-distance and center-near designs. The center-distance version allows for alteration of the center zone with a target size of 1mm smaller than the pupil diameter in normal lighting. The center-near design has a fixed 3mm zone size.



**At left, OCT imaging of a scleral contact lens shows debris in the post-lens tear layer. Refitting this patient into a hybrid contact lens resulted in much less debris in the post-lens tear layer.**

### OPTIONS FOR THE IRREGULAR CORNEA

Much like its Duette counterpart, the UltraHealth lens comes in two iterations. The traditional UltraHealth design is typically used for ectatic corneas, such as those traditionally seen in keratoconus. Compared with earlier designs for irregular corneas, this UltraHealth lens has a mild reverse-geometry profile, a more forgiving landing zone and improved oxygen transmissibility.

For corneas that exhibit a more extreme oblate profile, the UltraHealth FC lens has expanded capabilities. The UltraHealth FC is most often used for corneas that have suffered post-refractive surgery ectasia, although it may also have clinical utility for corneas which exhibit an exceptionally low cone.<sup>9</sup>

Take special care when fitting a patient who has previously undergone radial keratotomy surgery. As the corneal rigidity has been compromised in these cases, these corneas exhibit a propensity to mold to the shape of the lens.<sup>10</sup> This may result in prolonged periods of spectacle blur following removal of the contact lens.

An ill-fitting hybrid lens, especially those that result in a tight-fitting relationship, will result in poor movement and poor tear exchange beneath the lens. This may also re-

sult in the formation of neovascularization. It has been postulated that chronic dilation of limbal vessels as the result of tight-fitting contact lenses may exacerbate new vessel formation.

### FOGGING

One area in which hybrid lenses may prove useful as a problem-solver is related to persistent fogging of the post-lens tear reservoir in scleral lenses. Such fogging often occurs due to excessive clearance over the corneal limbus, asymmetric landing of the scleral lens haptics and stagnation of corneal metabolites due to limited tear exchange beneath a scleral lens.<sup>11</sup>

In such instances, a hybrid lens may prove beneficial to help clear corneal debris due to lower corneal clearance and improved tear exchange. The smaller overall diameter of the hybrid contact lens may also eliminate the need for toric landing zones that are more commonly seen in scleral lenses that land far from the corneal limbus.

Whether using a piggyback arrangement or a hybrid contact lens, the full-scope practitioner has a wide variety of options available to maximize a patient's vision. While there are limits to the clinical utility of each,

piggyback systems and hybrid lenses allow for a more simplistic approach to fitting. Thoroughly understanding their benefits may help you realize how much of a solution the two can be. **REEL**

*Dr. McKinnis is a consultant to SynergEyes.*

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# MATERIAL MANAGEMENT IN A SCLERAL SOCIETY

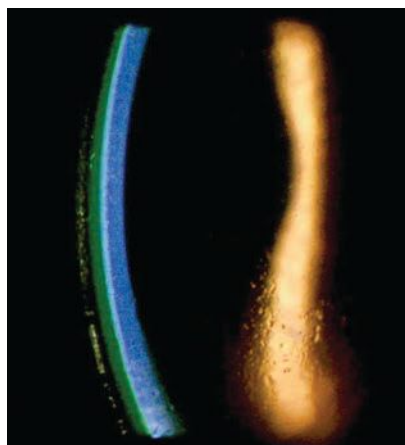
Have a comprehensive understanding of all your options prior to beginning the fitting process.

By Tyler Persson, OD, MS

Lens materials are often taken for granted when fitting and prescribing scleral contact lenses. Fortunately, eye care providers have the insight of in-house fitting consultants to rely on when choosing lens materials and designs. I regularly lean on their expertise and have found it increasingly useful to better understand the unique properties of specific lens materials as I expand my scleral lens practice. Becoming more knowledgeable about the materials that make up the lenses we prescribe leads to more accurate fits earlier in the process and, ultimately, happier patients with optimal vision.

## SCLERAL BACKGROUND

Scleral lenses have undergone vast improvements since their genesis. Today, they are used with great success and can improve vision in patients with compromised corneas and dry eyes and offer more stable options for patients with multifocal or high astigmatism requirements. Patients with keratoconus, corneal trauma or irregularity, post-refractive surgery complaints, corneal degeneration and Sjögren's syndrome are increasingly being fit with scleral lenses for improved vision and enhanced comfort.



This slit lamp cross-section shows a posterior tear reservoir of approximately 250 $\mu$ m.

Since the first scleral lenses were invented in the 1880s, material advances have increased oxygen permeability, improved structural integrity and customized the fit for patients with many different conditions and eye shapes.<sup>1</sup> Having a variety of materials has led to greater success in improving and correcting vision while promoting patient comfort.

Identifying the right material is an intricate process that involves many interlocking factors and considerations. It takes a comprehensive patient history, unimpeded patient-doctor communication and

sometimes trial and error to find a lens that balances vision correction with eye health and patient comfort.

## PHYSIOLOGICAL CONSIDERATIONS

Scleral lenses create a semi-seal surrounding their interface with the conjunctiva and sclera, resulting in limited tear exchange behind the lens. This is important, as the cornea obtains most of its oxygen from the atmosphere. A scleral lens is in effect a barrier between the cornea and its primary source of oxygen. This has been shown to cause corneal hypoxia, resulting in corneal swelling and edema.

The extent of corneal swelling is highly debated and is a main consideration when discussing the long-term health of scleral lens wear. A number of studies have observed varying amounts of corneal edema with scleral lenses, while others

## ABOUT THE AUTHOR



Dr. Persson is a partner in a multi-location optometric practice in Denver, CO, where he founded the Scleral Contact Lens Institute. He is a 2013 graduate of the Ohio State University College of Optometry.

## Clinical Examples

**Case #1.** A 66-year-old Caucasian female presented to our clinic inquiring about multifocal lens wear options. She expressed frustration about the lack of choices available for her visual needs. Her history included soft multifocal dropout, mild to moderate dry eye and a prescription consisting of +2.25-1.00x167 OD and +2.25-1.00x150 OS with an add power of +2.50.

Due to the patient's relatively small prescription, we opted to go with Optimum Extreme in an EasyFit multifocal lens design from Acculens and use Hydra-PEG coating to help address her dry eye. Unfortunately, she started to notice anterior surface deposits after the first three to four hours of wear. We switched to Optimum Extra with the same parameters. This lens performed much better, resulting in 10 to 12 hours of comfortable lens wear and stable vision. If the issue still had not resolved, we likely would have tried the same design but switched to Tyro-97 or Onsi-56 if Tyro-97 had also resulted in deposits.

**Case #2.** A 29-year-old Caucasian female presented to our clinic asking about contact lens options to treat recurrent corneal erosion secondary to corneal epithelial dystrophy. Her history included chronic bandage contact lens use over the past three years and phototherapeutic keratectomy in the past nine months. Her main goals were to increase her vision, decrease the incidence of corneal erosions and improve her overall comfort.

We chose to move forward with Optimum Infinite manufactured with Hydra-PEG coating in a Maxim scleral lens design from Acculens. We chose a higher Dk material to decrease hypoxic stress on the patient's already damaged corneal surface. The initial few weeks of wear went well for the patient, and we continue to monitor how her cornea responds to chronic scleral lens wear while using this hyper Dk material.

have found that corneal edema secondary to scleral lens wear is not as significant as originally thought.<sup>2,3</sup>

Lens Dk measures the oxygen permeability of a material; therefore, the easiest way to improve oxygen permeability is to choose a material with a high Dk. There are a number of suggested ideal Dk values for scleral lenses, with some studies recommending a Dk of 150 or higher.<sup>2</sup> Although there are materials that boast Dk values of up to 200, there are other factors we must consider when selecting lens material,

Though difficult to measure, the wetting angle is an important consideration, especially as higher Dk materials often have a larger wetting angle. This may result in poor surface wetting, leading to dry eye and discomfort.<sup>4</sup>

A material's wetting angle may decrease with the addition of Hydra-PEG coating (Tangible Science), which can be considered as a material enhancer, since it is

part of the lens manufacturing process. This biocompatible polymer covalently bonds to the surface of the lens material to create a more consistent and durable coating.<sup>5</sup> Originally introduced in 2017, it has been shown to improve lens comfort and dry eye symptoms and decrease lens fogging.<sup>6</sup> It is now available with most gas permeable lens materials and may improve the experience for patients who are chronic depositors, suffer from dry eye or require a higher Dk lens.

Higher Dk materials typically have higher silicone content, increasing the likelihood of surface deposits, and a lower modulus, increasing the risk of lens flexure and resulting in irregular power changes and difficulty quantifying on-eye fitting relationships.

A higher Dk material may also have the opposite effect and result in lower oxygen transmissibility if we fail to take the refractive index into account and risk ending up with a thicker lens.

The relatively small range of refractive index options available for scleral lens materials (1.3 to 1.5) makes this factor less important when determining lens center thickness, unless you are dealing with a very high plus or high minus prescription.<sup>7</sup> It has been argued that the ideal center thickness to prevent corneal edema falls between 250µm and 400µm.<sup>2</sup> Keep in mind that designing a lens as thin as possible may actually result in unwanted lens flexure or warpage.

The recommended tear reservoir depth is another topic that is debated in the literature, and there are a number of suggestions ranging from 100µm to 200µm to minimize the risk of corneal edema.<sup>8</sup> On the other hand, another study found no significant correlation between the post-lens tear reservoir and corneal edema.<sup>9</sup> Despite these mixed recommendations, I typically strive for a post-lens tear reservoir of around 200µm six to eight hours post-insertion and consider this when selecting the ideal lens material.

## MATERIAL OPTIONS

### *Menicon Z, Optimum Infinite.*

Until recently, Menicon Z (tisilfocon A, Menicon) carried the highest Dk label at 163, leading to it earning FDA clearance for 30-day continuous wear. As it is made from a hyper Dk material, this lens has a slightly larger wetting angle, which could lead to decreased wettability.

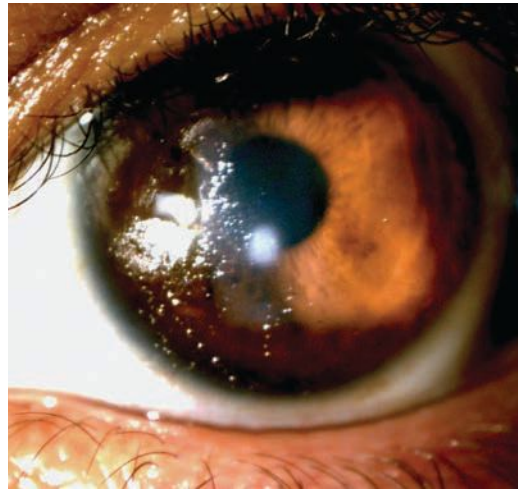
Optimum Infinite (tisilfocon A, Contamac) is one of the newer lenses to hit the market. With a Dk of 180, structural stability and quality surface wettability, this lens has many of the characteristics we look for in a scleral lens.<sup>10</sup> It may become a go-to lens option for many newer scleral patients regardless of their condition, especially those with multiple anterior surface comorbidities.

In addition to being offered in gas permeable lenses, tisilfocon A is a popular option for orthokeratology due to its FDA approval for use while sleeping. One study found no corneal endothelial morphology changes after a year of almost continuous wear.<sup>11</sup>

**Optimum Extra and Extreme.** These lenses work well for simpler designs and patients who have not demonstrated other corneal surface disease. Optimum Extra (roflufocon D and E, Contamac) offers a Dk of around 100 and an extremely low wetting angle of 3°, while Optimum Extreme (roflufocon D and E, Contamac) has a Dk of around 125 and a wetting angle of around 6°. <sup>10</sup> Based off these characteristics and its proven machinability and strong modulus, Optimum Extra seems to be the material of choice between the two for many seasoned clinicians.

**Acuity 200.** This lens offers a hyper Dk of 200 and is currently only available outside of the United States, though it is working its way through the FDA approval process. Acuity 200 (fluoroxyfocon A, Acuity Polymers) has been commended “for its ability to solve challenging specialty lens cases, particularly in the areas of irregular cornea and diseased eyes.”<sup>12</sup>

**Acuity 100, Boston XO.** Both lenses offer a high Dk of 111, making them viable options for most scleral lens users. However, Acuity 100 (hexafocon A, Acuity Polymers) and Boston XO (hexafocon A, Bausch + Lomb) may not perform as well for dry eye patients, due to their material’s higher wetting angle of around 49°. <sup>13</sup>



**Poor wetting is seen nasally with this scleral lens.**

**Boston XO2.** This lens offers a hyper Dk of 141, which is ideal for oxygen permeability, but it has a higher wetting angle of 38° and a lower modulus of 1,160MPa. <sup>14</sup> This means Boston XO2 (hexafocon B, Bausch + Lomb) may perform well for patients who require a higher Dk but not as well for those who are depositors, have dry eye or have prescription requirements that may promote lens flexure. Hydra-PEG coating may improve the dryness and depositing issues previously seen with hexafocon B.

**Tyro-97.** This is a good entry-level scleral lens with its relatively high Dk of 97. Tyro-97 (hfofocon A, Lagado) is marketed for its higher Dk, high strength factor and hydrophilic properties that create a wetter surface for improved tear film interaction. <sup>15</sup>

**Onsi-56.** This lens’ lower Dk of 56 makes it a less-than-ideal solution for scleral lens fitting. Monitor corneal endothelial cell counts and pachymetry closely if prescribing this lens. That being said, Onsi-56 (onsifocon A, Lagado) could work wonders for patients who have a history of deposits and dry eye when fit with higher Dk materials. <sup>15</sup>

As scleral lenses become more popular, it is becoming increasingly important to understand the fitting characteristics associated with each lens material, especially if you are looking to expand your specialty lens practice. These patients often have higher expectations and shorter patience due to a lifetime of managing a debilitating visual condition. Choosing the right material at the beginning of the process can make a world of difference for them. **RCCL**

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# THE PANCAKE CORNEA CONUNDRUM

**Postsurgical flattening poses unique visual challenges that only GP lenses can counter. Read on to learn how we managed it—and you can, too.**

By Kenneth Chung, OD, Arthur Wong, OD, and Renee Houser, OD

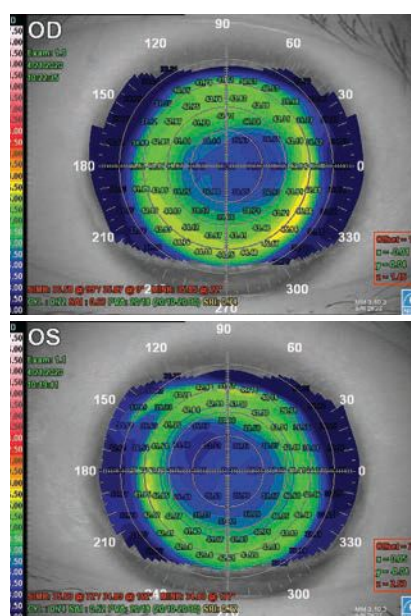
**R**everse-geometry rigid lenses have been the mainstay of post-surgical lens fitting for years. The modality's flatter posterior design allows a thinner tear layer and a more aligned fit on both oblate and prolate corneas.

From the first laser *in situ* keratomileusis (LASIK) performed in 1991 and its subsequent FDA approval in 1995, there have been an estimated 10 million Americans who have had LASIK. One study found that myopia greater than 1.00D typically develops in LASIK patients after 10 years; another reported that over half were under- or over-corrected by at least 1.00D at the 15-year mark.<sup>1,2</sup> The number of post-LASIK patients in need of corrective lenses to treat their post-refractive regression will only continue to grow as the number of surgeries increases.

This case report discusses a specialty contact lens fit on a patient with remarkably oblate corneal status post-LASIK, the factors that contribute to post-surgical myopic regression and the pathophysiology of the most common post-LASIK complication: dry eye. If you've ever experienced a similar presentation, pay attention to the takeaways offered here so you'll be better equipped moving forward.

## THE CASE

A 54-year-old Asian male presented with blurry vision and glare at



**Fig. 1. Post-LASIK placido disc topography of a highly myopic patient with a deeply central oblate pattern without ectasia, central islands or irregular astigmatism.**

night that had gradually worsened over several years. Ocular history included uneventful bilateral microkeratome-assisted LASIK in 2002 with a high pre-op myopic astigmatic prescription. He was referred for a specialty contact lens fitting due to unstable soft contact lenses fit.

Uncorrected visual acuities were 20/40±2 that pinhole-corrected to 20/20-2 OD and 20/100-1 that pinhole-corrected to 20/40+2 OS. The patient's manifest refraction

was  $-1.00+0.75 \times 165$  OD and  $-2.00$  OS with an add of  $+1.75$  and visual acuity of 20/20 OU. His cycloplegic refraction was  $-0.75+0.75 \times 165$  with visual acuity of 20/20 OD and  $-1.75$  with visual acuity of 20/20-2 OS.

Intraocular pressures were 16mm Hg OD and 12mm Hg OS. Slit lamp exam revealed well-healed LASIK flaps without striae, stromal haze, intrastromal debris, epithelial ingrowth or surface punctate epithelial keratopathy. The tear meniscus appeared normal in height bilaterally, but the tear breakup time was reduced by approximately six to seven seconds in each eye. Because post-op dry eye is a common refractive surgery complication, we performed phenol red thread testing to measure basal tear

## ABOUT THE AUTHORS



Dr. Chung practices at the North Florida/South Georgia Veterans Health Administration, where he teaches externs and residents and serves as the lead contact lens fitting specialist.



Dr. Wong practices at the Malcom Randall VA Medical Center in Gainesville, FL, where he has worked in both the optometry and compensation/pension services.



Dr. Houser practices in Southwest Florida. She graduated from the NSU College of Optometry and completed a residency in ocular disease, low vision and specialty contact lenses at the Malcom Randall VA Medical Center.

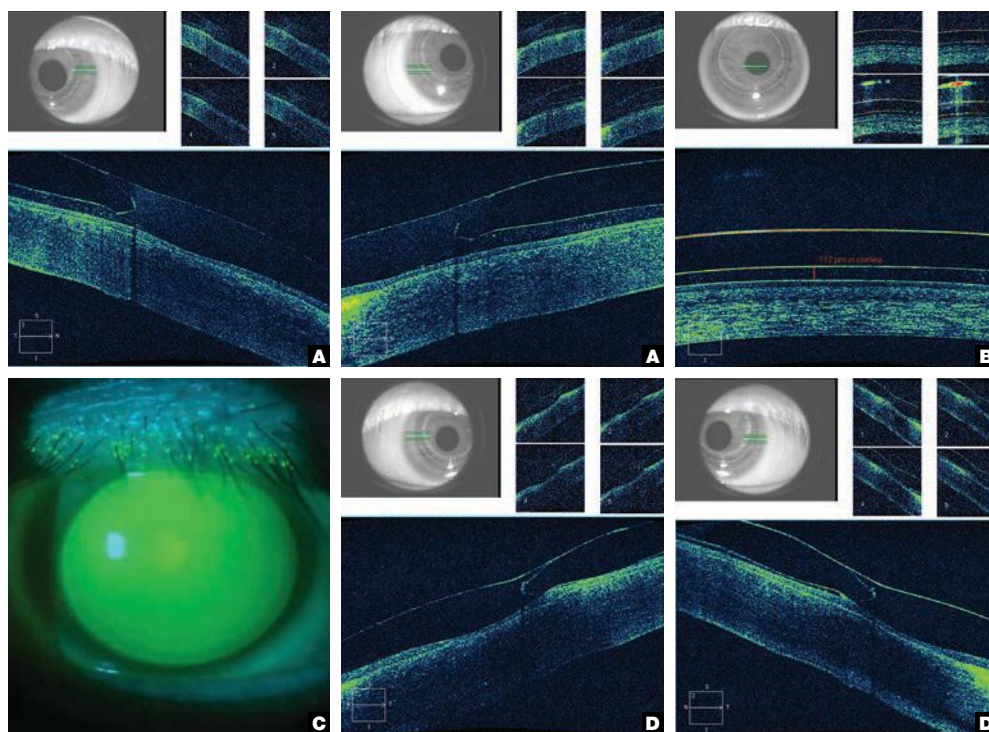
production.<sup>3,4</sup> The results yielded 30mm OD and 24mm OS, both of which were normal.

The topographical map of the patient's right eye depicted a central oblate pattern with uniform mid-peripheral steepening. There was no evidence of corneal ectasia or irregular astigmatism. Similarly, the left eye showed an even larger area of central flattening with uniform mid-peripheral steepening that indicated a well-centered flap, well-aligned ablation of the stromal tissue and absence of any central islands (*Figure 1*).

Due to the highly oblate topographies, we selected the SynergEyes UltraHealth FC hybrid contact lens for the diagnostic fit. As topography revealed deeply flat bilateral keratometric readings, we assumed the patient's pre-op K readings were also on the flatter end of the spectrum and, thus, chose a lower vault for the initial diagnostic lens.

### DIAGNOSTIC FITTING

The initial UltraHealth FC diagnostic lens selected for the right eye was 155 vault/medium skirt/-1.50D. This lens showed significant fluorescein clearance at the central apex and a very loose fit overall. We immediately replaced the lens with the next lower vault design with parameters of 105 vault/medium skirt/-1.00D. This lens demonstrated fluorescein alignment, mild inner landing zone (ILZ) clearance and soft skirt alignment on the sclera (*Figure 2a*). Anterior segment OCT (AS-OCT) showed an apical tear film thickness of 150µm.



**Fig. 2. (A) Mild ILZ clearance and satisfactory soft lens cushion support nasally (left) and temporally with UltraHealth FC diagnostic lenses. (B) AS-OCT depicts an ideal apical alignment fit with the lowest vault available in the UltraHealth FC diagnostic lens set. (C) The initial diagnostic lens shows apical alignment and tear layer thinning of the ILZ. (D) Nasal ILZ bearing on the corneal epithelium (left) and minimal tear vault on the temporal ILZ post-30 minutes of diagnostic lens settling.**

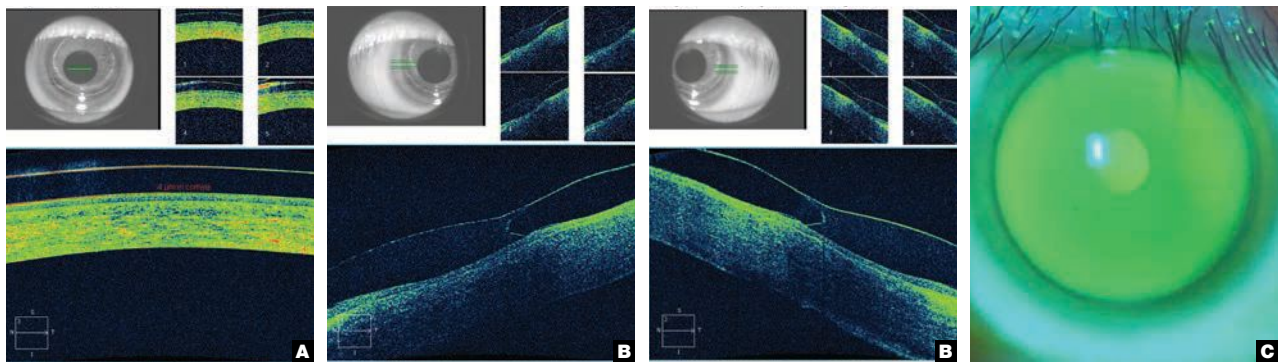
We believed we could achieve an even greater alignment fit with the lowest vault available in the diagnostic set, so we inserted a 55 vault/medium skirt/plano lens and determined this was the most appropriate vault for the patient's right eye (*Figure 2b*). An overrefraction of -0.25D corrected his vision to 20/20. The finalized contact lens parameters were 55 vault/flat skirt/-0.25D.

During the diagnostic fitting of the patient's left eye, the 105 and 155 vaults both showed "lens crash," or heavy central bearing on slit lamp exam and AS-OCT. The 205 vault/medium skirt/-2.50D diagnostic lens demonstrated apical clearance over the cornea and limbus. There was good centration and tear film alignment in the ILZ (*Figure 2c*). However, after 30 minutes of lens settling, the patient noted ocular

irritation and foreign body sensation. The nasal ILZ had "crashed" onto the peripheral cornea, and the temporal ILZ showed minimal tear layer vault (*Figure 2d*). With an overrefraction of -1.50D, the patient's left eye corrected to 20/20. After adjusting for the vertex distance and lens crash



**Fig. 3. Sodium fluorescein demonstrates apical alignment, ILZ clearance and slight lens inferotemporal decentration.**



**Fig. 4. (A) Apical “lens crash,” or lens bearing, on AS-OCT after one hour of lens settling. (B) Peripheral ILZ bearing nasally (left) and temporally after one hour of lens settling. (C) The sodium fluorescein pattern shows faint central bearing that starkly contrasts with overt lens crash.**

on the ILZ, we ordered lens parameters of 205 vault/steep skirt/-3.75D.

### DISPENSING

At the dispense visit, the patient had apical alignment, adequate lens centration and ILZ clearance OD (Figure 3). While the lens was decentered slightly inferotemporally, the patient stated he was satisfied with the visual acuity and comfort the lens offered, so further revision was not indicated. A case, however, could be made to flatten the skirt to lower the ILZ clearance, but that would increase the risk of even greater lens decentration and movement on blink.

Fluorescein showed apical clearance to pooling OS. The patient reported the lens was comfortable and read the 20/20 line without an overrefraction. However, after the lens settled for an hour, we discovered apical “lens crash” with ILZ bearing at both the nasal and temporal limbus (Figures 4a and 4b). Interestingly, the fluorescein pattern showed light apical thinning rather than frank or heavy bearing (Figure 4c). The proportion of the soft skirt and ILZ support was not ideal, so we revised to 255 vault/flat skirt/-4.75D.

This lens demonstrated apical alignment without any areas of touch or bearing, with the ILZ demonstrating ideal feather thinning and the soft skirt showing scleral alignment with-

out edge fluting or tightness (Figure 5). AS-OCT demonstrated ideal tear film alignment of the lens and cornea after four to five hours of lens wear (Figure 6). The tear layer on the nasal ILZ showed satisfactory clearance with ideal soft lens cushion support. Temporally, the lens and soft skirt junction showed an optimal 80/20 relationship between the soft cushion of the skirt and the alignment of the ILZ tear layer (Figure 7).

The patient reported good comfort after 30 minutes of wear and read the 20/20 line without an overrefraction, so we were satisfied with the outcome, dispensed the lens to the patient and asked him return for a follow-up visit. We recommended preservative-free 0.9% saline for lens insertion with a DMV contact lens handler and BioTrue multipurpose solution for lens disinfection and storage.



**Fig. 5. Fluorescein indicates central alignment without bearing or pooling of the ILZ.**

### FOLLOW-UP

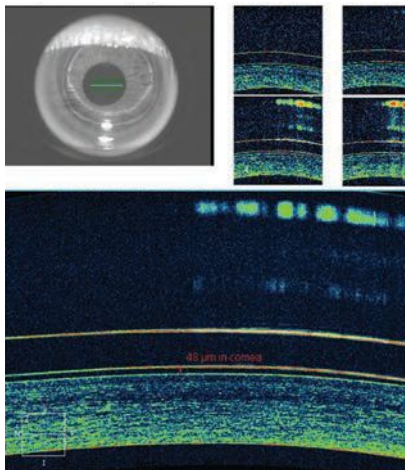
The patient returned one week later after having worn his lenses at least six hours. He had been using preservative-free 0.9% saline for insertion and BioTrue (Bausch + Lomb) for disinfection and storage as instructed without any adverse symptoms.

With the lenses, visual acuity was 20/20 with a plano overrefraction in each eye. Fluorescein showed ideal central alignment and light thinning in the ILZ on both eyes. though he still experienced minor lens awareness from time to time, he has been able to wear the lenses comfortably for at least eight hours each day.

We were happy with the fit, comfort and vision and asked him to return in a year, or sooner if he developed any ocular or visual issues. Note that despite the similar oblate Ks in both eyes, the final lens parameters were quite distinct from each other. The left eye required a much taller vault than the right, which highlights the importance of vaulting the central cornea and aligning to the peripheral cornea and sclera.

### DISCUSSION

A team of researchers found myopic regression can develop as early as three months in post-LASIK patients.<sup>5</sup> Post-LASIK myopic regression is multifactorial in nature. Although its exact cause is unclear, a study



**Fig. 6. AS-OCT demonstrates ideal tear film alignment over the central cornea with good lens centration after a few hours of wear.**

determined that flap unevenness due to poor microkeratome placement may contribute.<sup>6</sup> Similarly, a study investigating the prevalence of myopic regression in various flap-based surgeries reported more patients with mechanical microkeratome LASIK experienced myopic regression.<sup>7</sup>

Another study reviewed myopic regression following photorefractive keratectomy and determined that refractive treatments over -5.00D, optic zone treatment diameters under 6mm and unstable fixation during laser ablation all contributed to myopic progression.<sup>8</sup> Other investigators

confirmed that eyes treated within 6mm of the optic zone had a higher incidence of myopic regression.<sup>9</sup>

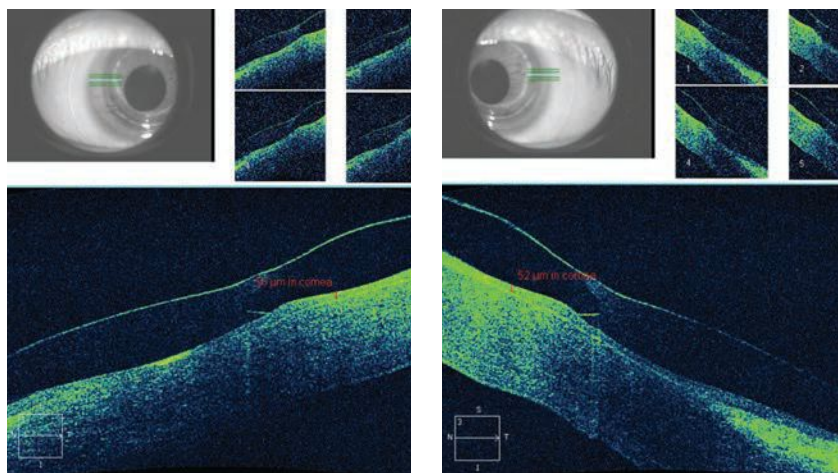
Several other factors have been documented to contribute to post-LASIK refractive regression. Corneal hysteresis (i.e., the cornea's ability to absorb pressure) is another possible contributing factor. Lower corneal hysteresis positively correlates with increasing degrees of myopia.<sup>10</sup> Other researchers observed a significantly higher frequency of myopic regression in cases with less than 350μm of residual stromal bed.<sup>9</sup> Post-LASIK dry eye was also shown to increase the prevalence of myopic regression.<sup>4</sup>

The most common complication of LASIK is dry eye, with virtually all patients developing some degree of dryness during the post-op phase.<sup>11</sup> The prevalence in the early post-op period has been reported as high as 95%.<sup>11</sup> Not surprisingly, refractive surgeons have reported dry eye as the primary post-op complication.<sup>1</sup>

Multiple theories have been proposed about the pathophysiology of post-LASIK dry eye. The most common is iatrogenic corneal nerve damage during creation of the flap and ablation of the stromal tissue from the excimer laser.<sup>11</sup> Loss of conjunctival goblet cells has also been documented after LASIK

surgery due to direct damage from the high-pressure suction device used during creation of the corneal flap.<sup>11</sup> Post-op inflammatory changes may also contribute.<sup>12</sup> Elevated levels of matrix metalloproteinase-9, a pro-inflammatory proteolytic enzyme produced by stressed epithelial cells and neutrophils, have been measured in the tear film in post-op patients.<sup>13</sup> This marker is responsible for prolonging healing, exacerbating dry eye symptoms and causing post-op haze.

**T**he importance of providing specialty lens fittings for patients with post-op corneas cannot be overstated. As they are typically limited in their surgical enhancement options and generally have active lifestyles, it is crucial to offer specialty options if soft lenses provide a poor fit. It is equally important to develop a robust skillset in performing and troubleshooting these challenging fits, given the multitude of variables associated with post-LASIK regression. **hcc**



**Fig. 7. Ideal 80/20 support of the soft cushion of the contact lens with tear alignment posterior to the ILZ nasally (left) and temporally after settling.**

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## Autologous, Allogeneic and PRP:

# THE MANY FACETS OF SERUM TEARS

**These new therapeutics could be an important addition to your dry eye patient's routine.**

By Molly B. McGinty-Tauren, OD, and Morgan Cornelius, OD

**D**ry eye disease (DED) affects nearly a quarter of patients seeking eye care in the United States and, for many, commercially available lubricants provide adequate symptom relief. However, artificial tears only augment the lubrication and mechanical clearance provided by natural tears, and they require frequent use with decreased efficacy over time.<sup>1,2</sup> In addition, these over-the-counter treatments include preservatives that can cause irritation and fail to supply the ocular surface with the nutrients that support epithelial growth and differentiation.<sup>3</sup> They lack the composition—water, salts, hydrocarbons, proteins and lipids—of natural tears.<sup>4</sup>

Ultimately, these traditional therapies often fail for the most severe sufferers.<sup>5</sup> Ocular surface injury is the hallmark of severe DED, and treatments must target surface improvement.<sup>5</sup> Today, clinicians can consider prescribing serum tears to meet the needs of patients who fail to improve with other dry eye treatments. Blood serum shares much of the biologic composition of natural tears and can provide essential epithelial support and antimicrobial activity.<sup>1</sup> When natural tears are depleted or imbalanced,

### The First Applications of Serum Tears

Hematopoietic therapy for severe dry eye was first introduced in 1975 for severe ocular burn and Stevens-Johnson Syndrome patients via continuous ocular perfusion of autologous and homologous serum and plasma.<sup>1</sup> Later, in 1984, other researchers used serum tears to treat keratitis sicca patients whose signs and symptoms of dry eye persisted with the use of commercial artificial tears.<sup>2</sup> All 15 patients enrolled in the study showed improvement in objective and symptomatic findings with serum tear treatment.<sup>2</sup> The serum protein was hypothesized to provide the nutrients and bacteriostatic agents required for healing.<sup>2</sup>

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serum tears—whether autologous, allogeneic or platelet rich plasma (PRP)—play an important role in restoring ocular surface health.

### A LOOK UNDER THE HOOD

Corneal and conjunctival epithelial cells are imperative for wound healing with their proliferative, migratory and differentiating abilities.<sup>1,6,7</sup> The aqueous component of the tear film enables and supports these functions through its mechanical properties and nourishment.<sup>1</sup> The antimicrobial role of the tear film is triggered by the inflammation of the ocular surface, as proteins and complement factors are released into the aqueous to participate in microbe destruction via macrophages and lymphocytes.<sup>1</sup>

When the tear film is deficient,

the impaired support system compromises the integrity of the ocular surface. In particular, growth factors known to reduce inflammation are diminished in dry eye patients, and their imbalance may be responsible for dry eye pathogenesis.<sup>3,8</sup>

### ABOUT THE AUTHORS



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## RESTORING BALANCE

For moderate to severe DED patients, the chemicals present in serum tears play a significant role in restoring the ocular surface.<sup>2</sup> Serum and natural tears share vital components, albeit at differing concentrations, including: epidermal growth factor (EGF), vitamin A, fibronectin and transforming growth factor- $\beta$  (TGF- $\beta$ ).<sup>1</sup>

EGF accelerates the proliferation of the corneal epithelium, vitamin A prevents the epithelium from undergoing squamous metaplasia and fibronectin influences cell adhesion and migration during the healing process.<sup>1,9</sup> Both fibronectin and vitamin A aid in the integrity of the ocular surface, and the tissue becomes compromised when the tear film is deficient.<sup>8</sup>

TGF- $\beta$  is a particularly tricky component to balance in serum tears, considering it suppresses autoimmune reactions at normal tear levels but can cause an inflammatory response and suppress ocular surface wound healing at higher levels.<sup>4,10</sup> Because of this, serum tears are diluted to produce a substance analogous to natural tears in its TGF- $\beta$  concentration.<sup>4</sup> Several variations of serum tears exist, most notable being autologous, allogenic and PRP.

**Autologous serum tears (AST).** These are produced from a patient's own blood sample. A pronounced benefit of this type is the lack of antigenicity.<sup>1</sup> AST may be used alone or in conjunction with more traditional therapies, such as commercial topical therapeutics, bandage or scleral contact lenses and punctal plugs.<sup>1</sup> Their lack of preservatives makes them a merited alternative to other available topical treatments.

**Allogenic serum tears.** These are produced from another patient's blood and are an equally effica-

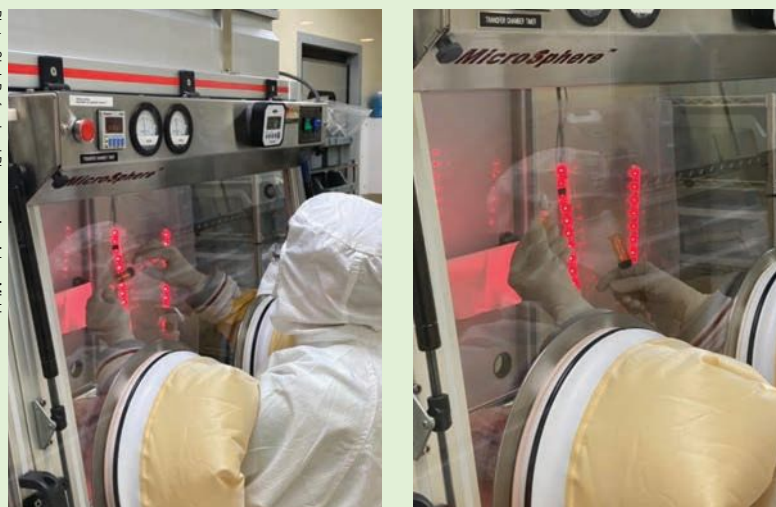
## How They're Made

The production and storage of serum tears types are relatively alike. Potential donors undergo a rigorous screening process for infectious diseases, such as hepatitis, syphilis and HIV, as well as for circulating drugs and inflammatory mediators.<sup>1,11</sup> Children, pregnant women and patients with comorbidities, such as cardiac or pulmonary disease, are also excluded as donors.<sup>4</sup>

For acceptable donors, whole blood is collected, allowed to clot and then centrifuged.<sup>1</sup> Serum is harvested and diluted with sterile saline.<sup>1,11</sup> Although post-dilution concentrations vary, 20% is most widely used.<sup>1,4</sup> The diluted product is bottled into single-use, preservative-free vials, sealed and stored.<sup>1</sup>

Unused tears are stored at  $-20^{\circ}\text{C}$  for up to three months.<sup>1,4</sup> Opened bottles may be kept at  $4^{\circ}\text{C}$  for up to 24 hours.<sup>1,4</sup> Serum tears are not regulated by the FDA, as they are a blood product rather than a pharmaceutical.<sup>6</sup> Although some state regulations exist, there is no established protocol for the production or use of serum tears.<sup>6</sup>

Photo: Clark Professional Pharmacy, Ann Arbor, Michigan.



**In a sterile lab, technicians harvest serum from donor blood and dilute it with sterile saline.**

cious alternative for patients not suited for AST, such as those who cannot safely partake in frequent blood sampling.<sup>7,10,11</sup> Allogenic tears may also be a good option for patients with decreased EGF concentration in their autologous serum, a common finding in patients with systemic factors influencing dry eye.<sup>7,10</sup> An additional benefit of allogenic serum is the ability to produce it in larger quantities, increasing cost-effectiveness.<sup>11</sup> Potential allogenic donors are of group AB, the universal plasma donor blood type, without A/B antibodies.<sup>11</sup>

**Platelet rich plasma.** This type of hematopoietic therapy has 1.5 times higher concentration of platelets

than autologous or allogenic serum tears.<sup>12,13</sup> Because the elimination of platelets in serum preparation significantly lowers growth factor levels, PRP may hold a therapeutic advantage over the other two types of serum tears.<sup>2</sup> To produce PRP, collected whole blood is centrifuged along with an anticoagulant, leaving the plasma and buffy coat portion of blood to be collected, diluted and stored.<sup>12,13</sup> Platelet adhesion to damaged tissue releases cytokines and growth factors that expedite healing.<sup>12</sup> Research suggests PRP can further enhance the restoration of the ocular surface through more potent proliferative and anti-inflammatory effects than AST and allogenic serum tears.<sup>2</sup>

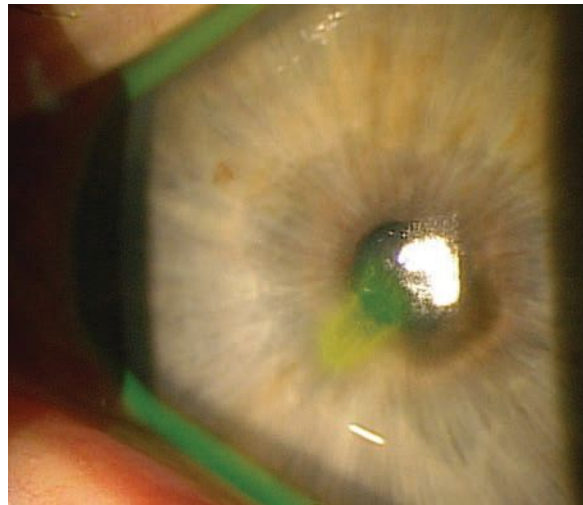
## WHO AND WHY TO TREAT

The 2018 American Academy of Ophthalmology's Dry Eye Syndrome Preferred Practice Patterns recommends treatment with serum as third-line therapy in the management of dry eye.<sup>7</sup> Before initiating serum tears, clinicians should first try environmental and dietary modifications, lid hygiene and both high- and low-viscosity lubricants.<sup>7</sup> Second-line therapies to consider before ASTs are preservative-free artificial tears, punctal plugs, moisture chambers, topical corticosteroids, cyclosporine A or LFA-1 antagonists.<sup>7</sup>

However, some experts favor serum eye drops as a second-line therapy, citing their potential advantages over traditional therapies.<sup>14</sup> Although the indications remain limited, serum tears are becoming a more common treatment option, particularly for these conditions:<sup>15</sup>

**Dry eye.** Serum tear research is sharply focused on treating severe DED. Succinct prescribing trends have not emerged for reasons that range from discrepancies in disease assessment to variabilities in serum concentration or treatment duration. Recommendations for frequency of application differ as well, varying between three to eight applications per day depending on disease severity.<sup>1,4</sup> Despite this, serum tear research has demonstrated therapeutic benefits across the severe DED spectrum.

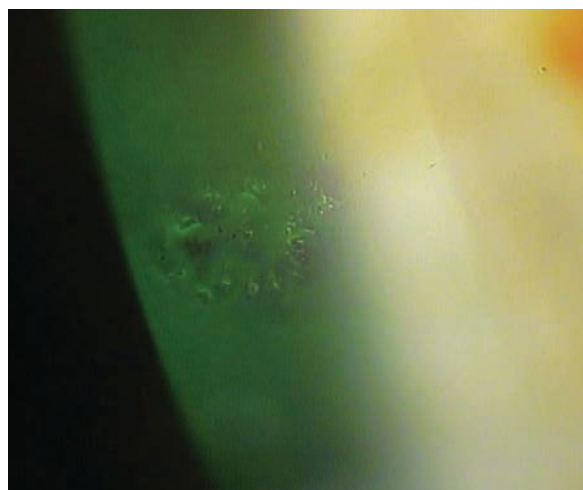
Patients who are tear deficient due to Sjögren's



**This patient with a non-healing abrasion may benefit from the epithelial support and antimicrobial activity provided by serum tears, and PRP in particular.**

syndrome demonstrate improved vital staining with serum tear application.<sup>9</sup> In addition, serum tears show a superior efficacy over preservative-free artificial tears through improved tear film and subjective comfort.<sup>8,16</sup> Research shows AST concentrations as high as 50% are safe and effective at improving symptoms and Schirmer's scores.<sup>3</sup> Serum drops improve the conjunctival surfaces of dry eye patients as well.<sup>14</sup>

However, critics of serum tear research cite low evidence certainty



**Serum tears can be an important therapeutic option for patients with recurrent corneal erosions.**

and bias risk.<sup>4</sup> Added to that, hyperosmolarity is seldom, if ever, measured.<sup>4</sup> Because increased osmolality and surface inflammation is central to the pathogenic mechanism of DED, its absence in study design methods is glaring.<sup>7,17</sup>

**Persistent epithelial defects (PEDs).** These also respond well to serum tear treatment. PEDs often occur secondary to rheumatoid arthritis, neurotrophic keratopathy, keratoconjunctivitis sicca and other chronic inflammatory conditions.<sup>1,12</sup> One study shows that 63%

of PEDs refractory to more than two weeks of treatment with lubricants and bandage contact lenses were completely healed after four weeks of serum tear treatment.<sup>1</sup> In addition, 90% of PEDs displayed a reduction in defect size after treatment with serum tears.<sup>6</sup>

Another study found decreased recurrence of PEDs when serum tears were used four times a day for two weeks following removal of a bandage contact lens.<sup>18</sup> PRP was found to result in increased rate of epithelial healing compared with autologous serum in PEDs secondary to infectious keratitis.<sup>13</sup>

**Recurrent corneal erosions (RCEs).** Research shows RCEs exhibited decreased recurrence with six months of PRP treatment.<sup>13</sup> One study comparing conventional RCE treatment alone (bandage contact lens and preservative-free artificial tears) with the addition of PRP found that 80% of conventional treatment patients and just 26% of PRP patients experienced a major recurrence.<sup>13</sup> Minor



recurrences were experienced by 100% of conventional treatment patients but only 37% of PRP patients.<sup>13</sup>

**Superior limbic keratitis.** This is another condition responsive to serum tear treatment. One study found that 82% of patients reported improvement in discomfort and 100% improvement in epitheliopathy after using 20% serum tears ten times per day for one month compared with previous therapies, such as frequent artificial tears, topical corticosteroids and topical vitamin A.<sup>1</sup>

### LIMITED ROADBLOCKS

Complications, contraindications and barriers to serum tear treatment are few. The regularity of blood draws requires serum tear candidates have a healthy tolerance for blood volume loss and venipuncture.<sup>4</sup> The non-preserved nature of the drop means new bottles are opened each day and discarded within 16 hours.<sup>1</sup> The lack of preservatives also increases the risk for infection and contamination; however, storage and usage protocols are intended to mitigate this as much as possible.<sup>1,6</sup> Serum preparers and patient caregivers are also at risk of viral transmission, further underscoring the importance of donor serology screening.<sup>1</sup> Secondary microbial keratitis has been reported in rare cases due to using tears in patients with a bacterial or fungal ulcer; therefore, corneal sterilization prior to initiation of treatment is essential.<sup>1,6,12</sup>

The literature notes that some rheumatoid arthritis patients have experienced scleritis or scleral melt following treatment with serum tears.<sup>1,4</sup> Investigators hypothesize that circulating antibodies within serum eye drops may combine with corneal antibodies to form an immune complex, which may

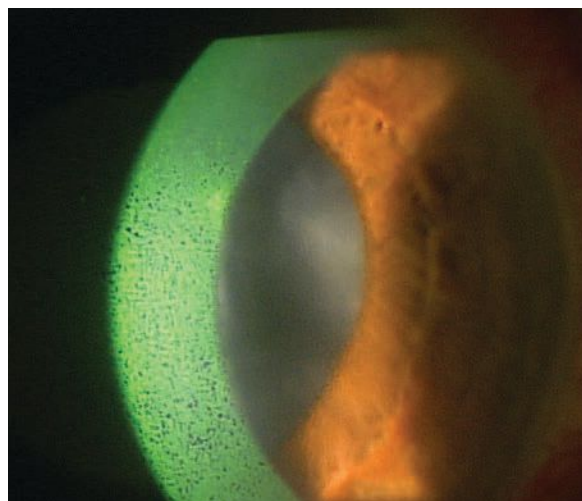
elicit this inflammatory response in rheumatoid arthritis patients.<sup>1</sup>

Furthermore, many patients successfully treated with serum tears experience relapse in symptoms if serum tears are fully discontinued.<sup>1,6</sup>

Despite their benefits, serum tears are not readily available to many patients. They must be produced at compounding pharmacies, eye banks or well-equipped ophthalmology offices.<sup>6</sup> Insurance coverage is also varied, and patients could pay as much as \$200 for a 30-day supply.<sup>6,11</sup>

**S**erum eye drops are an effective therapy for severe dry eye patients. The shared biochemistry with natural tears offers potential advantages over traditional therapies, including improved surface restoration, the avoidance of adverse reactions due to preservatives and the lack of antigenicity. Because of these possible benefits for patients, clinicians should consider adding serum tears to their dry eye toolkit for their moderate to severe dry eye patients. **CCCL**

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**Dry eye is the focus of most serum tear research that suggests AST concentrations as high as 50% could be safe and effective options to reduce signs and symptoms of DED.**

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# When Scleritis is Infectious

This destructive form of the disease requires early identification and aggressive treatment for the best chance at preserving vision.

**A** 65-year-old female presented due to severe pain, redness and blurred vision in her right eye. Ocular history was significant for cataract surgery OU and pterygium excision OS. She did not have a history of autoimmune disease.

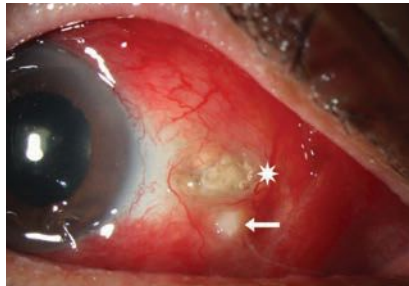
Prior to the patient's visit to our office, another eye care provider had noted scleral thinning and inflammation OD. This was thought to have been caused by an eroding scleral hyaline plaque, which was then manipulated but not removed. Over the subsequent month, her condition worsened and she developed conjunctival breakdown, pain, blurred vision, adjacent corneal thinning and a small hypopyon. At that point, she was referred to our ophthalmic emergency department.

## EXAMINATION

At presentation, the right eye showed severe diffuse injection, an exposed calcific plaque with underlying scleral thinning and an adjacent abscess (*Figure 1*). Vision had decreased from a previously documented measurement of 20/25 to 20/100.

Visualization of the posterior segment was limited due to incomplete pupillary dilation. An ultrasound revealed diffuse choroidal thickening, shallow 360° anterior choroidal detachment, an inferior serous retinal detachment and Tenon's infiltration nasally. The vitreous cavity was clear, ruling out vitritis (*Figure 2*). Clinical features suggested an infectious component, so a cornea surgeon obtained a scleral culture.

The patient was placed on fortified vancomycin, fortified tobramycin,



**Fig. 1. Intense scleral injection with focal necrosis associated with eroded calcific plaque (white star) and scleral abscess (white arrow).**

oral moxifloxacin, oral vitamin C and a topical cycloplegic agent. Corticosteroids were withheld until inflammatory and infectious lab results became available. The blood test results were non-contributory, but the scleral culture revealed the diagnosis: infectious scleritis secondary to *Pseudomonas aeruginosa*.

## DISCUSSION

The word “scleritis” likely conjures up a clinical picture of a deeply inflamed sclera with boring pain. It may be accompanied by headache, photophobia and even vision loss. Scleritis is an umbrella term often defined by location (anterior vs. posterior) or clinical features (e.g., nodular, diffuse, necrotizing). An additional way we can identify scleritis, which may be overlooked due to its rarity, is by the presence or absence of an infection.

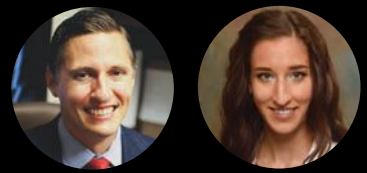
The distinction between infectious and non-infectious scleritis carries significant weight from an early point in the management process. Immune-mediated scleritis is typically less severe and more common than its infectious counterpart, making up approximately 90% to 95% of

all cases of scleritis.<sup>1</sup> Non-infectious scleritis may be idiopathic, but up to 50% of cases are associated with an underlying autoimmune disorder or connective tissue disease, such as rheumatoid arthritis, inflammatory bowel disease, granulomatosis with polyangiitis or relapsing polychondritis. Infectious scleritis, on the other hand, has unique risk factors, clinical features and treatment protocols.

Infectious scleritis presents clinically with significant redness, tearing, pain and often an anterior chamber reaction. Suppurative discharge and the presence of a scleral ulcer or abscess, which appears as a white or yellowish nodule under the conjunctiva, should raise suspicion. In some cases, there may be an associated calcific plaque.<sup>2</sup>

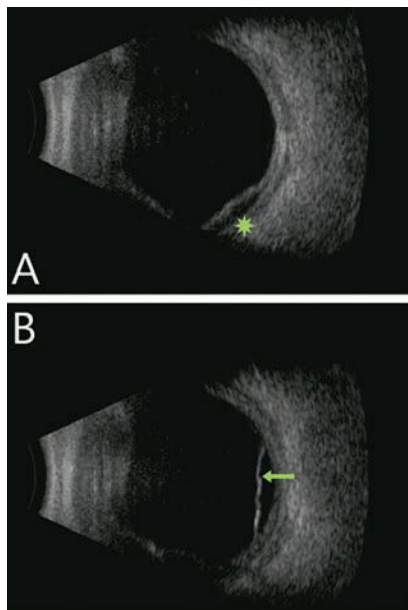
In suspected infectious scleritis, the importance of a complete ophthalmic history cannot be overstated, as it often reveals prior ocular trauma or surgery. A retrospective review found that the shortest interval between an inciting event and the onset of infectious scleritis occurred in cases of ophthalmic trauma, in which symptoms appeared between zero and three months (average of 0.2 months).<sup>3</sup> Retina, glaucoma and cataract surgeries were associated with a slightly longer interval (1.0 to 1.6 months).<sup>3</sup> The period before symptom onset was considerably longer in pterygium surgery, averaging 49 months (range of zero to 183 months), but it has been documented up to four decades later.<sup>3,4</sup>

Among the procedures implicated as risk factors for developing infectious scleritis, the most common is pterygium excision.<sup>3</sup> This surgery



causes scleral thinning and is often coupled with antimetabolites, such as mitomycin C, or adjunctive therapies, including beta irradiation, aggressive vessel cautery and bare sclera techniques. These can compromise episcleral vascular supply and lead to inadequate wound healing and avascular necrosis, thereby providing a nidus for microbial adherence.<sup>5</sup>

Obtaining a scleral culture is critical in infectious scleritis. Bacterial strains, specifically *Pseudomonas* species, are by far the most common causative organism of infectious scleritis in developed countries.<sup>1,3,5-8</sup> A study conducted in India revealed the most commonly implicated pathogens in the country's population were fungi (38%) and filamentous bacteria (*Nocardia*: 24%).<sup>1</sup> This suggests humid climates and agricultural so-



**Fig. 2. Diffuse choroidal thickening with focal choroidal detachment (green star) and with shallow serous retinal detachment (green arrow). Notably, the vitreous cavity is quiet in both images.**

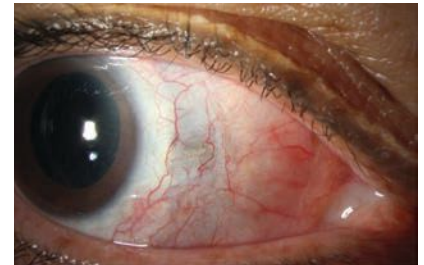
cieties may be at higher risk for these atypical forms of infection.<sup>1</sup>

Fortified antibiotics are typically initiated at presentation, but subsequent use is guided by lab findings. Due to the avascular and densely packed nature of scleral tissue, however, antibiotic treatment alone is often insufficient. Oral antibiotics have proven to be an effective treatment for bacterial scleritis, and potent anti-inflammatory agents, such as corticosteroids, may be judiciously added after appropriate antimicrobial treatment has been initiated.<sup>8</sup> Severe infectious scleritis often necessitates surgical interventions, such as glued or sutured amniotic membranes and debridement of necrotic tissue. These methods are employed to decrease inflammatory response and increase drug penetration.

Negative long-term effects of infectious scleritis are common. Scleral perforation, glaucoma, retinal detachment, cataract and endophthalmitis are all potential complications. Enucleation is ultimately required in 4% to 33% of these cases.<sup>3,8,9</sup> Unfortunately, even with prompt treatment and infection resolution, vision is often compromised, with worse presenting visual acuity translating to poorer visual outcomes.

### CASE OUTCOME

Our patient returned for frequent follow-up. One week after presenting, she underwent necrotic scleral tissue debridement with antibiotic washout and amniotic membrane graft placement. She later received a sub-Tenon's triamcinolone injection and was maintained on a combination of topical and oral antibiotics, topical and oral corticosteroids, vitamin C,



**Fig. 3. Improvement in injection and resolution of abscess. Residual scleral thinning is evident by the bluish hue.**

doxycycline and topical cycloplegia. In the following months, she developed diplopia as a complication of secondary myositis, but spontaneous resolution of the choroidal and serous retinal detachments was noted.

Six months into treatment, her pain resolved and her visual acuity stabilized at 20/200. Her extraocular motilities, though mildly restricted, continue to be followed (Figure 3).

Despite the rarity of infectious scleritis, it is important to be aware of this disease and its complications. Early recognition, effective treatment and appropriate surgical consult are integral to preserving vision and, in severe cases, the eye. **RCCT**

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## A Stitch in Time

Corneal sutures provide a vector for infection. Here's what to watch for to keep patients safe.

**A** 79-year-old male presented for a contact lens fit after a regrant penetrating keratoplasty (PKP) of the right eye, with two sutures remaining. He presented without complaint of discomfort or change in vision but noted increased foreign body sensation for the past week. The two sutures had both eroded and both had surrounding infiltrates. The sutures were removed and he was started on moxifloxacin QID. At a one-week follow up, the infiltrates had resolved and there was no epithelial defect. He was fit into a gas permeable lens.

Corneal sutures pose a risk for infiltrative keratitis, with one study showing 3.6x increase in a graft infection when sutures are present.<sup>1</sup> These sutures are typically made from nylon, which is classified as non-absorbable, but these sutures do biodegrade over time and will pro-

gressively lose tensile strength. They loosen and may rupture. Corneal sutures are typically removed (or break) within two years.<sup>1</sup> Longer suture presence increases the risk of a keratitis event, with one report showing a 71.6% incidence over four years.<sup>3</sup> Ocular surface disease (strongly), re-grafts, glaucoma and herpes simplex keratitis (weakly) all increase the odds of developing suture-related microbial keratitis.<sup>4</sup>

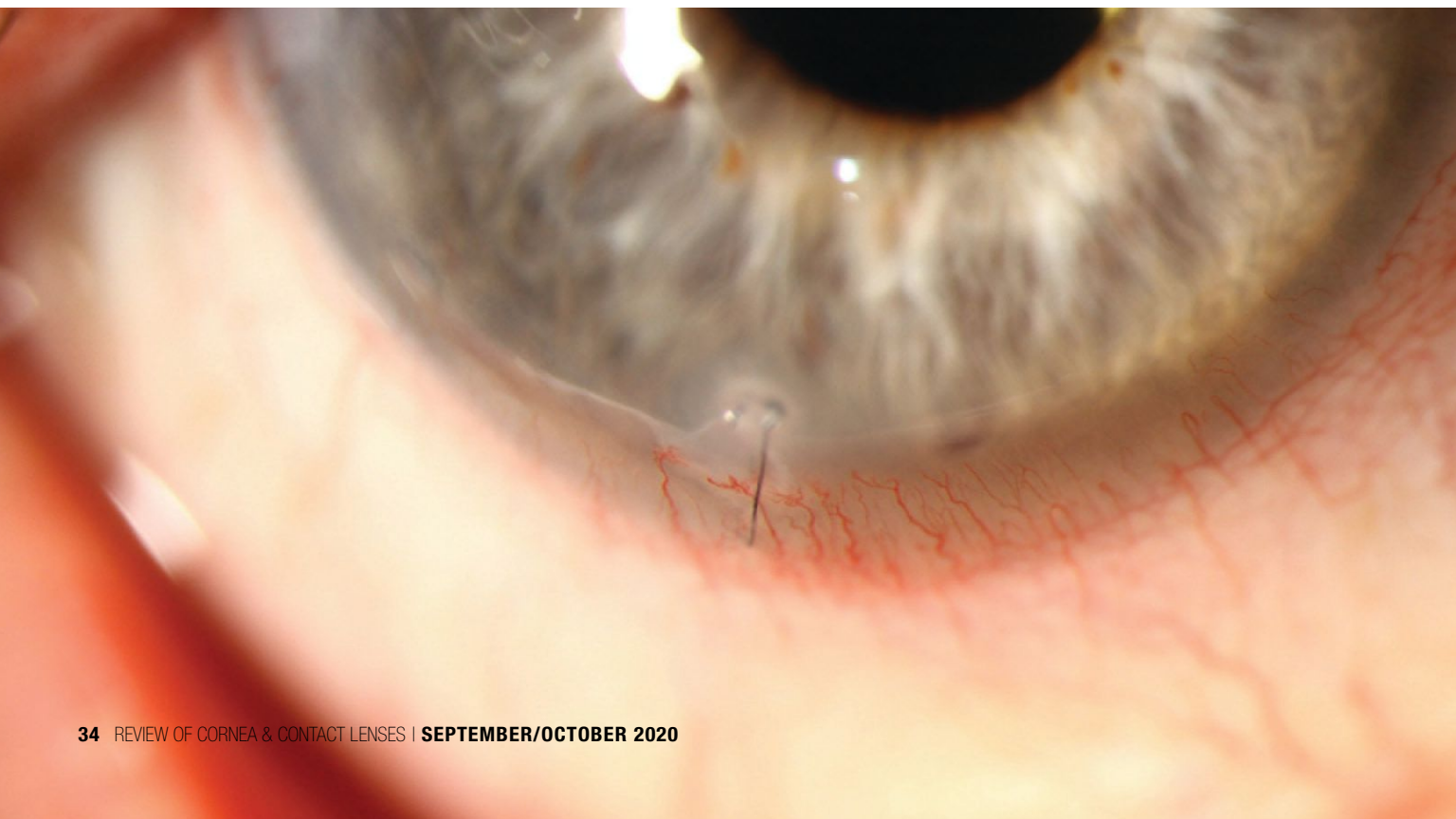
Gram-positive cocci (e.g., *Staphylococcus aureus* and *epidermidis*) are the most commonly isolated organisms of exposed sutures, while gram-negative organisms (e.g., *Moraxella*) are more common in the absence of sutures. Polymicrobial infections are common.

Nylon suture materials can harbor biofilms—a complex mixture of different bacterial organisms encased in a protective coating. Bacteria in

biofilms are significantly more resistant to antibiotics.

Corneal sutures act as a nidus for the colonization of pathogens, which promotes the invasion of a compromised epithelial surface. If an unusual pathogen is not suspected and there is no evidence of endophthalmitis, a broad-spectrum antibiotic, with good gram-positive cocci coverage, is recommended. Suture removal is important in order to eliminate the scaffolding of microbial invasion and biofilm formation. Patients should be followed closely to monitor resolution of the disease. [RCC](#)

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