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REVIEW OF CORNEA & CONTACT LENSES
SEPTEMBER/OCTOBER 2024
SCLERAL LENS ISSUE

Clinical Applications of Today's Scleral Lens

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SEPTEMBER/OCTOBER 2024

SCLERAL LENS ISSUE

Clinical Applications of Today's Scleral Lens RESEARCH

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1. CooperVision data on file 2021. Rx coverage database; 14-70 years.
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3. CVI data on file 2021. Decision Analyst online survey of 376 Biofinity prescribing ECPs in USA, Japan, Germany, France and Spain.

Dry Eye Signs, Symptoms Associated with Periodontitis, Study Finds

Elevated levels of proinflammatory cytokines produced in response to gum disease might reduce lacrimal gland function, researchers suggest.

Dry eye disease (DED) and periodontitis have been speculated to share common inflammatory pathways. Researchers in Turkey recently performed a cross-sectional study to provide further insights, revealing a significant association between gum disease and the severity of dry eye signs and symptoms.[1]

The study included 168 healthy control subjects, 172 patients with both dry eye and periodontitis, 175 patients with dry eye and 169 patients with periodontitis. The researchers gathered data on subjects' tear break-up time, Ocular Surface Disease Index (OSDI) scores, tear osmolarity, Schirmer values and Oxford corneal staining score. Since prior research found that the neutrophil-to-lymphocyte ratio, an inflammatory biomarker, is elevated in DED, researchers examined this metric when comparing DED patients to those with both dry eye and gum disease.[2]

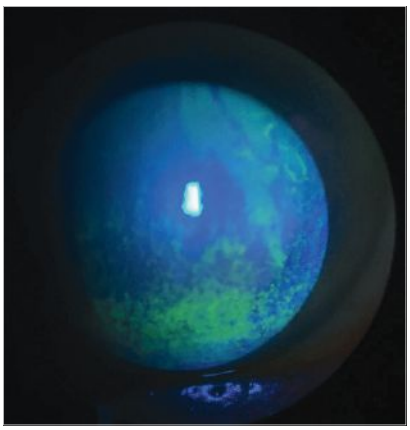

Photo: Scott G. Hauswirth, OD.

This study noted elevated tear osmolarity levels in patients suffering from both periodontitis and DED vs. patients with only one or none of those conditions.

Patients with both DED and periodontitis exhibited significant elevations in tear osmolarity levels, increased OSDI scores and decreased TBUT and Schirmer values compared to DED patients without periodontitis. Similar results were observed when comparing DED and periodontitis patients to healthy subjects and periodontitis patients. However, no significant difference was shown in Oxford staining score between the DED and periodontitis patients and the other groups. Neutrophil-to-lymphocyte ratios were reported higher among patients with both conditions.

"This study [presumably] represents the first report to highlight a potential association between periodontitis and DED," stated the researchers in their study, adding that larger investigations are still needed.[1] They highlighted multiple limitations in their research, such as having a small sample and not assessing inflammatory markers or performing meibography when evaluating the tear film.

"Based on these statistically significant findings, we strongly advocate for periodontologists and [eyecare providers], despite being from distinct disciplines, to comprehensively evaluate their patients for both ocular and oral symptoms," they concluded. "It is also crucial to recognize the impact of periodontal health on overall ocular health to provide comprehensive care to these individuals."[1]

1. Kaya F, Eliaçık BK, Koc H, Eliaçık M. Effect of periodontitis on dry eye disease signs and symptoms: a cross-sectional study. Oral Hlth Prev Dent. 2024;22:309-16.

2. Ozcan DO, Kurtul BE, Ozcan SC, Elbeyli A. Increased systemic immune-inflammation index levels in patients with dry eye disease. Ocul Immunol Inflamm. 2020;1-5.

IN BRIEF

■ A recent study on patients with Fuchs' endothelial corneal dystrophy (FECD) and subclinical corneal edema observed increased levels of higher-order aberrations in this subgroup compared with controls. These aberrations, which enhance as FECD progresses, could potentially serve as early indicators for the disease, preceding clinically observable corneal edema.

"Early tomographic analysis can aid in detecting subclinical corneal edema with varying magnitude of high-order aberrations compared with patients with FECD without subclinical edema or healthy eyes, which, in turn, can help characterize the patients' visual impairment and decision-making for early endothelial keratoplasty," the researchers concluded in their *Cornea* paper.

Blöck L, Son HS, Köppe MK, et al. Corneal high-order aberrations in fuchs endothelial corneal dystrophy and subclinical corneal edema. Cornea. July 30, 2024. [Epub ahead of print].

■ Allergic conjunctivitis (AC) may diminish the effectiveness of orthokeratology (ortho-K), a new study in *Contact Lens and Anterior Eye* reported. It involved 309 children divided into two groups (AC and non-AC). All participants were fitted with ortho-K lenses and followed for three years, at which point **the AC group showed greater axial elongation (0.96mm) vs. the non-AC group (0.69mm).** The AC group also experienced **more corneal adverse events (42.6% vs. 28.6% of non-AC group), leading to longer discontinuation periods of ortho-K lens wear.**

Based on these findings, the researchers advise that "implementing timely and effective measures to control ocular inflammation can reduce the duration of lens wear cessation, thereby allowing ortho-K lenses to more effectively control the progression of myopia."

Niu X, Zhang H, Zhang M, et al. Long-term effect of orthokeratology on controlling myopia progression in children with allergic conjunctivitis. Cont Lens Anterior Eye. July 23, 2024. [Epub ahead of print].

RCCL REVIEW OF CORNEA & CONTACT LENSES

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Combined CXL/PRK Safe, Effective in Stable and Progressive Keratoconus

The tandem procedure demonstrated comparable visual, refractive and tomographic outcomes between groups.

Older keratoconus patients have not been as lucky as their younger counterparts, who can get good stabilization earlier in the disease course from corneal crosslinking (CXL). However, researchers now suggest these patients may benefit from dual treatment of topography-guided PRK and CXL as a means of offering visual rehabilitation, a new study finds.

A comparative analysis was conducted for the combined procedure in visual, refractive and tomographic outcomes in stable vs. progressive keratoconic patients. The retrospective, case-control investigation included 101 eyes (93 patients) that underwent simultaneous topo-guided PRK and CXL. Follow-up duration was one to three years. Sixty-two eyes were considered progressive and 39 stable.

The researchers found all baseline characteristics were similar between both groups except for age at surgery, which was over a decade greater in stable eyes (23.4 years progressive; 36.0 years stable). Corrected distance visual acuity improved in both groups with no differences. Similarly, both groups experienced decreased maximum keratometry, with no differences seen between them. Other tomographic outcomes were also similar between groups, and pachymetry decreased after surgery but remained stable throughout the follow-up.

In their paper, the authors noted that the combined treatments lead to corneal regularization and significant visual improvements in both patient subsets. They explained, "This brings breakthrough evidence to expand our current indications for CXL, allowing for older patients to benefit from the visual rehabilitation of TG-PRK."

The current role of CXL is arresting disease progression rather than improving vision, but topo-guided PRK shows more favorable visual and refractive outcomes in irregular corneas. As such, the combination of both addresses the issue of structural weakness of keratoconus while regularizing and reshaping the cornea. The investigators are hopeful "this strategy can improve the visual outcomes of CXL in patients that need it to arrest disease progression but, potentially, also expand the indications of CXL to include those patients who are not progressing but need visual rehabilitation."

Gil P, Gil JQ, Dias M, et al. Comparative analysis of combined topography-guided photorefractive keratectomy and corneal crosslinking in progressive vs. stable keratoconus. Cornea. July 31, 2024. [Epub ahead of print].

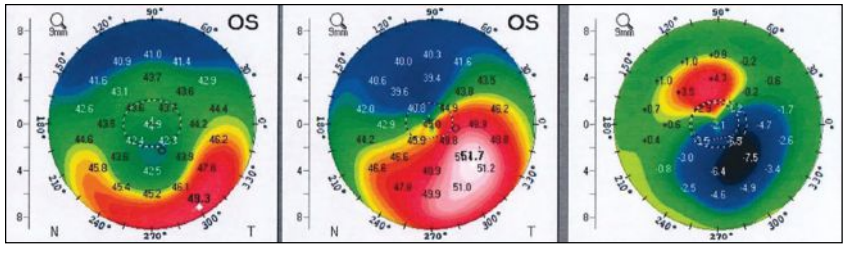

Photo: John Gelles, OD

Even stable patients with stiffer corneas showed a marked improvement in visual outcomes and corneal regularization after combined use of both procedures.

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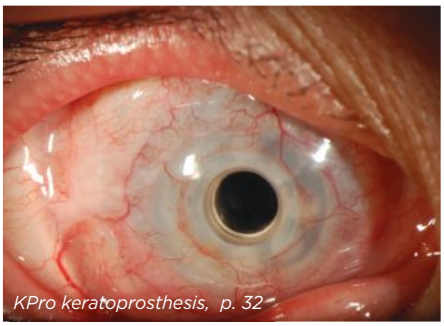

KPro keratoprosthesis, p. 32

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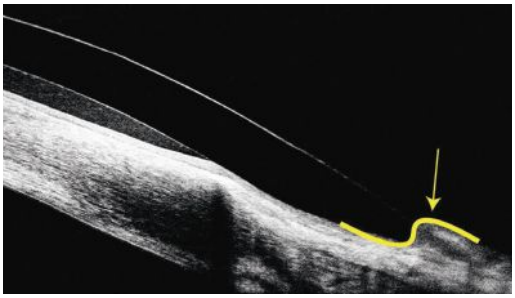

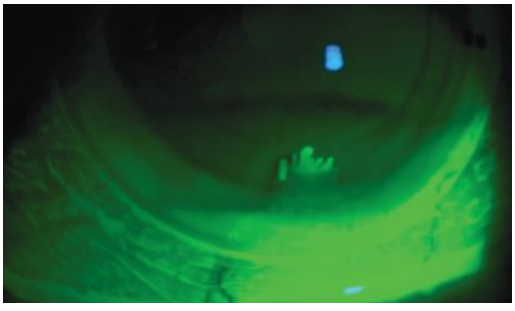

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Why Get Involved in Research?

Learn why you might consider this option in practice in this first part.

Current statistics show that only 3% of physicians (healthcare providers) in clinical practice have participated in clinical trials.[1] Have you ever considered participating in clinical research? Some of us have taken a close look at whether it might add to our busy day by getting involved in doing research. Some clinical practices have already participated in different forms of research. There's a full range of options available, such as marketing research and FDA pre-market approval studies in contact lenses and pharmaceuticals to collaborative data collection that might be funded by the National Institutes of Health.

For those in clinical practice who might be interested in research and haven't yet taken the plunge, let's take a close look at some considerations that might help you. Specifically, why should one get involved? I'll attempt to answer this question in this issue, and, in the next, I'll share some ideas on how to best get involved if you're committed to getting started.

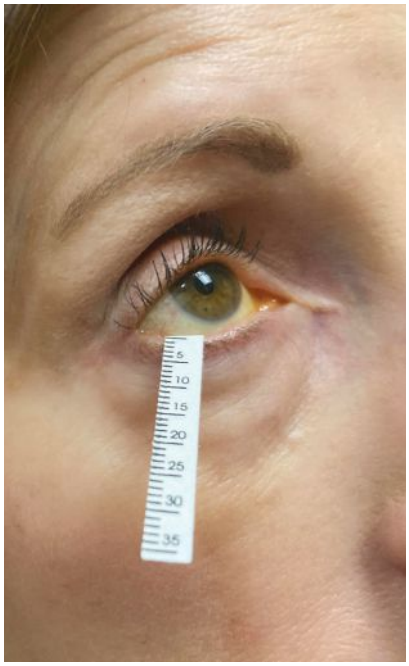


Photo: Jessica Steen, OD

Schirmer's strips are still an often used mainstay of clinical trials for dry eye drug performance.

MOTIVATIONS FOR PURSUING RESEARCH PROJECTS

Here are some insights I think optometrists should take advantage of if they seize this opportunity:

1. Expanded access to new products, testing capabilities and care.[1,2] If your patients are eligible, they will have access to new treatment options and receive additional attention and close follow-up often without additional cost.[1-3] Contact lens and pharmaceutical manufacturers are often interested in gathering additional information from a marketing perspective, and this is a great entry point for eyecare providers.

2. Advancing innovations through clinical trials.[2,4] You might have the opportunity to move a new product or drug successfully through the regulatory pipeline prior to approval or help develop additional research questions to answer a specific question that might aid in innovation.

3. Boosting your own knowledge/staying up to date with developing technology.[1] Clinicians will often comment about much they glean from the information gathered during clinical studies. Discussing results and ideas with contemporaries can also be quite invigorating and sometimes stimulate new clinical questions that might have value with added research.

4. Increased clinical trial patient retention rates with higher patient satisfaction scores supporting your practice reputation.[2,3] When your patients know you're striving to stay abreast of the newest information and that your practice is willing to take the time to advance knowledge, it boosts their confidence in you and your practice. In addition, they generally receive additional time and attention (more frequent tests and visits).[2]

5. Potential for additional financial compensation.[1,2,4] This definitely helps add to the bottom line of your practice at the end of the year.

Consider taking on one of the avenues to do research in your practice. You won't be sorry that you do. I find studies intellectually stimulating and provide a variety of work experiences. What really makes it rewarding for me is when research ultimately improves patient care with previously unmet needs for our patients.

Stay connected! So, come up with a thought-provoking question to get started and look for the right team partner. RCCL

In the next issue, we'll look at some additional ideas on how to get started in clinical research.

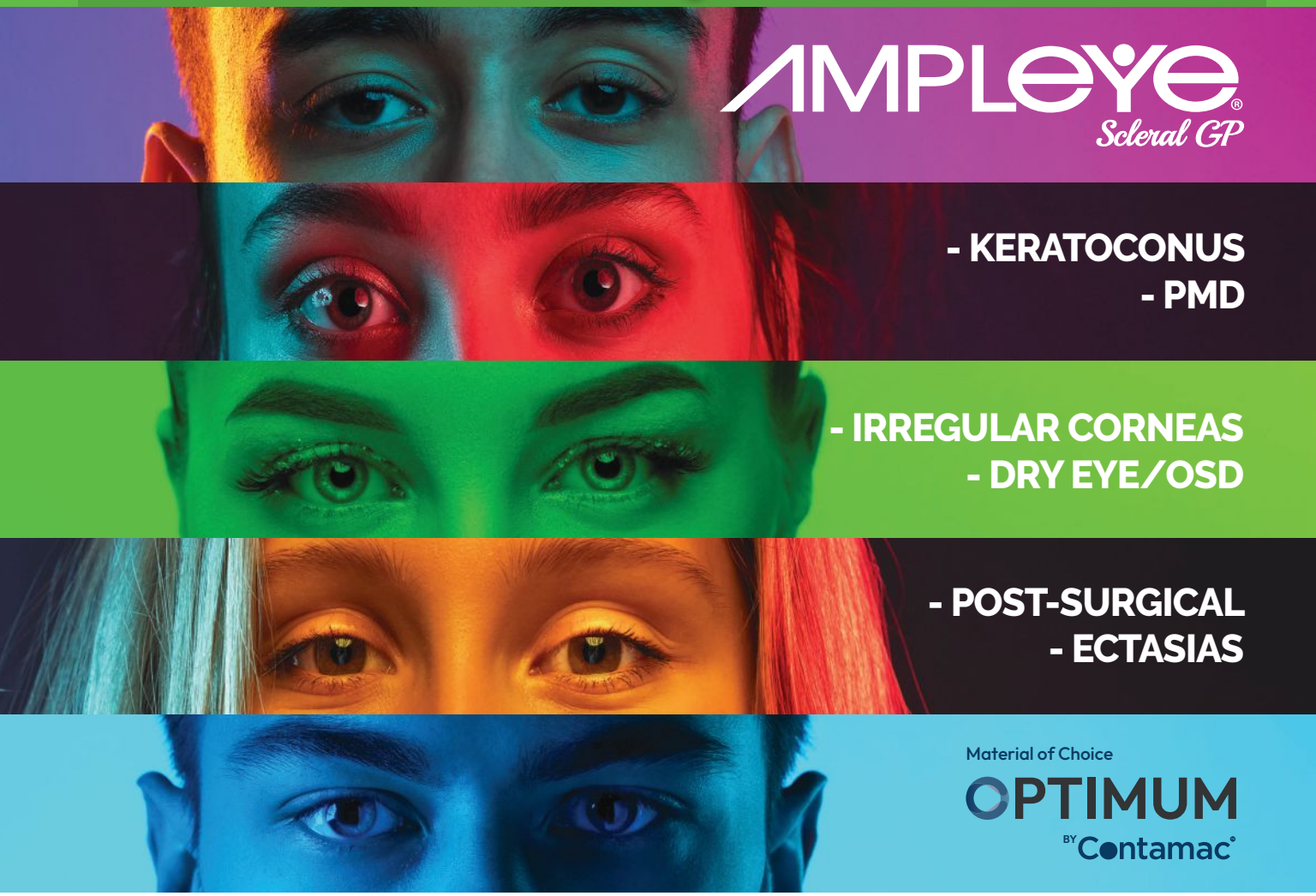
1. Lazas D. Five reasons physicians should integrate clinical trials into their practice. Applied Clinical Trials. www.appliedclinicaltrialsonline.com/view/5-reasons-physicians-should-integrate-clinical-trials-into-their-practice. July 31, 2023. Accessed August 1, 2024.

2. Lazas D. How integrating clinical trials into private practice can benefit both patients and physicians. Pharmacy Times. www.pharmacytimes.com/view/how-integrating-clinical-trials-into-private-practice-can-benefit-both-patients-physicians. May 9, 2023. Accessed August 1, 2024.

3. Obrenović Ž. Doing research in practice. Research & Practice. 2014;20(4):15-7.

4. How to get started in clinical trials. Retina Times. 2022;40(1):93.

YOUR PATIENTS, OUR PASSION



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By Marin Nagelberg, OD
and Lindsay A. Sicks, OD

Getting Out of the Way

When fitting corneal lenses, avoid obstacles and prevent complications.

When fitting a GP lens on a patient with any prior history of ocular surgery, it is crucial to perform a complete anterior segment evaluation. This will allow you to clearly see any "obstacles" to the fitting process and select an appropriate lens modality. Depending on the patient's history, these obstacles could be pingueculae, sutures, a filtering bleb, a tube shunt or some combination of the aforementioned. While corneal GP lenses may seem to be an ideal option for these patients, the fits can be challenging, and close follow-up is warranted. The overall diameter of the corneal lens should be altered to avoid or vault any associated obstacles. It is crucial to remove the lens and stain the cornea at each follow-up visit to ensure there are no adverse effects on the ocular surface (or the ocular obstacles).

CASE #1

A 62-year-old habitual ThinSite (Art Optical) corneal GP lens wearer with degenerative myopia and primary open-angle glaucoma OU presented for a re-fit after complicated cataract extraction with MIGS OU. The corneal GP parameters prior to surgery were OD 7.5/9.5/-24.25DS with a BCVA of 20/200 and OS 7.50/9.5/-26.50DS with a BCVA of 20/80+. Visual acuity was more limited OD due to prior retinal detachment and subsequent repair two years prior. Externals were notable for a 2+ APD OD and a constricted visual field by confrontation OD.

Anterior segment findings included a filtering bleb with tube shunt superior temporal OD along with residual embedded sutures both nasal (one) and inferior temporal (two). The patient is pseudophakic OU. We fit in ThinSite corneal lenses with parameters OD 7.30/9.0/-10.50DS and OS 7.20/9.0/-5.00DS based on fit and over-refraction of her habitual lenses, bringing her vision to 20/80 OD, 20/50+ OS, and 20/40- OU. The lenses were dispensed.

The patient returned for follow-up one month later reporting that the lens material was "too soft" and that she "could not hear the lenses when she dropped them" as she could in the past. While the lenses were manufactured in the same Boston EO material worn previously, we suspect she was noticing the thinner edges of the now lower-powered lens. Despite this issue, she thought the lenses were comfortable overall, and noted her vision was stable. Slit lamp exam revealed corneal fluorescein staining in an area surrounding the suture at two o'clock OS (*Figure 1*). The patient was advised to limit wear time, use preservative-free artificial tears every hour to lubricate the eye, and the lens was reordered in a smaller overall diameter OS (*Figure 2*).

The new 7.20/8.5/-4.50DS lens allowed the lens edge to land further inward from the embedded sutures. After dispense, she returned for follow-up several weeks later to reveal no staining in the area of concern. Given the reduced best-corrected vision in corneal lenses, we prescribed bifocal glasses for full-time wear over the top in polycarbonate material.

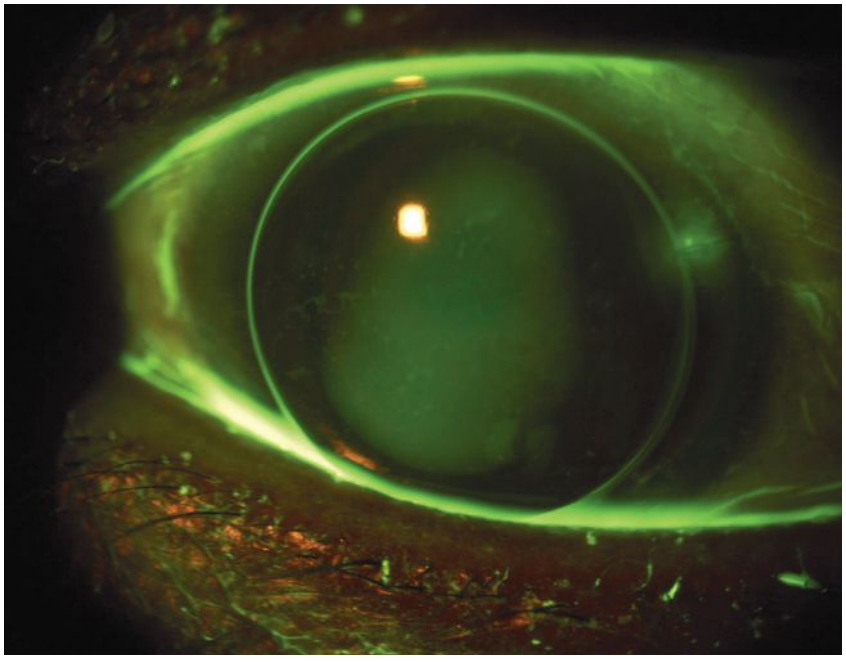

Fig. 1. Corneal lens on eye with nasal embedded corneal suture showing staining. Overall fit was steep, so the lens was reordered with a smaller diameter to improve fit and avoid the suture.

CASE #2

A 30-year-old female with history of trauma to the left eye in 2023 with surgical repair and resultant aphakia

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Getting Out of the Way

(continued from previous page)

presented for a first-time contact lens fitting in the left eye only. Entering uncorrected visual acuity was 20/20 OD, 20/200 (pinhole 20/100) OS. Externals were notable for an irregular superonasally displaced pupil OS.

Refraction was OD +0.25DS with BCVA 20/20 and OS +13.00 -2.00x036 with BCVA of 20/25. Anterior segment findings were unremarkable OD. Findings OS included two sutures superonasal located temporal to the limbus, an irregular pupil margin decentered superonasal and iridodonesis.

The patient was fit diagnostically with a Biofinity XR Toric soft contact lens (CooperVision) achieving 20/20 vision, but there was some concern as the lens edge landed near the existing conjunctival sutures. A ThinSite corneal lens was trialed OS with BCVA 20/20. The patient proceeded with the GP lens due to reduced risk of complications as the sutures could be avoided. The initial order was for ThinSite +15.75/7.6/9.50/Boston EO (Art Optical) OS only.

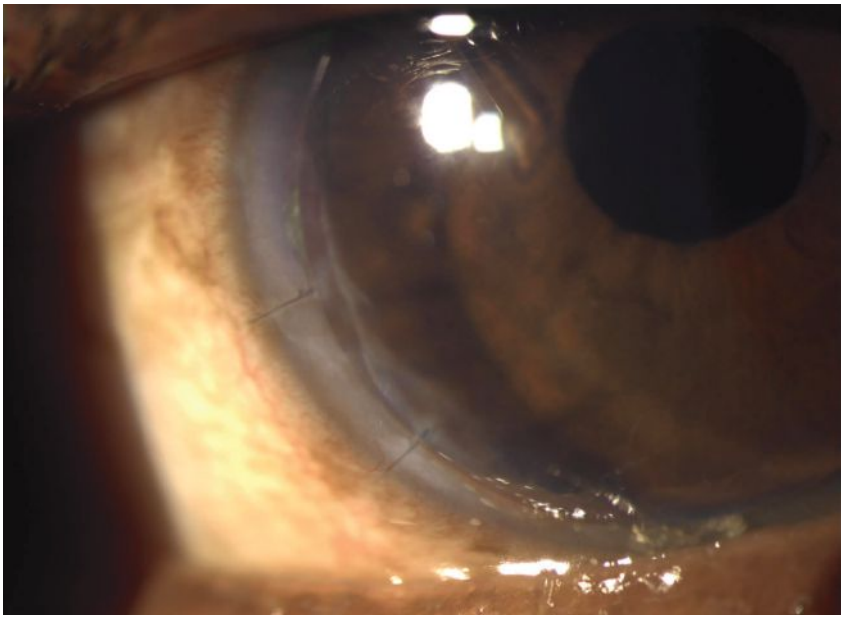


Fig. 2. The smaller overall diameter also helped avoid staining at the inferotemporal embedded sutures in Case #1.

At the initial dispensing visit, the patient was able to see 20/20 OS with a plano over-refraction. Evaluation revealed that the lens was decentered inferotemporally. While this was ideal as it avoided the two sutures superonasal, the pupil was not fully covered due to its superonasal displacement. The lens was reordered with a 10.0mm diameter to increase the sagittal height and improve centration.

At the second dispensing visit, trace staining was present at the sutures. The larger diameter lens allowed for improved centration, and the patient noted better comfort and vision (*Figure 3*). At follow-up, the staining at the sutures had resolved and the lens was finalized. Polycarbonate spectacles with a reading prescription were recommended for protection.

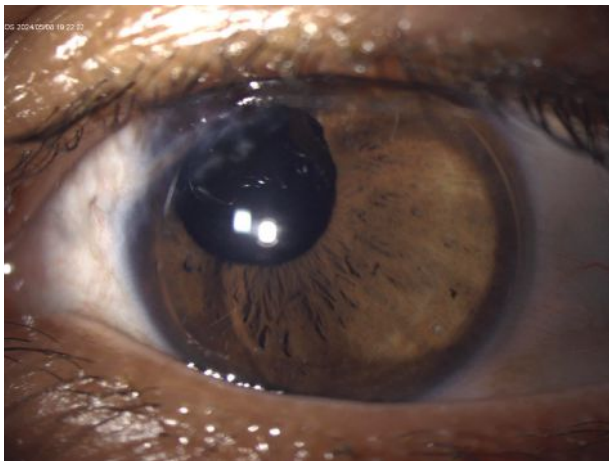
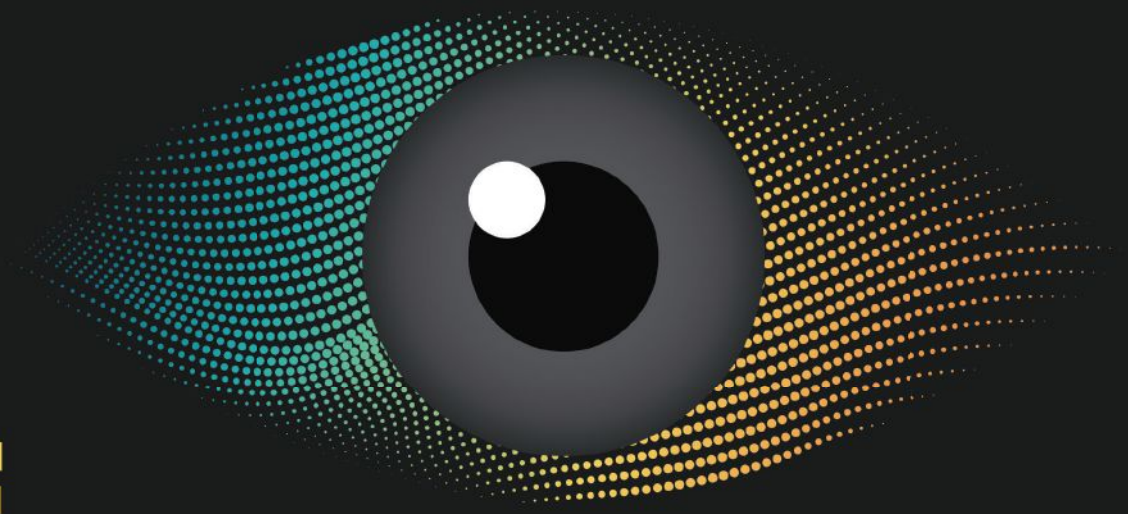


Fig. 3. Corneal lens on eye with nasal conjunctival sutures in Case #2. Centration and stability of the lens were important due to the nasally displaced pupil.

While both patient cases presented their own fitting challenges, each were successful in corneal lenses. When fitting patients who have embedded sutures, it is crucial to follow up closely and ensure the sutures are unaffected by the contact lens wear. Consider altering the diameter to avoid any fitting obstacles or improve centration, and don't forget to stress the importance of polycarbonate spectacles for protection! RCCL

The authors would like to acknowledge Bethany Peebles, executive director of consultation services at Art Optical, for her assistance with consultation in both of these cases.



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

Pushing Back Presbyopia

Using ortho-K lenses, one patient was satisfied with cycling wear vs. non-wear to achieve his optimal distance and near vision needs.

A 49-year-old male presents for his annual contact lens evaluation. The patient habitually uses orthokeratology (ortho-K) lenses and reports excellent distance vision with 20/20 entering visual acuity in both right and left eyes. He reports wearing his lenses for eight hours the night prior to his examination, though he often skips up to three nights, with no reported adverse side effects related to overnight contact lens wear. He does, however, report near vision blur the day after wearing his lenses overnight and his near visual acuity with both eyes open was 20/40. He also reports that he has to do very fine, meticulous near work, as he is a handyman. On days when he did not wear his lenses the night prior, he reports comfortable near vision. During a separate visit, he had not worn his lenses for three nights and his manifest refraction was -0.50 Sph OD and -0.50 Sph OS with a +1.25 add OU. Prior to ortho-K wear, his refraction was -0.75 -1.00x154 OD and -0.75 -1.00x0.35 OS. He wishes to continue wearing ortho-K but improve his near vision.

CONSIDERATIONS

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

Dr. Pfeifer: Patients who are developing presbyopia provide a unique challenge, in that they're losing part of their functional vision in a normal, expected way. For eyecare practitioners, this is something that is very mundane, but for the patient, their world is changing. Giving the appropriate weight to their concern, while talking about options for improvement, will allow them to feel heard, but also hopeful. Patients in ortho-K, especially long-time wearers, may struggle with this insidious near blur as they have become accustomed to not wearing correction throughout the day. This can amplify the burden of wearing readers and leave the patient feeling dissatisfied.

Given this, my preference would be to incorporate a +1.00D to +1.50D "boost" into the nondominant eye's lens to give a usable range of vision. If the patient is not amenable to modifying his lenses or his wear schedule, informing him that the near vision blur will only increase as time passes is essential. He will likely begin to need supplemental near vision glasses for days following lens wear and distance vision glasses for tasks like driving on days when he skipped lens wear. He also has the option of wearing multifocal soft or specialty contact lenses on days after he skips ortho-K wear. Supplementation with pharmaceuticals targeted at improving near vision in presbyopic patients could also be considered. Ultimately, the patient is going to dictate how he approaches presbyopia once he is aware of all the realistic options. If he decides to discontinue ortho-K wear, a multitude of soft or specialty extended depth-of-focus or multifocal options are a possible solution going forward.

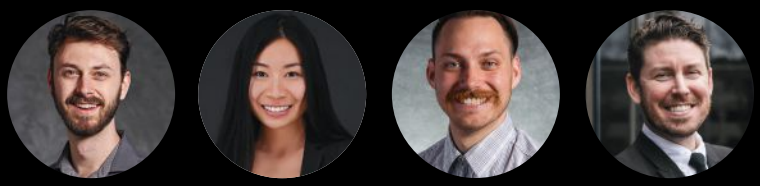
Dr. Su: In this case, the patient has excellent distance vision with ortho-K but struggles with near vision, and he often skips wearing the lenses for three nights at a time. It's important to clarify whether these lapses are accidental, which coincidentally improves his near vision, or if they are deliberate efforts to enhance his close-up vision. Understanding the patient's behavior and expectations is crucial, as well as setting realistic expectations. If he wants to maintain his 20/20 distance vision while improving his near vision for work and not have the need to wear reading glasses, a blended vision approach could be beneficial. I find that adding a +1.25D or +1.50D add in the nondominant eye often successfully meets most patients' needs without significantly reducing stereoacuity. However, to test this, I'd recommended a washout period and trial this with soft lenses for about a week.

Dr. Noyes: Though I don't do ortho-K in my clinic, creative applications such as over-spectacles, under-correction and monovision could do well for this patient. Too many practitioners conceptualize ortho-K as being "kids only," and this case demonstrates widening its use in a safe and effective way.

Dr. Gelles: There are a few considerations to be made here. First is his occupation: the obvious option is for him to use an occupation pair of glasses at work; it will give him a near add, but more importantly, double as a pair of safety glasses.

If we are looking specifically at options to modify his current ortho-K wear, we must keep in mind the patient is myopic and reports that under-correction from the ortho-K makes him happy at work. An easy fix could be to reduce the target power to give a little less myopic correction, allowing him to have clearer near vision. If near work is 90% of his need, over-spectacles with the rest of the myopic correction can be used as needed.

A classic line from the podium



is, "Orthokeratology is inherently multifocal," as the correction causes increased spherical aberration similar to a center distance multifocal contact lens. A smaller optic zone will give more multifocal effect by pushing the reverse zone inward, increasing spherical aberration and thus providing more depth-of-focus. An alternative to that is the use of blended vision, where the dominant eye is fully corrected and the non-dominant eye is corrected to -1.25D. The issue here is that detailed near work generally needs good binocularity and this is likely not the best option.

If he likes clearer vision at distance on the weekends, in this case, having two pairs of ortho-K lenses might offer the best solution: one pair for fully corrected distance worn on Friday and Saturday night for a distance task-heavy weekend, and the other worn Sunday through Thursday with reduced target correction for his occupational needs.

Ultimately, if the patient is happy and healthy, why change? The cycle seems to be meeting his needs, so let him keep doing what he's doing, get him a pair of distance spectacles for when he's under-corrected and keep monitoring his health. If he's considering discontinuing ortho-K for convenience, a refractive lens exchange with a premium intraocular lens could satisfy his needs.

DISCUSSION

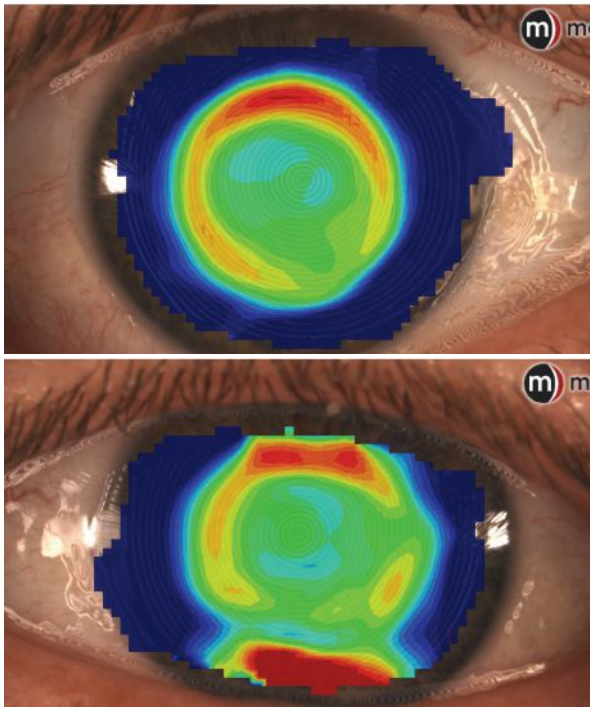
Presbyopia can be a challenging obstacle to conquer when fitting any contact lenses. Focus is typically placed on the best possible distance vision, which can result in a worsening of near vision in many patients with reduced accommodative ability, including those wearing ortho-K. There are many options to address this near demand, including near vision only glasses, refitting into a monovision treatment or using presbyopic ortho-K designs. Patients' lifestyles will often determine how presbyopia is handled. Are they comfortable wearing reading glasses some of the time? If so, distance vision correction with ortho-K may be ideal. Do they require fine stereopsis or work with sharp detail at near? Monovision may not be the best option for that patient. Ortho-K can be very flexible in the vision it provides patients, and, as a greater number of presbyopic designs are becoming available, it may be a more commonly used presbyopia treatment modality.

RESULTS

This patient requires the ability to see very fine detail at close distances for his typical workday. An extended trial of monovision correction was considered using a soft contact lens to simulate under-correction in the nondominant eye. However, when the patient tried this modality in the office, he immediately noticed that his near vision was reduced, thus prompting him to not elect pursual of monovision.

He was comfortable with his distance vision being slightly blurry, and, as he had reported, he often went multiple nights sleeping without his lenses before returning to them for one to two nights. He felt that this cycle allowed him to maintain very good near vision with usable distance vision most days.

We elected to refract him after a three-night washout period and write a spectacle prescription for distance vision use after not sleeping in his lenses for two to three nights at a time. At his six-month follow-up visit, he reported that his ortho-K cycle was working well, though he was reminded that other modifications will likely be needed as his presbyopia progresses.



Topography of the right and left eye after skipping ortho-K wear for three nights; note the light but well-centered treatment pattern.

Scleral Lens Design: Beyond the Vault

Creating proper secondary and peripheral curves helps prevent issues of comfort and vision quality.

By Paymaun Asnaashari, OD

Imagine if all homes were built with the same cookie-cutter design and material no matter the location, elevation or environment. Would every home last? Certainly not. Some materials and designs can work well for most, but every homeowner and plot of land has different needs. The same is true for scleral lenses, whose advancements and popularity have made some of us believe that any design can provide a solution to unique ocular problems. However, the more fittings you complete, the more unique challenges you will encounter, whether related to patient management or lens troubleshooting. Most patients will be satisfied with the vision scleral lenses can provide, but redness, fogging and inadequate comfort can lead to multiple adjustments and remakes. One design does not fit all, and we should look more carefully beyond the limbus to find solutions.

Most scleral lenses are designed with a common foundation (*Figure 1*). Successful fitting starts with understanding how to modify the multiple peripheral curves and base curve when challenges arise. Here's guidance on designing these curves to avoid potential trouble from a poor fit.

SCLERAL SHAPE VARIABILITY

A key principle to remember is that the further beyond the limbus you go, the more asymmetric the sclera becomes. Evidence of this comes from the Pacific Scleral Lens Study, which looked at multiple eyes of normal and keratoconic patients to assess the differences in scleral shape.[1] Two chord lengths—measured as the total diameter between one edge and the other, similar to horizontal visible iris diameter—were used to assess scleral shapes; namely, 15.0mm and 20.0mm (*Figure 2*).

With the 20.0mm chord, the scleral angle variability increased significantly, from 36.6° to 43.2° (*Figure 3*). This illustrates that the further from the limbus, the more variable the scleral shape becomes. Another study—the Scleral Lens Shape Study—also illustrated large differences in scleral lenses, especially between the nasal region (shallower angle) and the temporal-inferior region (steeper angle; *Figure 4*). This is also why you may see scleral lenses decenter temporally and inferiorly, especially if they are too large in diameter or have excessive apical clearance.

This research highlights the need for toric peripheral curves as the size of the scleral lens increases. Imagine what could happen by putting a scleral lens with a spherical back surface on a toric sclera; the asymmetrical scleral lens anatomy can result in a poor fit. In that case, you might see three o'clock and nine o'clock compression or staining and edge lift at six o'clock and 12 o'clock.

DOUBLE UP THE DYES

Vital dyes are very useful for assessing the ocular surface and contact lens fitting relationship. If you don't have access to fancy equipment (like how I started), the use of sodium fluorescein (NaFl) and lissamine green (LG) simultaneously has become increasingly valuable in assessing the total ocular surface. We all have been accustomed to adding NaFl to the lens bowl before insertion, which will allow you to see the tear fluid reservoir depth and limbal clearance. However, the addition of LG after the lens is inserted is undervalued. I suggest waiting a minimum of 20 minutes before adding LG. This dye

ABOUT THE AUTHOR

Dr. Asnaashari graduated in 2018 from the University of California Berkeley School of Optometry. He currently works full time in private practice and owns Arden Park Optometry in Sacramento, CA. After finishing school, he organically developed an emphasis in the areas of myopia management and custom contact lenses for patients with corneal disorders. He is a fellow of the American Academy of Optometry and Scleral Lens Education Society. He is currently serving as President of his local optometric society, the Sacramento Valley Optometric Society. He has no financial disclosures.

will allow you to assess the lens periphery and can also be used to assess the lens edge if it's lifting off, influx of the stained fluid in the reservoir (under the lens fogging) or conjunctival irritation and impingement. In my opinion, LG has become just as important as NaFl—if not more—to assess the scleral lens edge because of the high contrast of its green color with the white sclera. See *Table 1* on the following page for the different characteristics of NaFl and LG and their uses.

After waiting long enough for the scleral lens to settle, I always suggest doing an LG tear uptake test to check the lens edge and potential for fogging. This involves applying a generous amount of LG either directly onto the lens or the lower lid margin. *Figures 5 and 6* illustrate the impact LG installation can have on the scleral lens fitting relationship; in *Figure 5*, a mild amount of LG accumulation is seen inferiorly under the lens, suggestive of potential debris build-up. This may indicate areas where there is a loose edge to tighten the angle. Look along the edge of the lens for areas of LG build-up to indicate areas where the dye could be leaking through. A lens that seems like the perfect fit could have potential for fogging, which may go unrecognized without an LG test.

In *Figure 6*, you may notice there is a lot more LG accumulating under the lens changing the iris color. This type of fitting would induce a significant amount of fogging within a short time. In addition, pay attention to lens movement. If you see a lot of LG uptake, you should expect to see lens movement with the blink, another hallmark sign that the lens is still too loose. Consider tightening the secondary or peripheral curves to tighten the fit of the scleral lens, which, in turn, will help reduce lens movement and tear exchange under the lens. Another viable modification is switching to a smaller-diameter lens. As shown in *Figure 6*, the scleral lens becomes more spherical the closer it is to the limbus, allowing it to land more evenly across the sclera, which reduces gabs and edge lift where the tear film could leak in. Large-diameter lenses (≥16.0mm) can likely benefit from adding a toric back surface design.

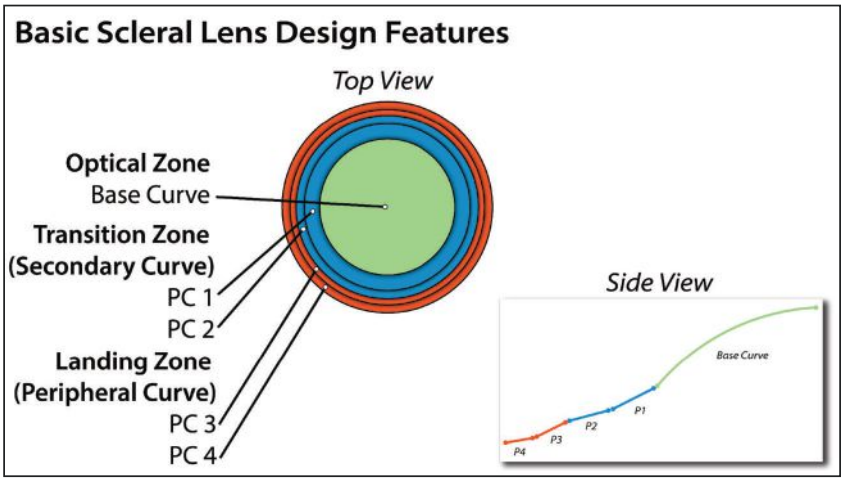


Fig. 1. Most scleral lenses share these common design features.

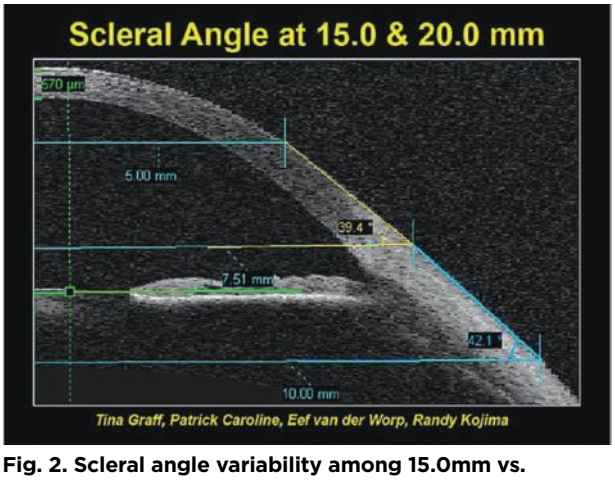


Fig. 2. Scleral angle variability among 15.0mm vs. 20.0mm chord lengths.[1]

MANAGING BLANCHING AND REDNESS

A common challenge scleral fitters will experience from their patients is that they develop redness after wearing the lenses, whether after a few hours or a full day of wear. Edges may look aligned during lens dispensing, but the real test is when patients return for their follow-ups. (*Quick tip: Try to schedule these appointments in the afternoon so that lenses have plenty of time to settle.*)

When troubleshooting this complaint, it's critical to evaluate the location and pattern of vessel blanching. If you see circumferential blanching along the lens edge, it could mean the peripheral curve is digging into the tissue and pinching the conjunctiva. This will cut off blood flow in that area, leaving it blanched. A remedy to help reduce blanching along the lens edge is a flatter peripheral curve, allowing the edge to land at an angle better aligned with the contour of the sclera to reduce conjunctival blanching.

Another adjustment that could reduce vessel blanching is flattening the base curve. This will flatten the angles of the entire edge of the lens, but this could impact your central clearance. If you experience asymmetric blanching in scleral lens wearers, meaning certain areas are blanching while other areas have good alignment, this could be due to the anatomical shape of the sclera. A common example is when you see blanching at three o'clock and nine o'clock; this type of fit would ben-

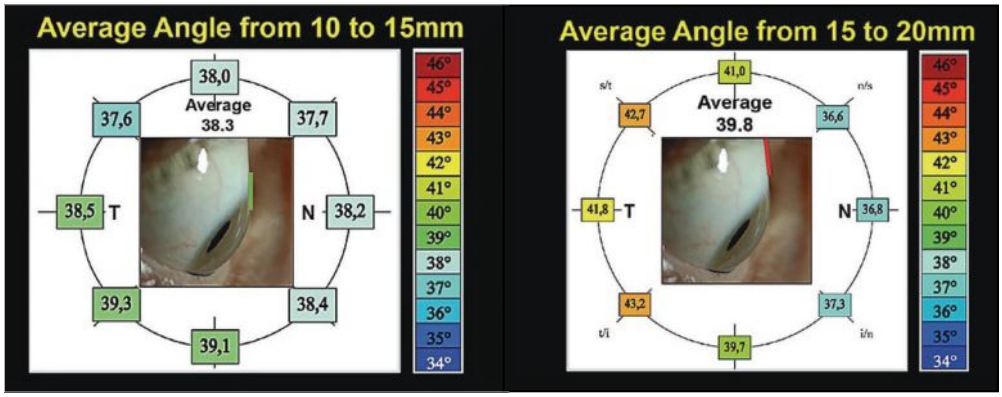


Fig. 3. Among the 15mm chord, scleral angles showed very little variation (left). When compared, the 20.0mm chord showed much more scleral angle variability (right).[1]

efit from a back surface toric design by modifying the secondary or peripheral curves. Anterior segment OCT (AS-OCT) is another valuable tool to use in these cases, as it allows us to see the lens edge in much greater detail than the naked eye. So, next time you see blanching or redness, see what the AS-OCT shows.

RESIDUAL ASTIGMATISM AND FRONT SURFACE OPTICS

As much as scleral lenses can provide visual recovery to many patients, residual astigmatism and aberrations may arise, resulting in suboptimal visual performance. This section will share options that may be added to the anterior surface of the scleral lens to optimize vision and restore problems with binocular vision.

The fluid reservoir beneath a scleral lens acts as a refractive lens. Studies have shown that approximately 88% of the anterior corneal astigmatism is equal to the total astigmatism, and the posterior corneal astigmatism will counteract 12% of the anterior corneal astigmatism.[2,4-8] The fluid reservoir has a different refractive index compared to the cornea. Dividing the refractive index of the fluid reservoir (1.336) by the refractive index of the cornea (1.376) reveals that 89% of the anterior corneal astigmatism is countered by the fluid reservoir. Therefore, the fluid reservoir overcorrects the total corneal astigmatism by 1%.[2,4-8] When doing over-refraction, practitioners can reveal the presence of sphero-cylindrical correction, described as ocular residual astigmatism. This is induced by the posterior corneal surface and the crystalline lens, though it's thought to mainly result from the latter, which is why it's known as "lenticular astigmatism."[2,9]

The residual astigmatism during a scleral lens fitting may be induced for multiple reasons. It can be due to the fluid reservoir, lens centration, lens warpage or lens flexure. Scleral lenses can exhibit inferior-temporal decentration caused by excessive apical clearance, large diameter, excessive limbal clearance, a toric sclera and weight of the lens. The mechanism can be multifactorial and can be a challenge to identify, altering the lens optics and inducing prismatic effects resulting in residual astigmatism.[10,11] Residual astigmatism may persist despite making adjustments to help remove residual cylinder, such as reducing corneal and limbal vault, adding a toric back surface design or changing the diameter, Dk, thickness, design or modulus of the lens. To avoid this, adding a toric anterior surface will correct the cylindrical over-refraction.

Table 1. Characteristics of NaFl and LG[2,3]

	Vital Dye	
Characteristics	NaFL	LG
Color	Orange	Green
Peak Absorption	465nm to 495nm	624nm to 635nm
Slit Lamp Illumination	- Cobalt Blue - White	White
Primary Ocular Surface Staining Area	Cornea	Conjunctiva
Time of Observation	Immediately to 8 minutes	1 to 4 minutes
Staining	- Staining spaces where a cell is missing - Damaged or altered cells	- Damaged or dead conjunctival cells - Marx's line
Scleral Lens Assessments	- Corneal areas - Limbal areas	- Lens alignment on the conjunctival tissue - Edge lift - Scleral toricity - Fluid influx in post-lens tear reservoir - Conjunctival areas

SCLERAL PROFILOMETRY AND WAVEFRONT-GUIDED OPTICS

Adding advanced technology, like scleral profilometry, can help practitioners navigate fitting challenges by providing individualized image-driven guidance. New technology such as

scleral topography and profilometry can take the traditional empirical fitting process and instead provide a near-perfectly fit lens that matches the ocular surface on a micron scale. This can help save time and provide optimum comfort and vision for patients. According to the Scleral Lens Shape Study, only about 6% of scleras are simple spheres; therefore, we do not have the big picture of the scleral shape without profilometry.

Irregular corneas can induce higher-order aberrations (HOAs). Studies have shown that eyes with keratoconus can induce five to six times as many HOAs as those with normal corneas.[12-14] HOAs can also significantly increase following keratoplasty, especially in eyes that undergo penetrating keratoplasty (vs. deep lamellar endothelial keratoplasty and Descemet's stripping automated endothelial keratoplasty).[15-16] HOAs may also result from the crystalline lens and posterior cornea, which partially compensate for the anterior corneal aberrations in the naked eye. In addition, HOAs may also be induced with lens decentration, giving rise to coma and astigmatism. Customized wavefront-guided scleral lenses can be considered to help reduce HOAs by incorporating wavefront-guided optics to help increase visual acuity and contrast sensitivity. Customized scleral lenses with a customizable HOA front-surface design can be affected by various factors, such as lens decentration, rotation and wettability.[17]

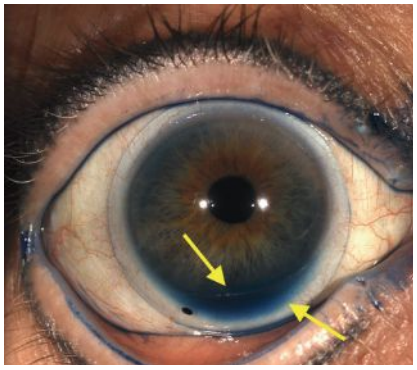


Fig. 5. Notice the mild accumulation of lissamine green inferiorly along the limbus.

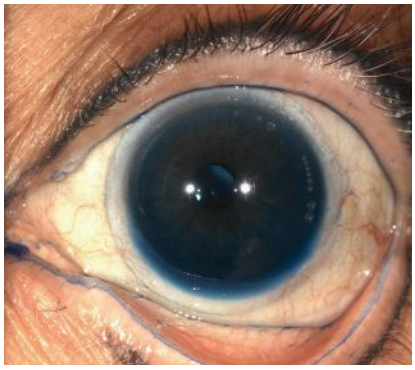


Fig. 6. Notice the large amount of LG throughout, causing the iris to be artificially more blue/green.

HOAs can also be influenced by the changes happening in the tear film; studies have reported that variations in the tear volume and fluid dynamics can induce HOAs in regular corneas.[18-19] Therefore, it is crucial to manage dry eyes and ocular surface diseases to help reduce unnecessary HOAs.

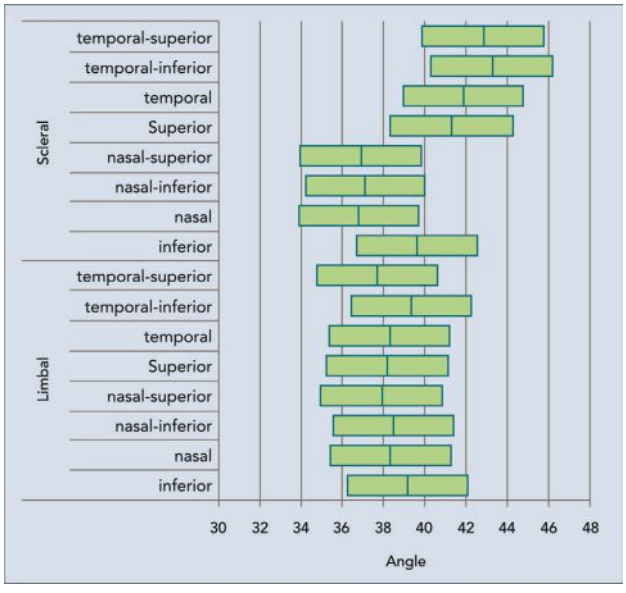


Fig. 4. Variability of scleral lens angle in different meridians.[1]

ADJUSTING FRONT-SURFACE ECCENTRICITY

Eccentricity is a measure of how much the deviation of a curve has occurred from the circularity of a given shape. In terms of contact lenses, eccentricity refers to the amount of asphericity in a lens. The higher the eccentricity, the more quickly a contact lens flattens out from the center to the periphery.[8] This means the center of the lens will have the most positive power and the power will become increasingly more negative towards the lens periphery.[8] This type of geometry was found to induce negative spherical aberration and had a positive impact on visual acuity performance in studies.[20-22]

Rigid contact lenses with front-surface eccentricity (FSE) improved visual acuity compared to conventional spherical contact lenses.[22] A study by Gumus et al. looked at the effects of modifying the FSE in Boston Scleral lenses. Multiple lenses were designed adding FSE of 0.3, 0.6 and 0.8 on patients who have keratoconus, penetrating keratoplasty, post-refractive surgery and ocular surface diseases. The lenses induced a meaningful reduction in HOAs (69% to 77%) in the group with added eccentricity over those that had a spherical front surface design.[20] Another study by Hussoin et al., which evaluated vision improvement with the addition of FSE of Boston scleral lenses for corneal ectasia patients, found that an FSE of 0.6 and 0.8 had noticeable improvement in high-contrast and low-contrast visual acuity.[21] Furthermore, Mahadevan et al. showed the impact FSE can have on improving visual acuity of 17 patients with corneal ectasia; in that study, patients with FSE of 0.6 had significant

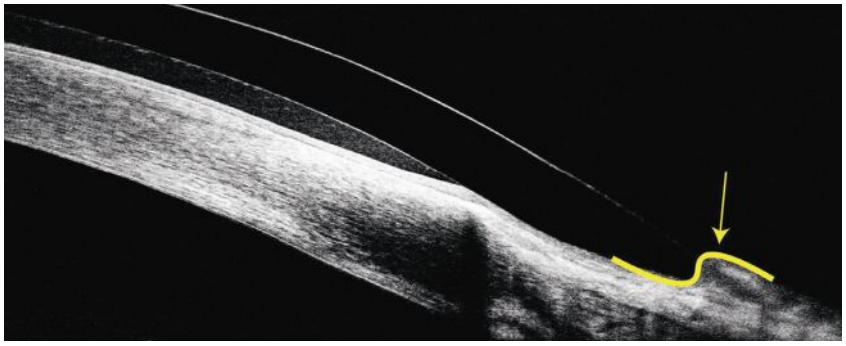


Fig. 7. This steep peripheral curve has caused the conjunctiva to start riding over the anterior surface of scleral lens.

improvement in their vision compared to the group without eccentricity.[22] This type of geometry added to scleral lenses has shown the impact FSE can have on inducing negative spherical aberration and reducing HOAs, ultimately helping to improve visual acuity.

PROLATE VS. OBLATE DESIGNS

There are two general designs of scleral lenses: prolate and oblate. The former describes a design in which the back optic zone radius is steeper than the peripheral radius. Conversely, an oblate design has a back optic zone radius flatter than the peripheral radius. Prolate designs are generally indicated in all forms of keratoconus and ectasias, while oblate designs are generally designed for cases in which the cornea is flatter centrally compared to the periphery, such as post-surgical for myopia or radial keratotomy. Fitting a prolate lens on an oblate cornea the lens can create excessive clearance centrally and can create touch in the mid-peripheral cornea.

Excessive central clearance can reduce oxygen transmissibility to the cornea, create lens decentration, fogging and reduced vision quality due to the prismatic effect of a decentered ectasia.[23] Oblate designs will help create a proper vault in the mid-peripheral cornea while maintaining the appropriate central clearance. Fitting an oblate design on a prolate cornea can have advantages because the peripheral cornea is steeper than the central. This allows for adequate vault over the decentered ectasia. Furthermore, the central lens area will be closer to the cornea, resulting in greater oxygen delivery, reduction of the lens minus power, a larger optic zone diameter and better on-eye stability.[23]

TAKEAWAYS

Scleral lens designs continue to expand and improve to meet ever-increasing demand for them. When making a life changing impact to someone's sight with scleral lenses - it should not be quick or a 'one-size fits all'. Understanding that the sclera becomes more toric the further beyond the limbus is important. If you are using a scleral lens larger than 15.0mm, look at the relationship between secondary and peripheral curves on the ocular surface as carefully as possible. Use a combination of the tools listed above to help you improve your fitting success and efficiency. RCCL

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AVOID These Common Scleral Lens MISTAKES

Novices may be unaware of certain intricacies these lenses possess, which can make a big difference in outcomes.

By Caitlin J. Morrison, OD

Over the past decade or so, scleral lenses have experienced a significant surge in popularity due to their remarkable ability to enhance vision, accommodate complex ocular conditions, manage dry eye syndrome and even maintain wearer comfort. These lenses have revolutionized patient care in recent years by providing a unique opportunity for sharper, more comfortable vision.

My practice, located in Scottsdale, AZ, is dedicated exclusively to the design and fitting of specialty contact lenses. We do not conduct comprehensive eye exams, dispense eyeglasses or even fit commercially available soft contact lenses. Consequently, the majority of our patients present with complex cases, often requiring scleral lenses to address the visual issues they are experiencing. It is immensely rewarding to witness patients with advanced, challenging-to-fit ocular conditions achieve comfortable and clear vision through our efforts. Throughout my years of practice and consultation, I have encountered a plethora of scleral lens fittings. Here, I will share some common mistakes observed during the fitting process of this particular lens.

1. SELECTING THE INCORRECT DIAMETER

When opting for this lens modality for a patient, the first step in fitting a scleral lens is to select the appropriate diameter. Each fitting set will have suggested values, so it is advisable to consult with your fitting consultant for your preferred lens to understand the process for determining the initial diameter needed.

A common mistake among novice fitters is choosing lenses that are either too small or too large. If the lens is too small, it will not adequately lift off the limbus, regardless of adjustments to the limbal zone. Conversely, if the lens is too large, it will land too far from the limbus, causing the conjunctiva to be drawn under the lens resulting in sagging. This issue causes the lens to come very close to the superior limbus while having excessive vault inferiorly, which cannot be corrected simply by limbal adjustments.

Horizontal visible iris diameter (HVID) is the measurement of the horizontal width of the iris from limbus to limbus, where the cornea meets the sclera. It is typically measured using calipers on the slit lamp, digital imaging systems or specialized instruments like a keratometer or corneal topographer. You can also measure HVID with just a ruler.

The larger the HVID, the greater the depth of the anterior segment. This translates into needing larger diameter scleral lenses in order to create a larger vault to clear the cornea. Choosing a proper diameter for the lenses is the first step to ensure that the scleral lens will vault over the cornea without causing pressure or discomfort. It's an important measurement for those with asymmetrical eyes as well as determining edge lift and clearance.

The average HVID is approximately 11.7mm to 11.8mm.[1-3] For patients with this corneal diameter, a variety of lens diameters can be successful.

ABOUT THE AUTHOR

Dr. Morrison, FAAO, FSLS, is the owner of In Focus: Specialty Contact Lens & Vision Solutions, a private practice in Scottsdale, AZ, that specializes in contact lenses for advanced ocular conditions and comprehensive care for difficult visual cases. After graduating from the New England College of Optometry, Dr. Morrison completed a Cornea & Contact Lens Residency at SUNY College of Optometry. She is the recipient of both the Bert C. and Lydia M. Corwin Contact Lens Residency Award and the Johnson & Johnson Award for Excellence in Contact Lens patient care. Prior to moving back to AZ, Dr. Morrison worked in the cornea department of New York Eye and Ear Infirmary of Mount Sinai specializing in corneal diseases and complications. She is inspired by her patients who have overcome many visual obstacles and are motivated to regain quality vision.

Generally, for corneas with a diameter under 11.5mm, smaller lenses around 14mm to 15mm might work well. For corneas with a diameter of 12.1mm or greater, larger lenses, around 17mm to 18mm, are usually more suitable. It is important to note that the actual diameter may vary; this is dependent upon the specific lens design.

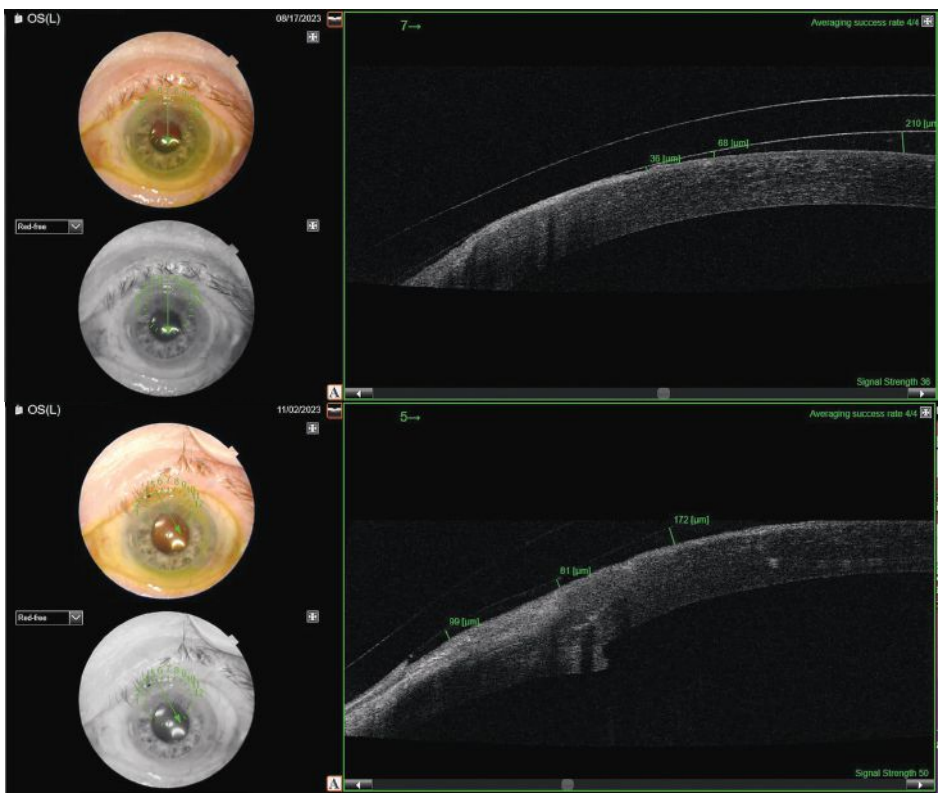
Understanding the differences between HVID and vertical visible iris diameter (VVID) is also essential in contact lens design—especially for specialized lenses like scleral lenses used for patients with corneal irregularities. VVID measures the vertical height of the iris from the superior to the inferior limbus. Like HVID, this measurement can be taken with various tools designed for ocular measurement, but I have found that measuring it with calipers on my OCT on the photo of the eye is the easiest for me. Like with HVID, VVID can also be measured in a slit lamp or with a ruler.

Large changes in HVID vs. VVID may indicate higher amounts of astigmatism and may require changes in the optic zone shape—such as an oval optic zone—which will change the vault horizontally vs. vertically. There are also lens designs coming out with changes to the back optic zone so that the horizontal and vertical curvatures vary and are in better alignment with the shape of the eye. This results in a lens that centers more easily and induces less fogging.

This concept is less relevant with freeform scleral lenses. Freeform lenses include such as those designed through scanning or impression techniques, as these methods allow the limbus to be defined by software rather than relying on a predetermined landing design.

If I find that there is a large difference between the eye's HVID and VVID, I will frequently encounter the scleral lens trials in-office decentering inferiorly or inferior-temporally. In these cases, I usually recommend a freeform design or a design with some sort of back surface bi-elevation. Bi-elevation refers to the differing curves between the horizontal and vertical meridians on the back of a scleral lens. This nomenclature will differ depending on which conventional scleral lens design you are using, so I would suggest discussing with your scleral lens lab if they have this capability.

In terms of a practice management technique, I have found that my patients just want what is going to yield them the best results. If I see a trial scleral lens on the eye that decenters hugely and is a very poor fit, I recommend switching to a freeform design right away and discuss the difficulties that a conventional scleral lens fitting might present to both myself trying to fit said lenses and to the patient in wearing them.



The top image depicts a lens that is much too large for the eye, causing inferior decentration and superior corneal touch. This patient felt discomfort after three to four hours of wear (the exact time the lens would have settled down to touch the cornea). The bottom image displays a smaller version of a scleral lens over the same eye. This lens is vaulting over the superior cornea and is not touching.

2. FAILING TO REMOVE THE LENS AND APPLY FLUORESCEIN STAIN

Another frequent fitting error I have observed is the provider's omission of lens removal to stain the cornea and conjunctiva with fluorescein. By performing staining after the lens has been removed, clinicians can identify areas where the lens edges may be excessively tight, as evidenced by conjunctival staining. Additionally, this practice

allows for the detection of corneal contact points and subtle regions of corneal microcystic edema.

3. NOT ASSESSING EDGE LIFT WITH FLUORESCEIN

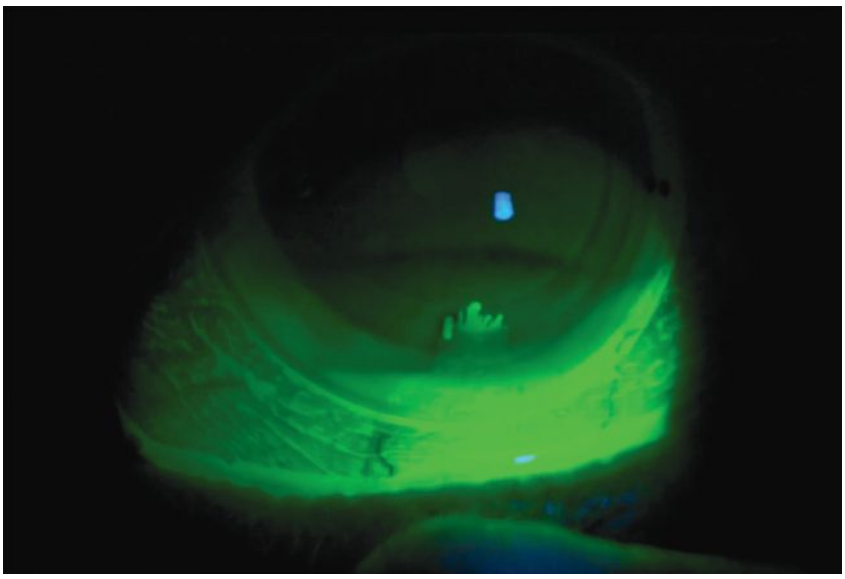
To evaluate edge lift, apply fluorescein to the superior conjunctiva over the lens and immediately examine the lens via slit lamp. Observe if and how quickly the fluorescein penetrates beneath the lens. Proper edge alignment is crucial for eliminating midday fogging, which occurs when natural tears mix with the clear saline beneath the lens. Natural tears are not as clear as the saline solution; this is due to tears' composition, which can cause blurry vision. By identifying areas where fluorescein seeps under the lens, you can determine where to tighten the edges to reduce fogging. If no fluorescein seepage is observed and the patient reports blurry vision, consider other factors, such as prescription accuracy or the presence of corneal edema.

4. NOT ASKING THOSE OVER AGE 40 WHAT THEY WANT TO DO ABOUT READING GLASSES

We've all forgotten to do this, right? You put the initial scleral lens in the patient's eyes, their vision is 20/20, they're seeing great and then they call the office saying, "I can't read anything!" I have a sheet in my office that details the three options for all patients over the age of 40: distance lenses with readers, monovision lenses or multifocals. We will always go over their preference for reading capabilities on the first exam prior to me ordering lenses. I also reiterate this choice at their next appointment and give them a recommended reading strength that is written down.

5. CHANGING WHAT ISN'T BROKEN

You've heard the phrase before: If it ain't broke, don't fix it. However, we're all susceptible to occasionally look for problems that may not exist. I personally have many times adjusted parameters of a lens to achieve a more textbook fit, only to have the patient tell me they prefer their old lenses. When evaluating lenses, particularly those fit by other providers, it is crucial to consider the patient's existing satisfaction. If their lenses maintain optimal eye health, clear the cornea and offer good vision and comfort, there is no need for significant changes. Adjusting central clearance from 275µm to 200µm, for instance, is often unnecessary. Exceptions to this rule include cases where the patient experiences issues such as fogging, corneal edema or discomfort, or if they have a low endothelial cell count, in which case, lower clearances and lens thickness may enhance long-term eye health.



Here, fluorescein is put over the lens during a follow-up examination. This patient was complaining of midday fogging, but when I inserted the fluorescein initially, there was no uptake. I gently added some pressure with the lid to the bottom of the lens and fluorescein went into the lens easily. Here, I could tell that the vertical meridian of the peripheral curves needed some steepening. After this adjustment, the midday fogging decreased.

TAKEAWAYS

Scleral lenses are so gratifying to fit and I think the real skill in designing great fitting lenses for patients lies in fixing potential complications before they arise. I also think discussing with patients why you are choosing certain designs over others based on their anatomy is a great way to develop a following of patients who trust you and your decisions. With each lens you fit, your skill level will increase. I am 10 years in and I still keep a spreadsheet with my designs and unique things I've done to fix complications. You start seeing patterns when you do this enough, and that's when you can order lenses based on the pattern you expect to see develop. This shortens the fitting process and increases patient satisfaction with their lenses. Don't be afraid to take the plunge in starting to fit these versatile lenses! RCCL

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Clinical Applications of Today's Scleral Lens Research

Catch up on the latest findings and how they can apply to clinical practice.

By Boris Severinsky, OD, and Aysha Shafi, OD

As advances occur within the field of specialty contact lenses, their utility expands to encompass wider purposes. Originally posed as a corrective measure for irregular corneas, scleral contact lenses have quickly found use for refractive error correction, including high astigmatism, keratoconus and other ectatic corneas, post-surgical eyes and eyes suffering from significant dryness from any underlying disease process. With a wider patient base that could potentially benefit from scleral lenses, optimizing the fitting process outcomes becomes an important goal.

FITTING AND DESIGN

Technology advancements in scleral lens design are promoting efficiency in the fitting process and increasing customization capabilities. Any scleral lens fitter is familiar with the multiple-visit process that specialty lenses typically require, which involves various tweaks on prescription, sagittal depth, limbal clearance and peripheral landing zones. With the advent of profilometry devices, scleral lenses could be designed from anterior surface imaging, such instruments include Eaglet, Cornea Scleral Profile (CSP) on Pentacam and similar. With these technologies, elevational differences of sclera vs. corneal toricity are more easily assessed, as compared with using diagnostic lenses and evaluating lens settling after a period of 30 to 45 minutes.[1] A recent study looked into a data provided by 423 practitioners who fit scleral lenses for keratoconus comparing image-based vs. impression-based technology. Practitioners with image-based technology used it for 25% of lens fittings, those with impression-based technology used it for 9% of fittings and those with both types of technology used image-based devices for 23% of fittings and impression-based for 8% of fittings.[2]

The benefit of corneoscleral profilometry is the ability to determine, without using a diagnostic lens, the necessity for a spherical, toric or quadrant-specific edge design, as well as the potential need for a microvault (*Figure 1*).[3] These technologies have opened new possibilities for efficiently achieving optimal scleral lens fit, even in patients with extreme variations in surface elevation. Dual-elevational scleral lens technology is being adopted by a greater number of practitioners to incorporate advanced designs into their clinical practice. One of the studies presented at the last Global Specialty Lens Symposium 2024 meeting looked at predicting dual-elevation scleral lens rotation. The average dual sagittal depth difference was 263µm, and a difference of 200µm to 300µm was achieved in 87.5% of eyes. Average rotation was 19.7° with these lenses.[4] Another poster compared the sagittal depth measurements of seven different clinically available instruments in one subject. The Medmont, sMap3D, Visante and Cylite measurements were found to be within 60µm of each other through four of five

ABOUT THE AUTHORS

Dr. Severinsky is an assistant professor at Emory School of Medicine and practices at Emory Eye Center in Atlanta, where he focuses on fitting specialty contact lenses. He is a fellow of the American Academy of Optometry, the British Contact Lens Association and the Scleral Lens Society.

Dr. Shafi has just completed her residency at Emory Eye Center and is now at University of California, San Francisco, where she is continuing her passion for anterior segment disease.

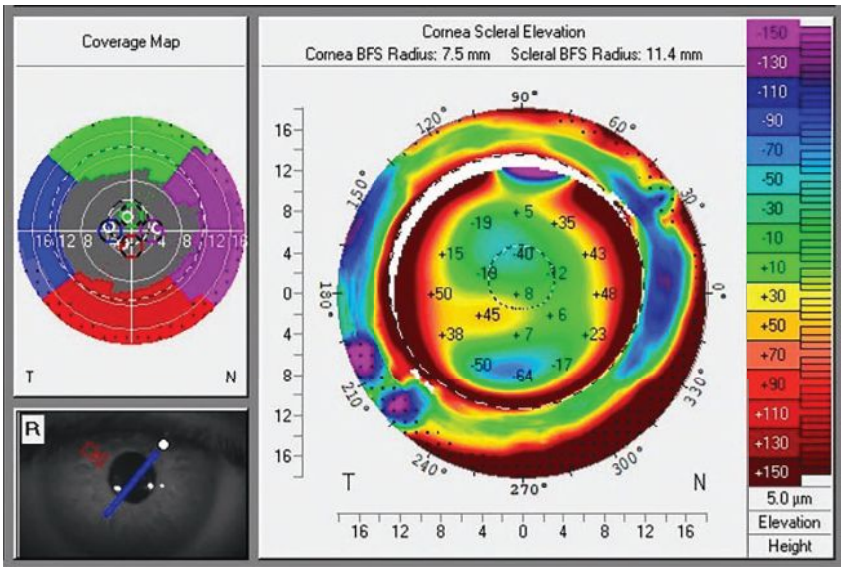

Fig. 1. CSP scan of keratoconic eye with marked scleral asymmetry, note scleral principal meridians do not follow corneal toricity.

chords. Some instruments measured consistently higher or lower values than others.[5]

NEW DEPTHS

Dual-sagittal depth and quad-sagittal depth scleral lenses, such as the Bi-elevation and Echo lens designs from Bausch + Lomb allow for further customizations to increase stability and optimize fit. Eyes with significant corneal toricity and elevation differences, such as post-trauma or with advanced keratoconus, are not optimally fit with a standard scleral lens design where a single sagittal height separates the lens from the corneal surface (*Figure 2*). An ideal chamber depth for a scleral lens vaults around 200µm to 250µm across the entire cornea post-settling, which is an important balance of reducing suction pressure vs. avoiding cornea-lens touch, while maximizing visual quality.[6] These customizations allow for even distribution of post-lens tear film (vault) across the entire cornea, promoting stability of the lens and reducing debris accumulation within the tear chamber and optimizing visual acuity.[7]

Quad-sagittal depth lens design (Echo) was developed on principles of its predecessor, the Bi-elevation lens, by allowing quadrant-specific sagittal height adjustment and rotation of the peripheral landing zone of the lens to correct a mismatch in corneal versus scleral elevation and toricity, therefore improving lens chamber centration over the cornea and providing better scleral alignment. The amount of landing zone rotation against the corneal chamber could be extrapolated from profilometer imaging, and the amount of elevational differences along principle corneal elevational meridians could be implemented when designing an initial trial scleral lens.

TACKLING PROBLEMS

Considering the progress that has been made with scleral lens technology warrants inquiry into the challenges being addressed.

A common issue faced by many scleral lens wearers is mid-day fogging, which is the accumulation of cellular debris, mucin and the natural tear film components within the fluid reservoir.[8] Anywhere from 26% to 46% of scleral lens wearers suffer from mid-day fogging, which results in blurry vision, discomfort and the need to remove and refill the scleral lenses, sometimes multiple times per day.[8] With extensive research being conducted on the contents of fogging, there is the possibility of pro-inflammatory markers contributing to the debris due to unbuffered or unbalanced pH saline surface toxicity and mechanical impact to the corneal and limbal epithelial cells.[9,10]

Suggested modifications to the scleral lens to avoid this debris include proper alignment of the lens haptics to the peripheral sclera 360°, avoiding excessive limbal vault or contact and reducing central clearance of the lens.[11] Adding a

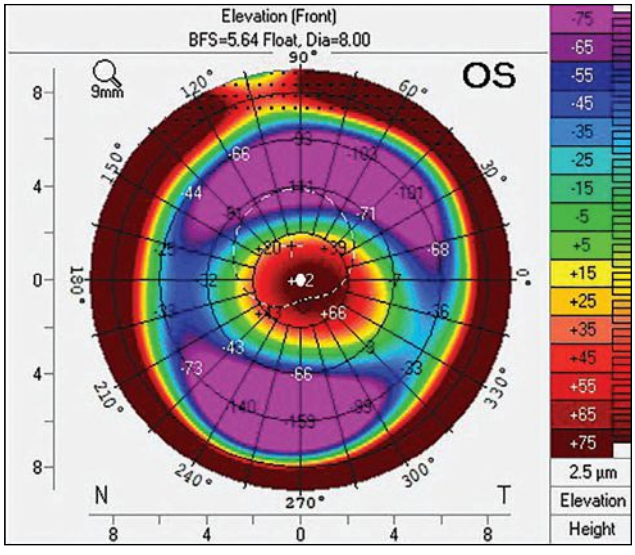

Fig. 2. Pentacam front elevation scan of keratoconic cornea with marked elevational differences along horizontal and vertical meridians.

viscous, preservative-free solution within the lens, such as Refresh Celluvisc (Allergan), can reduce the tear exchange to eliminate the need to repeatedly refresh the lens solution, or at a minimum prolongs wear time.[11]

An additional challenge faced by specialty lens fitters is higher-order aberrations and their degradation to a patient's optical quality. A cornea with high irregularities, whether from surface elevation, scarring or other causes, will have increased aberrations, which lead to halos, ghosting and overall reduced quality of vision.[12] Newer developments to reduce these aberrations include wavefront-customized scleral contact lenses, which map out an aberration profile in these irregular eyes which can then be used to design a scleral lens that neutralizes those aberrations to an acceptable level.[13]

Other scleral lens designs incorporate various levels of higher order aberration control, which can be used diagnostically with patients to determine the best subjective endpoint (BostonSight). For patients who have already achieved an ideal fit but still subjectively suffer from poor vision, higher order aberration control should be considered.

USES FOR DRY EYE

Applications of scleral lenses discussed thus far have mainly covered refractive error and irregular corneas, but these lenses also offer significant therapeutic benefits. Patients who are immunocompromised, undergoing oncological treatments, suffering from autoimmune conditions or on multiple systemic medications typically will have some degree of dry eyes.[14,15] Dryness may present as aqueous-deficient, where there is not enough liquid within the tear film, evaporative, where there isn't enough oil being produced to prevent the tears from evaporating, or inflammatory, where cytokines and other inflammatory markers continue a cycle of inflammation as a response to an irritated surface.[14]

Often, surface involvement is multifactorial and has some degree of all these components, such as in cases of ocular cicatricial pemphigoid (OCP; *Figure 3*). This rare autoimmune, sight-threatening disorder affects women twice as much as men. Corneal and conjunctival cicatrization from ocular surface inflammation and compromised lid anatomy, along with decreased tear production, may lead to corneal opacification, ulceration, perforation and devastating vision loss. To address these debilitating complications, treatment for OCP involves systemic immunomodulation for active disease control as well as corneal and eyelid surgery for complications that fail to be controlled with topical or systemic medications.

When the acute phase of the disease is under control, scleral lenses and shell use may further benefit the ocular surface providing liquid bandage effect and mechanical protection. In a study conducted at Emory University, daily use of scleral lenses have been shown to improve keratopathy grades, prevent fornix shortening progression and improve vision in 20 patients (36 eyes) fitted for OCP management. The researchers found that 96% of fitted eyes responded well to therapy and continued scleral lens wear. They concluded that scleral lenses should be given a strong consideration as an ancillary therapy in patients with OCP.[17]

However, despite the underlying reason for the dryness, each of the prior-mentioned conditions can benefit from the presence of a scleral lens. Scleral lenses, when fit properly, do not maintain contact with the corneal surface, and rather keep a fluid reservoir between the lens and the cornea.[17] This reservoir is filled with a nonpreserved saline solution prior to insertion, which serves to maintain sharp optical

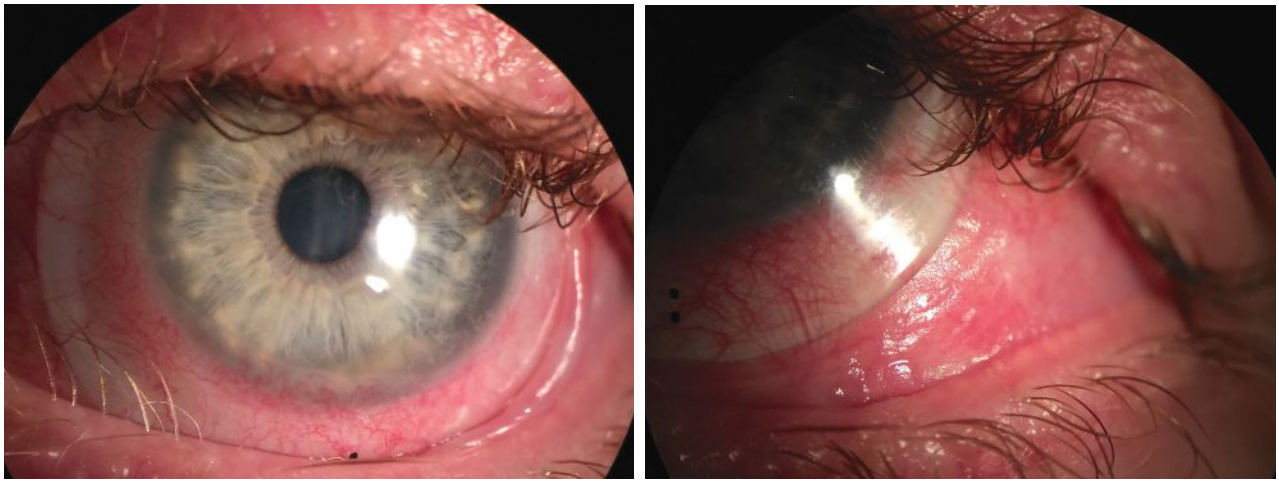

Fig. 3. Scleral lenses in setting of OCP. Note the presence of trichiasis and symblepharon and conjunctival keratinization.

Table 1. HA and modified-HA Artificial Tear Products				
Product (Company)	**Active Ingredient**	**Notes**	**Status**	**ClinicalTrials.gov Identifier**
Vismed (TRB Cedemdica)	0.18% Sodium hyaluronate (SH)	Preservative free	Phase III completed, marketed in UK, Europe and sia	NCT00599716
Vislube (TRB Cemedica)	0.18% SH solution	Preservative free	Marketed in Europe, Australia and Asia	NCT01363414
Hylabak or Hyabek (Spectrum Thea Pharmaceuticals	0.15% Hyaluronic acid (HA) or SH	Preservative free Phosphate free	Marketed in Russia, Lebanon, Argentina and Germany	–
Hyalein	0.1% SH	Active control in Phase III study	Phase III completed, marketed in Japan	NCT00885079
Opticalm (Omega Pharma)	0.2% SH	Preservative free	Marketed in Europe, Australia and Asia	–
Hylovis (TRB Cemedica)	0.18% SH solution	HA listed as inactive ingredient	Approved; Phase IV completed	NCT01061268
Rejena (sponsor)	0.18% HA	Data considered weak	Not approved by FDA	NDA 22-358
JDE-001 (Jade Therapeutics)	THiolated carboxy-methyl HA	Designed to improve tear film stability	Pre-IND Stage	–
SI-614 Ophthlamic Solution	Modified HA	Possibly improves residence time and tear film stability	Phase III ongoing	NCT02205840

quality, avoid mechanical contact of the lens to the eye and additionally functions as a liquid bandage.[6]

Patients with severely dry and ocular surface inflammation can experience significant problems, from keratinization to corneal thinning and perforation.[17,18] Often, a persistent ocular surface inflammation may lead to a formation of non-healing corneal epithelial defects, which in turn carry significant risk for infection with a consecutive damage to the cornea.[18] Multiple studies have shown the efficacy of scleral contact lenses, as elucidated by the liquid bandage effect and mechanical protection from the eyelids, in successfully healing refractory corneal epithelial defects.[17,19] Another potential benefit is the addition of a preservative-free antibiotic, such as moxifloxacin within the fluid reservoir of the scleral lens to serve as a prophylactic against further infection in these vulnerable eyes.[20] Even in the setting of a cornea with significant dryness and no epithelial defect, the liquid bandage effect can help to promote corneal epithelial regeneration, reduce surface inflammation and redness and vastly improve patient comfort and vision.[6,21] For any patients living with constant dry eye, scleral lenses can be considered as an adjunct therapy to improve their symptoms and ocular surface.

NEW MATERIALS

The therapeutic benefits of the scleral lens greatly help improve patient quality of life; however, certain considerations regarding the lens should be taken. Firstly, with extended wear time of the lenses, one may consider the oxygen permeability (Dk) of the contact lens. With corneal gas permeable (GP) lenses, there is less of a concern regarding Dk, since the tear film is freely moving underneath the lens, allowing for oxygen exchange under the lens surface.[23] However, with a scleral lens, there is almost no or limited tear exchange due to the fitting philosophy, particularly when the fitting aims to achieve better scleral alignment such as quadrant specific or profilometry-based scleral lenses.[22] In such cases, although patient comfort with the lens may be improved as a result, fresh tear and oxygen ingression under a scleral lens is reduced. With this consideration in mind, there are newer hyper Dk GP lens materials available at our disposal.

Commonly used GP scleral lens materials include Boston XO and Boston XO2, with Dks of 100 and 141 correspondingly, that had proven results over the last 10 to 15 years.[23] One of the newer GP materials being recently developed is Acuity 200, which boasts a hyper Dk of 200.[24] Studies that investigated hypoxia-induced corneal swelling have found statistically significant reduced corneal edema on eyes wearing material with a Dk greater than 150 when compared to lower Dk materials, an important consideration for more vulnerable eyes requiring scleral lenses for vision, surface rehabilitation, such as after corneal transplant or with overnight wear.[12] Although it may seem simple to continuously choose higher Dk materials, it is important to consider the potential non-wettability issues of a lens as the Dk increases, and the increased deposits that may occur as the oxygen permeability of the lens increases.[2,24] Secondly, scleral lens replacement should be encouraged every one to two years, especially for more vulnerable eyes (post-penetrating keratoplasty, OCP, Stevens-Johnson syndrome, etc.), due to the decrease in oxygen permeability of GP materials.[25]

Finally, extended wear use of the scleral lens should only occur for therapeutic indications, such as ocular pain or persistent epithelial defect management. Overnight use will typically involve 12/12-hour wear of two separate lenses that are alternately used and cleaned.[27] Altogether, it can only be advantageous to have a variety of materials to choose from in order to provide the healthiest balance for our patients, but proper wear and care need to be thoroughly discussed and understood by the patient.

NEW SOLUTIONS

As the potential patient population that may benefit from scleral lenses increases, so do the tools at our disposal to use in conjunction with these lenses. Typically, the bowl of a scleral lens is filled with a preservative-free sterile sodium chloride solution prior to insertion. However, when we consider the natural tear film composition, there are a variety of minerals and electrolytes present in the liquid component (potassium, calcium, magnesium, phosphate and bicarbonate, etc). These solubles maintain the integrity of corneal epithelium and help keep the pH of the tear film balanced at about 7.0.[11] A non-buffered solution such as sterile sodium chloride has an acidic pH closer to 5.5, which can lead to discomfort in some sensitive patients.[9]

New buffered additives to commercially available saline solutions, such as Nutrifill (Contamac) and Scleralfil (Bausch + Lomb), contain ions such as boric acid and magnesium while maintaining a pH of about 7.4 to mimic the natural tear film.[21] When working with patients who have more sensitive eyes or a very low natural tear film, buffered solutions may be considered to improve wear time and patient comfort. Lubricating agents that may help promote wettability of the scleral lens once on the eye include drops containing hyaluronic acid, which serves to enhance corneal epithelial healing, restores morphology and function of conjunctival goblet cells and reduces ocular surface inflammation.[28]

Preservative-free drops currently on the market containing povidone, hyaluronic acid or a derivative of it include Ivizia (Thea Pharma), Biotrue Hydration Boost (Bausch + Lomb), Optase Hylo and HyloGel (CandorVision). The surface tension created by hyaluronic acid allows the drop to function as a gel while the eye is open and as a less-viscous lubricant when blinking.[28] This dynamic capability gives excellent functionality in dry eye patients who greatly benefit from reduced inflammation, improved ocular surface function and preservative-free formulation that allows for use with or without scleral lenses. An optimum hyaluronic acid concentration to achieve maximum tear film stability is recently being investigated in several clinical trials (*Table 1*).

The world of specialty lenses is truly exciting due to the forward-thinking technology constantly being proposed by its passionate researchers. As providers, we should think about applications of new technology to see if it can help us to better serve our patients. With the advent of customized aberration control, imaging technology made to expedite the fitting process, finer lens modifications, more breathable lens materials and a bounty of new wetting drops and solutions, there is no shortage of materials to experiment with. RCCL

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U.S. Pharmacist The Pharmacist's Resource for Clinical Excellence

By Richard Weisenberger, OD, and Suzanne Sherman, OD

When All Else Fails

A string of complications following a *Pseudomonas* infection prompted implantation of the Boston KPro.

A 58-year-old Caucasian male presented to the emergency room with worsening vision loss and right eye pain over the past three days. Prior to examination, the patient reported poor compliance with his contact lenses and admitted to sleeping in them for extended periods of time. The patient reported being seen by an outside provider four days prior who had diagnosed him with a corneal abrasion. A bandage contact lens was placed and he was started on ofloxacin q2h. He reported not starting the ofloxacin for two days after that visit and had worsening vision with ofloxacin once started, which prompted his visit to the emergency room. The patient's systemic history was non-contributory.

Entrance testing was performed with the following results: visual acuity was measured at counting fingers OD and 20/25 OS with prescription glasses; pupils were ERRLA without afferent pupillary defect OU; confrontation visual fields were full to finger counting OU. Slit lamp examination was performed showing a near complete corneal epithelial defect with large superior arcuate infiltrate measuring 5mm horizontal by 3mm vertical OD, mucopurulent/suppurative discharge OD and 3+ anterior chamber reaction with 2mm hypopyon OD. The slit lamp exam OS was unremarkable. Intraocular pressure (IOP) was measured with Tono-Pen Avia (Reichert), reading 45mm Hg OD and 12mm Hg OS. The patient was dilated OD with two drops of 1% cyclopentolate in-office. A dilated fundus exam was attempted OD, but the fundus was unable to be appreciated. A B-scan was performed OD showing no anterior chamber spillover, vitritis, retinal masses or detachment.

There was strong suspicion for *Pseudomonas* due to the characteristic soupy purulence and fibrinous exudate; however, culturing was ordered for confirmation. The patient was started on the following medications: fortified vancomycin 25mg/ml q1h and fortified tobramycin 15mg/ml q1h alternating every half hour OD, dorzolamide-timolol 22.3mg-6.8mg/ml twice a day OD, doxycycline hyclate 100mg twice a day and vitamin C 1000mg. He was instructed to follow up the next day with the outpatient clinic.

Testing results were returned the following day with gram staining showing the presence of a gram-negative rod bacteria suggestive of *Pseudomonas*. Culturing results confirmed the presence of over 100 colonies of *Pseudomonas aeruginosa* which was susceptible to amikacin, cefepime, ciprofloxacin, meropenem, piperacillin/tazobactam and tobramycin.

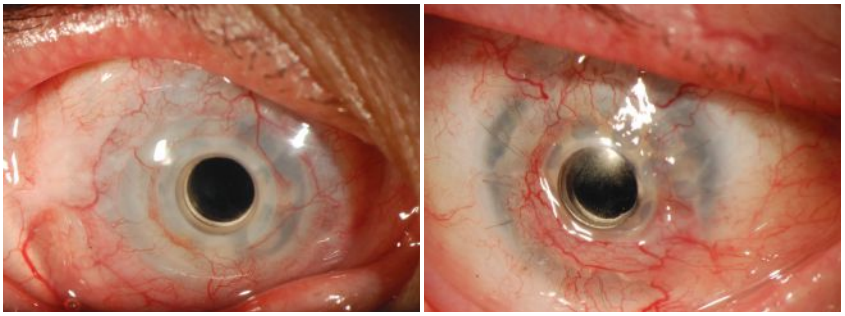
The patient did not return the following day, instead electing to follow up with his local ophthalmologist, but ultimately returned to the clinic six weeks later following his visit to the emergency room. He was noted to have non-responding elevated IOP of 45mm Hg OD with an increasingly shallow anterior chamber. A slit lamp exam showed a 5mmx5mm non-healing central epithelial defect without infiltration, significant corneal scarring and neovascularization. At this time, it was decided he be scheduled for an Ahmed glaucoma valve (New World Medical) with scleral patch graft, penetrating keratoplasty and possible cataract extraction with intraocular lens implantation, anterior vitrectomy and anterior chamber reconstruction.

Throughout the next few months, the patient experienced several complications, including scleral melt with scleral abscess exploration and intravitreal injection, corneal melt with Tutoplast pericardium allograft (Coloplast) and amniotic membrane. Following this string of complications, the patient was scheduled and underwent surgery for implantation of the Boston aphakic keratoprosthesis Type I (KPro; Massachusetts Eye and Ear Infirmary).

KPRO CHARACTERISTICS

Over the past 30 years, the Boston KPro Type 1 has become an increasingly popular option for patients with significant ocular pathology. Indications include Stevens-Johnson syndrome, ocular cicatricial pemphigoid, autoimmune etiologies, ocular burns and severe graft-vs.-host disease.[1,2] Consequently, optometrists are becoming more likely to see this once-rare ocular prosthesis in their exam lanes. It is important to understand the device design, clinical indications and visual outcomes for when it does appear.

The KPro contains three main components: a front plate, a corneal graft button and a back plate. The former is made of polymethylmethacrylate (PMMA). This plate contains an optical stem which allows light to the retina. The back portion of this stem contains a locking interface which allows the back plate to be attached. Additionally, the back plate can be ordered in either PMMA or titanium. Donor tissue lies between the front and back plates. Throughout the years, advances have been made to the original Boston KPro design, including the addition of holes in the back plate which allows for the diffusion of aqueous to support the

The KPro prosthesis as it looks in the eye.

donor graft stroma and keratocytes. It is this back plate containing multiple fenestrations that gives the KPro its characteristic appearance. Those of us who fit scleral lenses can think of this similarly to a scleral lens modality. Later, the titanium locking c-ring was altered to create a threadless assembly of the Boston KPro. The most recent advancement was the addition of a titanium back that is believed to improve biocompatibility and retention of fluid.[3]

Initially, the KPro was designed and approved in the usage for severe corneal disease and multiple corneal transplant failures. The approved indications have steadily increased to include conditions like advanced limbal stem cell deficiency and even eyes which have undergone silicone oil implantation. At the time of this article's publication, the most common indication remains the usage following multiple corneal transplant failures. Studies continue to show the survival rate of penetrating keratoplasties declines with each successive surgery. One study showed the survival rate of secondary grafts at two and five years to be 64% and 46%, respectively, compared to primary grafts in a Canadian study which showed survival rates of 79% and 65%.[4,5]

Recent studies have shown that using the KPro as an initial procedure instead of corneal transplantation followed by KPro produced better visual outcomes.[6-8] The majority of patients who underwent implantation showed an improvement in best-corrected visual acuity (BCVA) better than 20/200. Underlying cause for surgery appears to play a role in visual outcome as well. For example, of patients with chemical injury causes, approximately 65% reached BCVA greater than 20/200 compared with only 25% of patients with herpes zoster as the cause.[9,10] The majority of KPro recipients are of adult age, as pediatric patients tend to have a lower device retention rate, but studies and patient populations are limited.[11]

The Boston KPro exists in more than one type—Type I and Type II. The Type II KPro is usually reserved for extreme cases and is done with an accompanying permanent tarsorrhaphy.

With knowledge of the basic components of the KPro, it is important to know what else to look for if one is in your chair. Commonly, these patients are also outfitted in large-diameter soft contact lenses. These bandage contact lenses are necessary for KPro patients to maintain adequate corneal graft hydration while minimizing the risk of complications.[12,13] My next column will focus on what type of bandage contact lenses are used for Boston KPro and how to examine them for proper fit and complications.

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On the Bubble

Perfluorocarbon migration is a rare but typically harmless surgical complication.

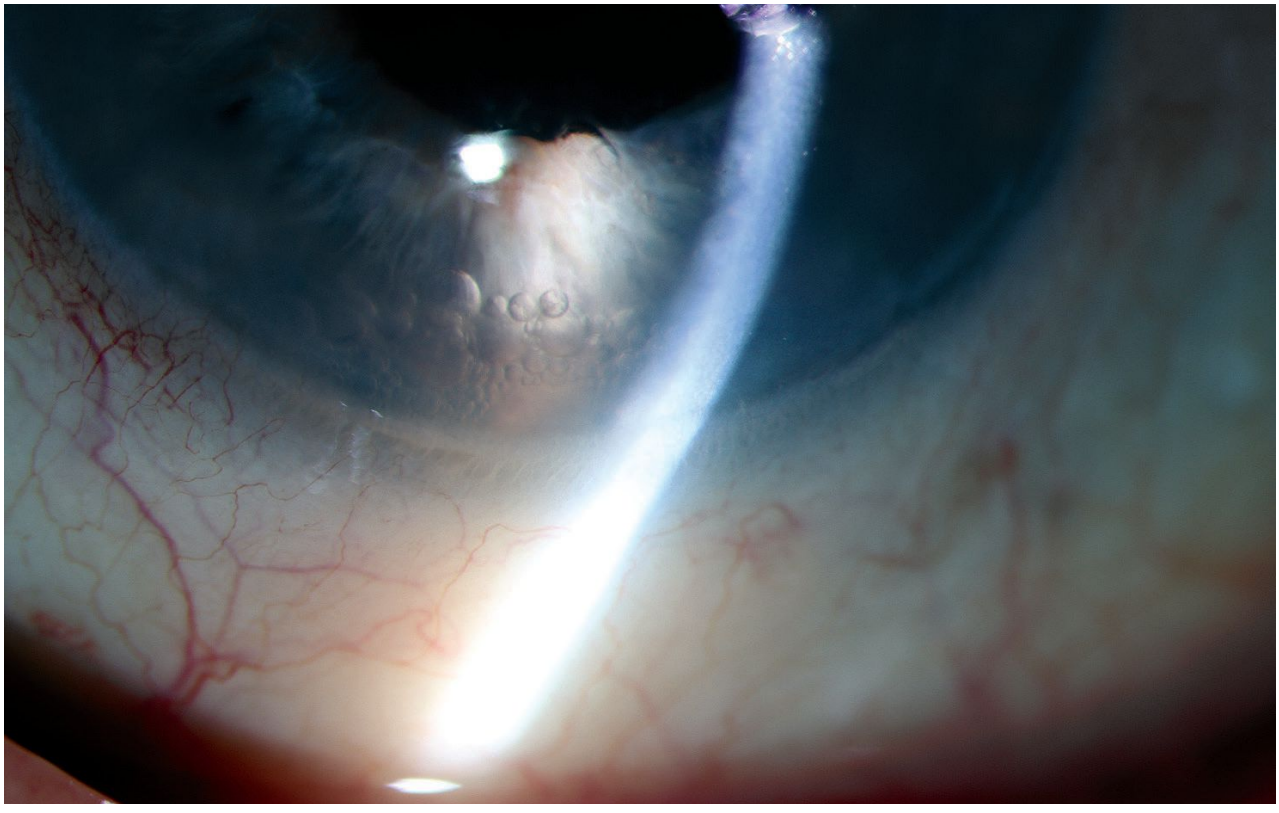
This patient presented with a left-eye history of posterior capsule rupture during initial cataract extraction, with subsequent posterior dislocation of the intraocular lens. The subluxed lens was retrieved and a scleral-fixated intraocular lens (IOL) was attempted, which too fell posteriorly. This resulted in a shallow temporal retinal detachment. He was seen by a retina surgeon, who performed pars plana vitrectomy for removal of remaining capsular material, as well as laser repair of the temporal rhegmatogenous retinal detachment. A sutureless scleral-fixated IOL was applied at this time.

Around three weeks post-IOL placement, the patient noted a decline in vision and was found to have a recurrent rhegmatogenous retinal detachment, for which he underwent pars plana vitrectomy for exploration and repair.

Following the final RD repair surgery, the left eye had persistent ocular hypertension, raising concern for progressive pupillary block/synechiae formation. He was managed on timolol-dorzolamide (Cosopt) and Diamox, and underwent a YAG laser iridotomy. Despite this, the intraocular pressure remain elevated (in the low-30s) with shallow chamber due to the gas bubble (needed for the retinal detachment repair) and limited adherence to positioning (per family's report).

He was taken back to the operating room for synechiolysis and deepening of the chamber, to resolve the pupillary block. Intraoperatively, he was found to have 360° iris and corneal synechiae and occluded angle. After lysis of these synechiae, he had blood staining of the central cornea. The staining and endothelial failure required Descemet's membrane endothelial keratoplasty (DMEK) and subsequent rebubble.

In this photo, accumulation of small perfluorocarbon bubbles in the anterior chamber is observed. His entering visual acuity is 20/60, with an IOP of 8mm Hg. The DMEK tissue is well attached and the cornea is clear and compact. Mild cystoid macular edema was found on examination. He is being maintained on prednisolone acetate QID and Cosopt BID.



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Reference: 1. Thea Data on File.

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