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Research Shows Merits of Genetic Testing in Keratoconus Even as Commercial Product Fails

In a confluence of events, a new paper documented the value of polygenic risk score assessment of ectasia patients at the same time that the AvaGen test exited the market.

Researchers have long known that a host of genetic factors can predispose patients to many ocular conditions, most notably inherited retinal disorders like achromatopsia, Leber’s retinitis pigmentosa and Stargardt’s. Studies have also shown a range of potential genetic influences on AMD, glaucoma and keratoconus. Efforts to create clinically valuable in-office tests for that second group of conditions, however, have struggled to establish a use case that leads to widespread adoption.

A study published in American Journal of Ophthalmology added to the literature on the genetic underpinnings of keratoconus and researchers’ efforts to devise a multi-trait polygenic risk score (PRS) with predictive value. Four days later, Avellino Labs notified customers that it was discontinuing its AvaGen test marketed with this premise in mind.

The AJO study included a total of 1,478 young adults aged 18 to 30 from a single center. Of these, 609 returned for an eight-year follow-up.

Scheimpflug imaging was conducted and subjects were genotyped, then a previously validated PRS was applied. Analyzed against the PRS as outcome measures were Belin/Ambrosio enhanced ectasia display (BAD-D) score and the presence of keratoconus, defined as BAD-D ≥2.6.

The keratoconus prevalence in the cohort was 2.5%. Each incremental increase in PRS was associated with a worse BAD-D and 1.6x increased odds of keratoconus. Those in the highest PRS decile were more likely to have incident keratoconus in the third decade of life compared with the rest of the cohort. With each PRS increase, eight-year change in BAD-D score worsened.

From these observations, the authors list two potential important clinical implications for the setting of the PRS. “First,” they wrote in their paper, “genetic testing could be used as a tool to screen for those at risk of corneal ectasia prior to undergoing refractive surgery.” They equate this fact to the current rise of myopia prevalence, especially in younger generations.

Ectasia induced by refractive surgery is preventable and adds to both patient morbidity and increased workload in the eyecare sector, the authors note. As such, they believe that the PRS may help younger adults: “For people in this age group, it may be worth avoiding laser refractive surgery in those with high genetic predisposition to keratoconus.”

As another possibility, they propose that “a second utility of genetic testing is the prediction of keratoconus progression.” The authors stress that the condition typically stabilizes naturally around the fourth decade of life with varying degrees of severity seen. As such, it is critical to identify rapid progressors as well as patients of an older age at disease stabilization, since treatment methods, especially corneal crosslinking, are highly effective and cost-efficient in preventing progression and preserving vision.

Commenting on the discordance between the promising research and lackluster clinical track record of keratoconus PRS tests, San Diego’s Brian Chou, OD, who cares for a large keratoconus patient base, says, “I believe the market failure of AvaGen was due to the lack of credibility. The concept was good, but the results did not demonstrate compelling predictive value, even for known keratoconus patients.” He says he hopes the experience “does not poison the well” for future attempts to launch such tests. “As this AJO article supports, there is value in genomics with keratoconus.”

Dr. Chou mentions that good research on the genetics of keratoconus was conducted by Yaron Rabinowitz, MD, who passed away last November. Others will surely take up the mantle.

Twenty-year Study on Corneal Fungal Infections Shows Shifting Patterns

Candida, Aspergillus and Fusarium were the most common organisms. Patients with filamentous keratitis had different risk factors, better outcomes and decreased need for surgical intervention compared to yeast keratitis.

Fungal keratitis is rare, with a 2022 incidence of in North America of 0.03 cases/100,000 people, making it difficult to detect trends in epidemiology. Patients and physicians also often miss early signs and symptoms of infection due to lack of familiarity. To better understand the trends and clinical outcomes of fungal keratitis, researchers in Canada conducted a 20-year study. Here are their methods and results.

Cases of yeast and filamentous keratitis from 2003 to 2022 were examined, involving a total of 138 patients (138 eyes), 54% with yeast keratitis and 46% with filamentous keratitis.1 Corneal scrapings were performed about 21 days after symptom onset.

The most common risk factors for fungal keratitis in this study were ocular surface disease, contact lens (CL) wear, topical steroid use, topical antibiotic use and previous ocular surgery. Ocular surface diseases were more prevalent in patients with yeast-based keratitis vs. the filamentous group (79% vs. 28%), and the most frequent type in both groups was HSV keratitis (n=16).

CL wear has long been recognized as a risk factor for fungal keratitis.2 This activity was found to be more associated with filamentous-based species than yeast-based infectious organisms (78% vs. 19%). Of the 138 cases, 45% of patients were contact lens wearers, including both bandage lens and refractive correction uses, and CL-related cases “were most common during the years with the highest incidence of fungal keratitis, from 2016 to 2019,” the authors stated in their paper in American Journal of Ophthalmology. About 25% of patients reported overnight wear of their CLs, and 17% also engaged in water-contact while wearing lenses.

After treatment, patients with filamentous keratitis showed a significant improvement in visual acuity (~20/500 to ~20/250) while those with yeast keratitis actually worsened (~20/1260 to ~20/1590).

“Given that these observations have occurred in a geographic area characterized by temperate and continental climate, the [eyecare] community should maintain a high level of suspicion for fungal keratitis in patients with contact lens-related infections not responding to standard empirical treatment,” concluded the researchers in their paper. “Further research would be needed to elucidate the mechanisms underlying this long-term shift in fungal ecology and risk factors, and to possibly define preventative public health strategies.”


In this study, Candida species was found in 96% of yeast keratitis cases while Aspergillus (32%) and Fusarium (26%) were the most common species identified with filamentous patients.
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An abstract review of the latest intriguing and clinically practical cornea and contact lens research papers presented at this year’s meeting.
By Review Staff

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A Blood Pressure Drug for the Cornea

Will losartan eventually make it to market for these uses?

Eyecare providers face several challenges when it comes to treating corneal injury. Fortunately, new research initiatives have identified some of the many mechanisms at play when the cornea is injured, and exciting potential options to aid in wound healing are on the rise.

Losartan, a commonly used angiotensin II receptor blocker (ARB) for hypertension and heart failure, has been shown to aid in wound healing in animal models and may show promise in doing the same in humans for injuries and various diseases of the cornea.1-3 Topical losartan penetrates the intact corneal epithelium/epithelial basement membrane and full stroma to get to the endothelium, with little ocular surface toxicity noted in normal or fibrotic corneas.1,4 Losartan inhibits transforming growth factor (TGF)-stimulated stromal type IV collagen production and also inhibits myofibroblast development and fibrosis with four weeks of treatment.2,3 Since myofibroblast development is persistently dependent on ongoing TGF signaling, topical losartan should be effective for prophylaxis to prevent fibrosis and treatment when scarring fibrosis is already present.4

CORNEAL MANAGEMENT

Topical losartan has potential uses for any significant injury to the cornea by impeding TGF signaling.2 A list of potential uses includes thermal or chemical burns, microbial keratitis (bacterial, fungal, protozoan), herpetic keratitis, persistent epithelial defects (including neurotrophic keratitis) and other injuries such as lacerations or surgical complications of the cornea. Considering its mechanism of action, losartan may be suitable treatment for TGF β-induced corneal dystrophies. Conjunctival fibrotic diseases such as ocular cicatricial pemphigoid and Stevens-Johnson syndrome are also part of a list of potential uses.

Other uses may apply to glaucoma surgery (filtering and tube procedures) and even diabetic retinopathy or other fibrotic retinal diseases. Active infections will require concurrent antimicrobial therapies. Losartan could also help with existing scars and haze following late photorefractive keratectomy haze, breakthrough haze, as well as complicated LASIK, SMILE or corneal crosslinking haze.5,6 When there is significant inflammation, a topical steroid will enhance the process of healing.3

Depending on the corneal or conjunctival condition being treated, multi-drug therapy will undoubtedly be required when using losartan or another appropriate ARB agent. For example, a topical nerve growth factor can be used along with losartan for persistent epithelial defects. Topical netarsudil and losartan for deeper corneal injuries with endothelial cell damage (descemetorhexis, endotheliitis) have been shown to affect the healing response favorably.1,3 Also, losartan appears to have some efficacy in minimizing or improving corneal neovascularization.7 Topical sunitinib or axitinib, tyrosine kinase inhibitors, can be added to losartan if corneal neovascularization develops.8 As our retinal colleagues use them daily, these second-generation tyrosine kinase inhibitors work by blocking angiogenesis, tumor growth and metastases.

Prior to any approved label indications for topical losartan in preventing and treating corneal scarring, large scale human trials are needed to provide reasonable assurance of safety and efficacy and to further evaluate recommendations for proper dosages and duration of treatment. Nevertheless, some providers are now ordering compounded losartan at a 0.8% concentration, which can be used six times a day for weeks to months, depending on the insult to the cornea without significant concerns for toxicity.4

To date, the results available from animal studies and limited human study appear to be exciting. Will losartan be the go-to topical agent for corneal haze, scarring or other ocular disease indications? We’ll see if this medication is picked up soon by a sponsor/manufacturer. Unfortunately, the cost to bring a product to market is overwhelmingly high, but I think we’ll see this topical option in the future. In the meantime, for those who like the research so far and are willing to use unapproved or off-label products, compounded losartan options are available. Personally, I’ll wait for additional studies beyond the rabbit.8


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AMERICAN ACADEMY OF OPTOMETRY
Myopia Matters

How to manage progressive axial length elongation.

A 10-year-old Chinese girl presented for a prescription check. She reported recent concerns about gradual blurriness in her distance vision. Her entering visual acuity (VA) was 20/40 OD and 20/40 OS. Her last comprehensive eye exam, conducted four months prior, revealed a prescription of -1.75sph OD and -1.25-1.00x180 OS. Following cycloplegic refraction, her updated prescription was determined as -2.50sph and -2.00-0.75x180 with a best-corrected VA of 20/20 OU. Placido disc topography (Myah, Topcon) showed an average keratometry reading of 44.42D and 44.23D in the right and left eyes, respectively (Figure 1). Furthermore, axial length measurements were compared, noting an increase from 24.35mm to 24.58mm OD and from 24.21mm to 24.39mm OS over the same four-month period.

CONSIDERATIONS

Here we highlight our thought process and consider how we would proceed:

**Dr. Su:** Given the moderate prescription change and a 0.2mm axial length shift observed within a short span, it’s imperative to initiate a dialogue with both the patient and parents or guardian about the implementation of myopia control. At 10 years old and with several years of ocular development ahead, it’s crucial to emphasize the significance of slowing down progressive myopia by subsequently slowing down axial length elongation. Our primary aim is to prevent progressive myopia and mitigate the risk of irreversible eye disease in the future.

There are a range of myopia control methods, including orthokeratology (ortho-K), multifocal soft contact lenses (CLs), low-dose atropine drops and combination therapies. Fortunately, as a practitioner in Canada, I have access to myopia control spectacles as well. To determine the most suitable approach, I would assess the patient’s and parents’ lifestyle factors. Is the child involved in sports such as swimming or gymnastics? Do the parents prefer to be actively involved in lens care?

**Dr. Pfeifer:** When this much change in prescription and axial length is seen in less than one year, alarm bells should be going off in the practitioner’s head. The amplitude of these alarms should only get louder with younger patients—such as in this case. This patient’s eyes are growing too fast and she has many

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Fig. 1. Topography of the patient’s right and left eyes.
years of development left, so one can only guess how long the eyes may become. The conversation of slowing down the progressive axial length elongation to protect this patient’s vision needs to be had with this patient and her family.

Luckily, we currently have many options for slowing axial length elongation. Various factors, both ocular and non-ocular, influence the likelihood of success of these options. Patients involved in activities such as sports or dance may wish to pursue a spectacle-free option, whereas kids who may not have ideal hygiene may be better off with parents instilling atropine every night. Of the ocular factors, corneal curvature plays the largest role, especially in CL options. Success in ortho-K relies on average-to-steeep corneal curvature with a low-to-moderate amount of astigmatism. Elevated corneal astigmatism can also reduce the availability of center distance multifocal CLs. This is less of a factor with glasses designed to slow axial length elongation, although they are not yet available in the US, which is something that parents should be aware of as an potential future option. Atropine is typically viewed as a catch-all treatment option, as the main contraindication is an allergy and children typically don’t suffer from increased glare.

This patient would be a great candidate for ortho-K, so that would be my ideal choice of treatment. With her corneas possessing curvatures on the steeper side of average and her corneal astigmatism relatively matching her refractive astigmatism, she would likely attain great vision with a well-centered treatment zone.

If the patient does not wish to pursue ortho-K at this time, soft center-distance multifocal CLs would be my secondary choice. I would stress the importance of taking breaks from near work and to get outside every day as well. I would also reassure the parents that the patient will be regularly followed every six months to monitor for progression and to alter or add treatment modality if any unwanted change occurs.

Dr. Noyes: My practice only provides care for patients needing medical CLs for severe corneas and ocular surface disease. We do not provide ortho-K or myopia control. I will defer to my colleagues on this one.

Dr. Gelles: This patient is undergoing progressive axial length elongation (PALE), and with the observed rapid changes, it could even be described as precipitous axial length elongation. No matter how it’s described, intervention is necessary. There are four main interventions to slow PALE, all of which are well-supported by the literature: atropine, defocus soft lenses, ortho-K and various myopia-specific spectacle lenses. In this case, how do I choose what is best for the patient? My biggest question when selecting PALE treatment is always, “What does the cornea look like?” Myopia is a sum of its parts, the most impactful being axial length and corneal curvature. The pediatric population is where PALE and keratoconus overlap, so it is important to evaluate the cornea to know before you treat.

The way I approach myopia control is similar to the way a surgeon approaches refractive surgery. If the cornea is normal and the prescription is within reasonable parameters, I will initiate a corneal-based treatment with ortho-K. If the cornea is suspicious, I will initiate a non-corneal-based treatment with atropine, defocus soft lenses and/or spectacle lenses, which will preserve the anterior corneal metrics for comparison over time. I use corneal tomography to evaluate these patients, as Ks are grossly inadequate for corneal evaluation and topography is not sensitive enough to catch the earliest signs of keratoconus (thickness and posterior corneal metrics) which are critical in this population. A recent US-based study using corneal tomography to screen pediatric patients found a high prevalence of keratoconus and keratoconus suspects—a combined prevalence 1:223.1

In this patient, the topography images may not be the most reliable on the right eye since motion blur can be seen in the image, but the left appears to be better quality without evaluating the mires image. In both topography maps, there is slight asymmetry from inferior to superior; on the OS at the 6mm OZ it appears to be about a 1.5D asymmetry. This is suspicious and warrants further investigation with corneal tomography to specifically evaluate anterior and posterior elevation, thinnest point and global pachymetry change across the cornea, as well as epithelial thickness metrics to determine if keratoconus is present. If decisions are going to be made based on this topography data alone, in an abundance of caution, I would start with defocus soft lenses and monitor the patient at three- to four-month intervals with emphasis on evaluating the cornea for changes. If PALE was still progressing at a
higher than normal rate, I would add 0.05% atropine.

The use of other CL options, such as hybrid, corneal gas permeable or scleral lenses, with simultaneous multifocal optics could be used to deliver the myopic defocus optical profile with the potential advantage of masking corneal astigmatism; however, unlike the other options, this has not been thoroughly studied and well-established and would be my last resort.

DISCUSSION
Progressive myopia can be managed in several ways and selecting the right treatment requires a personalized approach. The primary goal is to reduce the risk of visual impairment. While slower prescription changes are also desirable, they are just an added benefit. Age, genetics, environment, maturity, daily activities and parental involvement all influence the choice of intervention. Frequently, questions about the safety of CL wear in the pediatric population arise. The risk benefit comparing the risk of microbial keratitis to the lifetime risk of severe visual impairment as a result of high myopia (>6.0D) or long axial length (>26mm) in children undergoing myopia control treatment with CLs and ortho-K is in favor of treatment with both options.2

Following these patients at short intervals—typically every three to six months—is important, as changes can happen rapidly and axial length gained cannot currently be undone. Monitoring these patients takes more than a phoropter and keratometer. Devices such as a topographer and biometer are essential for effective monitoring. Myopia is a sum of its parts, so ensuring corneal stability and directly measuring axial length is critical.

RESULTS
During the initial visit four months prior, a discussion about myopia control was had with the patient and her parents. At that time, they opted to postpone any further action until the following year, feeling that the patient was comfortable with her current spectacles. Upon revisiting the topic at a later point, both the doctor and parents agreed that ortho-K would be the most suitable option, especially considering the patient’s regular swimming routine of four days a week.

Ortho-K lenses (Moonlens Flex, Precision Technology Services) were ordered and the patient underwent follow-up appointments at one day, two weeks and one month post-wear. By the one-month follow-up, the patient reported excellent vision throughout the day without any complaints. The topography comparison map revealed a well-centered treatment zone (Figure 2). The lenses were removed and there was no staining to the cornea. Additionally, due to the family’s frequent international travels and concerns about potential loss of CLs, they opted to add myopia control glasses as well, equipped with Highly Aspherical Lenslet Technology (Stellet, Essilor). Axial length measurements were scheduled every three months to monitor progress. At the six-month follow-up, both the patient’s prescription and axial length remained stable.1


Fig. 2. Comparison map of pre- and post-wear topography scan, highlighting the change in corneal shape caused by ortho-K.
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Lessons Learned at ARVO 2024

An abstract review of the latest, intriguing and clinically practical cornea and contact lens research papers presented at this year’s meeting.

By Review Staff

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

This year’s meeting was held in Seattle from May 5-9. The theme of ARVO 2024 was “imagining innovation and intelligence in vision science.” Vision research is continually being transformed by new information and technologies. The findings summarized here are only a snippet of those presented at the meeting, of course, but show the rich expanse of insights ARVO generates each year.

CORNEA

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

Corneal complications common in peds patients with herpetic keratoconjunctivitis (HKC). Pediatric ocular surface inflammatory diseases can greatly impact the vision and quality of life of these young patients, but limited data has been presented on the three most common forms—blepharokeratoconjunctivitis (BKC), HKC and vernal keratoconjunctivitis (VKC). Researchers investigated the clinical features and practice patterns of these conditions using a real world data asset with de-identified administrative claims and electronic health record data.

A total of 6,116 patients aged 18 years and younger over a one-year span were included. Clinical information from six months before to three years following the clinical appointment (index date) was analyzed.

Corneal complications were more prominent in HKC, while high-potency corticosteroid use was more common in those with BKC. The limited use of topical immunomodulators suggests the potential for improving treatment approaches.

“Up to the index date, blepharitis was observed in 5.3%, with higher rates in BKC (13.5%) than HKC (4.9%) and VKC (3.6%),” the researchers explained in their abstract. Giant papillary conjunctivitis was found in 10.4% of BKC, 11.3% of VKC and only 3.6% of HKC cases. Corneal scarring and ulceration rates were significantly higher in HKC compared to BKC and VKC both before and after the index date.

“Antivirals were more common in HKC cases,” the authors continued. “Surgical interventions for complications were uncommon, with corneal perforations limited to BKC cases.”

Insulin eye drops may aid corneal healing. In two posters presented at ARVO 2024, a new possible treatment was investigated for corneal wounds.

Be mindful of elevated corneal scarring risks in pediatric HKC patients, new research advises.
The first was a retrospective review of patients with neurotrophic keratitis resistant to conventional treatment, while the second study dealt with neurotrophic corneal ulcers. Re-epithelialization was faster and more successful with the treatment vs. conventional methods.

In the first study, patients between ages 55 and 69 were classified into two groups: Group I received topical insulin therapy with 4 units per mL of concentration and Group II received conventional treatment. Of the 52 patients included (52 eyes), 27 eyes were designated to Group I and 25 to Group II.¹

Mean time between diagnosis and start of treatment was longer in Group I than Group II, and no differences were seen in baseline characteristics between the two groups. Re-epithelialization was achieved in 74% of Group I (20 eyes) and 64% in Group II (16 eyes). Mean time to re-epithelialization was also shorter in Group I than Group II (32.3 days and 82.5 days, respectively). Final defect area was smaller in the insulin group as well, but no significant differences were seen between groups in visual acuity. There were also no observed differences in recurrences, complications and subsequent surgical interventions.

The study authors reason, “the use of insulin aims to support nerve regeneration and enhance the overall repair process in the affected eye. This approach holds potential for improving the outcomes and management of neurotrophic keratitis.”²

Similarly, the second study also used insulin drops for treatment of refractory neurotrophic corneal ulcers in vivo and investigated cellular mechanisms underlying re-epithelialization of corneal epithelial wounds in vitro. Included were patients with the condition treated with topical insulin eye drops; corneal epithelial wound closure was monitored daily. As well, human primary limbal epithelial cells were incubated in serum-free medium either with or without different insulin concentrations, ranging from 0.05µg/mL to 150µg/mL, for 24 hours.³

The researchers observed that all 20 eyes achieved complete corneal re-epithelialization after insulin standard treatment regimens (25U/mL or 0.5U/drop). However, outcomes were not enhanced by higher doses, instead appearing to induce corneal angiogenesis. A significant dose-dependent effect of insulin on epithelial migration was most effective with lower doses (0.5µg/mL to 1.0µg/mL). Upregulation of genes FSCN2 and TSPAN1 was found, both of which are involved in cell migration. Conversely, downregulation was seen with cell adhesion molecules, including integrin subunits, after exposure to 1.0µg/mL to 5.0µg/mL of insulin. Even greater insulin doses (50µg/mL to 100µg/mL) induced a 2.5-fold upregulation of vascular endothelial growth factor A.³

In both studies, topical insulin treatment is not yet available, but they display the possible benefits and prospects for its future use.

**Corneal edema post-cataract more common in diabetics.** While cataract and refractive surgical procedures have evolved tremendously in recent decades, postoperative corneal edema is still commonly present.

Researchers at the Icahn School of Medicine at Mount Sinai in New York City studied which factors increase the risk of developing corneal swelling and which patients eventually required corneal transplantation after cataract surgery. Their study demonstrated that people with diabetes were more likely to have corneal edema after surgery. Older individuals also had a higher risk, and this risk increased with age. Notably, different racial and ethnic groups had a higher likelihood of developing corneal edema and needing a corneal transplant compared with Caucasian patients.⁴

The researchers collected data from a nationwide sample of 192,150 Medicare beneficiaries 65 years old and older who received cataract surgery. Patients with diabetes were more likely to develop corneal edema compared with non-diabetic patients after cataract surgery (odds ratio [OR]: 1.25). Compared with patients aged 65 to 74, patients aged 75 to 84 (OR: 1.38) and over 85 (OR: 2.40) were more likely to develop corneal edema. Compared with Caucasian patients, Black, Asian, Hispanic and North American Native patients were significantly more likely to develop both corneal edema and eventually require corneal transplantation. Female patients had lower odds of requiring corneal transplantation postoperatively (OR: 0.53).

In these patients, the presence of macular edema was associated with increased odds of developing
corneal edema (OR: 1.86). However, the researchers found that the severity of diabetic retinopathy, diabetic kidney disease and the presence of peripheral circulatory disease were not associated with increased odds of corneal edema. **Humidity may be a risk factor for keratoconus.** The progressive changes wrought by keratoconus, if left unchecked, can be devastating, leading to distorted vision and visual impairment. Researchers are curious about what factors may affect its development. Given the wide variance by ethnicity, there is a genetic component at work. At ARVO, one group of researchers presented their results detailing climate-related variables and their relation to the condition. The group systematically reviewed studies on keratoconus prevalence and incidence in the general population. Climate datasets like the ERAS as well as its derivatives were used to find data for each studied region. The climate exposure period consisted of the 10 years preceding data collection for each prevalence study. Averages of relative humidity, wind speed, ultraviolet radiation and maximum daily temperature were calculated over this period.2

Included were 18 total systematic reviews reporting prevalence of keratoconus across different geographical locations. In the multiple regression model, only humidity and keratoconus prevalence yielded a negative association; maximum daily temperature, wind speed and ultraviolet radiation did not display significant associations with prevalence of the condition.

The authors subsequently pose that “low humidity might therefore be an unexplored risk factor for keratoconus,” they noted in their ARVO abstract. “Further research is needed to investigate the importance of humidity for the cornea and to assess whether humidification might have preventive and therapeutic applications.”

**Allergies, atopic disease linked to higher crosslinking (CXL) failure rate.** For keratoconus suspects and patients, asking pertinent questions about a history of eczema, asthma, allergy and eye rubbing should be part of the entering case history. A study presented reinforced the necessity of this step, as it determined that allergy and topic disease were associated with a higher treatment failure rate of corneal CXL.6

Researchers from Wills Eye Hospital in Philadelphia conducted a retrospective claims-based analysis of patients from a 15-year period. They excluded patients who had enrollment beginning less than one year before initial CXL and patients who had undergone previous penetrating keratoplasty (PK) or deep anterior lamellar keratoplasty (DALK). The primary study outcome was time to treatment failure repeat CXL, PK or DALK identified by CPT-4 codes. The analysis involved 3,107 eyes from 2,356 patients with keratoconus who underwent CXL. Mean age was 31.8 years, and 67.5% of patients were male. Mean enrollment length was 4.6 years, and 1.2% of eyes (n=37) from 35 patients experienced treatment failure. Of this group, 31 underwent a repeat CXL. The mean time to repeat CXL, DALK or PK was 182 days.

The researchers noted that CXL failure was more likely to occur in patients with allergic or atopic disease (56.8% vs. 40.0%). There was no difference in failure rates by pediatric status (18.9% vs. 12.9%), sleep apnea (21.6% vs. 14.8%) or sex (40.5% vs. 33.2% female).

“Our study characterized rates of corneal CXL failure in patients with keratoconus using a large insurance claims database,” they emphasized in their ARVO abstract.

**CONTACT LENSES**

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

**No meaningful rebound effect seen after discontinuing multifocals for myopia control.** In late 2019, the Bifocal Lenses in Nearsighted Kids (BLINK) Study found that +2.50 add center-distance multifocal contact lenses slowed eye growth and myopia progression compared with single vision contact lenses or +1.50 multifocal lenses. At ARVO 2024, the research team presented the results of BLINK2, in which “the same children all wore the high-add multifocal for two years and then were changed to single vision contact lenses for the last year to determine if eye growth returns to a normal rate or if there is an acceleration of eye growth faster than expected for their age (i.e., rebound),” says lead author of the ARVO paper and one of the principal investigators of the BLINK study, David A. Berntsen, OD, PhD, of the University of Houston.

BLINK2 included 248 (59% female) myopic children between the ages of 11 and 17 (mean age: 14.9). Axial length (AL) was measured every six months using optical biometry and spherical equivalent refraction (SER)
was measured annually by cycloplegic autorefraction. While there was a statistically significant increase in eye growth and myopia progression after discontinuing multifocal contact lens wear, the increases were small and not clinically meaningful.\(^7\) “We did not find evidence of a rebound or faster than normal eye growth, at least when you wait until children are older like they were in BLINK2,” Dr. Berntsen explains.

After all participants switched from multifocals to single vision lenses at year two, there was an increase in AL growth of 0.04mm/year that did not depend on the original BLINK treatment assignment. For SER, there was also an increase in myopia progression (-0.16D/year) after switching from multifocals to single vision lenses at year two that also did not depend on the original BLINK treatment assignment. There continued to be a difference in AL and SER throughout BLINK2 based on the BLINK Study treatment assignment.

“Knowing that we did not find evidence of a rebound after discontinuing multifocal contact lens wear is helpful because the effect needs to remain after discontinuing treatment,” Dr. Berntsen says. “Our results provide evidence for eyecare providers that if they wait until the late teen years, they should not expect a rebound effect when discontinuing myopia control contact lenses.”

The most surprising result the researchers noted, according to Dr. Berntsen, is described not in the ARVO presentation but in a recently published research paper looking at whether defocus explains the high add multifocal treatment effect. “We did not find evidence that retinal defocus does a good job of explaining which children will benefit most from wearing a multifocal contact lens. This means there must be something else caused by the optics of the contact lens that signals to the eye to slow growth when wearing a multifocal,” says Dr. Berntsen. “More work is needed to understand the mechanism behind the treatment effect so we can optimize treatments.”

**Smaller back optic zone diameter improves ortho-K results.** Overnight wear of orthokeratology (ortho-K) lenses elicits a flattening of the central portion of the cornea as well as a steepening of its peripheral portion. The flattened central portion of the cornea improves daytime vision, while the steepened peripheral causes a relative corneal refractive power shift from the baseline, leading to myopic defocus on the peripheral retina. Many researchers have suggested this as the underlying mechanism of slowing AL growth. A recent study presented highlighted that a smaller back optic zone diameter (BOZD) in an ortho-K lens was associated with a greater accumulation of relative corneal refraction power shift in the central 4mm area.\(^8\)

The prospective study involved a collaboration between Tianjin Eye Hospital in China and Nova Southeastern University in Fort Lauderdale, FL. In 34 children (14 boys and 20 girls; ages nine to 12), one eye was randomly assigned to wear a 5mm BOZD lens and the other eye a 6mm BOZD lens. Evaluation visits were scheduled at baseline, one day, one week, one month, three, six, nine and 12 months after the initial lens wearing.

At baseline, there was no difference in refractive error (-2.52D vs. -2.45D) or axial length (24.50mm vs. 24.50mm) for eyes wearing lenses of different BOZDs. After treatment, eyes in the 5mm optic zone group had a smaller treatment zone (6.63mm\(^2\) vs. 8.11mm\(^2\)), although there was no difference in decentration. Axial length growth was significantly smaller for eyes in the 5mm optic zone group (0.19mm vs. 0.26mm). Significantly greater relative corneal refraction power shift accumulated within the central 4mm area (15.54D\(^*\)mm\(^2\) vs. 10.40D\(^*\)mm\(^2\)) was also observed in participants wearing 5mm lenses. Relative corneal refraction power shift was significantly associated with axial length growth.

“Children wearing ortho-K lenses with smaller BOZD showed much smaller AL growth,” the researchers concluded in their abstract.

**OCULAR SURFACE**

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

**First specific genetic locus detected for dry eye.** Dry eye disease (DED) has been somewhat difficult to phenotype, in turn, limiting the application of large-scale genome-wide association studies (GWAS). One group of researchers used the VA Million Veteran Program biobank to study the genetic basis of DED.\(^9\)

The authors created a case-control algorithm based on ICD-9/10 codes and prescription records, which was then reviewed and validated manually with a chart at different VA eye clinics. When the algorithm was used in this particular biobank, it detected 48,794 cases of DED and 29,224 controls. From there, the researchers classified cases into ancestry groups (European, African, Hispanic and East Asian).

After compiling this data, the researchers saw that their chart review revealed a positive predictive value of 98% and a negative predictive value of 93%. DED was found to be associated with factors of female sex, age, African ancestry and score on the Charlson Comorbidity Index, a measure of the relative one-year risk of mortality based on 17 possible comorbid conditions. They also found specific associations with comorbidities of depression and sleep apnea.

“In addition to identifying the first GWAS locus for DED, we attained a significant overall genetic signal,
motivating expanded GWAS meta-analyses and the development of polygenic risk score models.” For clinicians, this provides new insights into the genetic basis of DED and sheds light on underlying causes.

**DREAM Study cohort shows dry eye test repeatability needs improvement.** Clinicians have several tools at their disposal for diagnosing and monitoring patients’ DED, but experts note that there’s no single gold standard test. Also worrisome is the variable repeatability of many such tests. At ARVO, DREAM Study researchers reported retrospective findings on dry eye test repeatability, an indication of a test’s reliability as a diagnostic tool. They focused on eyes with moderate to severe disease. In the moderate to severe patient population, they found only moderate test repeatability.10

The randomized DREAM study included a screening visit and a baseline visit about two weeks apart. At both visits, DED was assessed by the same physician in the same order: tear break-up time (TBUT), corneal fluorescein staining, meibomian gland dysfunction (MGD), conjunctival lissamine staining and Schirmer test. The researchers of the present study calculated the agreement of dry eye signs for 1,046 eyes (523 patients) between the two visits. They reported variable measurement agreement between visits. Corneal staining score had the least variability, followed by conjunctival staining score. These were followed by Schirmer test, MGD and TBUT, respectively.

A substantial percent of eyes showed clinically significant absolute differences between visits, with two or more points in conjunctival staining score in 17.8% of eyes, three or more points in corneal staining score in 9.9% of eyes, three or more seconds of TBUT in 6.2% of eyes, 5mm/5 min or greater in 22.7% of eyes for Schirmer test and greater than two points in 13.7% of eyes for MGD.

“These findings suggest the need to consider test-retest variability of DED measurements when designing dry eye clinical trials and monitoring disease progression,” the researchers concluded.

**Maximum blink interval helps detect dry eye cases with mismatch of signs vs. symptoms.** It is confounding in dry eye care when patients’ signs and symptoms don’t align, with one or the other factor out of proportion based on what would be expected. To better observe and assess dry eye cases with such discrepancies, researchers from Japan evaluated the maximum blink interval—or duration someone can keep their eyes open before blinking—in patients without a history of cataract surgery.11

A total of 364 patients were examined to determine whether they had positive or negative dry eye symptoms (DES) according to the Japanese version of the Ocular Surface Disease Index (OSDI) as well as positive or negative corneal epithelial damage (CED) after finding the patients’ corneal fluorescein staining score.

Participants were divided into two groups (presence or absence of discrepancy), then split again into four subgroups. The discrepancy groups separated patients into these subgroups:

- symptoms (+), signs (-)
- symptoms (-), signs (+)
- Subjects with no discrepancy either had both symptoms and signs together or neither of those findings.

The maximum blink interval results for the “symptoms but no signs” group were significantly shorter compared to the “no symptoms, no signs” group (10.9 sec vs. 14.6 sec). Also, the group with signs but not symptoms achieved a significantly longer maximum blink interval than the group with both (12.2 sec vs. 9.6 sec).

The researchers did two more subgroup comparisons: symptomatic vs. asymptomatic patients without signs and the same symptomatic vs. asymptomatic comparison in those with signs. They found a significant association between maximum blink interval and symptom/finding discrepancy for each pair of groups. Researchers did not find any significant differences between TBUT and tear secretion volume.

“Maximum blink interval may be able to evaluate cases with high symptoms-to-findings discrepancy that cannot be well-assessed using traditional diagnostic strategies,” explain the researchers in their study. “Our findings suggest a potential usefulness of these interval measurements in identifying atypical dry eye cases, where patients have prominent corneal findings but no symptoms.”

**Artificial tears effectiveness comparison.** A limited number of studies have compared the performance of different OTC drops for DED, prompting
researchers to conduct a new study evaluating the effectiveness of 13 artificial tear preparations in improving objective measures of tear film anatomy and function in patients with dry eye. The results indicated that no artificial tear excelled across the board, so tailoring specific drops to patients with certain aspects of DED dysfunction may be beneficial.12

The study included 242 eyes from 122 patients. Tear meniscus height, noninvasive keratographic tear breakup time (NIKIBUT) and central lipid layer thickness were measured using advanced keratography and interferometry. The artificial tear formulations tested included Systane Complete PF, Refresh Relieva, GenTeal Gel, Hylo-Tear, IviZia, Systane Ultra, Refresh Optive Mega 3, Similasan, Soothe XP, Up&Up, Visine and GenTeal Tears. Saline was used as a control.

While all artificial tear preparations resulted in an improvement in some tear parameters, no single artificial tear performed consistently better at all time points for all measures. The best performer for tear meniscus height was GenTeal Gel; for NIKIBUT, the winners were Systane Ultra, saline and Refresh Relieva. The most improvement in lipid layer thickness was seen with Hylo-Tear and Soothe XP. These findings suggest that the composition of artificial tears plays a crucial role in their relative performance.

High BMI as a risk factor for dry eye symptoms in children. Researchers from the Illinois Eye Institute found that high BMI is a significant risk factor for dry eye symptoms in children between the ages of five and 18. A total of 160 children (76 boys, 84 girls from ages 5 to <18) underwent a comprehensive eye exam and were surveyed regarding electronic screen time and filled out a modified, child-friendly OSDI. The second OSDI question (eyes that feel gritty) was modified to “eyes that feel something inside.” The seventh OSDI question (driving at night) was removed based on the age of the study population and the eighth OSDI question (working with a computer or bank machine) was modified to “using an iPad or tablet.” Parents were surveyed on their child’s screen time, diet and outdoor activity. BMI was calculated using measured height and weight.13

High BMI was a significant risk factor for dry eye symptoms in children aged five to <18 years; however, the OSDI score was not associated with age, race, gender, screen time, outdoor activities and diet.

The mean OSDI score was 14.7, with 16.9%, 8.8% and 12.5% of the children having mild, moderate and severe dry eye symptoms, respectively. Average screen time per week was 9.2 and 8.5 hours reported by children and parents, respectively. Significant correlation was found between the screen time reported by children and parents.

“Our studies suggest that dry eye disease is frequently undiagnosed in pediatric patients. In our data analysis, multiple regression showed that high BMI was a significant risk factor for dry eye symptoms in children; however, the OSDI was not associated with age, race, gender, screen time, outdoor activities or diet,” says Lindsay Sicks, OD, of the Illinois Eye Institute, one of the researchers. There is mixed literature on the connection between BMI and dry eye and meibomian gland dysfunction in adults, and even less evidence in children, she points out. “We wanted to investigate this association among our clinic population, which is primarily African American and Hispanic.”

Dr. Sicks notes the mechanism connecting BMI to dry eye is unclear at this time. “There are a lot of other facets to dry eye,” she explains. “In a separate analysis of this cohort (forthcoming OVS publication, Fall 2024), we found evidence that BMI is correlated to meibomian gland morphological changes (atrophy and tortuosity) as well as survey information collected about diet.” More analysis is needed to link the signs to the symptoms and to assess the relationship between all of these variables, Dr. Sicks stresses. “Still, I don’t think we can extrapolate what we find in our particular pediatric population to the general adult population at this point,” she adds.

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

10. Chen A, Augello P, Axbell PA, Ying G. The repeatability of tests for dry eye signs in the Dry Eye Assessment and Management (DREAM) study.
13. Piang Y, Parikh M, Sicks L. Lifestyle risk factor for dry eye symptoms in children aged 5 to <18 years. ARVO 2024 annual meeting.
In the March/April issue, the article “Corneal Topography: Get to New Heights” discussed the purpose of corneoscleral elevation data and the currently available technologies. In this second part and conclusion to the discussion, corneoscleral elevation focus shifts will be covered and how to incorporate this data into useful daily practice will be reviewed. Of course, elevation of the cornea, particularly the posterior cornea, is of paramount interest in screening and monitoring keratoconus and similar ectasias, but perhaps an even more practical usage of sagittal elevation data can be applied to what eyecare practitioners perform every day: contact lens (CL) fittings.

The landscape of the contact lens industry is changing, with more manufacturers adopting an elevation-based approach—particularly with specialty lenses, such as corneal rigid gas-permeable (GP) lenses, scleral lenses and orthokeratology (ortho-K) lenses. Even commercial soft contact lenses are revealing insightful evidence pointing to elevation data being the key to a predictably successful, empirical lens design.

**CORNEAL GP LENSES SET THE STAGE**
For most of the 20th century, rigid contact lenses were the only CL option. Over time, hard polymethylmethacrylate (PMMA) lenses eventually gave rise to flexible, more oxygen-transmissible GP materials, but they were still rigid in shape—thus needing to be fit as predictably similar to the corneal shape as was measurable at the time.

In those early years,fitting could be based on adjusting your GP fit to match in-situ CL characteristics.

**ABOUT THE AUTHOR**
Dr. Wolf received his Doctor of Optometry from the University of Houston in 2009. He is the owner of the private practice, Austin Optometry Group, in Austin, TX, focusing on ocular surface disease and specialty contact lenses, including scleral lenses and orthokeratology. Dr. Wolf provides topography-guided and tomography-guided corneal, scleral and orthokeratology lenses, ocular impression-based lenses and custom HOA-correcting lenses. He is the first doctor in Texas to earn all the following clinical fellowships: fellow of the American Academy of Optometry, fellow of the Scleral Lens Society and fellow of the International Academy of Orthokeratology and Myopia Control. He has served as a speaker, consultant or provided case reports for Eaglet Eye, Medmont, Oculus Wave, Ovitz, EyeXY and Acculens.
from a set of diagnostic lenses or by measuring the curvature of the central cornea from keratometry to arrive at a well-aligned lens curvature more quickly. The overall diameter (OAD) tended to hover around 75% of corneal size, making a typical lens OAD between 8.0mm and 9.5mm. This proved to be a successful size range because most of the central base curve (BC) of the CL could be adequately fitted from very limited central cornea measurements of keratometry; these smaller lenses provided more tear exchange that was necessary for oxygen transmission (Dk) for the low Dk materials of the time.

Enough was known and observable about peripheral corneal eccentricity that one or multiple progressively flatter peripheral curves could be incorporated to provide an ideal lens fit to a presumably normal cornea; however, without the means of the time to directly measure the peripheral corneal topography—which can be increasingly unpredictable and asymmetric—larger lenses risked corneal binding. Thus, fitting methods in general were more reactive than proactive.

The arrival of subsequent projection-based topography and tomography instruments (discussed in Part I) provided a much greater area of the cornea capable of being measured with precision, leading to dramatically improved predictability of central and peripheral lens alignment. Along with the advancements in greater Dk materials, a trend in larger corneal GP lenses, or intralimbal lenses, evolved, whereby the OAD may be precisely designed upwards of 85% to 95% of the corneas's size (Figure 1). These larger corneal GP lenses can

**Fig. 2. CAD/CAM corneal GP software with in-situ fluorescein simulation from internal Medmont software, internal Pentacam software and external Eaglet Eye export to Wave software.**
provide greater lens stability that is advantageous for advanced optics such as multifocal or toric correction due to improved lens centration and generally less lens awareness by decreasing the amount of lens movement.

With today’s advancements in the ability of corneal imaging technology to measure the entire cornea—out to the limbus or beyond—with greater precision, it has become easier than ever to accurately design intralimbal GP lenses even to very irregular corneal geographies. As discussed in Part 1 in the March/April issue, with these improved technologies came the transition from corneal curvature metrics as the leading data source to that of sagittal elevation data, which is not only a better representation of ocular surface shape but also ties more directly to modern manufacturing technology.

Some topographers include computer-aided design (CAD) and computer-aided manufacturing (CAM) software either internally or externally linked to the topography map for the ability of the practitioner to design a truly custom lens; this allows them greater ability to use their preferred fitting philosophy combined with clinical information not always revealed by the map, such as eyelid anatomy, conjunctival obstacles or dexterity challenges. Then, that design file is sent directly to a lathe for manufacturing.

Figure 2 shows examples of various internal and external corneal GP design CAD/CAM software. Notice that the lens design and fluorescein fit simulations record the tear film thickness (TFT) and lens sagittal depth (SAG) values in microns, offering more customization to alter a greater number of control points on the lens. Below is a case demonstrating the usefulness of this technology when dealing with distorted or challenging corneas.

**Case 1.** A patient with a penetrating keratoplasty corneal transplant often provides a very irregular corneal surface and is a challenging fit for any practitioner. The extreme precision of the corneal tomography (Oculus Pentacam AXL Wave) map of the corneal front surface out to the limbus as well as the ability to create a freeform GP lens both contribute so that many variable elevation points can be controlled individually and are on full display. As demonstrated in Figure 3, not only is a satisfactory fit on a very challenging and distorted cornea made possible, but the accuracy of the elevation maps and in-situ fluorescein pattern are nearly mirror images of each other and closely predicted by the TFT-simulated pattern of the design software (Wave Contact Lens System). On the elevation map, warmer colors are higher and cooler colors are lower,
precisely transferring to the areas of mild touch on the highest elevation points and greatest fluorescein depth over the areas of lowest elevation.

**ELEVATION DATA IN SOFT CL FITTING**

With the market domination of soft CLs in the second half of the 20th century, the demand for fitting GP lenses largely reduced; the pliable lens material was much more forgiving in achieving comfortable alignment to the average eye. This pliability of soft lenses explains why the BC of commercial soft lenses—typically averaging around 8.5mm—is so significantly different than the mean K of most corneas they are fitted to—which average closer to 7.5mm. Manufacturers can anticipate the conformity and laxity of the lens based on their designed polymer and selected BC and OAD, allowing the lens to align to the greatest number of normal corneas.

Although this approach is quite successful in most regular cornea patients, it is not a customized approach and will not always yield optimal results even in healthy and predictable corneal anatomies. Likely these effects are multivariable, from factors of lens polymer, water content, corneal diameter, OAD, lens power, lens dehydration and even manufacturing inconsistencies. Another major contributing factor is something discussed even less—corneoscleral sagittal elevation height. Perhaps elevation data could prove to be a more predictable measure to anticipate successful CL fitting than corneal keratometry.

Research by Eef van der Worp et al. has shown interesting results when studying the fitting effects of silicone hydrogel lenses of shared BC and power. They found that, despite similar parameters, there were marked differences in sagittal height among the lenses in both daily disposable or

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<th>Table 1. Sagittal height reference for daily disposable spherical soft CLs.</th>
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<th>Table 2. Sagittal height reference for reusable spherical soft CLs.</th>
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<th>Table 3. Sagittal height reference for toric soft CLs.</th>
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reusable lenses and spherical or toric lens designs, differing sometimes dramatically by several hundred microns. This is incredibly illuminating—for decades, the approach to selecting an initial soft CL has been based on keratometry (Ks) and more so mean or mid-K.

Another consideration was if the lens proved to be fitting too tight or loose. In these cases, it was advised by manufacturer recommendations and conventional practices to then select a flatter or steeper BC, respectively. This may be a misguided approach. Instead, with known corneoscleral sagittal height information, purposefully targeting another soft CL product altogether could be the faster and easier route to a better fitting lens. Using Tables 1, 2 and 3 and directly measured or estimated sagittal height data from various corneal topographers, a more personalized approach to contact lens fitting can be achieved dependent on each eye’s characteristics. The cases below use these tables to illustrate their value.

**Case 2.** This patient has a very spherical, regular cornea with a very average mean K of 43D (Figure 4). Referencing the soft CL sagittal height tables, it is observed that 14.2mm is the most common spherical lens OAD. Using a small-cone Placido disc topographer (Medmont Meridia Pro) and selecting this OAD as the measurement chord, this patient’s estimated corneoscleral SAG is around 3,300µm. Although the mean K of 43D is a very typical and average keratometry value for all regular cornea patients, it is likely that selecting an initial lens from the left of the table may provide a superior fit to those listed in the middle or right of the table.

Despite a very average K reading of 43D and that an 8.5mm BC is much more commonly utilized, it is evident based on this eye’s SAG data that, for example, a 9.0/14.3 Acuvue Oasys 1-Day (Johnson & Johnson Vision) would provide a better fit than the more commonly used 8.5/14.3 Acuvue Oasys 1-Day alternative of the same brand. If selecting a monthly reusable soft lens modality, this data would indicate that the Proclear (CooperVision) 8.6/14.2 lens may be a better fit on this patient than the identical parameters of the alternative Air Optix Aqua (Alcon) 8.6/14.2.

**Case 3.** This patient also shows a regular cornea with the same mean K of 43D as in **Case 2**; however, this one is mildly astigmatic, requiring a toric soft lens (Figure 5). For toric soft lenses, 14.5mm is the most common OAD. Using this as the measurement chord with a corneal tomographer (Pentacam AXL Wave) with directly measured corneoscleral topography, this eye’s average SAG is around 3,500µm. This is interesting because despite the typical K of 43D, this patient has a very low ocular SAG compared with most toric options. Referencing the lens tables, even if a practitioner desired a daily disposable toric CL option from the same manufacturer, it is apparent that this eye may be better suited to the 8.6/14.3 Clariti 1-Day Toric (CooperVision) over its similar alternative of the 8.6/14.5 MyDay Toric (CooperVision).

Furthermore, to the keen observer, it can be noted that, although the cornea reveals with-the-rule astigmatism, the sclera conversely reveals against-the-rule astigmatism. This proves that scleral shape and corneal shape do not always correlate and should not be assumed as such. This also may be relevant in toric soft lens design, in that some use a prism ballast, where a single quadrant lens thickness weighs the lens into proper orientation, while others opt for a blink-stabilizing design, where instead two opposite edge quadrants are thicker to stabilize the lens between the upper and lower lid. These observations open further interesting questions about which design may be better suited for against-the-rule scleral shapes—questions in which further studies may answer.

Some limitations in elevation-driven soft CL fitting include that most practitioners do not use corneoscleral elevation technologies on their soft lens patients, the sagittal height data of commercially available soft lenses are not currently provided by manufacturers and that, because there are so many available soft lens choices, if a lens doesn’t provide good comfort or fit, then it is easy and affordable to simply try multiple others until reaching an acceptable fit.
Driving Innovation, Defining Excellence: LEADING THE MARKETPLACE FORWARD

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SCLERALS TO ALIGN ANY GEOGRAPHICAL FEATURES

This modality of contact lens has enjoyed a resurgence of interest over the last decade. SLs are primarily sagittal height-focused in their design and fitting due to the goal of the lens to adequately vault over the cornea and land safely and be evenly supported along the sclera. Although it has not always been the standard to directly measure corneoscleral sagittal height, it was indirectly determined as an effect of adjusting scleral lens SAG until ideal clearance was achieved. However, with the availability of corneoscleral profilometry mapping today, we can precisely measure the necessary heights at any desired location and accurately visualize the ocular geography, as well as efficiently and empirically design a scleral to fit any eye, regardless of anatomical features. Below is one case demonstrating when a scleral lens was the best option.

**Case 4.** This patient has an eye with keratoconus and a raised nasal pinguecula—a geographical challenge encountered often by practitioners. Although cutting out a piece of the lens edge, or notching, around the conjunctival obstacle is an option, it can be difficult to notch precisely and smooth the edges enough to avoid tissue irritation. Instead, designing the lens landing zone to precisely follow the precisely measured elevation changes of these obstacles to softly align the ocular surface can be more comfortable for the patient, physiologically gentler and provide better lens rotational stability. Corneoscleral profilometry imaging of the ocular surface by devices such as the Eagleal Eye Surface Profiler or Pentacam AXL. Wave may then be exported to CAD/CAM software, EyeXY Gaudi Hypergeometric design software in this case, providing a perfect fit (Figure 6) to the eye’s geographical contours. With corneoscleral profilometry, the corneal elevation can be accurately measured to ensure a comfortable fit.
scleral profilometry technology, even without CAD/CAM design software, the exact details of the width and height of the obstacle can be provided to lab consultants for a customized edge profile.

**ORTHO-K: ELEVATION-BASED DESIGN APPROACH**

With ortho-K lenses, the industry has seen a shift in both design and parameter nomenclature. For example, some ortho-K manufacturers’ prior curvature-based terms, such as *alignment curve*, have transitioned more recently to encapsulate changes in the terms of *alignment zone* or *landing zone* while *reverse curve* has changed to *return zone* and *peripheral curve* is now called *edge lift.* With these, their prior metrics of associated lens back surface BC are now often noted in SAG values. For many designs, lens landing zone toxicity was previously recorded in BC toxicity but is now notated in SAG difference at a specified chord.

Today, almost all ortho-K manufacturers and CAD/CAM design software developers have acknowledged the improved intuitiveness of communication in terms of SAG regarding lens parameters and simulated TTF. For example, from anterior corneal elevation data, ortho-K designs from both EyeSpace and WAVE CAD/CAM software show toric ortho-K lens schematics in both total lens SAG metrics and simulated TTF in microns at any point of the lens with interactive software, using elevation data as the primary language of design and simulated fit, rather than curvature metrics of old (*Figure 7*).

Given the mechanism of ortho-K using fluid dynamic forces in a reverse geometry posterior lens reservoir, precise elevation data is of utmost importance to create the desired reshaping effect of the cornea without creating inappropriate bearing forces or tear exchange seal-off. Even the determination of spherical vs. toric landing zones can be attributed to elevation data. Study findings recommend a toric corneal landing zone when at least 30µm of toxicity is present at 8mm.10,11

Although the effect of ortho-K treatment has always been measured as the reshaping of corneal curvatures, what is actually happening physically is the compression and expansion of the corneal epithelium to create the desired physiological and optical changes to the cornea (*Figures 8 and 9*).12 During the topographical review of post ortho-K wear, anterior corneal curvature difference maps, known as subtraction maps or comparison maps, are used to assess the resultant changes to corneal shape.

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**Fig. 5. Pentacam CSP Pro Scheimpflug tomography with measured corneoscleral sagittal height data to determine preferred toric SCL.**
Fig. 7. EyeSpace and Wave CAD/CAM ortho-K design software using front corneal elevation data, SAG lens design data and TFT simulation in microns.

Fig. 8. MOK tangential (top) and elevation (bottom) difference maps demonstrating both dioptic power changes as well as physical elevation changes to the corneal surface as mapped by Scheimpflug tomography.

and refractive power. This theory of reshaping of the corneal tissue can cause confusion amongst patients and practitioners alike who are unfamiliar with ortho-K because it is often discussed as reshaping the cornea as a whole; in reality, only a few microns of epithelial tissue are being both compressed and expanded to create an optical lens effect out of the epithelium, with a concave effect in myopic ortho-K (MOK) (Figure 8) and an inversely convex effect in hyperopic ortho-K (HOK) (Figure 9).13

Currently, familiar tangential and axial curvature or power difference maps are used to assess treatment centration, treatment size and evenness of the annular reservoir indicating evenness of fluid dynamic forces— all of which are signs of achieving a great result with ortho-K. However, those refractive and curvature topography findings do not always transfer equally to subjective refractive changes or clinical examination findings.

What is seldom discussed are the elevation difference maps. If it is well understood that the fluid reservoirs are at once flattening the central area while also steepening the mid-peripheral corneal epithelium, how exactly is it doing so? This is where elevation maps may provide a clearer picture for eyecare practitioners. Seen in
both Figures 8 and 9 are the physical changes to the epithelium which can be precisely measured and monitored with elevation difference maps.

With its origins in laser refractive surgery, Munnerlyn’s formula is one that allows us to calculate corneal thickness alterations with how much refractive error can be safely targeted.14 This can be modified to be applicable to ortho-K treatment too, as we can measure with tomography the epithelial layer thickness of each patient. With the understanding of adding the expanded epithelial layer to the compressed epithelial layer for a total depth value, it can be determined for each patient the limits of ortho-K for each eye.

Using topography or tomography elevation difference maps, could it be possible that ortho-K could perhaps be monitored more precisely or repeatably than curvature data? More focus in this area amongst the ortho-K community is needed, but with increasing precision in available diagnostic imaging, elevation difference maps may play an increasing role in ortho-K. Below are two examples.

**Case 5.** This moderately high myopic patient is undergoing successful corneal MOK. Figure 8 demonstrates ideal topographical difference maps, including elevation difference maps showing total elevation differential within and around the treatment zone of only 15 µm to 20 µm. Note that the colors of MOK and HOK maps are opposite of each other, as they are changing the corneal characteristics in opposite directions.

**Case 6.** This mildly hyperopic and presbyopic patient is undergoing successful transscleral HOK of post-myopic LASIK over-correction. Figure 9 demonstrates ideal topographical difference maps, including elevation difference maps showing total elevation differential within and around the treatment zone of only 10 µm to 15 µm.

**TAKEAWAYS**

Topography is used commonly outside of eye care, but never elsewhere with curvature data to represent those landscapes. You wouldn’t think about the curvature of a shoreline or mountain range, of course, but you would want to know of the height above sea level. That’s because elevation is more intuitive and easier to visualize.

The contact lens industry is evolving, as is our growing understanding of unique fitting characteristics of these various lens modalities available today. A common language is needed between lens design, lens evaluation and lens manufacturing. There is no better language in this industry than sagittal height to bind those aspects together. That’s where the future is headed, if not already there.

Overcoming OBSTACLES with Scleral Lens Fitting

Follow along with these two tough cases to sharpen your techniques and help set expectations for patients with severe corneal compromise.

By Ellen Shorter, OD

Scleral contact lens fitting can be an excellent option for patients with both corneal irregularities and ocular surface diseases (OSDs), even when the initial assessment poses challenges. The following cases outline strategies aimed at assisting patients to achieve successful lens wear despite initial obstacles.

The first case describes scleral lens fitting for a child with partial limbal stem cell deficiency and severe dry eye. Special considerations were taken in order to ensure the patient and his family felt at ease, while adjustments to lens design and overall diameter were made as proficiency in lens application and removal was achieved.

The second demonstrates that although visual improvement could be attained with corneal gas permeable (GP) and hybrid lenses in a patient with corneal irregularities and a history of glaucoma surgery, ultimately an impression-based custom scleral provided optimal comfort, with ocular surface support and exceptional visual clarity.

CASE ONE
A 10-year-old Asian male was referred due to severe dry eye and light sensitivity in both eyes. His past ocular history included keratoconjunctivitis sicca, corneal neovascularization, limbal stem cell deficiency, high myopia and bilateral amblyopia. His current ocular medications included cyclosporine ophthalmic emulsion 0.05% twice daily, non-preserved artificial tears every two hours and non-preserved lubricating ophthalmic ointment twice daily.

He received his first pair of prescription spectacles at age eight and had no prior contact lens use.

His medical history was significant for ichthyosis follicularis, alopecia and photophobia (IFAP) syndrome, an extremely rare X-linked oculocutaneous genetic disorder is caused by a mutation to the MBTPS2 gene. The patient’s diagnosis was confirmed by a pediatric dermatologist with genetic testing. Worldwide, only around 40 patients have been identified to have IFAP syndrome. The patient was adopted internationally at age seven and his family medical history was unknown.

Upon arrival in the United States, he was noted to have visual issues. He was holding things close to see them while also avoiding bright lights and seeking out shade. On physical examination, he had nail dystrophy, no body hair on the head nor extremities and scaly skin on the arms, legs and the bottoms of the feet.

Initial Evaluation
The patient’s entering visual acuities were 20/80 OD and 20/100 OS with spectacle correction of -9.25D sphere OD and -13.00D sphere OS.

Pupils were equal and reactive, and the extraocular muscles had full range of motion. Slit lamp examination was challenging due to severe photophobia. There were no eyebrows or eyelashes. Silicone punctal plugs were present in the lower puncta, which had been placed during an exam under general anesthesia. There was mild diffuse conjunctival injection and diffuse 2-3+ punctate epithelial erosions with

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peripheral subepithelial opacity and vascularization of both corneas. The anterior chambers were deep and quiet and the lens clear. The dilated fundus exam was normal.

There was a long discussion with the patient and his parents about scleral lenses, their benefits and handling requirements. It is important to answer all questions and discuss the need for daily application and removal, and follow the patient closely prior to initiating lens fitting to manage expectations.

Lens application was attempted with a small-diameter 15mm scleral lens on the right eye. The patient squeezed his eyelids causing eversion and pulled backward repeatedly. Despite additional attempts using an LED light to help maintain downward fixation, as well as filling the lens with a viscous non-preserved artificial tear, attempts at lens application were unsuccessful.

The decision was made with the family to continue close follow-up with the pediatric cornea specialist and return for repeat evaluation in the future. They were also advised to practice holding the eyelids at home to increase familiarity with the lens application process.

**Repeat Scleral Lens Evaluation**

Three years later, the 13-year-old patient was again referred by their cornea specialist for evaluation for therapeutic scleral lenses. Visual acuity with spectacles was 20/125 pinhole 20/100 OD and 20/100 pinhole 20/70 OS. Slit lamp examination findings remained stable with peripheral corneal pannus and diffuse punctate epithelial erosions OU.

After numerous attempts, a diagnostic scleral lens with a 14.9mm diameter, 7.4mm base curve and -3.50D spherical power was successfully applied to the right eye without application bubbles. The lens demonstrated excessive post-lens tear reservoir with scleral landing zone edge compression and vascular blanching. An over-refraction of -20.00D sphere improved vision acuity to 20/50 in the right eye.

We discussed scleral lenses and daily handling requirements with the patient and his parents. Potential issues with lens wear including fogging or clouding of the vision and lens front surface non-wetting, which may require lens removal, cleaning and reapplication during the day were discussed.

Although the long-term goal was to fit both eyes in order to provide ocular surface protection, the decision was to start with the right eye only due to significant difficulty and stress of applying the right lens in office. The initial right scleral lens was ordered in hyper-GP material tisilfocon A to maximize oxygen transmissibility due to corneal neovascularization. The lens was designed with an unusually small 14mm overall diameter to facilitate easier lens application during the upcoming training visit. A flatter base curve was also selected in order to reduce the refractive power of the lens as well as to ensure complete clearance of the limbus due to the patient’s history of partial limbal stem cell deficiency. Prior treatments included topical steroid and elimination of topical preservatives. Only a right lens was ordered with the plan to use it for fitting of the left eye once in-office lens application was successful.

**Pediatric Scleral Lens Application and Removal Training**

The patient was scheduled on a day when there was ample time to allow for an extended training session with time for breaks. The exam room lights were dimmed to reduce light sensitivity. A scleral lens stand with LED fixation light was used during scleral lens application training (Figure 1).

A cup of hot water was used to warm the non-preserved viscous artificial tears to body temperature. The warmed solution can reduce some patients’ reflex to pull back. Additionally, a viscous filling solution can help reduce the likelihood of application bubbles. The parents were guided to help coach the patient and observe lens application from the side, which allowed them to let the patient know when to pull back and stop if he was off-center or if his eyelids were bumping the scleral lens.

The first scleral lens with 9.0mm base curve, 14.0mm diameter and -10.75D power with toric scleral landing zone was applied bubble-free to the right eye (Figure 2). Vision in the right eye was 20/50 with -0.50D spherical over-refraction. The lens overall diameter was small for the patient’s cornea.

Next, the lens was removed from the right eye and used as a diagnostic fitting lens for the left eye (Figure 3). Vision was 20/40 with plano sphere over-refraction.

With extensive training, the patient was able to safely apply and remove the 14mm scleral lens on his right and left eyes at this visit. The family was educated that a larger-diameter lens would be needed in the future. A new set of lenses were ordered with plan for repeat lens application and removal training at the next visit. The right scleral lens was ordered with 14.0mm diameter, decreased sagittal height and a power -11.25D. The initial left scleral lens was ordered with tisilfocon A material, 9.0mm base curve, 14.0mm diameter, -10.75D power and decreased central sagittal height with toric scleral landing zone.
OVERCOMING OBSTACLES WITH SCLERAL LENS FITTING

Follow-up
One month later, the patient returned for repeat lens application and removal training with the new right and left 14.0mm scleral lenses. He reported good comfort with the lenses and easier lens application with the right eye compared to the left eye initially using a stand with LED light. Vision was 20/50 OD and 20/50 OS. The right lens had 250μm in the post-lens tear reservoir, mild inferior decentration, adequate palpebral clearance and mild scleral landing zone edge compression. The left lens had 200μm in the post-lens tear reservoir, mild inferior decentration, adequate palpebral clearance and mild scleral landing zone edge compression.

He was provided with clear written instructions describing the lens application, lens removal and disinfection process, which included images of the recommended lens filling and disinfection solutions. He was instructed to limit lens wear to four to six hours until his next visit scheduled one week later.

Midday Corneal Evaluation
The patient returned one week later as directed wearing scleral lenses in both eyes. His vision was 20/50 OU. He reported no issues with lens application but did note that at end of the day that the lenses “felt stuck” and were difficult to remove.

The right lens had 200μm in the post-lens tear reservoir, mild inferior decentration and adequate palpebral clearance with mild scleral landing zone edge compression. The left lens had 100μm in the post-lens tear reservoir, mild inferior decentration and adequate palpebral clearance with mild scleral landing zone edge compression as well.

The lenses were slightly difficult to remove despite wetting the patient’s eyes and removal suction cup with non-preserved saline solution prior to removal and placing the suction cup near the edge of the lens. After removal, his ocular surface was evaluated with fluorescein dye. There were no corneal punctate epithelial erosions; however, there were impression rings on the conjunctival from the scleral lenses on both eyes (Figure 4).

A new set of lenses were ordered; they were redesigned with a larger diameter and flatter scleral landing zone in order to more evenly distribute the weight of the lens on the conjunctival tissue. The patient was instructed to limit his lens wear to four to six continuous hours until the new lenses were received and to return for follow-up one month later.

Follow-up
The patient returned using the newest 16mm-diameter scleral lenses. He reported good comfort and clear vision with the lenses. On the day of the exam, he had worn the lenses for four hours continuously. He noted occasionally fogginess of his vision that would improve with lens removal, cleaning and reapplication. He reported no further difficulties with lens application or removal. Visual acuities were measured as 20/40 OD and 20/30 OS.

Both lenses had 300μm of post-lens tear reservoir, with complete limbal clearance and adequate scleral landing zone alignment. The lenses were removed easily without evidence of corneal or conjunctival impression or stain with fluorescein dye.

Over the past three years, the patient has continued to successfully wear his therapeutic scleral lenses 14 hours per day. His cornea specialist recommended midday removal and reaplication with fresh non-preserved saline solution when possible to reduce the likelihood of inflammatory cytokines building up in the post-lens tear reservoir.

This case demonstrates the value of fitting therapeutic scleral lenses in patients with limbal stem cell deficiency and severe dry eye even when lens application is initially challenging. This patient had improvement in dry eye symptoms while also improving his vision. When working with pediatric patients, it is important to proceed slowly to gain their trust and achieve long-term success. OSD has been reported to be the most common indication for pediatric scleral lens fitting. Scleral lenses can be particularly beneficial for pediatric patients with OSD and irregular astigmatism like this patient. Scleral lens wear has been shown to stabilize the ocular surface, enhance vision and improve ocular comfort while minimizing progression in ocular signs of a
patient with limbal stem cell deficiency related to ectrodactyly-ectodermal dysplasia-clefting syndrome over a period of 10 years.³

It is important to closely monitor patients with limbal stem cell disease when initiating therapeutic scleral lens wear. Particular attention should be made to ensure proper lens fitting without negative impact on the ocular surface. Efforts should be made to scheduling follow-up visits in the middle to late afternoon in order to evaluate the lens after settling. The scleral lens should be removed during every office visit to fully evaluate the ocular surface with fluorescein dye and allow for early identification of potential issues.

**CASE TWO**

A 59-year-old Caucasian male was referred by his glaucoma specialist for evaluation. His chief complaint was blurry vision in his left eye with a “ghost/overlapping” image. He had no visual complaints with his right eye.

The patient’s past ocular history included moderate open-angle glaucoma status post-endoscopic cyclophotocoagulation OU, Baerveldt glaucoma drainage implant surgery OS, bilateral pseudophakia, pars plana vitrectomy for rhegmatogenous retinal detachment OS, high myopia status post-LASIK refractive surgery, OSD with neurotrophic keratitis, chronic uveitis and cystoid macular edema OS.

He reported past use of corneal GP lenses 25 years ago and soft contact lens use 15 years prior. Ocular medications included dorzolamide 2%/timolol 0.5% twice daily, latanoprost 0.005% daily, non-preserved methylprednisolone three times daily, 50% autologous serum eye drops and cyclosporine ophthalmic emulsion 0.05% twice daily. Past medical history included gastroesophageal reflux disease and benign thyroid nodule.

**Initial Evaluation**

His baseline uncorrected visual acuities were 20/25 pinhole 20/20 OD and 20/60 pinhole no improvement OS. Corneal tomography revealed irregular corneal astigmatism with simulated Ks of 42.58/40.74@ 108 OD; 42.56/41.42@ 138 OS. Extraocular muscles had full range of motion and there was a left relative afferent pupillary defect. Intraocular pressures were 21mm Hg OD and 14mm Hg OS.

Baseline pachymetry readings were 432 OD and 413 OS. Manifest refraction of +0.25D sphere corrected vision to 20/20 OD and -0.25D +1.25Dx116 to 20/60 OS.

Slit lamp examination revealed 1+ inspissated meibomian glands and mild ptosis OS. His glaucoma drainage device superior temporal left eye was well covered with no evidence of conjunctival erosion (Figure 5).

His corneas had peripheral LASIK scars. The right cornea was clear centrally and the left had 1-2+ central punctate epithelial erosions. The anterior chamber was deep and quiet in the right eye and quiet with well-positioned tube in the left eye, flat iris and posterior chamber intraocular lenses present both eyes.

**Contact Lens Evaluation**

The patient’s complicated past ocular history as well as chief complaint were taken into consideration when considering the contact lens modality to consider initially. Special considerations were made due to his history of OSD and glaucoma with abnormal conjunctival elevation left eye after glaucoma drainage device implantation.

**Left Eye Scleral Lens Evaluation**

The decision was made to trial a diagnostic scleral lens on the left eye due to the presence of keratopathy, irregular corneal astigmatism and minimal improvement in visual acuity with manifest refraction. An oblate lens design was selected due to the corneal shape after refractive surgery with a standard spherical landing scleral zone. Despite visual acuity improvement

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**Fig. 4.** The patient’s eyes after 14mm scleral lenses were removed. There is an impression of the conjunctival tissue as well as staining with fluorescein.

**Fig. 5.** The patient’s left eye had a glaucoma drainage device superior temporal.
to 20/40, fitting was not immediately pursued further due to poor comfort in office and moderate scleral landing zone compression of the conjunctival tissue covering the glaucoma drainage device superior temporally.

Left Eye Corneal GP Lens Evaluation
Next, a corneal GP lens was considered to address the patient’s chief complaint of doubling or overlapping images in his left eye. A diagnostic corneal GP lens was selected with an 11.0mm diameter, 7.85mm base curve, and +1.00D spherical power. The lens fit was evaluated with fluorescein dye revealing mild central pooling with adequate edge lift. Visual acuity improved to 20/40 with a -2.50D sphere over-refraction.

Options were discussed and the plan was to proceed with a trial of a piggyback system of a soft daily disposable contact lens to support the ocular surface with a corneal GP lens over the top to improve visual acuity. A soft daily disposable lens was fit for use as a piggyback lens. The corneal GP lens was ordered in a flatter base curve of 7.94mm, diameter 11.0mm, power -1.00D sphere with standard peripheral curves.

At the next visit, the patient reported discomfort, foreign body sensation and blurry vision with the piggyback lens system. Visual acuity was measured as 20/40 with no improvement with over-refraction in the left eye. He was provided the option to use the soft daily disposable lens alone as a therapeutic soft lens vs. the GP lens over the top to maximize visual clarity.

Repeat Commercial Scleral Lens Fitting
The patient returned and complained of continued poor vision in the left eye. He was using the soft therapeutic lens alone and had issues with lens retention with frequent lens loss later in the day. His vision in the left eye was 20/40 improving to 20/30 with pinhole.

During slit lamp examination, he was noted to have 2+ punctate epithelial erosions with multiple filaments OU. Intraocular pressures remained stable at 12mm Hg OD and 13mm Hg OS. The right eye was fit with a daily disposable silicone hydrogel lens to support the ocular surface.

A diagnostic scleral lens was placed on the left eye with bi-tangential scleral landing zone and 16mm overall diameter. His vision improved to 20/20 OD and 20/25 OS.

A left scleral lens was ordered with base curve of 8.6mm, decreased overall diameter of 15.5mm, sagittal height of 3300µm, +0.25D power with the flattest scleral landing zone available from the manufacturer.

Despite these modifications to the scleral lens design, the landing zone continued to have moderate compression of the conjunctival tissue superior temporal in the location of the glaucoma drainage device.

One Month Follow-up
The patient returned with frequent complaints of ‘debris’ affecting his vision 15 minutes after lens application despite proper lens handling and disinfection. Vision was 20/20 OD with a soft daily disposable lens and 20/25 OS improving to 20/20 with over-refraction. He also complained of discomfort in the left eye requiring him to remove the scleral lens and take a break for a few days after using it.

On the day of the visit, he reported two hours of continuous lens wear time. The right lens was centered and had full corneal coverage and good movement with blink. The left scleral lens was decentred inferior nasally. The posterior tear film was estimated to be 350µm with complete limbal clearance. The flat scleral landing zone was at 75° with moderate conjunctival compression. Upon lens removal and evaluation with fluorescein dye, there was noted to be impression and staining of the conjunctival tissue superior temporal and inferior nasal.

Left Eye Refitting Considerations
There was a long discussion with the patient regarding borderline fit with the left scleral lens and evidence of compression and stain of the conjunctiva overlying the glaucoma drainage tube. The scleral landing zone toxicity had already been adjusted, and we were unable to further flatten the scleral landing zone.

After discussing the risks (including conjunctival erosion over the tube, infection, vision loss and need for additional surgery), the decision was made to discontinue scleral lens wear in the left eye. Alternative options included refitting into a hybrid lens, fitting a scleral lens with a custom notch to avoid the elevated glaucoma drainage device or refitting with a custom impression-based lens design to better align with the ocular surface.

The patient was fit with a hybrid contact lens with a GP center lens surrounded by a silicone hydrogel soft skirt (Figure 6). This lens could potentially improve visual acuity by masking irregular corneal astigmatism with

Fig. 6. The patient was fit with a hybrid contact lens.
Impression-based Fitting

The patient was instructed to discontinue lens use and to return for impression. At this visit, his vision was 20/80 pinhole no improvement OS. The impression was acquired using an FDA-approved ocular compound and an insertion tray, and the mold was sent to the manufacturer for custom lens design and fabrication. The desired optical parameters were requested based on previous GP lens data.

Impression-based Lens Dispensing and Follow-up

The initial impression-based custom scleral lens was designed with fluorosilicone acrylate material, Tangible Hydra-PEG lens coating, base curve 8.093mm, diameter 17.5mm power, -0.25D sphere and optic zone of 9.43x7.77mm. Vision was 20/20 OS. The lens oriented properly with two dots down and no rotation. There were 300μm of posterior tear film centrally and adequate limbal clearance 360°. The scleral landing zone was well-aligned to the conjunctival elevations with no vascular blanching (Figure 7).

The lens was easily removed in office. There was no conjunctival impression or stain with fluorescein dye. This case highlights the use and benefits of a variety of contact lens modalities in a patient with OSD on long-term topical glaucoma therapies. Consideration should be made to switching patients to non-preserved or BAK-free formulations of glaucoma medications when possible to improve OSD. Soft therapeutic daily disposable lenses are an option to support the ocular surface, improve epithelial healing and reduce pain in patients with mild to moderate OSD. In patients with visual complaints due to irregular corneal astigmatism, corneal GP and hybrid lenses can improve visual function after LASIK such as this patient. Scleral lenses can be used to both improve visual acuity and support the ocular surface and have been identified as the first option for management of corneal irregularity more frequently than corneal GP lenses, while scleral lenses are typically considered for management of OSD topical medical therapies, meibomian gland expression and punctal occlusion are attempted.

Patients with complex eye disease who were unable to successfully use standard scleral lenses can achieve visual and therapeutic success with custom, impression-based scleral lens.

In patients with abnormal conjunctival elevations, such as this patient with history of glaucoma drainage device, close monitoring is required with lens removal and evaluation with fluorescein to identify any risk of conjunctival impression or erosion of the conjunctival tissue. These patients benefit from close collaboration between their contact lens and glaucoma specialist to ensure long-term safety. A custom, impression-based lens design can be used to closely align the ocular surface and prevent conjunctival erosion and further serious complications.

TAKEAWAYS

Practitioners should allocate extra time and leverage highly trained support staff to assist pediatric patients and their families effectively. Follow-up appointments, ideally scheduled for mid to late afternoon, should include lens removal and a thorough assessment of the ocular surface to identify potential fit issues and guide adjustments to lens design.
HZO Redux

My last column left off with the patient’s vision shifting after initial oral antivirals, ocular hypertension drops and steroids. Here’s what happened after.

Our 63-year-old male patient was dealing with resolving pseudodendrites. One month later, the same patient called in for an emergency visit. He reported that his left eye had worsened over the weekend and he was experiencing more pain and redness. He was still taking valacyclovir 1g PO daily and had slowly tapered off the steroid eye drops. His uncorrected visual acuity OS was 20/60; intraocular pressure (IOP) was 10mm Hg. A corneal slit lamp exam revealed a LASIK flap, guttata, no keratic precipitates, central and peripheral nummular stromal infiltrates and early scarring. There were no signs of cells in the anterior chamber, and the posterior views were unremarkable. He was diagnosed with zoster stromal keratitis, also known as nummular keratitis. The patient was told to increase his Valtrex (valacyclovir, GlaxoSmithKline) use to three times a day as well as to restart his prednisolone drops twice a day OS.

BACK IN THE CHAIR

One week later, the patient was back in my chair and his nummular presentation was fully resolved. He struggled with side effects of fatigue from the high amount of valacyclovir but felt he did not want to reduce the dosage. It was decided to do an exceptionally long taper of the prednisolone that would span over one month. Within that month, the patient was seen again and the Valtrex was reduced to BID, while prednisolone was kept at QD. Another week later, the patient called in again with an urgent request to be seen due to blurred vision OS. He was seen in the office and it was confirmed this was his third recurrence with nummular keratitis present.

To summarize, this patient had a third instance of worsening vision, symptoms and keratitis while still on Valtrex PO BID and prednisolone QD within a span of four months. At this point, we increased his prednisolone back to QID and reached out to his primary care provider about long-term use of high dosages of Valtrex.

Since the last attack, the patient had been able to reduce Valtrex PO to QD and tapered to prednisolone TID; BID is where we decided to keep him. His keratitis resolved and his corneal scar had reduced dramatically. This leaves the question of how to manage him long-term.

HZO

Herpes zoster ophthalmicus (HZO) is a manifestation of the herpes zoster virus and is present in 20% of all herpes zoster cases. It is a severe variant of shingles and occurs when the immune system is weakened, causing the virus responsible for chicken pox to reactivate. HZO can affect all parts of the eye, and ocular onset usually occurs two to four weeks after the first appearance of a rash.

Initial treatment with antiviral therapy reduces the risk of chronic ocular complications by 20% to 30%. Initial treatment for HZO ideally begins within the first 72 hours of symptom onset. Antiviral options include acyclovir 800mg orally five times a day for at least seven days, valacyclovir 1000mg orally every eight hours for at least seven days or famciclovir 500mg orally three times per day for at least seven days. If the patient is immunocompromised, intravenous acyclovir or foscarnet may be necessary. When considering IV antivirals, keep in mind that there is a higher association with acute kidney injury and renal failure due to intratubular crystal precipitation and rapid excretion in the urine. Preventative treatment includes the vaccine, which can reduce the risk of viral reactivation; however, this only lasts for about eight ears.

The treatment and management of recurrent disease can be incredibly challenging. Often, prophylaxis treatment is given due to evidence that, during clinically quiescent times, subclinical viral transcription and translation may occur when an intact cell-mediated response is disrupted. Management becomes even more difficult since there is no consensus on exact dosing, frequency, duration or even the effectiveness of dosing.

The Zoster Eye Disease Study (ZEDS) is a prospective, multicenter, randomized control trial seeking to determine if prolonged suppressive antiviral therapy (Valtrex 1g daily) reduces anterior segment complications with HZO. In a survey conducted by the ZEDS investigators, over half of respondents reported using oral antivirals for a prolonged period for treatment of HZO. Long-term prophylactic antiviral treatment of acyclovir 400mg BID is often used to prevent reactivation of varicella zoster virus in the eye; however, this is not yet evidence-based. In this case, our patient was taking the valacyclovir dosage equivalent or higher than the recommended prophylac-
The patient presenting with nummular stromal keratitis caused by HZO.

...lack of appetite, loss of interest, tiredness and trouble sleeping. There have not been long-term studies on the Valtrix use for ocular herpes zoster, but there are many studies on its long-term use for genital herpes. In these, long-term use of valacyclovir (≤1,000mg per day) or acyclovir (800mg per day) was not associated with hematologic or clinical chemistry abnormalities. Valacyclovir use in immunocompromised patients can be more concerning due to possible liver function abnormalities. When choosing to prescribe oral antivirals (valacyclovir, acyclovir, etc.), renal impairment must be considered.

Another component in this case that we will have to manage long-term is the use of topical steroids. Our experience with this patient taught us that we cannot taper off topical prednisolone at this time, even if the patient appears quiescent and is on prophylactic orals. The patient has already had two slow tapers over the period of a month, in which his condition returned. Therefore, a lengthy conversation about the potential side effects of long-term topical use of steroids took place. The patient and providers agreed that the risks from topical steroids did not outweigh the potential loss of sight, and he will now only be tapered to BID until his cornea is clear for an extended period. During this time, we will continue to monitor his IOP and perform comprehensive exams.

The lessons learned from this patient were vast, starting with knowing there is not a standard protocol for managing patients once their initial HZO outbreak has healed. Literature evidence on taking oral Valtrix at higher dosages for extended periods of time has been proven safe when tested for other conditions; therefore, clinicians should be less eager to taper their patients off their oral antiviral quickly. Talking to patients about the side effects of long-term topical steroids and the risk of tapering them off too fast must be done at initial presentation. This way, both the patient and the doctor can feel confident in treatment until the virus has gone back into latency.

Deplore the Spore

Fungal keratitis is often resistant to therapy and poses serious risk to ocular health.

A 57-year-old contact lens wearing male presented with a corneal ulcer OS. He was doing yard work and said he may have gotten something in his eye. The next day, he noticed irritation and difficulty focusing. His local optometrist started him on moxifloxacin and cyclopentolate OS. As irritation and blurred vision continued to worsen, a local ophthalmologist added erythromycin and valacyclovir. Three days later he lost vision in the left eye and was referred to a cornea specialist, who added fortified vancomycin and fortified tobramycin. When he did not improve, he was referred to the ED.

In our hospital-based ophthalmology department, corneal scrapings stained positive for fungal elements. He started on topical natamycin and oral fluconazole. Two days after, he felt improvement with less pain. Although the epithelial defect was smaller, he had mild corneal melting, so medroxyprogesterone was added.

Fungal keratitis is a challenge to diagnose and treat. Over 100 fungal species have been implicated, the most common being *Fusarium, Candida* and *Aspergillus*. *Candida* predominantly invades pre-existing epithelial defects, while filamentous fungi are commonly implicated in post-traumatic infections. Risk factors for fungal ulcer include contact lens wear, ocular surface disease, topical steroid use, atopic disease and trauma (specifically exposure to vegetative matter).

Fungal origin should be suspected any time there is an unusual presentation of keratitis not responding to therapy. It may appear as stellate lesions with an intense inflammatory response and tissue necrosis. Fungi can also infiltrate the sclera and induce scleritis and pan-ophthalmitis, or breach Descemet’s and cause fungal endophthalmitis.

Definitive diagnosis is made with Giemsa or Gram stains, although PCR and confocal microscopy are also sensitive techniques. It is also prudent to PCR test for HSV and confocal/scrape for *Acanthamoeba* at presentation.

Natamycin 5% is first-line treatment. Voriconazole 1%, considered to have better penetration, may be a superior alternative. Steroids are contraindicated due to risk of fungal proliferation. However, medroxyprogesterone was added as a protective agent due to its anti-collagenase activity. It reduces inflammation with less wound repair suppression. There is a high risk for vision loss with fungal keratitis and diagnosis should be made quickly.
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