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## ON THE COVER
Optometry student photoshoot image courtesy of Cardiff University in Cardiff, Wales, United Kingdom.
IN BRIEF

Certain characteristics including increased vascularity may be a risk factor for recurrence of pterygium following surgery, reports research published online in the journal Cornea. Researchers in Korea collected clinical and demographic variables of 149 subjects including length, width, area and vascularity of pterygium and age and sex of patients. Anterior segment photos were taken prior to the procedure, and patients were followed up at one year postoperatively. Recurrence rate was defined as 8.8% of the patients, with univariate analysis demonstrating that relative length and width of the pterygium and degree of vascularity were all correlated with the trend. Multivariate analysis, however, demonstrated only higher vascularity was correlated with recurrence. As such, automated image analysis of anterior segment photos could assist with determining which patients might develop pterygium again, the researchers concluded.


Soft contact lens wearers with dry eye symptoms may also exhibit reduced tear menisci, reports a study in the May 2016 issue of *P&CL*. A reduction in tear volume is one of the common factors associated with ocular surface disease, in which previous research has indicated there are more abnormal corneal nerve morphologic changes in patients with the aqueous tear deficiency form of dry eye. However, to date no research has examined whether symptomatic contact lens wearers have had a similar reduction in corneal nerve density due to reduced tear volume. In this study, scientists in China found that upper and lower tear menisci height and area were significantly lower in patients who wore soft contact lenses, compared with those who did not. Interestingly, this effect occurred specifically in the midperipheral area of the cornea.


A study investigating corneal densitometry and higher-order aberrations (HOAs) one year post-photocoagulation of Bowman’s layer found that corneal HOAs decreased for both anterior and posterior corneal surfaces following surgery, while corneal backscattering increased. Neither trend correlated with alterations in corrected distance visual acuity, however. These results, published online in the journal Cornea, suggest further research involving larger populations with patient-specific visual outcomes and contrast sensitivity analysis is needed to help further explain the effect of corneal backscattering on optical quality.


Considering New Treatments for Neovascularization

Aflibercept may be a better alternative than bevacizumab in regulating the advancement of corneal neovascularization, reports research published online in the journal *Cornea*. Previous studies have investigated whether targeting vascular endothelial growth factor—a key cytokine in the development of blood vessels in both normal and abnormal patients (i.e., in the case of a tumor or in tissues undergoing abnormal angiogenesis)—is a good way to possibly treat this condition.

Researchers from Tel Aviv University in Israel investigated the effects of aflibercept or bevacizumab administered to Sprague-Dawley rats with induced chemical burns. Thirty-one animals were randomly divided into both the control and bevacizumab groups; the latter is not as effective in this application. In conclusion, this suggests that aflibercept may hold promise as an effective modality for use in patients with corneal neovascularization,” the researchers conclude. As such, “further investigation is warranted to determine the efficacy of subconjunctival aflibercept in inducing regression of preformed versus mature corneal vessels, its minimum effective dose and safety profile and other possible modes of application in animals and humans.”


Study on SPK Lesion Size May Lead to Better Equipment

Data from a study on epithelial lesion size in superficial punctate keratitis (SPK) could help with the development of automated algorithms to obtain more objective and reliable classifications for corneal staining, report researchers from France in the journal *Cornea*.1

The isolated lesions that so often characterize SPK are small fluorescent dots of differing size and intensity that are scattered across the corneal surface. In some cases, they can become confluent, creating fluorescent areas in which the individual lesions are no longer distinguishable. Because the number and specific locations of these dots is an important clinical criterion directly connected to the level of surface integrity, differentiating between them is critical—especially during clinical trials. The new algorithms could help ease this issue.

In this study, the team from Jean Monnet University, the University Hospital of Saint-Etienne and the Institut Universitaire de France instilled fluorescein into 10 patients with dry eye graded using the Oxford Scheme. Pictures were taken using a standard slit lamp with cobalt blue light and no barrier filter to simulate the most common conditions of image acquisition.

Two magnification settings (i.e., x10 and x16) were used to focus on the corneal objects in question that measured 14.40µm and 7.81µm under each setting, respectively. SPK size did not differ between the five Oxford Scheme grades of dry eye, but did appear to be slightly smaller than typical superficial epithelial cells, which measure approximately 25x50µm.

“Our data on the size of SPK staining lesions in this study is not directly relevant to clinicians,” the researchers acknowledged. “However, it will prove useful for researchers developing new devices and image analysis algorithms to improve SPK severity grading. Indeed, if the size of isolated epithelial lesions characterizing SPK is known, it will be possible to optimize device resolution to detect individual lesions using the appropriate filters or thresholds and ultimately to precisely quantify corneal staining.”

Surgical Trends

A national study from Switzerland suggests the number of keratoconus-related corneal transplants has decreased in the last 10 years, while lamellar techniques are being increasingly performed. Furthermore, among anterior lamellar keratoplasty techniques, maximal depth DALK is the most prevalent keratoplasty. Frequency of penetrating keratoplasty (PKP) is expected to remain stable!


Corneal Crosslinking: Its Time Has Come

Though the main treatment for ectasia remains contact lens use, a new procedure could ease the fitting ordeal.

The Food and Drug Administration’s recent approval of the corneal collagen crosslinking procedure in the United States means that we have gained another valuable tool for treating eye disease. Photrexa Viscous (riboflavin 5’-phosphate in 20% dextran ophthalmic solution) 0.146%, Photrexa (riboflavin 5’-phosphate ophthalmic solution) 0.146%, and the KXL system (Avedro) will be promoted as the only current FDA-approved therapeutic treatment for progressive ectatic disorders like keratoconus.

The approval process for this technology included three separate studies over a period of several years that were ultimately combined for meta-analysis to provide reasonable assurance of both safety and efficacy. The NDA submission studies were randomized (i.e., treatment eye vs. sham treatment), parallel group, open label placebo-controlled 12-month trials conducted in the United States. Resulting data found that the collagen crosslinked eyes demonstrated increased improvement in their steepest keratometric readings from month three to month 12.1 Yet while the system has been approved for use, many eye care practitioners may still have questions regarding the procedure itself—namely, what does it involve and what are the goals to focus on when recommending corneal crosslinking to a patient? In general, the procedure is simple to perform. It involves use of a photosensitizer/enhancer (i.e., riboflavin) that helps “cure” the cornea with application of UVA light at 365nm to 370nm for approximately 30 minutes provided at well-defined intervals and strength levels. The goal of the procedure is to halt further progression of corneal disease and reduce corneal surface and posterior irregularity in patients with corneal ectasia.2 Total office visit time for both eyes is roughly 90 minutes.

IN THE CHAIR
The procedure works on the principle that when collagen fibrils are crosslinked, they form strong chemical bonds with one another.2 As we age, the cornea naturally forms stronger bonds due to an oxidative process that occurs during end-stage changes to the collagen. This may help explain the fast progression of corneal weakening that happens earlier in life in patients who develop keratoconus.2,3 The Europeans were the first to employ corneal crosslinking at the University of Dresden in 1998 when animal model corneas exposed to riboflavin and treated with UV light were found to be “stiffer” and resistant to enzymatic change over time.2

Potential candidates for the procedure include anyone with progressive ectasia, though most often the procedure is performed on those with keratoconus. Note, however, there are a few contraindications like advanced ocular surface or autoimmune disease, significant corneal scarring or opacity, infection or prior herpetic disease. These are listed as such because irradiation is part of the procedure.

Interestingly, adjunct studies to evaluate corneal crosslinking’s efficacy in treating corneal infections are still being conducted; however, results to date remain mixed. Additionally, though this is less of a concern in cases when the epithelium remains in place during the procedure, corneal thickness cannot be exceedingly thin or there is risk of toxicity to the endothelium.

Investigators continue to look for alternatives for crosslinking beyond use of riboflavin and UVA, such as use of rose Bengal as a marker and green light for treatment. In the meantime, however, Avedro should be congratulated for sponsoring several well-designed clinical trials that went beyond simply including the observational evidence that was originally submitted for review. Considering the limited number of potential patients and the uncertainty regarding whether insurance carriers will provide coverage, Avedro remained committed throughout the approval process. They may eventually be able to expand indications for this procedure to include treatment of infectious keratitis, pain relief in bullous keratopathy and other novel indications.

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Recycling Cyclosporine

New formulations of an old drug may mean better treatments for dry eye.

These days, it seems that there is such a heavy emphasis on drug delivery systems that many of our current ophthalmic pharmaceuticals are simply being reformulated as “novel” therapies, rather than replaced entirely.1 Because the shortcomings of topical drops are well-known, these delivery systems are aimed at eliminating variability in drug concentration with each dose to decrease dose frequency and increase absorption.2

FIRST OUT

One such drug is CyclASol (Novaliq), which incorporates EyeSol, an ophthalmic drug delivery technology based on semi-fluorinated alkanes (SFAs).3 SFAs have been used for over a decade in the management of retinal detachments and overall have been well-tolerated by patients. They are physically, chemically and physiologically inert and stable as well as water insoluble.4,7 Research shows the EyeSol preparation does not require preservatives, so a multidose bottle can be prepared without concern for contamination. Droplet size of SFAs is only 15µl compared with the 40µl or 50µl size of aqueous drops. SFAs also exhibit low viscosity and low surface tension, making them less likely to cause blurry vision and allowing for better wettability.3

Viscous vehicles like polyethylene glycol and hyaluronic acid currently used for ophthalmic solutions can effectively solubilize hydrophilic drugs. However, drugs that are lipophilic (i.e., hydrophobic) like cyclosporin A are more challenging; as such, SFAs are effective solvents for these medications.5,6 CyclASol contains cyclosporin A in combination with perfluorobutylpentane, a unique formulation with an SFA.

Earlier this year, 207 patients were enrolled in a Phase II clinical trial of CyclASol’s safety, tolerability and efficacy in treating moderate to severe dry eye disease. Patients were randomized into one of four treatment groups, including two CyclASol groups (each containing a different concentration of cyclosporin A), a vehicle control group and an open-label cyclosporin A 0.05% ophthalmic emulsion (Restasis) group. Patients were directed to use the study medication twice a day for four months; researchers will then evaluate the primary outcome measure of corneal fluorescein staining. Results are expected by the end of 2016.4

Other research has already demonstrated the drug’s absorption profile. In a pharmacokinetic study involving rabbits, CyclASol penetrated the lacrimal gland significantly better (14-fold increase) than an oil-in-water emulsion.7 Additionally, results from a Phase I trial of healthy volunteers who received CyclASol eye drops or a placebo and then switched to the alternate option in the second phase of the study found the drug offered excellent tolerability and safety.2

SECOND ONE IN THE RUNNING

Another drug under consideration is Seciera (Auven Therapeutics), a nanomicellar formulation of cyclosporine previously known as OTX-101. Nanomicelles are tiny particles comprised of a hydrophobic core surrounded by a hydrophilic shell that measure 10nm to 100nm large. They are used to solubilize hydrophobic drugs and are believed to increase ocular bioavailability, minimize degradation and improve penetration of the drug—all of which make them an excellent drug delivery method. Use of nanomicelles allows for cyclosporine to be formulated in a clear, preservative-free, isotonic aqueous solution.9,10

In a Phase IIb/III clinical trial, 455 patients in a randomized, double-masked study at 28 sites received either 0.05% cyclosporine, 0.09% cyclosporine or the vehicle as the control. All drops were administered twice a day for 84 days. Co-primary outcome measures consisted of changes in both conjunctival staining and global symptom scores from baseline. Results indicated both concentrations of Seciera were statistically superior to the placebo on both co-primary endpoints. Additionally, the 0.09% concentration also demonstrated an improvement in tear production and corneal staining.

Ultimately, however, the 0.09% concentration was superior to the 0.05% and so will be used in an additional Phase III trial to confirm some of the earlier findings.5,11 This study will enroll 700 patients at 50 sites who will be randomized to receive either cyclosporine 0.09% or the vehicle (control) for 12 weeks. Researchers will look for the number of subjects with a clinically significant increase in Schirmer’s score as compared with baseline. Secondary measures include lissamine green conjunctival...
staining, fluorescein corneal staining and changes in symptom score. Enrollment for this study began in February 2016. It is expected to conclude by the end of the year. Reports suggest a long-term safety study is also planned for 2016 that, if successful, may yield a new drug application for Seciera in 2017.

**KICKING KERATITIS TO THE CURB**

Ikervis (Santen Pharmaceutical) was approved last year as the first topical ophthalmic drug to treat severe keratitis in adults with dry eye in Europe. Ikervis contains 1mg/mL of cyclosporin A and is formulated as a cationic oil-in-water emulsion. Drug retention time was improved using a cationic nanoemulsion platform technology (i.e., Novasorb). The drug is formulated as a series of nano-sized droplets, which increase the surface area-to-volume ratio and improve ocular surface exposure to the drug, allowing Ikervis to be given to the patient just once a day. Also, Santen recently completed a Phase III study, Vektis, evaluating a 1mg/mL formulation of cyclosporin A for the treatment of severe active vernal keratoconjunctivitis (VKC) in Europe. The drug—tentatively named Vekacia—met its primary and key secondary endpoints in a multicenter, randomized, placebo-controlled study of patients ranging in age from four to 18 years old.

**CYCLOSPORINE REBORN**

Allergan announced last fall it had submitted a supplemental document to the FDA for approval of a multi-dose preservative-free bottle of cyclosporin A 0.05%. The bottle will contain the equivalent amount of 60 single-unit vials and is a first-of-its-kind product with a unidirectional valve and air filter technology designed to prevent the need for a preservative to be included. The FDA did request more chemistry, manufacturing and control (CMC) information regarding the bottle.

Monitoring clinical trial outcomes of these drugs will surely be an interesting process. Restasis may soon have to share the limelight with more cyclosporine-based cousins.

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**What’s In a Name?**

Cyclosporine was initially developed to suppress the immune response and prevent organ rejection in transplant patients. It was later brought to market in 1983 for oral and parenteral administrations; however, the drug exhibited poor solubility and had widely variable bioavailability, so it was then formulated as a microemulsion in 1995 to address some of the malabsorption concerns. The drug is referred to by at least three nonproprietary names: cyclosporine by the United States Adopted Names Council, cyclosporin by the British Pharmacopoeia and cyclosporin as the drug’s international non-proprietary name designed by the World Health Organization. It is also commonly referred to as cyclosporin A, as an alternative to cyclosporine, in some applications.
Widespread change is happening at a breakneck pace in the ophthalmic field, though new research and concepts for future studies remain cornerstones for all advancements. This year’s Association for Research in Vision and Ophthalmology’s (ARVO) meeting in Seattle, Wa. offered practitioners a peek at some of the newest discoveries and advances designed to aid in clinical practice. Areas of study included dry eye and associated comfort issues, keratoconus and its treatments and bacterial infections related to contact lens wear.

INFECTION AND INFLAMMATION
Data collected on antibiotic resistant-bacteria highlights changing trends, report researchers who evaluated the frequency of methicillin-resistant *Staphylococcus* (MRS) keratitis as it appeared in a referral ophthalmology center in Mexico City, Mexico from February 2014 to February 2015.\(^1\) The bacteria identified via diagnosis of infectious keratitis and positive culture predominantly included *Staphylococcus*, with those organisms that were drug resistant noted as being non-responsive to oxacillin and/or cefoxitin disk diffusion. These results are concerning because resistance to multiple antibiotics means treatment options are limited.

Antibiotic resistance trends should be kept in mind when selecting therapy preoperatively, researchers from New York suggest.\(^2\) Use of topical antibiotics is key to help with minimizing intraocular infections prior to and following surgery, as bacterial resistance continues to be a prevalent issue and can inhibit an otherwise positive therapeutic effect. In this study, the investigators examined the resistance profiles of common bacterial pathogens to the antibiotics that are routinely used by ophthalmologists. One hundred and seventy-two aqueous and vitreous humor isolates of note were collected from the ARMOR surveillance study, including 11 with *Haemophilus influenzae*, 10 with *Pseudomonas aeruginosa*, 21 with *Streptococcus pneumoniae*, 30 with *Staphylococcus aureus*, and 100 with coagulase-negative *Staphylococci* (CoNS). Minimum inhibitory concentrations (MICs) were determined by broth microdilution and the isolates were categorized as susceptible, intermediate or resistant according to systemic breakpoints. Results from the study indicated antibiotic resistance was most prevalent among *staphylococci*, particularly CoNS, with higher rates of opposition observed to azithromycin, ciprofloxacin and oxacillin/methicillin. At least 70% of the methicillin-resistant *staphylococci* samples collected demonstrated multidrug resistance; furthermore, among *S. pneumoniae* isolates, resistance was highest to azithromycin, chloramphenicol and oral penicillin.

Another study evaluated povidone iodine (PI) as a potential disinfecting solution for contact lenses, focusing on its antimicrobial efficacy against ocular bacterial strains in planktonic form and following biofilm formation in the contact lens case.\(^3\) Researchers in New South Wales, Australia found that the PI solution performed exceptionally well against the planktonic forms of all bacteria strains tested; in fact, no viable organisms were recovered following the minimum recommended disinfection time. The PI solution was also effective to varying degrees at removing the bacterial biofilm; air-drying or wiping the lens case

ABOUT THE AUTHOR
Dr. Shovlin is the senior optometrist at Northeastern Eye Institute and a member of the adjunct faculty at the Pennsylvania College of Optometry. He is also the clinical editor for *Review of Cornea & Contact Lenses*, associate clinical editor for *Review of Optometry* and president-elect for the American Academy of Optometry.
with a tissue and then air-drying was deemed most effective (71% of the biofilm was removed), while recapping the lens case wet was less so (35% removed). As such, results demonstrate not only that ocular strains of bacteria are susceptible to povidone iodine in planktonic and biofilm form, but also reiterates the importance of air-drying in maintaining lens case hygiene.

Directed energy at certain wavelengths may be capable of eliminating the presence of *Acanthamoeba* from contact lenses and lens cases, report researchers in Pennsylvania, who hypothesized that certain levels of ultraviolet energy administered with and without riboflavin will eradicate *Acanthamoeba* while maintaining the clarity of the contact lens. To test this theory, the team administered multiple modes of energy in microjoules/cm² x 100 in a dose-dependent manner. Three groups were prepared: *Acanthamoeba castellanii* (10⁶ cysts in saline) exposed to just UVE; *Acanthamoeba castellanii* (10⁶ cysts in saline) plus soft contact lens exposed to just UVE; and *Acanthamoeba castellanii* (10⁶ cysts) plus soft contact lens exposed to UVE in a saline solution or 0.01% riboflavin. The soft contact lenses were evaluated for clarity following exposure via spectrophotometry. Results indicated a total UVE amount of 89,991 microjoules/cm² x 100 for a time length of 180 minutes is required to eliminate the presence of *Acanthamoeba castellanii* in all three groups.

Though the rate of complications associated with scleral lens wear remains low, certain issues continue to be prevalent and should be further monitored, according to researchers from Minnesota, Illinois, Ohio and Massachusetts, who collected data from a 19-question survey regarding scleral lens wear and management practices administered to eye care practitioners between January 12, 2015 and March 31, 2015 by the Mayo Clinic Survey Research Center. Nine hundred and eighty nine individuals responded to the survey, 723 of whom reported fitting five or more patients with scleral lenses for a total of 84,735 scleral lens patients represented. Reported issues included edema, neovascularization, infiltrates, toxic keratopathy, bullae and microbial keratitis as well as limbal stem cell compromise, elevated intraocular pressure, uveitis and retinal detachment. Handling error was reported as the primary cause of these problems in 448 patients.

**DRY EYE**

Keratoconjunctivitis sicca (KCS) pathology may be improved via topical antioxidant therapy, report researchers from the United States, Finland and Lithuania. In this study, six-week-old mice were exposed to a desiccating environmental chamber with airflow and humidity levels set at 15 L/min and 5%, respectively, for 10 days. Each mouse received transdermal scopolamine in their left eyes twice daily with superoxide dismutase (SOD) mimetic Manganese (III)-5,10,15,20-tetrakis (N-methylpyridinium-2-yl) porphyrin Pentachloride (MnTM-2-PyP, EMD Millipore) diluted in physiological saline at 0.05%. Their right eyes served as controls and were treated with saline. Study results indicated the topical administration of the MnTM-2-PyP significantly improved lacrimal gland pathology compared with the effects of the saline control, suggesting topical antioxidant therapy may be feasible as a treatment for KCS.

A study from investigators at Cornell Medical College, University of Illinois College of Medicine and Indiana University of Medicine suggested exposure of the corneal surface to hyperosmotic tears may cause considerable damage to corneal subbasal nerve fibers. The researchers studied the relationship between tear hyperosmolality and corneal nerve abnormalities for the recorded first time ever in an effort to explain the common signs and symptoms associated with dry eye disease. Results indicated the
responses of the corneal neurons to the drying of the cornea were depressed or completely abolished by hyperosmolar tears in a timely and dose-dependent manner. The researchers observed that the disappearance of action potentials occurred as quickly as two minutes, but generally within three hours following application of the tear solutions and suggested these findings are consistent with the abnormal activities of trigeminal ganglion neurons demonstrated by electrophysiological recordings and may account for the signs (i.e., morphological abnormalities) and symptoms (i.e., abnormal sensations) reported in dry eye patients.

Dry eye disease may also play a role in inhibition of corneal graft survival, says a team of scientists from Schepens Eye Research Institute, Harvard Medical School and the Juntendo University School of Medicine in Japan. These researchers evaluated the effect of the condition on allosensitization and graft rejection by transplanting healthy corneas with dry eye disease from donor mice onto recipient mice. Graft survival rates and opacity scores were evaluated with slit lamp biomicroscopy. Corneas and draining lymph nodes were harvested at day 14 post-transplant and findings demonstrated that the transplant recipients with the DED donor corneas demonstrated significantly reduced graft survival (i.e., 10%) as compared with control mice (50% survival).

Other research from Germany on omega-3 fatty acids (O3F) indicates they could be used as potential topical adjunct therapy for dry eye. Oral and topical treatments that use omega-3 fatty acids have previously demonstrated positive effects on the severity of dry eye. In the current study, experimental dry eye (EDE) was induced in mice and topical therapy was administered. Therapeutic treatment of mice with omega-3-fatty acids using a semi-fluorinated alkane (F6H8) as a preservative-free lipophilic carrier demonstrated a significantly earlier decrease of epithelial damage following EDE as compared with untreated controls or another treatment. The amount of tear fluid also increased following O3F/F6H8 treatment as compared with levels of the same in untreated controls or those treated with F6H8 alone or with artificial tears, as did the number of goblet cells.

Additionally, anterior segment optical coherence tomography (AS-OCT) may be appropriate for clinicians to use in assessing the level of ocular dryness in patients with conjunctivochalasis, report researchers from the University of Jukui in Japan, who compared tear meniscus area and height in patients with the disease and those with normal eyes. Potential relationships between TMA or TMH and fluorescein film tear-breakup time, fluorescein staining score and the extent of conjunctivochalasis were also evaluated in the conjunctivochalasis group. Results indicated that conjunctivochalasis eyes exhibited a reduced TMA and increased TMH as compared with the normal eyes. Note, a more severe dry eye condition in conjunctivochalasis is commonly associated with a reduction in TMA, despite a high level of TMH due to the conjunctival fold. As such, AS-OCT technology may be appropriate for use in this type of patient scenario.

Japanese researchers in the field also suggest that addressing the presence of patient sleep disorders may help alleviate cases of dry eye. A cross-sectional case control study involving 715 outpatients diagnosed with DED, chronic conjunctivitis or allergic conjunctivitis incorporated the Pittsburgh Sleep Quality Index (PSQI) and Hospital Anxiety and Depression Scale (HADS) as a means to evaluate their well-being. Regression analysis of patients with DED revealed correlations between higher PSQI and HADS and the...
presence of DED, rather than other forms of ocular surface disease. There was also a connection to the condition's level of severity, further raising quality-of-life concerns and supporting the theory that providing psychiatric help to address a patient's sleep issue may have a direct effect on the improvement of their ocular health.

Patients who use digital devices throughout the day, regardless of their age, may experience adverse impacts on their work performance, productivity and quality of vision, suggests a team of researchers from Illinois, Pennsylvania, California and Tennessee. Overall, eye care practitioners have noted an increase in dry eye symptoms as the use of digital devices—including handheld tablets, smartphones, laptops and computers—increases. Data collected from questionnaires related to digital device use as well as additional answers regarding vision fluctuation concerns and contact lens wear were used to generate results for the study. Six hundred and eighty-six subjects were evaluated, with the average number of hours spent on devices per day noted at 6.35 hours for the <40 age group and 4.83 hours for the >40 age group. Average ocular comfort was recorded on a scale of one to ten as one at the beginning of the day and seven at the end of the day following gratuitous digital device use, further demonstrating a positive correlation.

A second study organized by researchers in Indiana and California in cooperation with CooperVision found that frequent and severe eye fatigue is prevalent among soft contact lens wearers who use digital devices. Previous reports have found that eye strain or eye fatigue occurs in roughly 60% of student and working populations that use digital devices and typically results in a notable decrease in quality of life. This study attempted to quantify the symptoms most frequently associated with eye fatigue while using digital devices in soft contact lens wearers, who were asked to complete a survey with questions pertaining to the condition. Eighty-eight percent reported experiencing eye fatigue once per month, while 74% reported experiencing eye fatigue at least once per week. Reported symptoms included dryness, eye irritation, eye strain and tired eyes. Strain, soreness, tiredness and headache comprised primary sensation factors, while burning, irritation and dryness comprised the secondary sensation factors in the study. Additionally, blurring, doubling and moving/ floating were noted as visual sensation factors. The researchers concluded that frequent and severe eye fatigue is highly prevalent among the population of soft contact lens wearers that use digital devices, and that the recorded symptoms can be used to better identify members of this population.

According to German investigators in Cologne who examined the onset of DED pain symptoms like burning, stabbing or photophobia that presented without accompanying clinical signs including normal visual acuity, intraocular pressure, Schirmer test and corneal fluorescein staining in combination with pathological Ocular Surface Disease Index score, there is a correlation between patients with a discrepancy of signs and symptoms in dry eye that are resistant to therapy and the presence of psychosomatic diseases and/or previous eye surgery. Typically, in these cases of symptoms without signs, corneal neuralgia is postulated; however, the results from this study that indicate the co-morbidities of psychosomatic disease or prior eye surgery suggest there may be different sensitization pathways for the proposed development of corneal neuralgia than previously believed. Furthermore, incomplete analgesia following topical corneal anesthesia supports the assumption of a central sensitization that would explain the resistance to topical therapy, the researchers concluded.

A cross-sectional study open to all participants of the American Academy of Optometry's 2015 annual meeting suggested that the
Standard Patient Evaluation of Eye Dryness (SPEED) questionnaire may not be as successful at detecting dry eye in contact lens wearers as it is in those who do not wear lenses. One-hundred and fifty contact lens wearers and 134 non-lens wearers elected to participate in the study by answering the questions listed as part of the SPEED questionnaire and undergoing tear meniscus height photographic assessment and tear volume testing. Unfortunately, while the questionnaire was accurately able to predict the dry eye status in non-contact lens wearers, it was unable to predict the same in those wearing lenses. The researchers concluded additional work should be conducted to further assess the study’s usefulness in contact lens wearers.

Furthermore, artificial tears may be less beneficial than initially believed for patients with ocular surface disease, according to investigators from Virginia who incorporated a modified version of the Schirmer test into their research. Study participants were divided into three groups: a control group not treated with artificial tears, a group with ocular surface symptoms that responded to artificial tear treatment, and a group with similar ocular surface symptoms that did not respond to the tears. No significant difference in standard Schirmer test scores, modified Schirmer test scores, punctate epithelial erosion presentation (PEE), meibomian gland dysfunction (MGD), blepharitis tear break-up time (TBUT) or Ocular Surface Disease Index (OSDI) scores was noted in any group. The researchers concluded that current clinical tests are not able to adequately identify the subset of patients who might most benefit from artificial tear use. Given the low cost and morbidity of artificial tear treatment, they suggest a trial treatment of the prescribed drops be performed in patients with chronic ocular surface symptoms and add that future studies should take into account the type of artificial tears used as well as frequency of use.

KERATOCONUS AND ITS POTENTIAL REMEDIES

In Australia, investigators examined changes in corneal sensitivity and their association with other clinical parameters in keratoconus patients. Ocular symptoms using validated questionnaires, corneal topography, tear osmolarity, tear meniscus height measurement, tear volume, ocular surface staining with fluorescein and lissamine green dye, corneal sensitivity using Cochet-Bonnet aesthesiometer and corneal nerve mapping using HRT II confocal microscopy were recorded, and correlations were made using either Spearman’s or Pearson’s coefficient. Subjects were graded as having either mild or severe keratoconus, and partial correlation was performed to control the effect of confounding factors. Only data from each patient’s most severe eye was included in the study. Results found central corneal sensitivity to be lower in the severe keratoconus group, while in bivariate correlations, decreased corneal sensitivity in keratoconus was associated with condition severity, lower central nerve fiber density, contact lens wear, contact lens tolerance, patient age and duration of disease. Researchers further observed a distinctive trend in which age and duration of keratoconus was also associated with decreased corneal sensitivity and that contact lens wear-intolerants exhibited higher corneal sensitivity compared with tolerant wearers. They concluded that decreased corneal sensitivity was associated with age and duration of disease, and that reduced tolerance of keratoconic patients to contact lens wear was associated with increased corneal sensitivity.

Hair cortisol concentration as a biochemical correlate of chronic psychological stress may be an observable risk factor for keratoconus, report German scientists who analyzed strands of hair taken from both healthy and keratoconic

A slit lamp view of a keratoconic patient with hydrops. Research is increasingly looking at the implications of this irregular corneal condition and potential methods for its management.
patients. As hair segments of 3 cm in length represent the prior three-month stress profile of an individual, the researchers used sections of hair this length located most proximal to the scalp. Cortisol levels were determined using the hair by the Institute of Biopsychology of the TU Dresden; a standardized questionnaire for chronic stress was also administered to all subjects. Results indicated hair cortisol was higher in patients with progressive keratoconus compared with those with a stabilized form of the disease or those who were healthy. Furthermore, the study suggested increased hair cortisol concentration could be a risk factor for the progression of keratoconus.

Other research from Germany supports the concept that axis alignment could be used in an algorithm to support the diagnosis and staging of keratoconus. Scientists compared the power and axis orientation of anterior and posterior astigmatism in 861 eyes with keratoconus and 500 healthy eyes as part of a retrospective study, finding posterior axis alignment of corneal astigmatism is in line with the alignment of the anterior surface in the majority of cases of keratoconus. In contrast, the majority of the healthy eye group demonstrated a vertical posterior axis alignment independent of anterior astigmatism. The difference is attributed to the inadequate regeneration of nerve fibers in the corneal stroma.

Other abstracts from ARVO 2016 highlight alternative treatment options, surgical techniques and potential concerns on the horizon to be aware of. As always, practitioners are encouraged to review the full list of available abstracts, not just those chosen for this report. So, go take a look!

Despite the advances in PRK and LASIK in the past two decades, there are still patients who have complications from these procedures that keep them from experiencing the vision they expected. In these circumstances, contact lenses can help restore vision. However, many individuals who have elected to undergo surgery are often unhappy about the idea of wearing correction again. Therefore, it is important to be both skilled and efficient at fitting contact lenses for this population.

Gas permeable (GP) lenses are a good choice for fitting patients after refractive surgery. These lenses have excellent optics and can mask several diopters of regular and irregular astigmatism. Additionally, the practitioner has complete control over the lens parameters and the lenses can be made in high Dk materials. This article will review GP lens fitting after refractive surgery using a series of case studies.

**CORNEAL SHAPE CONSIDERATIONS**

Fitting patients who have undergone refractive surgery is challenging due to their altered corneal shape. A typical cornea has a prolate shape, i.e., steeper centrally with flattening towards the periphery. The rate of flattening towards the periphery can be described by its eccentricity value. Normal corneas typically have eccentricity values of 0.5 to 0.7.

Hyperopic LASIK/PRK is accomplished by ablating the peripheral cornea in order to steepen the central cornea. These patients have a corneal profile similar to keratoconus and an eccentricity value of greater than 1.0. And so, keratoconic design lenses can be helpful in fitting those who have had a hyperopic procedure done.

Myopic surgery is accomplished by ablating the central cornea in order to make it flatter, which causes the peripheral cornea to steepen. This reverse corneal configuration is oblate in shape and has a negative eccentricity value. A reverse geometry design contact lens can be used to align better with the corneal profile of a patient who has had myopic refractive surgery.

The initial contact lens design after refractive surgery can be determined by looking at the eccentricity value. Values greater than...
1.0 could be fit into a keratoconic lens. If the eccentricity value is negative, consider fitting a reverse geometry design.3

Corneal topography can also help practitioners choose contact lens parameters after refractive surgery. The initial base curve of a corneal GP lens can be determined after refractive surgery by taking an average dioptric curvature 4.0mm away from the center on axial curvature maps and 2.0mm on tangential curvature maps.4 Additionally, a height map shows linear distances between positions on the cornea and a reference sphere. This reference sphere over the cornea gives an idea of what the GP fluorescein pattern may look like.5 And so, a base curve calculated from a tangential or axial map could be applied as a curvature reference sphere on a height map to see how a corneal GP lens may fit on the eye.

CORNEAL GP LENSES
The notable differences in shape present between ablated and non-ablated corneal areas after refractive surgery can make GP lenses challenging to fit. Often, corneal GPs do not exhibit a classic alignment pattern on a surgically altered cornea. Instead, there will be pooling in flatter ablated areas and bearing over the steeper untreated areas. Nonetheless, this may be acceptable as long as there is adequate lens movement and room for a healthy tear pump behind the lens, and if the lens does not cause any harsh areas of punctate erosion.

Hyperopic procedures leave the cornea highly prolate. Patients who have had hyperopic refractive surgery can be fit into keratoconic lens designs.1,3 In contrast, myopic refractive surgery will cause the cornea to become oblate in shape; a reverse geometry design in which the base curve is flatter than the adjacent peripheral curve will align better in oblate corneas.1,3

Iatrogenic corneal ectasia following myopic corneal refractive surgery results in anterior bulging of the ablated cornea to cause a keratoconus-like situation. This poses a unique challenge in fitting corneal GP lenses because the topography will have a combination of steeper areas at the apex of the cone and in the untreated periphery, and will be flatter in the non-ectatic ablated areas. If the apex of the cone is central, a prolate keratoconus design lens can be fitted. In contrast, oblate reverse geometry designs will work better if the apex is decentered. In cases of iatrogenic corneal ectasia, consider a large diameter lens (i.e., greater than 10mm), as the increased size typically centers better over broader areas of irregularity.1

Refractive Error After Hyperopic LASIK. A 58-year-old female presented with complaints of blurry vision while reading at near. She had undergone monovision hyperopic LASIK four years prior, during which her right eye was corrected for near reading and her left eye for distance. Although she presented with 20/20 distance vision OU, she could only read J5 at near. Her manifest refraction corrected her to 20/20 and J1 (-0.50-0.75x035 OD and plano OS with a +2.25 add).

Prior to the LASIK procedure, she had been a long-time monovision corneal GP wearer and desired to have her vision corrected with this same modality. Since she was fully corrected for distance in the left eye, we only fitted the
right eye. Her topography showed a normal eccentricity value and a topographic keratometry reading of 47.00@40/47.67@130 OD (Figure 1). Because her eccentricity values were normal (steep E value of 0.64 and flat E value of 0.59), she was fit into a regular geometry tricurve corneal GP lens. This lens was fit half a dioptral flatter than K. Her final lens parameters were: 46.50/+2.00/9.60 OD, and the lens demonstrated a close-to-alignment fluorescein pattern (Figure 2). She reported successful wear of this lens about three times a week when she wanted to be free of spectacles.

**Flap Fold Irregularities Corrected with Corneal GP.** A 65-year-old female with a history of myopic LASIK presented with complaints of light sensitivity and glare OS while driving at night. These symptoms were caused by irregular astigmatism from a flap fold (Figure 3). Her vision was 20/40 with a spectacle correction of -0.25-0.75x085 and her corneal topography showed an oblate corneal shape with keratometry values of 39.09@164/39.56@074 (Figure 4).

Since her eccentricity value was negative, a 4D reverse geometry corneal GP with the following parameters was trialed: 40.00/0.00/10.8. However, the lens ultimately appeared to be about 0.75D too steep with minimal edge lift. A new lens with a flatter base curve and periphery was created with an over-refraction of +0.25D. The final lens parameters were 39.25/+1.00/10.8, and she was able to see 20/20. This lens showed mild apical touch and moderate bearing in the horizontal mid-periphery (Figure 5). Nonetheless, the lens had great movement and good tear exchange, and the patient’s corneal health looked great at subsequent follow-up visits.

The patient was happy with her improved visual acuity and nighttime vision and was able to wear her lens for the entire day.

**SCLERAL LENSES**

In contrast to fitting corneal GP lenses—a process in which corneal topography is crucial to lens design—a scleral lens has the advantage of being able to vault the cornea and rest on the anatomy of the scleral-conjunctival area. This makes scleral lenses ideal for fitting over highly irregular corneas after refractive surgery, such as in the case of uneven ablation zones or iatrogenic corneal ectasia. These large lenses center well and offer stable vision and good comfort; additionally, their fluid-filled reservoir offers therapeutic applications in the case of LASIK-induced dry eye. Scleral lenses are available in both regular and reverse geometry designs.

**INDICATIONS**

Patient complications following refractive surgery include the overcorrection or undercorrection of refractive error, anisometropia, a decentered or uneven ablation zone, flap irregularities and the development of iatrogenic corneal ectasia. Any of these may lead to symptoms of reduced spectacle-corrected acuity and contrast sensitivity, or ghost images. LASIK-induced dry eye is another common complication. While its pathophysiology is unknown, it is believed to result from neurotrophic epitheliopathy due to damage of the sub-basal nerve plexus from the creation of the LASIK flap. GP lenses are capable of addressing all of these concerns.
3 Flap Fold Irregularities Corrected with Scleral Lens. A 31-year-old male presented to the clinic with complaints of seeing glare around lights and decreased vision OU for the past year. The patient has a history of myopic LASIK OU and, within a week of undergoing the procedure, reported being aware of his symptoms. Anterior biomicroscopy revealed multiple LASIK flap folds OD>OS (Figure 6).

His manifest refraction was plano-1.00x065 OD and plano OS, which corrected him to 20/50 and 20/25, respectively. Corneal topography indicated a myopic ablation profile with keratometry readings of 38.26@012/38.71@102 OD and 39.40@126/39.00@036 OS (Figure 7). A 16mm 4.00D reverse geometry scleral lens with a 42.00D base curve and plano power was trialed in both the right and the left eyes. The lens demonstrated excessive vault of 500µm upon insertion over the central corneal surface, and the lens decentered inferiorly OU. Overrefraction values of -9.50D and -7.50D were found in the right and left eye, respectively, which led to the 20/30 OD and 20/20 OS visual acuity. As such, the following flatter lenses with compensated powers were ordered: 40.00/-8.50/16.0 OD and 40.00/-6.75/16.0 OS with a 2.00 D peripheral haptic OU (Figure 8).

Following dispensing, the lenses centered well and had approximately 250µm of vault centrally after 40 minutes of allowance for settling OU. The lenses were dispensed to the patient and he reported less glare and better quality of vision in both eyes at the three-week follow-up appointment. The patient also had healthy corneas and noted being able to wear the lenses comfortably for 12 hours.

4 Intacs and LASIK-Induced Dry Eye Syndrome. A 54-year-old male with a history of myopic LASIK OS presented to the clinic having formed subsequent iatrogenic corneal ectasia and dry eye four months after the procedure. Additionally, he had undergone intracorneal ring segment implantation in his right eye. The patient admitted to using preservative-free artificial tears once every hour to treat his dry eyes. His keratometry values were 47.25@032/43.12@125. Though he was corrected to 20/25 with a spectacle prescription of -4.25-2.50x140, he desired to be free of glasses.

Due to his dry eye syndrome, he wanted to try a scleral lens to gain some symptomatic relief. A 45.00/-1.50/18.0 lens was trialed and with a -1.00 over-refraction, the patient could see 20/20. This lens also demonstrated adequate vault over the limbus and aligned in the periphery (Figure 9). A final lens was ordered with the parameters of 45.00/-2.50/18.0. The patient reported improved nighttime vision and was able to decrease his drops to application once every four hours.

5 Lagophthalmos Complicates LASIK-Induced Dry Eye Syndrome. A 73-year-old female with a history of myopic LASIK...
OU 14 years prior was referred in for scleral lens fitting to treat her severe dry eye symptoms. The patient stated that her eyes had remained relatively dry since her LASIK procedure, but that the severity of dryness had increased three years ago with the advancement of her Parkinson’s disease. The patient reported self-administering autologous serum drops hourly, topical steroids BID, preservative-free artificial tears every 15 to 30 minutes, doxycycline hyclate 50mg tablets PO daily and 1,000mg of omega-3 PO daily. Additionally, she had installed humidifiers in all the rooms of her house to help with her dry eye symptoms.

Despite all of these efforts, however, none of the treatments gave her significant relief. Additionally, she stated that her eyes constantly felt like they were “on fire.” A slit lamp examination demonstrated inferior punctate staining and a decreased blink rate of once every 30 seconds.

The patient was correctable to 20/20 at distance and J1 at near with a mild hyperopic and astigmatic correction of +0.50-0.75x040 OD and +0.50-0.75x180 OD with a +3.00 add. Her topography showed a myopic ablation profile OU and keratometry readings of 43.87@062/43.12@152 OD and 43.75@128/41.12@038 OS (Figure 10). The following 4D reverse geometry diagnostic scleral lenses were placed on her eyes: 46.00/-2.00/18.0 OD and 45.00/-1.50/18.0 OS. Following 45 minutes of wear in the office, the patient stated 60% relief of her symptoms. A -3.00D OD and 2.00D OS overrefraction was added to the front surface of the final scleral lens order. The lenses showed good vault over the corneal surface and aligned well with the scleral shape of both eyes (Figure 11). Following one month of wear, the patient stated that her symptoms were completely resolved and that she had discontinued all of her topical drops.

Though most patients who undergo refractive surgery exhibit good visual outcomes, there are still some who need to wear contact lenses afterwards to rehabilitate their vision and/or health of their eyes. Fitting contact lenses after these procedures can be challenging due to altered corneal shape and unenthusiastic patient attitudes about wearing lenses again. Knowledge of the various contact lens designs and the ability to interpret corneal shape after LASIK and PRK is key to helping this population succeed in contact lens wear. In most cases, GP lenses are a great choice and offer relief for surgically altered corneas.

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The use of custom rigid lenses to reshape the cornea is increasingly prevalent throughout the world, albeit more so in Asia than in Europe and the United States.1-3 Therapeutic orthokeratology lenses are typically fit in Europe to eliminate the need for glasses or contact lenses, while in Asia they are primarily used to control the progression of myopia.1 Europe’s orthokeratology fitting process employs corneal topography with a software-based approach that is supplemented with trial lenses. This is achieved via the manufacturing of contact lenses by a third party, so the practitioner’s knowledge of back surface parameters remains limited. In Asia, however, the fitting process for orthokeratology incorporates topography, trial lenses and fluorescein pattern evaluation, meaning practitioners typically achieve a greater amount of confidence and success with the fitting process, though this is not always the case. This article will discuss the orthokeratology lens fitting process in the context of calculating back lens parameters individually for unusual cases.

**1 TEENAGE PATIENT**  
*Presentation.* A 17-year-old patient underwent an orthokeratology fitting to control her myopic progression, as her mother had myopia in both eyes corrected with eyeglasses (sph -18D). She presented with moderate myopia (-5.50D), a steep and small cornea and a medium-to-low eccentricity value. Her refractive and corneal data were as follows: Rx sph -5.50 cyl -0.50x175° BCVA 20/20, Ks 7.26/7.09mm, average corneal eccentricity E = 0.24, horizontal visible iris diameter 10.60mm and pupil size 3.60mm in the right eye; and Rx sph -5.00 cyl -0.50x10° BCVA 20/20, K 7.24/7.03mm, average corneal eccentricity E = 0.30, horizontal visible iris diameter 10.70mm and pupil size 3.70mm in the left eye.

For this patient, the prescribed lens back surface exhibited a tetra-curve design with a back optic zone (BOZ); a first peripheral zone or reverse curve steeper than the BOZ (BPZ1); a second peripheral zone or landing zone flatter than the previous one (BPZ2); and a third peripheral zone steeper than the second one (BPZ3). This approach uses one of several different modern reverse orthokeratology lens designs available on the market. In theory, more curves could occur to smooth the junction’s angle between one curve and another to produce conformal periphery and to increase the lens centration. Methods. When choosing the back optical zone radius (BOZR) for the first trial lens, it’s possible to use different formulas.4-7 Additionally, instead of selecting the BOZR, it’s possible to use sag fitting methods.7,8 The indications to calculate these orthokeratology lens parameters (using the Jessen Factor formula) are demonstrated in Table 1, while the parameters of the first pair of lenses fit on the patient in question are shown in Table 2. For the purpose of this discussion, however, it is not relevant which formula is used to calculate the first lens back surface parameters, because the final parameters were revised after evaluating the lens fit on the eye as well as its position, its movement and its fluorescein pattern.

In comparing these parameters with those indicated in the literature, note that the chosen BOZR is 0.36mm shorter; from this, a residual refractive error of 1.75D in the right eye (OD) and 1.25D in the left eye (OS) was then expected. Additionally, the BPR1 was longer with a lower inversion than

**ABOUT THE AUTHOR**

Dr. Fadel specializes in fitting contact lenses for the irregular cornea as well as in scleral lens fittings and orthokeratology. She has a contact lens private practice in Italy where she designs special customized contact lenses. She lectures and publishes especially on the aforementioned subjects. She can be reached at dfadel@tin.it.
normal, while the BPR2 was longer than 0.40mm; this could mean a possible lifting of the optical zone with modest result in the treatment. Additionally, note that the lens is fit steeply with central corneal staining most visible after lens removal (Figures 1 and 2). Corneal topography demonstrated the typical central islands that can be induced from a steep lens.

Following this evaluation, new lenses were calculated based on the parameter analysis of the first trial lenses and the fluorescein pattern. The BOZ was flattened according to calculations made previously, which automatically increased the reverse curve, leaving the same BPR1 (Table 3). The BPZ2 was also flattened to allow a lifting of the optical zone to prevent corneal abrasions and allow for a better distribution of epithelial tissue.

Results. Five days after the patient was fit with an orthokeratology lens, her UDVA was 20/25+2 OD with residual refractive errors present in the spectacle plane sph -1.00D and 20/20 OS with residual refractive errors sph -0.50D. Twenty days after the fitting, the patient’s UNVA was 20/16-1 OD with residual refractive errors: sph -0.25D; 20/16 OS with no residual refractive errors; and 20/12.5 in both eyes (OU). The patient reported having good vision with the lenses for up to 15 hours per day, but complained that she sometimes observed visual halos around lights. At her three-and-a-half month follow-up appointment, the UDVA was 20/16 OD with residual refractive errors sph -0.25D and 20/16 OS with no residual refractive errors. The low contrast UNVA was 20/25 OD, 20/25 OS and 20/12.5 OU.

Discussion. Previous research has suggested that low corneal eccentricity is predictive of a lower refractive error change. As such, these results are in agreement with other studies demonstrating that low eccentricity may not be an absolute contraindication to orthokeratology, despite the fact that the patient’s cornea was small and steep with a medium-to-high degree of myopia.8-12 In these cases, the corneal shape becomes oblate due to the negative eccentricity (i.e., E = -1.62 OD and E = -1.50 OS). In the case of this patient, her issue was resolved using a four-curve reverse lens with a mean back optic zone diameter and relatively small total diameter.

Table 1. Tetracurve Lens Parameter Calculations for Myopia up to 4.25D

<table>
<thead>
<tr>
<th>Tetracurve RGL for Myopia &lt; -4.25D</th>
<th>BPR2 alignment with peripheral cornea</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Jessen Factor (JF) 0.50 - 1.00D)</td>
<td>0 &lt; e &lt; 0.30 BPR2 = K</td>
</tr>
<tr>
<td>BOZR = Kp + m. target + J.F.</td>
<td>0.31 &lt; e &lt; 0.55 BPR2 = K + 0.05mm</td>
</tr>
<tr>
<td>BOZR = 7.25 + 1.15 + 0.15</td>
<td>0.56 &lt; e &lt; 0.70 BPR2 = K + 0.10mm</td>
</tr>
<tr>
<td>BOZR = 8.56mm</td>
<td>BPR2 = 7.20mm</td>
</tr>
<tr>
<td>BOZD = 5.80 - 6.40</td>
<td>W2 = 1.0 - 1.3mm</td>
</tr>
<tr>
<td>BPR1 = 6.00mm</td>
<td>W2 = 1.2mm</td>
</tr>
<tr>
<td>BOZD = BOZR-2x/2.6x(m.t.+J.F.)</td>
<td>BPR3 = 10.5 - 12.5mm</td>
</tr>
<tr>
<td>BPR1 = 8.56 - 2 x (1.15 + 0.15)</td>
<td>BPR3 = 10.5mm</td>
</tr>
<tr>
<td>BPR1 = 5.96mm</td>
<td>W3 = 0.4mm</td>
</tr>
<tr>
<td>W1 = 0.4 - 0.6 mm</td>
<td>TD = 10.0 - 11.50mm</td>
</tr>
<tr>
<td>W1 = 0.6mm</td>
<td>TD = 10.4mm</td>
</tr>
</tbody>
</table>

*The spherical equivalent was considered as the myopic target (-5.75D) and Jessen factor value of 0.75D.
lenses to eliminate the need for eyeglasses. She had previously worn soft contact lenses, but had stopped due to resulting dry eye symptoms. Her refractive and corneal data at the time of presentation was Rx sph -0.75 cyl -2.50x170° BCVA 20/16, Add 1.50D, K 7.81/7.49mm, E = 0.10, horizontal visible iris diameter 11.60mm and pupil size 3.40mm OD; and Rx sph -1.50 cyl -1.50x20° BCVA 20/16, Add 1.50D, K 7.51/7.29mm, E = 0.20, horizontal visible iris diameter 11mm and pupil size 3.50mm OS.

It was noted the patient’s cylindrical component was three times larger than the spherical one in the right eye, while in the left eye they were equal. Also, there was refractive astigmatism (cyl -2.50 OD and cyl -1.50 OS higher than corneal astigmatism (i.e., -1.82D OD and -1.39D OS) and low eccentricity present. Additionally, though the patient’s marginal dry eye was not an absolute contraindication to orthokeratology lens wear, it could challenge the practitioner’s ability to create a reliable topography map, since corneal topographers are typically more effective at generating a clear image when evaluating a wetter corneal surface.12

Few published studies currently exist on the subject of toric orthokeratology for astigmatism, though conference abstracts and case reports on the subject are numerous.13-21 One study was conducted on patients who have astigmatism greater than 1.25D at any orientation.13 The lenses used in this project contained five toric zones with double reverse curves, with the second and the fourth zones being the reverse ones. This design is known as a full toric double reservoir. The researchers suggested that to achieve an adequate effect with a toric orthokeratology lens, mechanical and hydrodynamic forces must occur in different ways in each corneal meridian, with greater flattening in the meridian where the myopia is greater.20 Results demonstrated an 85% change in initial astigmatism.

Another study on patients ranging from six to 12 years old with myopia of 0.50D to 5.00D and with-the-rule astigmatism of 1.25D to 3.50D incorporated a lens characterized by an alignment...
toric zone with spherical back optics and a reverse zone design. According to the authors of this study, the advantage of placing a spherical optic zone on a toric cornea is that the flattest lens meridian creates a normal orthokeratology effect, while the steepest meridian results in a greater orthokeratology effect, leading to the correction of the corneal astigmatism. The study results demonstrated a fit success rate of 95% with a significant reduction in myopia and astigmatism.

Some of the case reports in existence in which authors fit different toric orthokeratology lens designs include:

- A case of a 22-year-old patient, sph -4.25 cyl -3.75x8° OD. The corneal astigmatism (CA) was -3.10x7°, and the lens used had two toric zones: the reverse and the landing zone. The reduction of a high CA can be achieved if the reverse zone design allows for a close tangential or alignment in each meridian to properly modulate the hydrodynamic forces, which enables for the flattening of each meridian to establish the orthokeratology effect. In the presented case, at two months post-treatment the CA was largely reduced, and the subjective correction was cyl -0.50Dx8° with UNVA 20/20.

- A case of a 44-year-old patient with a mixed astigmatism in which the cylindrical component was greater than spherical one. The patient presented with sph +1.00 cyl -2.00x180° OD and sph +1.25 cyl -2.25x180° OS. The lens fit on this patient was a hexacurve (i.e., six back curves) design with two back toric zones, dual toric zones and optical and landing zones. Also, the vertical meridian was steeper than the horizontal meridian in the landing zone and vice versa in the optical zone. Three months post-orthokeratology fitting, the subjective correction was sph + 0.50 cyl -0.50x10° (UNVA 20/16) OD and sph +0.25 cyl -1.00x5° (UNVA 20/16) OS.

**Methods.** Because there do not appear to be any set guidelines for toric orthokeratology lens parameter calculation in the literature, indications for spherical orthokeratology lenses were followed instead. The first pair of lenses used demonstrated a tetracurve design with two toric zones—one in the optical zone to correct the astigmatism and another in the landing zone to help achieve a centered lens. Parameters are listed in Table 4.

Fluorescein patterns for this lens fit demonstrated the presence of an upward decentration in the right eye, while in the left eye the pattern was suitable as the BPZ2 was aligned over the corneal peripheral meridians. The spectacle correction was sph +1.00 cyl -2.00x180° OD and sph +1.25 cyl -2.25x180° OS.

**Fig. 3. Fluorescein patterns of the second pair of lenses, 20 days post-orthokeratology. Both lenses are decentered, compromising the refractive outcome.**

<table>
<thead>
<tr>
<th>K f</th>
<th>K s</th>
<th>BOZR</th>
<th>BOZD</th>
<th>BPR1</th>
<th>W1</th>
<th>BPR2</th>
<th>W2</th>
<th>BPR3</th>
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<tr>
<td>BOZD</td>
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<td>10.0</td>
<td>0.50</td>
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Table 3. Comparison of the First and Second Pair of Lenses in Case 1

**Table 4.**

<table>
<thead>
<tr>
<th>TD 10.50mm; BVP 0.00 D</th>
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<tbody>
<tr>
<td>K f</td>
</tr>
<tr>
<td>OD</td>
</tr>
<tr>
<td>OS</td>
</tr>
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</table>

**Fig. 3. Fluorescein patterns of the second pair of lenses, 20 days post-orthokeratology. Both lenses are decentered, compromising the refractive outcome.**
tion was OD sph +1.00 cyl -1.25 x 145° (UNVA 20/32) and OS cyl 1.00 x 40° (UNVA 20/25). Once the treatment effect was underway in the left eye, the design was maintained via flattening of the BOZ by 0.2mm in the horizontal meridian.

The second pair of lenses was calculated and a tetracurve lens with three toric areas—the optical zone, the reverse zone and the landing zone—was selected based on the residual refraction with the first lenses (Table 5). Fluorescein patterns and corneal maps post-fit demonstrated lens decentration in both eyes, leading to poor refractive results and visual acuity (Figure 3). Parameters were sph +1.00 cyl -1.25 x145° (UNVA 20/32) OD and cyl -1.00 x 40° (UNVA 20/25) OS.

Next, a third pair of lenses was ordered; the parameters are shown in Table 6. It should be noted that the majority of new lens parameters do not necessarily respect the indication reported in literature for spherical orthokeratology lenses. For example, the width of the reverse zone (W1) was larger than the landing one (W2) to achieve a greater hydrodynamic force action, allowing a higher closing lens in each meridian to increase the effect of orthokeratology. For the lens stability, it was decided that the BPZ2 should be flatter than K. In this case, the BPZ3 was steeper than most literature indications to allow for a tear exchange, and the width of the third peripheral zone (W3) was the same as W2 to help balance corneal touch around all meridians.

Results. Twenty days post-treatment, the fluorescein patterns looked good, with regular and constant (real or apparent) touch in all the corneal meridians (Figure 4). The corneal profile post-orthokeratology is shown in the corneal maps (Figure 5). The subjective correction was cyl -0.75 x 150° (UNVA 20/16) OD, cyl -0.50 x 30° (UNVA 20/16-1) OS and UNOU 20/16. The patient demonstrated good UNVA for more than 13 hours a day. Additionally, topoaberrometry showed that corneal higher-order aberrations were not relevant except the spherical ones, which allowed the patient to have a good VA at different distances and hence setting up close.

The slit lamp examination showed instability of the tear film in both eyes but the patient reported no presence of symptoms throughout the day.

Discussion. As seen before, in the published studies, conference abstracts and case reports, there are a number of designs of toric contact lenses to treat astigmatism that work equally well. This second case was solved using a four-toric zone reverse lens, even if it was an apparently contraindicated scenario for this type of lens. In fact, the cylindrical component in the OD was three times larger than the spherical one, while in the OS they were equal. Also there was a refractive astigmatism (OD -2.50D, OS -1.50D) higher than CA (OD -1.82D and OS -1.39D) and a low eccentricity. The parameters of the back curve were then calculated manually.

Though FDA approval criteria states that orthokeratology is appropriate for myopia correction up to -6.00D, there is enough evidence to suggest that orthokeratology also has function for higher myopia and astigmatism. As such, the orthokeratology fitting process
in these instances could be made easier with the knowledge of all the lens’ back surface parameters. It enables the contact lens practitioner to become more familiar with the functionality of each parameter so that it can easily be changed to further improve the lens fit. These cases also suggest that a “simple” tetracurve lens could be considered as an option to resolve complex cases as well.  


Table 5. Parameters of the Second Pair of Lenses Fit in Case 2

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<tr>
<th></th>
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<th>K s</th>
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<th>BOZD</th>
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<td>11.00</td>
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</tbody>
</table>
TD OD 10.70; OS 10.30mm; BVP 0.00D.

Table 6. Parameters of the Third Pair of Lenses Fit in Case 2

<table>
<thead>
<tr>
<th></th>
<th>K f</th>
<th>K s</th>
<th>BOZR</th>
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<tr>
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<td>0.60</td>
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TD OD 11.50mm; BVP 0.00D.

Fig. 5. Corneal topographies after removing the third pair of lenses.
Corneal collagen cross-linking (CXL) available internationally for over a decade and now newly approved in the United States, is the only surgical procedure capable of slowing down or stopping the progression of keratoconus and secondary keratectasia after laser in-situ keratomileusis (LASIK) and photorefractive keratectomy (PRK).

CXL is also considered by many to be a vision-saving procedure, especially when performed on younger patients with the goal of preventing the need for future keratoplasty. Research suggests CXL may have beneficial visual and optical effects, as evidenced by the reduction in corneal steepness and improvement in uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA).

Despite these impressive outcomes, however, in many cases corrective lenses are still necessary to achieve the best possible vision following CXL.

Specialty soft contact lenses in particular continue to gain popularity among eye care practitioners due to advancements in lens materials and lathing technology. One such example is the silicone hydrogel mini-scleral (SHmS): a large 17mm diameter lens that vaults the limbus and central cornea with minimal bearing on the corneal apex to rest on the patient’s sclera. The lens’ central thickness varies from 0.5mm to 0.6mm and is responsible for the neutralization of corneal irregularity and the creation of a regular front refractive surface. Scleral support also results in the formation of a true aqueous tear lake underneath the lens, which enhances the ability to correct irregular astigmatism, similar to gas permeable (GP) scleral lenses (Figure 1). One major indication for this type of lens is visual rehabilitation following CXL, with the goal of the fitting being to provide a stable, distortion-free refractive surface and minimize interference between the recovering ocular surface—especially the epithelium—and the contact lens.

Examples of custom soft contact lenses for keratoconus include the NovaKone (Alden Optical), Flexlens Tricurve (X-Cel Specialty Contacts), and Eni-Eye Soft-K lens (Acculens).

Semi-scleral soft lenses can also be used as therapeutic bandage lenses following refractive or ocular surface reconstructive surgery, especially in eyes with high corneal toricity or steeper than average curvature, since a higher sagittal depth helps stabilize lens fit and reduce excessive lens movement. Examples include the Kontur (Kontur Contact Lens) or T74/85 (David Thomas Contact Lenses); however, the application of these designs is limited entirely to therapeutic purposes due to their inability to correct irregular astigmatism.

So, with the CXL era finally about to begin in the US, let us consider whether the approach to contact lens fitting shortly after CXL should be different from what we consider a standard of care for the irregular cornea patient through a series of case reports.

1 STANDARD PROCEDURE

A 29-year-old woman with a diagnosis of surgically-induced keratectasia was referred in for a specialty contact lens fitting due to decreased vision in her left eye for the last nine months. She reported that she had undergone LASIK for moderate myopia 12 years prior. The patient’s unaided visual acuities were 20/80 OD and 20/200 OS, and her refraction was +1.25/-3.75x140 OD and -5.00/-1.50x90 OS.

2 ABOUT THE AUTHOR

Dr. Severinksky recently completed a two-year doctor of optometry program for international graduates at the New England College of Optometry. Since 2001 he has specialized in specialty contact lens fitting and especially scleral lenses. Today his primary area of interest is designing and fitting contact lens for keratoconus and after corneal collagen cross-linking. He is a Fellow of the American Academy of Optometry, British Contact Lens Association and Scleral Lens Education Society.

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5.00x170 OS with best-corrected visual acuity (BCVA) of 20/30 and 20/80, respectively. Corneal topography revealed advanced keratectasia predominantly in the left eye (as compared with her right) with maximum keratometry (Kmax) values of 55.4D OD and 59.7D OS (Figure 2). The patient was subsequently evaluated by a cornea specialist and scheduled to undergo an epithelium-off corneal collagen crosslinking procedure to halt further progression. She was also given temporary spectacles with partial astigmatic correction in the right lens and plano correction in the left to wear following the surgery. Two weeks after, the patient underwent CXL in her left eye.

Five weeks later, following complete epithelial healing and the discontinuation of all steroid medications, the patient’s left cornea exhibited no signs of epithelial hypertrophy or superficial punctate staining. As such, she was scheduled for a contact lens fitting and given a front toric, prism-ballasted version of the SHmS lens with a base curve of 7.3mm and the power of -3.75/-2.25x180. The lens was manufactured in a Filcon V3 silicone hydrogel material (Definitive 74, Contamac). At the dispensing visit, the patient’s BCVA was 20/30 OS, with a minor complaint of ghost images. She was instructed to increase lens wearing time gradually, and was scheduled for a follow-up appointment in the next 10 days.

During the follow-up appointment, a slight reduction in visual acuity (i.e., 20/50) was noted, but the patient reported noticeable improvement in vision clarity and her ability to perform daily tasks, as well as good lens tolerance and average lens wear of nine hours a day. An examination revealed the presence of a well-centered lens with about 1mm of on-blink movement (Figure 3). An over-refraction of plano/-1.50x175 was able to improve her vision to 20/25 OS and significantly reduce the amount of ghost images seen. A new lens with an updated power was ordered; three weeks later, the patient was able to wear the revised lens up to 10 hours a day with stable contact lens-corrected vision. As a result of successful restoration of vision in the treated eye, the patient underwent an uneventful CXL procedure eight weeks later for her other eye.

2 PROGRESSION PROTECTION

A 29-year-old male construction worker was diagnosed with bilateral keratoconus (OS>OD) 12 years prior to presenting to the clinic. He reported he had undergone penetrating keratoplasty in his left eye in 2011; however, shortly after the procedure, the corneal transplant had begun to show signs of endothelial rejection, which eventually led to scarring and reduced vision. Numerous GP lens fits had been attempted but the patient had continued to demonstrate a severe intolerance to rigid lenses, especially while outdoors. In the last three years, he had successfully managed using a soft lens made for keratoconus (Soft-K, Soflex) with param-
refraction of -5.00/-6.50 x 125 VA 20/150 OD and -4.50/-7.50 x 110 VA 20/70 OS. Central keratometry readings of the right eye were 56.0/57.4 D with a Kmax value of 62.5 D (Figure 4). A slit lamp examination revealed a faint anterior stromal haze with an intact corneal epithelium (Figure 5). Fit assessment using the old right contact lens demonstrated an excessive rocking movement of the lens with fluting edges upon blink. Attempts to refit the patient's right eye with a steeper Soft-K lens did not provide sufficient visual improvement (BCVA of 20/60). Instead, the patient was selected for a trial fitting with a SHmS lens made from Definitive 65 (Filcon V4) rather than the practice's default material (Filcon V3, Contamac). Filcon V4 is a polymer with a higher silicone content than its predecessor, Filcon V3. Other than the high oxygen permeability (Dk = 62) previously mentioned, the Filcon V4 material also possesses the highest modulus of elasticity in the family of lathable silicone hydrogels (MPa = 1.0). Typically, lenses with a higher modulus are stiffer and will correct the underlying corneal irregularly more effectively, while those lenses with a lower modulus will simply drape over the cornea. Fitting of contact lenses with a higher modulus may be advantageous in terms of vision correction success, since lenses made of these materials help mask the entirety of corneal astigmatism and eliminate the need for a toric design. On the other hand, wear of stiffer lenses can lead to edge fluting, tarsal irritation and mechanically-induced allergy. In these cases, additional adjustment of the peripheral curves is often required for successful lens wear.

This patient was fit into a spherical version of the SHmS lens with a base curve of 6.5 mm, “steep” peripheral curve, diameter of 17 mm and central lens thickness of 0.6 mm (Figure 5). The lens power was -12.5 D. Four fenestration holes were added at the lens limbal zone to increase oxygen delivery and tear mixing.

Vision upon dispensing was 20/50. At the one-month follow-up appointment, the patient reported good lens tolerance with 12 to 14 hours a day of lens wearing. Visual acuity had decreased to 20/60, but improved back to 20/40 with overrefraction of +2.50/-1.50 x 050. The patient's central cornea exhibited trace central superficial punctate keratopathy, which appeared to relate to corneal apex bearing. A new lens with base curve of 6.4 mm, similar peripheral geometry and a power of -10.5 D was dispensed. Overrefraction demonstrated similar residual astigmatism findings of +0.50/-1.50 x 05. The patient was advised to wear polycarbonate spectacles for correction of residual astigmatism and ocular protection. Final visual acuity of the right eye improved to 20/30-. No significant corneal staining or corneal neovascularization were present at three-month follow-up. Current daily lens wearing time stands at 12 hours a day with the occasional use of lubrication agents for comfort.

Successful use of full-size scleral lenses after corneal crosslinking has also been previously reported in the literature.7 Regular sclerals offer the advantage of minimal mechanical interaction with the treated zone and help promote ocular surface healing and provide optical benefits.

In this third case report, a 19-year-old male with advanced keratoconus OS and documented progression underwent an epithelium-off corneal crosslinking procedure in May 2013. Prior to the surgery, his maximum corneal steepness was 64.5 D with an unaided vision measurement of 20/800 (Figure 6a). Unfortunately, no pre-treatment refractive data
was available for this patient but postoperative recovery was positive for hypertrophic epithelial formation and delayed healing, which was treated using antibiotics and a bandage contact lens during the course of four weeks. At week five, the patient presented back to the clinic with complaints of significant pain and cloudy vision OS. His vision was reduced to CF at three feet and severe stromal edema with ruptures in Descemet’s membrane was observed (Figure 7).

The patient was treated for corneal hydrops with a five-week course of topical steroids, in combination with antibiotic coverage during the first seven days and hyperosmotic eye drops. After the patient’s cornea cleared up and the edema diminished, the patient was referred for a contact lens fitting. A slit lamp examination revealed a stromal scar of moderate density at the inferior pupillary margin, trace punctate keratopathy of the inferior cornea, signs of meibomian gland dysfunction and floppy lid syndrome. Tear break-up time (TBUT) values were also low at seven to eight seconds. Corneal topography demonstrated a highly irregular corneal surface with significant flattening of the center and \( K_\text{max} \) value of ~50D as compared to pre-treatment findings (Figure 6b). Considering the patient’s complex corneal geometry and decompensated ocular surface, we decided to manage this patient with a 18.5mm GP scleral lens. Incorporating the advances of reverse geometry technology, we were able to design a lens with a flat enough base curve to more precisely follow an oblate central cornea (Figure 8). The patient’s lens-corrected visual acuity was 20/40, and, after a short adaptation period, he was able to achieve day-long uncomplicated lens wear. At his one-month follow-up, his BCVA was unchanged, the corneal epithelium was intact and his TBUT values had improved to 15 seconds.

**KEEP IN MIND**

Though CXL is considered a potentially vision-saving procedure in many cases, it is not free of complications. The most common side effects are delayed epithelial healing, longstanding SPK, noninfectious infiltrates and stromal edema with scarring (i.e., corneal hydrops) as well as minimal reduction in endothelial cell count secondary to UV irradiation damage.8 Despite the ocular surface complications attributed to crosslinking, however, the risks associated with corneal transplantation surgery still significantly outweigh those of CXL.

Currently, there are no clear recommendations regarding when it’s safe to begin or resume contact lens wear after corneal collagen crosslinking. Post-CXL corneal recovery can fluctuate over time. Crosslinking research with data on long-term follow-up has demonstrated that corneal thickness, as well as central keratometry, follows a dynamic curve in the first six months.9,10 While patients following an epithelium-on procedure may be fitted in a time frame of one to two weeks, patients who undergo the epithelium-off treatment may need a significantly longer recovery time and may also experience a higher rate of corneal healing-related complications.

Though the epithelial defect typically closes four to seven days after the procedure, continuous epithelial remodeling followed by the modification in the arrangement of stromal collagen fibers and corneal nerve proliferation may be seen over several months.
Consequently, it is imperative that healing is achieved prior to lens fitting to avoid mechanical disruption. These changes are also reflected in the further flattening and regularization of the central cornea, and may often lead to improved spectacle-corrected visual acuity and more success with contact lenses. For epithelium-off patients, we recommend resuming contact lenses. For epithelium-off patients, we recommend resuming contact lenses. For epithelium-off patients, we recommend resuming contact lenses. For epithelium-off patients, we recommend resuming contact lenses.

In the first months following CXL, the cornea may exhibit a thinner epithelial profile with decreased quality of adherence between the epithelial layers. These changes may cause a higher corneal vulnerability to contact lens-induced mechanical trauma. As such, fitting of traditional GP lens designs may prove problematic shortly after CXL; one of the most frustrating cases I have encountered recently is that of a 17-year-old male with advanced keratoconus (Kmax of 63D), who resumed wearing his old GP lenses three weeks after an epithelium-off procedure. One week later, he was admitted to the clinic with a complaint of significant eye pain, light sensitivity and blurred vision in the treated eye. Exam revealed dense infiltrative ulcerative keratitis at the center of the left cornea. After being on fortified cefazolin and gentamicin for almost two weeks, the ulceration resolved but left him with a dense corneal scar and best-corrected vision of 20/50 (Figure 9).

One study reports that patients fit with GP lenses three months after the procedure demonstrated evidence of epithelial cell stress with an increase in superficial epithelial cell size and a decrease in basal epithelial cell density.11 These findings are also accompanied by a decrease in corneal sub-basal nerve plexus density. The other area of concern regarding GP lens wear after CXL is that contact lens-induced mechanical irritation may lead to inflammation and consecutive keratoctye loss in the anterior stroma, in addition to apoptosis inflicted by UV irradiation.14

In summary, scleral and silicone hydrogel mini-scleral lenses in particular continue to possess clinical importance in today’s specialty contact lens practice. The use of these new lens designs may become a preferred alternative shortly after CXL. In addition to providing successful visual rehabilitation, they minimize contact lens influence on epithelial remodeling and allow uncomplicated ocular surface recovery after the procedure.

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Contact lenses are some of the smallest and least visible devices for correction of refractive error. Considered medical devices, they can be worn for therapeutic reasons; however, other reasons for wearing contact lenses exist, such as for cosmetic purposes. Contact lenses are an important part of the ophthalmologist practice, with the demand for them increasing day-by-day; indeed, millions worldwide currently wear them. Therefore, it is also important to take precautions and educate people when prescribing and fitting these lenses.

HISTORY
A 47-year-old female patient presented to the clinic with a red left eye that had been present for the past seven days. This was accompanied by a foreign body sensation and watering, but no discharge. She noted the presence of localized swelling on her left upper eyelid with a nodular-looking lesion. She was treated for lid cyst with chloramphenicol ointment by the general practitioner. Since then, however, the condition had not improved and so she decided to consult an eye specialist. The right eye appeared to be without complaint or redness. The patient was a gas permeable contact lens wearer with her last wear time occurring eight days ago.

The patient exhibited no other ocular history, and her family ocular history was negative for ocular problems. She wasn’t taking any systemic medications at the time of admittance and her best-corrected visual acuities were 20/30 OD and 20/25 OS. Pupils were round and reactive to light, with no relative afferent pupillary defect in either eye. Extraocular movements were full OU. A slit lamp examination demonstrated that the left eyelid was normal. Additionally, the left conjunctiva was white and quiet; the cornea, iris and lens were clear; and the anterior chamber was deep and quiet. Regarding the right eye, a 1.0mm by 0.7mm firm nodule on the center of the upper left eyelid was visible, with no periorbital erythema or edema or skin breaks (Figure 1). The right conjunctiva displayed hyperemic traits and the cornea was characterized by a few punctate epithelial erosions. The anterior chamber was deep and quiet, the iris was round and regular and the lens was clear.

Upon inversion of the left upper eyelid, a circular foreign body was made visible, surrounded by the tarsal conjunctiva (Figure 2). Attempts to shift it with a cotton bud were unsuccessful and subsequently, oxybuprocaine eye drops were instilled. The object—a contact lens—was removed using typing forceps. A yellow pus discharge on the contact lens was observed immediately (Figure 3). Both the lens and the discharge was sent for culture and sensitivity. The patient reported increased comfort, and was sent home with topical ofloxacin eye drops and the expectation that she would return in three days.

Culture results indicated the presence of Staphylococcus aureus, which proved sensitive to the ofloxacin. The patient reported no issue on follow-up, and was asked to continue the drop regimen for another week. A two-week follow-up appointment revealed everything had healed well.

DISCUSSION
Gas permeable contact lenses (GPs) are made of a complex polymer that includes silicone, PMMA and others. These lenses permit excellent perfusion of oxygen and are used to improve vision by correcting refractive errors. They work by focusing light so that it enters the eye with the proper power for clear vision. GP lenses have the main advantage of being durable with longer lifespans as compared with soft contact lenses. Modern GP lenses require a relatively short adaptation time as compared with older hard lenses, but patients still need some time to get used to them. Additionally, the size of the lenses is beneficial as it provides for easy insertion and the flexibility to allow them to move freely on the eye with each blink; however, their small size

CASE REPORT:
Look Before You Judge
The most unique cases sometimes present as the most mundane.

By Mohammad Tallouzi, OD

ABOUT THE AUTHOR
Dr. Tallouzi is a surgical practitioner working at Birmingham and Midland Eye Hospital. He specializes in treatment of ocular surface and inflammatory eye diseases and was awarded the NIHR Clinical Research Training Fellowship in 2015. He is currently working on his PhD at the University of Birmingham.
can be disadvantageous as the lens may move from its position during daily activities or sports and be lost. This also increases risk for debris to become trapped underneath the lens.

This patient in particular dislodged her contact lens from its original position to where it sat on the palpebral or tarsal conjunctiva. The conjunctiva then began to fold over the lens. The patient reported she was aware of the time she placed the contact lens on the eye, but that she was not aware if and when she had lost the lens.2

Contact lens complications can vary from mild irritation to sight-threatening issues, with resulting problems leading to disturbances of the eyelids and ocular surfaces that can result in long-term changes and a reduction in contact lens tolerance. In this case, the extended wear of a GP lens led to complications that likely began as a result of abnormal blinking of the eyelid, ptosis due to a reduction of the palpebral slit and meibomian gland dysfunction.6

Other complications that might present may relate to the tear film and result in dry eye due to the lack of lipids. This can lead to papillary conjunctivitis, which is intensified by the mechanical irritation of the conjunctiva. Additionally, the presence of hypoxia below the lid, accompanied with an immunological reaction may also induce corneal changes like microcysts and striae such that GPs may not allow enough transmission of oxygen for successful long-term extended wear. Wear of the lens may also result in disruption of the corneal epithelium, corneal erosion and keratitis if not treated promptly. Corneal edema and corneal ulcers are two sight-threatening complications that can occur with contact lens wear.2,7,8

Regardless of the brand of contact lenses, however, their use requires accompanying care to prevent damage and avoid sight-threatening complications. The majority of contact lens complications are caused by careless handling and overwear of lenses. As such, patient education is key, as is early identification of the above mentioned conditions so that necessary medical help can be sought.6

For those patients with certain medical conditions, contact lenses provide a distinct opportunity to improve patient quality of life in cases in which corneal shape is distorted or if a spectacle correction fails to provide adequate vision. Visual phenomena like glare, double vision and sensitivity to light can make processing images more difficult for patients; as such, in many cases non-elective procedures are the only solution to recapture a normal lifestyle. However, even when faced with the same procedures and diagnostic codes, each vision insurance company has its own guidelines to determine what constitutes a “medically necessary” contact lens. As such, the imbalance in coverage between vision insurance companies, coupled with rising health care costs, often means a policy nightmare for the eye care practitioner.

Today, most medical plans are coupled with vision care plans, though many limit medical coverage for specialty services to just the diagnosis of the condition and coverage of the treatment. This creates a problem for patients seeking resolution for an ocular issue: they have covered access to the diagnostic services used to identify the condition and the actual medical devices (i.e., corrective lenses) necessary to treat the issue, but not the medical procedures (i.e., surgery and medical treatment) they may have to undergo to enable the treatment to work. Ultimately, for patients to benefit, the medical portion must be covered under both the vision care and medical care sides of an insurance plan.

**INDICATIONS AND OPTIONS**

As specialty lenses are indicated primarily for patients with irregular corneas (e.g., in the case of keratoconus, pellucid marginal degeneration, scarring, post-surgical corneal abnormalities), gas permeable materials figure prominently in the approach to care. GP’s provide a rigid surface that neutralizes the corneal irregularity, in effect replacing it with the controlled regular surface of the lens. Some conditions are better served by sclerals rather than corneal GP lenses due to their design with an elevated dome and haptic zone that vaults the cornea to land on the sclera, respectively. Hybrids that combine a GP center with a soft lens periphery may also be possible to improve comfort while custom soft lenses may suffice for some patients.

Beyond irregular cornea indications, specialized custom contact lenses are typically also appropriate for most medically necessary criteria like:

- Binocular vision issues caused by the presence of nystagmus, anisometropia and anisocoria, as well as glare and light sensitivity resulting from aniridia and anisocoria.
- High myopic or hyperopic prescriptions if visual improvement (as defined using Snellen acuity) with contact lenses surpasses that which is possible with spectacle wear.
- Lens use following refractive surgery and other traumatic cases, in which improved visual acuity can be demonstrated with lens wear.

However, some disputes remain regarding insurance coverage. Though patients and/or health care providers may define a condition as medically necessary, guidelines for a specific health care plan may not agree.

Consider, for example, the role of scleral lenses. The lens design includes a fluid compartment underneath the lens’s surface to keep the cornea hydrated; as such, the cornea is not exposed to air. These lenses provide a more uniform surface over the cornea and can be useful in cases where the corneal irregularity is significant.

**ABOUT THE AUTHOR**

Dr. Davis practices in Oak Lawn, Ill., where he is the director of the contact lens clinic at Davis EyeCare. He is also a co-founder of EyeVis Eye and Vision Research Institute, where he works developing contact lens designs and furthering research on anterior segment pathophysiology. Dr. Davis has been recognized as a diplomate in the corneal contact lens and refractive technology section of the American Academy of Optometry and is an inductee in the National Academy Practice in Optometry as well as an advisor to the Gas Permeable Lens Institute and a recipient of the Gas Permeable Practitioner of the Year Award. He has also been honored as one of the 50 most influential optometrists in 2015.
<table>
<thead>
<tr>
<th>Condition</th>
<th>EyeMed</th>
<th>Davis</th>
<th>VSP</th>
<th>Superior</th>
<th>Humana</th>
<th>Spectera</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anisometropia</td>
<td>3D in any meridian.</td>
<td>≥4D BVA ≥ 20/40 Intact epithelium.</td>
<td>3D</td>
<td>4D and VA improves ≥20/60</td>
<td>&gt;3.5D with diplopia or with specs.</td>
<td>&gt;3.5D.</td>
</tr>
<tr>
<td>High Ametropia</td>
<td>±-10D</td>
<td>±-8D</td>
<td>±-10D</td>
<td>±-10D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Keratoconus</td>
<td>Not correctable to 20/25 Two lines better than 20/25.</td>
<td>K readings or topography BVA ≤20/40 Two lines improvement. Absence of hydrops. Intact epithelium.</td>
<td>K readings. OCT or topography.</td>
<td>K readings. OCT or topography and notes.</td>
<td>Two lines improvement. With documentation.</td>
<td></td>
</tr>
<tr>
<td>Corneal Ectasia</td>
<td>Achieve comfort and/or vision correction not possible with mid- to moderate keratoconus. Suitable for contact lens applications.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vision Improvement</td>
<td>Two lines better than specs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aphakia</td>
<td>BVA ≥20/100 Aphakia without implant. No corneal or vitreous opacity. Intact macula. Intact epithelium.</td>
<td>Included.</td>
<td></td>
<td></td>
<td></td>
<td>Acuity &lt;20/70 in spectacles and better than 20/70 in contact lenses.</td>
</tr>
<tr>
<td>Aniseikonia</td>
<td>Unequal image size between the two eyes. Intermittent or constant diplopia. Less than 100 degrees stereopsis. Intact epithelium.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aniridia</td>
<td>Surgical or traumatic.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Irregular Astigmatism</td>
<td>≥2D principle meridians are separated &lt; 90 degrees. Two lines of improvement. BVA &lt;20/70.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nystagmus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Included.</td>
</tr>
<tr>
<td>Corneal Transplant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Included.</td>
</tr>
<tr>
<td>Corneal Dystrophy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Included.</td>
</tr>
<tr>
<td>Colored Contact Lenses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>For achromatopsia, albinism, aniridia, anisocoria, or polycoria pupil abnormality.</td>
</tr>
</tbody>
</table>
these lenses are well-suited for the treatment of severe ocular surface diseases like corneal stem cell deficiency, Stevens-Johnson syndrome, chemical and thermal injuries to the eye, ocular pemphigoid, neurotrophic corneas, severe dry eye from Sjögren’s syndrome, chronic graft versus-host disease, ocular radiation, corneal exposure and corneal disorders associated with systemic autoimmune diseases such as rheumatoid arthritis. The question is, however, whether these are medical conditions, or whether they covered under primary vision care. It often varies among providers.

**TAKING RESPONSIBILITY**

Most health care plans determine the criteria for their respective covered population. For example, contact lenses for masking irregular astigmatism associated with keratoconus and other corneal disorders requires certain documentation from the initial exam and follow-up visits to cover requests for coverage. Additionally, the patient’s first visit to the clinic must include a comprehensive eye exam, performance of advanced corneal topographic modeling or keratometry and documentation of the lens fitting process. Failure on the part of the practitioner to adhere to these criteria may lead to disqualification from reimbursement.

Table 1 correlates the different covered conditions with corresponding vision care plans. Note that each offers different coverage for different conditions; uniformity is rare and should not be expected. As such, it is the responsibility of the practitioner to inform the insurance carrier of the needs of their patient population.

Because we live in an era where most doctors are held accountable for their actions—including and especially billing policies—proper documentation is the best way to guarantee passing an audit and receiving payment for the work provided. As such, the contact lens fitting, dispensing and follow-up visit must each be separately documented in the practice’s medical records, with a thorough record made of all services provided. This includes patient pick-up of a reordered contact lens prescription or other ancillary events that may occur later on.

Typically, records should include the prescription, number and material type of contact lenses dispensed; patient lens wear and replacement schedule; recommended care and cleaning instructions; any data from the fitting appointment; visual acuity measurements taken both through the lenses and overrefraction; and the date the final lenses were dispensed. Additionally, practitioners should ensure they have a documented contact lens history on file. This should include information on the use and care of the patient’s lenses in their work environment; hobbies and daily routines; previous lens experience and any type of lens accoutrement used.

The patient’s lens fit and evaluation appointment should include keratometry or topography, with proper diagnosis made if a corneal anomaly like corneal distortion or an ectatic disease is initially suspected. Recorded observations from a slit lamp should document both views with a diagnostic contact lens for the purpose of assessing fit and the patient’s eye sans-lens to assess the ocular health of the cornea, conjunctiva, sclera, tear film and eyelids. Overrefraction with the contact lenses should be recorded monocularly, with visual acuities noted for each trial lens tested.

**Table 2. EyeMed Insurance Coverage for Contact Lens Wearers**

<table>
<thead>
<tr>
<th>Test</th>
<th>New Wearer</th>
<th>Existing Wearer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Lens-Related History</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Keratometry and/or Corneal Topography</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Anterior Segment Analysis with Dyes</td>
<td>As Indicated</td>
<td>As Indicated</td>
</tr>
<tr>
<td>Biomicroscopy of Eye and Adnexa</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Biomicroscopy with Lens: Fluorescein Pattern (Rigid Lenses) or Orb Movement and/or Centration (Soft Lenses)</td>
<td>Required</td>
<td>As Indicated</td>
</tr>
<tr>
<td>Overrefraction</td>
<td>As Indicated</td>
<td>As Indicated</td>
</tr>
<tr>
<td>Visual Acuity with Diagnostic Lenses</td>
<td>Required</td>
<td>As Indicated</td>
</tr>
<tr>
<td>Determination of Contact Lens Specifications Determined to Obtain the Final Prescription</td>
<td>As Indicated</td>
<td>As Indicated</td>
</tr>
<tr>
<td>Member Instructions and Consultations</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Proper Documentation with Assessment and Plan</td>
<td>Required</td>
<td>Required</td>
</tr>
</tbody>
</table>
as well as the final contact lens prescription. A short narrative assessment of the patient’s subjective response and/or the doctor’s objective response regarding the state of the contact lens ordered should also be written; this should include comments on the clinical findings, impressions and diagnosis.

Additionally, practitioners should add notes on their planned treatment plan to the patient’s file, with information like the contact lens materials and parameters included. Dispensing visit documentation should contain instructions prescribed to the patient for their lens care regime, handling and wear schedule. Finally, a description on the patient’s ability to apply and remove the contact lenses, as well as financial records relating to the ordering of the final lens prescription and a comment regarding whether the contact lenses were dispensed from stock for record-keeping purposes may also be prudent to include.

Records taken at follow-up appointments of the patient’s progress should document their positive and negative comments related to wearing the lens, as well as the patient’s report of their level of compliance with practitioner instructions. Notes on the patient’s advances in their lens wear should include monocular acuities and overrefraction as well as slit lamp observations documenting the lens on the cornea and the health of the corneal surface and surrounding tissues. Finally, any new clinical findings or changes in lens care, wearing or replacement recommendations should be written down for the purposes of updating treatment plan records. When documenting medical necessity, it may be useful to include pachymetry, specular microscopy, tear film assessment including osmolarity, InflammaDry scores, staining assessment with both NaFl and lissamine green, meniscus height, tear break-up time and the status of the meibomian glands. 

Table 2 lists an example of one company’s (EyeMed) test requirements for provision of coverage to new and existing contact lens wearers. In comparison, other companies require itemized financial records for medically necessary contact lenses to include: patient name; date of service; contact lens brand, type, quantity and date dispensed; customary costs for services and materials; amount billed to the insurance, amount paid by the patient and method of payment.

**RETURN TO BASE**

Going back to the question at hand—whether medical care plans and vision care plans should make a greater effort to overlap coverage for the patient—a related point is this: even with dual coverage, many of the medically necessary treatments fall through the cracks because vision care plan providers and medical care plan providers believe the procedure in question is not in their sphere of coverage. As such, both practitioners and their patients are the ones to take the hit. However, we may have the ability to make a difference.

First and foremost, we as practitioners must educate the medical plan coordinator as to the difference between a vision care expense and/or the doctor’s opinion. ICD-10 is the first attempt to breakout diagnostic codes, and procedure codes will be the next project CMS will attempt to streamline. With the consolidation of medical insurance companies in our immediate future, the trickle-down effect will soon reach the vision care plan providers with medical guidelines filtering into our vision insurance plans. Educating administrators with regards to the complete needs of our patients—both on the vision care side as well as the medical care side—will also allow patients that may not be aware of current options to receive the services they require.

**Health care insurance is an ever-evolving entity, and contact lens practitioners must remain informed of changes that impact the care we provide. We must remember that some medical conditions require contact lenses as a serious form of treatment. For some people, they are not simply a cosmetic option.**

Brimonidine is an interesting molecule to consider. As an alpha-2 adrenergic agonist, many practitioners may most often think of this medicine for its use in treating glaucoma. The majority of brimonidine’s activity resides in its ability to decrease aqueous production from the ciliary body, though it also helps to facilitate some extra aqueous drainage through the trabecular meshwork. Currently, brimonidine is available in three commercial concentrations: 0.1%, 0.15% and 0.2%.1

So the question is, why would we bring this drug up in a contact lens column? Because brimonidine has an interesting side effect profile that may prove useful to some lens wearers. Due to its activity on the alpha-2 receptor, it also acts to prevent pupil dilation under mesopic and scotopic conditions. This is done via the inhibition of the release of norepinephrine from the pre-synaptic nerve terminal in the cleft of the dilator muscle, which allows the tonus of the sphincter muscle to take over and ultimately reduces the pupil’s size (Figure 1).2 Here, we will discuss three common uses for brimonidine in the contact lens wearer.

**Orthokeratology.** Some patients are able to wear orthokeratology lenses overnight to facilitate gentle progressive remodeling of the cornea’s shape to remove the need for spectacle or contact lens wear during the day. The most common type of refractive error corrected using orthokeratology lenses is myopia, though advanced designs now also allow for higher levels of astigmatism to be corrected as well via flattening of the central topography of the cornea to create a midperipheral steep curve. This results in a corneal appearance topographically similar to that of a postoperative LASIK cornea (Figure 2).

But, just as physiological pupil dilation can affect a postoperative LASIK patient’s vision in the evening, so too can it affect a patient who has undergone orthokeratology treatment, as the pupil has the opportunity to dilate out to the edge of the treatment zone in certain conditions, potentially affecting vision. Increasing the size of the treatment zone with modifications to the lens size or decreasing the sagittal depth of the lens can assist with increasing the size of the treatment zone. In this case, one alternative is to have a patient use a drop of brimonidine in mesopic and scotopic conditions where vision may be sub-par.

**Multifocal Gas Permeable Lenses.** Some of these rigid lenses may at times have their optical zones located on their front surface, while other options will contain some of the multifocal optics on both the anterior and posterior surfaces of the lens. Multifocal GP lenses are typically designed with the distance optics located in the middle of the lens and slowly progressing to the near optics towards the midperipheral and peripheral portions of the lens. Success with multifocal GPs requires appropriate centration both horizontally and vertically. Any significant displacement from the location of the pupil in either of these meridians will affect visual clarity for the patient.

When appropriately aligned, multifocal GPs provide excellent distance vision and the opportunity for translation into the near optics of the lens. Of course, there are environments that may make the vision somewhat more challenging for these individuals.

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**Fig. 1.** (a) infrared pupil readings prior to the instillation of brimonidine; (b) five minutes after the instillation of 0.1% brimonidine.
One example is levels of low light, such as when driving near sunset. Depending on the amount of pupil dilation that occurs in these individuals, their pupils may widen into the region of the lens in which the distance optics begin to transition into the near optics. Fortunately, most GP lens designs can be altered to increase the distance center portion of the lens to allow for pupil dilation with less interference of the near optics.

It is in this case that topical brimonidine may be beneficial as an alternative to moving the zones of the lens to compensate for mesopic and scotopic conditions. This would provide potential visual benefits to the patient without the need to change the properties of the lens itself. Additionally, since the GP lens material won’t absorb the medication, the drug can be applied without removing the lens.

Small Diameter Lenses for Corneal Ectasia. At times, the GP lenses that practitioners fit their irregular corneal patients with are slightly smaller than typical to compensate for how steep the curves on the back of the lenses are. Interestingly, this can create challenges for patients wearing these lenses in the evening, as their pupils may dilate outside of the optical zones of the lenses (Figure 3). In these instances, we can create larger lenses with aspheric back surfaces to compensate. Additionally, semiscleral, scleral and hybrid lenses are often times options for these individuals as well.

However, controlling pupil size with brimonidine may also be an option if the patient wishes for the lens characteristics to remain the same.

**PRESCRIBING HABITS**

Take note that while the above information constitutes suggestions for brimonidine use, minimizing pupil dilation with this drug is not an FDA-approved indication for the product. As such, before proceeding with a prescription for patients in the instances discussed, we feel it necessary to mention this fact to them to ensure they are comfortable using the medication in such a manner. As with any off-label indication, the benefits of treatment must outweigh the risk of adverse events that may result from it. Note, brimonidine use can in some cases lead to dry mouth or a tired feeling.

We typically prefer to prescribe brimonidine in its lowest commercially available concentration, which is 0.1% available as Alphagan P 0.1% (Allergan). We also send instructions with the prescription as follows: Sig: 1 gt OU prn for critical viewing tasks. This statement provides appropriate guidance to the pharmacist that the drug is not to be used on a chronic basis.

**Fig. 2.** Orthokeratology lens on the eye (left) and the topography of the cornea when the lens is removed (right).

**Fig. 3.** Small diameter lens off-center in which the lens edge is approaching the pupil margin nasally.

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Making the Best of It

Sometimes the situation does not go the best way it can. Here’s how the right attitude can make the difference for your patients.

The airline recently lost my bag. Nothing is notable about this fact in and of itself—actually, it’s happened before. And indeed, the initial drill this time was the same as every other time: wait in a line and fill out a form describing what the bag looked like, give the agent your the baggage stub and pray. Sometimes you get lucky and they find the bag with enough time to put it on the next flight; other times, you may receive it a few days later having survived with just your carry-on. I knew that chances were I’d get it back eventually, I just didn’t know when.

This particular time took a different turn, however, once I arrived at the front of the line to speak to the agent there. Admittedly, she had a pretty thankless job since by definition, everyone she deals with is unhappy, so I wasn’t expecting much. Of note, however, was the way in which she dealt with me specifically—it made me think about the way many of us and our staff members deal with the patients who come into our practices.

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Now, there isn’t much she could have done in terms of recovery short of snapping her fingers and producing the lost luggage then and there. What she did do, however, was display a funny and empathetic personality that helped ease the otherwise negative ordeal. Thinking about every other employee I’ve ever encountered or seen at the airport, she stood out as different to me in a profoundly positive way. My impression of her willingness to help, and the clear acknowledgment that I was truly inconvenienced by the lost luggage was even further helped when she said, at least what you’re wearing now will work great for everything from a corporate business meeting to a rock concert to a trip to the beach. But, I understand—you’d prefer the gold tuxedo in your suitcase. I’ll try and get it to you as quickly as I can.

KEEP ONE HAND ON THE WHEEL

There are many things that occur in the eye care office that to a large extent, we cannot control. Take for example, a patient with an insurance benefits package that only covers the cost of a single examination every two years. When you recommend to them that they come in each year, they may become frustrated. How do you soothe this situation? The knee-jerk response for many practitioners is to simply tell the patient, we’re sorry, that’s how your insurance works. It’s not our fault and send the patient on their way. However, though this is factually accurate, it’s not the best way to deliver this information.

Many of us understand the benefits of turning a bad customer service situation into a good one by going above and beyond using a service recovery strategy. Yet, few people recognize that even in day-to-day interactions with patients—whether things go smoothly from the get-go or not—an unexpectedly pleasant doctor and staff demeanor can be just as memorable. This behavior should be an integral part of your practice culture, as there are invariably many more times that things will go right instead of wrong as a result, and many more patients—essentially all of them—that will be impacted in a better way. As an exercise for your staff members, work out some hypothetical patient encounters that happen frequently and challenge your staff to consider the following: how can a routine, mundane patient-facing task be changed in such a way that patients immediately see it as a positive encounter instead of a negative or even neutral one? And, how can our personal execution and involvement in this task be modified so patients see us as a more memorable and positive advocate for their care?

Though the answer to these questions likely depends on the dynamics of the practice and its staff members, one factor to note: don’t think in terms of “big heroic actions” like getting a certain pair of back-ordered lenses in faster. Instead, focus on the key “daily grind” items like booking appointments, escorting patients, completing clinical tests and all of the other small tasks that, when done correctly and in a timely manner, gel together to form your patient’s good experience with your practice.
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