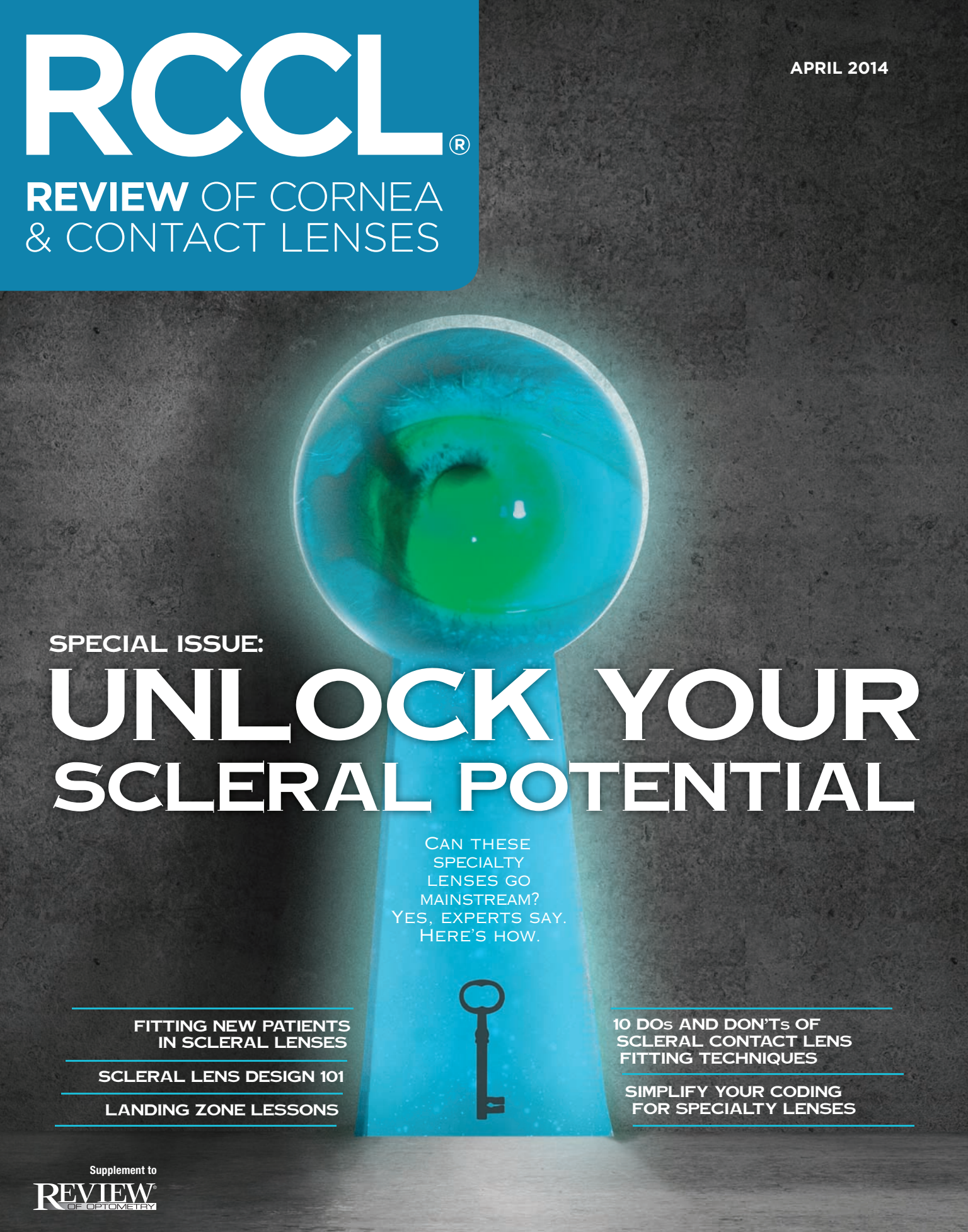
RCCL®
REVIEW OF CORNEA & CONTACT LENSES

APRIL 2014



SPECIAL ISSUE:

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FITTING NEW PATIENTS IN SCLERAL LENSES

SCLERAL LENS DESIGN 101

LANDING ZONE LESSONS

10 DOS AND DON'TS OF SCLERAL CONTACT LENS FITTING TECHNIQUES

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EARN 1 CE CREDIT – TREATING THE TEAR FILM: NUTRITION IS ESSENTIAL

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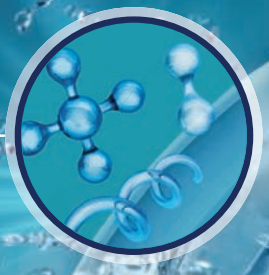

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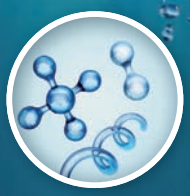

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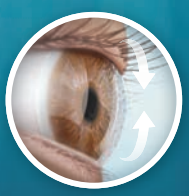

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*Based on DAILIES® AquaComfort Plus® sphere contact lenses.

Reference: 1. Wolffsohn J, Hunt O, Chowdhury A. Objective clinical performance of 'comfort-enhanced' daily disposable soft contact lenses. *Cont Lens Anterior Eye.* 2010;33(2):88-92.

See product instructions for complete wear, care, and safety information.

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IN BRIEF

• The use of an **aspirating speculum** on patients with **dry eye** may actually **aggravate** and exacerbate the condition, according to a recent prospective study, published in *Cornea*, that examined 58 eyes of 58 patients who underwent cataract surgery. Half the eyes were treated with an aspirating speculum and the other half with a non-aspirating speculum. The aspirating speculum group demonstrated significant aggravation by conjunctival staining on day one postoperatively, while no such staining was evident in the non-aspirating group. Additionally, the aspirating group exhibited an increased conjunctivochalasis grade from baseline to post-op day one (25 aspirating eyes vs. 13 non-aspirating eyes).

Moon H, et al. Short-term influence of aspirating speculum use on dry eye after cataract surgery. Cornea. 2014 March. 373-375.

• Bausch + Lomb recently launched a new hydrogen peroxide cleaning and disinfecting solution, **PeroxiClear 3%**, which it says can provide **up to 20 hours** of moisture. Additionally, while providing the same disinfecting capabilities of traditional peroxide solutions, the formula neutralizes in only four hours, according to the company. PeroxiClear will hit shelves in April and May 2014.

• Alcon has added toric and multifocal designs to its **Dailies AquaComfort Plus** line of one-day contact lenses. The new **Dailies AquaComfort Plus Toric** lenses come in a number of cylinder powers, including -0.75, -1.25 and -1.75 diopters, and offer 10 total axes. The **Dailies AquaComfort Plus Multifocal** lenses offer distance powers ranging from +6.00 to -10.00 and three levels of add power for both advanced and emerging presbyopes.

How Safe is DALK?

Newly developed corneal transplant techniques may result in poorer patient outcomes than older methods, according to a recent study published in the February 2014 *Ophthalmology*.

Researchers collected data from the Australian Corneal Graft Registry, established in 1985 to record the outcomes of corneal transplants performed nationally, and compared both graft survival and visual outcomes between patients who had penetrating keratoplasty, endokeratoplasty and deep anterior lamellar keratoplasty (DALK).

The data collected in the observational, prospective cohort study included 13,920 penetrating keratoplasties, 2,287 endokeratoplasties and 858 DALKs performed between January 1996 and February 2013.

According to the study, both graft survival ($p<0.001$) and visual outcome ($p<0.001$) were statistically better in patients who had penetrating keratoplasties than in those who received DALK.

Additionally, patients with Fuchs' dystrophy who received penetrating keratoplasties experienced better graft survival ($p<0.001$) and visual outcomes ($p<0.001$) than those who had endokeratoplasties. Penetrating keratoplasties also achieved better graft survivability than endokeratoplasties in patients with pseudophakic bullous keratopathy ($p<0.001$), but endokeratoplasties actually achieved better visual outcomes than penetrating keratoplasties in these same patients ($p<0.001$).

"This study's conclusion that lamellar corneal surgery achieves inferior outcomes as compared to the traditional full-thickness penetrating keratoplasty is based on life expectancy of the transplant and visual outcomes," says Eric Donnenfeld, MD, president of the American Society of Cataract and Refractive Surgery. But he doesn't believe these parameters tell the whole story.

"Penetrating keratoplasty is associated with a mean of five diopters of astigmatism and anisometropia," Dr. Donnenfeld says, "a risk of severe visual loss due to trauma approaching 1% and a dramatically higher incidence of glaucoma." Additionally, the study makes no mention of how the patients achieved their reported vision (i.e., via GP lenses or spectacles).

While the results suggest that graft survival in DALK and endokeratoplasty procedures is worse than that of penetrating keratoplasties with the same indications over the same timeframe, the researchers also note that more lamellar procedures are being performed every year.

"I agree that an interface associated with lamellar surgery will reduce best-corrected visual acuity by zero to two lines of vision," says Dr. Donnenfeld. He also notes that graft expectancy may be reduced, but the benefits of DALK make it a very reliable procedure overall.

"The dramatic increase in safety, speed of visual rehabilitation, reduced astigmatism and ease of repeat surgery make lamellar surgery the procedure of choice for most patients who have an option," Dr. Donnenfeld concludes.

Coster DJ, Lowe MT, Keane MC, Williams KA. A comparison of lamellar and penetrating keratoplasty outcomes: a registry study. Ophthalmology. 2014 Feb 1. [Epub ahead of print]

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JOBSON PROFESSIONAL PUBLICATIONS GROUP
11 Campus Blvd., Suite 100
Newtown Square, PA 19073
Telephone (610) 492-1000
Fax (610) 492-1049

Editorial inquiries (610) 492-1003
Advertising inquiries (610) 492-1011
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CLs Trump IOLs for Aphakic Infants

Using contact lenses to correct aphakia in infants following cataract surgery may provide better results than IOL implementation, says a study published in the March 6 *JAMA Ophthalmology*.

The Infant Aphakia Treatment Study, a randomized clinical trial conducted at 12 different sites, compared IOLs to contact lenses in 114 infants with unilateral congenital cataracts.

The infants were between one and six months old when cataract surgery was performed. Through random assignment, half were given IOLs while the other half received contact lenses to treat aphakia following surgery. Each child was assessed in a follow-up visit approximately four years following surgery (age 4.5).

No significant differences in median visual acuity were found between the two groups, but the children who received IOLs experienced significantly more adverse events than those who were left aphakic. The study also found that more subjects in the IOL group received at least one additional intraocular surgical procedure than those in the contact lens group (contact lens, 21%; IOL, 72%; p<0.001).

The researchers concluded that IOL implantation should be reserved for infants when the cost and handling of contact lenses would prove to be such an insurmountable obstacle that the end result would be significant periods of uncorrected aphakia.

Lambert SR, et al. Comparison of contact lens and intraocular lens correction of monocular aphakia during infancy: a randomized clinical trial of hotv optotype acuity at age 4.5 years and clinical findings at age 5 years. JAMA Ophthalmol. 2014 Mar 6. [Epub ahead of print]

Preservatives Linked to Discomfort

Preserved prednisolone acetate suspension 1% is more toxic to the cornea than non-preserved methylprednisolone sodium succinate 1%, according to a study published in the April edition of *Cornea*. Thirty-eight eyes received non-preserved methylprednisolone 1% hourly, and 34 eyes were treated with preserved prednisolone 1% followed by a two-week tapering regimen. Both groups demonstrated similar inflammation resolution, but subjects using non-preserved methylprednisolone 1% showed significantly lower corneal fluorescein staining score (p<0.001) and reported milder subjective ocular discomfort than those using preserved prednisolone.

Advertiser Index

Mixed Signals

Are omega-3 fatty acids beneficial or deleterious to the health of our patients? Faced with inconclusive data, how should we proceed?

As often as the tide comes and goes, headlines announce the most recent medical findings with perhaps a bit too much zeal. Waves of clinical trials over the past few decades have certainly altered the way we practice. Unfortunately, some study conclusions are based on poorly designed methods or a flawed data analysis. For example, controversy runs rampant in reviewing the literature on omega-3 fatty acid (FA) intake. One week it's the best thing we can recommend to patients; the next week we worry about the potential risks when prescribing these supplements.

Research has shown many potential benefits to supplementation with fish oil: improving memory, increasing weight loss for women, improving ADHD symptoms, treating acne and protecting infants from allergies.[1-5] Additionally, many studies have suggested serum lipid level improvement by supplementation. However, reviewing the literature reveals some controversies in health care specialty research.

SELECTING THE RIGHT SUPPLEMENTS

It is a common practice to prescribe omega-3 FA supplements for dry eye. Supplementation with the proper balance of omega-3 and omega-6 essential FAs improves TBUT and often relieves symptoms.[6] But recent research has suggested that omega-3 FAs have deleterious effects on prostate antigen levels and may increase the risk for prostate cancer.

The Selenium and Vitamin Cancer prevention Study (SELECT) examined the effects of selenium and vitamin E on prostate cancer.[7,8] The SELECT data analysis determined that a plasma concentration of long-chain omega-3 FA was associated with a 43% increased risk of prostate cancer among men who had the highest levels of omega-3 FAs in their plasma. They also noted a decreased risk of "low-grade" prostate cancer in men with a higher level of linoleic acid (omega-6).[7]

Proponents of prescribing omega-3 supplements point out some limitations of the SELECT study: (1) it wasn't designed to study the relationship between omega-3 FA intake and prostate cancer; (2) there was no standardized method documenting how men achieved their level of omega-3 FAs; (3) selenium and vitamin E may be confounders; (4) the statistical model used may not be appropriate for the conclusions drawn.[9]

Advocates note that other studies have determined the contrary for prostate and other cancers. Several studies demonstrated a benefit for increased omega-3 FA intake in regard to prostate cancer risk (Lietzman et al. 2004, Terry et al. 2001). Sixteen independent cohort studies found a dose-related response with a 5% lower risk of breast cancer with incremental increases of daily marine n-3 PUFA.[9,10]

HARD TO SWALLOW

So, should we suggest patients take these supplements or not? Are the fish oil supplements available different or incomplete without other components found in cold water fish? We will have to weigh the evidence that's currently available to us before making any recommendations to our patients.

Prudence is key; always consult the patient's primary care provider and specialty practitioner before initiating such treatment. It's essential to have a frank discussion with your patient; omega-3 FA supplements in moderation may have a beneficial effect on a dry eye, and not impart any significant risk to your patient.

In the meantime, stay tuned to the latest headlines and research before recommending anything to patients. Based on what we currently know, I'd say the jury is still out on omega-3s! RCCL

1. Stonehouse W, et al. DHA supplementation improved both memory and reaction time in healthy young adults. AJCN. March 2013.

2. Irene A, et al. Prior supplementation with long chain omega-3 polyunsaturated fatty acids promotes weight loss in obese adults. Food & Function. Feb 2013.

3. Milte C, et al. Eicosapentaenoic and docosahexaenoic acids, cognition, and behavior in children with attention-deficit/hyperactivity disorder. Nutrition. 2012; 28:670–677.

4. Burns-Whitmore, et al. Effects of fish oil supplementation on inflammatory acne. Lipids in Health and Disease. 2012; 11:165

5. D'Vaz N, et al. Fish oil supplementation in early infancy. Clinical and Experimental Allergy. 2012; 42:1206–16.

6. Jackson MA, et al. Efficacy of a new prescription-only medical food supplement in alleviating signs and symptoms of dry eye. Clin Ophthalmol. 2011; 5:1201-6.

7. Klein EA, et al. Vitamin E and the risk of prostate cancer results of SELECT. JAMA. 2011;306(14):1549-56.

8. Brasky TM, et al. Plasma phospholipid fatty acids and prostate cancer risk in the SELECT trial. J Natl Cancer Inst. 2013; 7.

9. http://www.omega3galil.com/wp-content/uploads/2013/10/Omega-3s-and-Prostate-Cancer-Risk.

10. http://www.medscape.com/viewarticle/808402?src=wnl_editspecol&uac=142918FK.

A Crack in the Surface

Improper lens care by your GP wearers can lead to expensive, unnecessary remakes. Educate patients on proper care techniques to prevent these costly situations.

There are many things patients do—things they will never admit to—that lead to the destruction of their GP lenses. Clearly, in their eyes, the fault must be some manufacturing defect. Or maybe it's a faulty lens? But one thing is for sure: it is not something the patient has done! After all, these are the same lenses they have worn for 30 years, and this is the first time this problem has ever occurred. These patients believe it is your responsibility to honor a warrantee (be it real or imagined) and exchange the lens.

Fortunately, there are a number of early signs that indicate improper lens care. Being well aware of these behaviors can help to prevent costly remakes.

THE TELLTALE SIGNS OF LENS ABUSE

• ***The crazed lens.*** A spiderweb-like pattern on the surface of the lens (*Figure 1*) is caused by the material coming in contact with alcohol, acetone, ammonia and—yes, I have seen this—paint thinner. Sometimes patients think they are disinfecting or 'super cleaning' (or, in some cases, actually removing paint) when they use these products to maintain their lenses. Other times, these chemicals are introduced inadvertently, usually through sprayed perfume or introduced in the lens case well when the patient cleans the bathroom.

• ***Deep lens scratches.*** Dropping the lens and sliding it across a counter will cause deep, 'swoosh-like' scratches on the lens surface. Educate patients about the many ways they can avoid this complication, such as wetting a finger and lightly touching the surface of the lens to pick it up by capillary action, using a plunger or floating the lens in a puddle of solution to lift it from the counter surface before actually picking it up.

Rough hands or the presence of microbeads in the cleaner will cause lighter, diffuse scratches with a more random pattern. Today's lenses made of silicone-containing, high-oxygen materials are much softer than the materials of the past. As such, you should recommend cleaners that do not contain microbeads and use a deep cleaner, such as Progent (Menicon), which does not require mechanically scrubbing the lens surface.

• ***Warped or distorted optics.*** A number of factors can lead to a warped lens. The most common is an irregular cornea—over time, the constant lid forces flexing the lens over the corneal surface will result in warpage. This complication seldom distorts the optics, though it may induce cylinder.

Typically, distorted optics are the result of 'pressure cleaning' the lens between the thumb and pointer finger. This process causes flexure of the plastic and may actually invert the lens.

Another lens distorting no-no is exposing the lens to extreme heat. So, be sure to inform your patients to avoid leaving their contact lenses in the car.

• ***Lens deposits*** can arise from a variety of behaviors. The most common cause is simply not cleaning the lenses using an appropriate care regimen. Many GP wearers have deep-seated cleaning habits, which include using dish soap and water. I've seen other strange GP care behaviors, which include removing lenses with odd things such as honey or chewed up tootsie rolls—I kid you not. It's best not to assume a long-time wearer knows how to properly clean and maintain their lenses, so it is essential to periodically review the correct care habits.

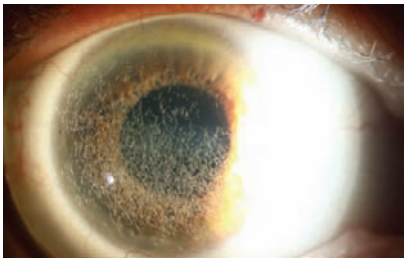


Fig. 1. A spiderweb-like crack on the surface of a GP lens as a result of chemical contact.

• ***Non-wetting lenses*** may be the result of coatings that form on the lens from either exogenous or endogenous sources. Glycerin and other moisturizers, as well as waterproof makeup, can stick to the hydrophobic surface and prevent the lens from wetting. Other sources of non-wetting, which tend to be more common in my experience, are endogenous to the wearer, such as meibum from the lids.

There are many ways for patients to destroy their lenses, none of which are not the doctor's fault, but can end up (repeatedly) being the doctor's financial responsibility. Such behaviors can be avoided entirely, so long as they are discussed with each patient. RCCL

By Mile Brujic, OD, and Jason Miller, OD, MBA

Stick the Landing

A poor scleral lens fit may lead to conjunctival blanching and patient discomfort. Prevent these complications to ensure your patients stay in their lenses.

Scleral lenses have allowed a number of our irregular cornea patients to see the world in a manner that may have previously been impossible. Because these lenses vault the cornea, they create a wholly new refractive surface—freeing the clinician from the constraints of the patient's corneal anatomy. Scleral lenses also provide a stable visual experience; unlike traditional small-diameter GP lenses, they do not move with each blink.

We have used sclerals on a number of normal corneas and have prevented patients from dropping out of lens wear. Patients with high levels of ametropia (specifically those with high levels of astigmatism), who are dissatisfied with the stability of their vision, have done quite well with this design. We have also used this modality to allow patients to re-enter lens wear following years of discontinuation.

But, as with any lens choice, we must consider the disadvantages of the modality along with its advantages so that we can exercise caution when prescribing these lenses. Because this lens is meant to clear the cornea entirely, an ideal fit must provide both adequate central and limbal clearance. As a result, the lens should rest solely on the conjunctiva and underlying sclera via its scleral landing zone. It is thus critical to respect the interaction between the lens and the conjunctiva—that may very well be what makes the difference between a successful and an unsuccessful fit.

Fig. 1. The ideal lens/eye relationship. Also shown is a schematic showing an ideal scleral landing zone relationship with the eye.

A PERFECT FIT

To achieve the ideal fitting relationship, the landing zone must be parallel to the conjunctival surface. This distributes the weight of the lens evenly across a large surface, reducing the burden on smaller areas of conjunctiva (*Figure 1*).

The challenge arises when the landing zone is not parallel to the conjunctiva, as this concentrates additional pressure upon localized areas of tissue. This produces excessive stress on those 'hot spots,' kicking off a familiar chain of events that we know all too well—discomfort » dissatisfaction » dropout.

To avoid this, we must address two clinical challenges when fitting scleral lenses: landing zone impingement and compression.

Impingement occurs when the very outer edge of the lens pinches into the conjunctiva. When initially placed on the eye, these lenses will feel very comfortable. But, comfort will gradually decrease as the patient continues to wear the lenses throughout the day. Impingement at the outer edge of the lens will often cause bulbar hyperemia as well.

Using a slit lamp, you can see the pressure that the lens is placing on the conjunctiva. It will be revealed by the appearance of conjunctival blanching under and adjacent to the edge of the lens, at the distal portion of the landing zone (*Figure 2*).

This complication is a direct result of the scleral landing zone of the lens being steeper than the

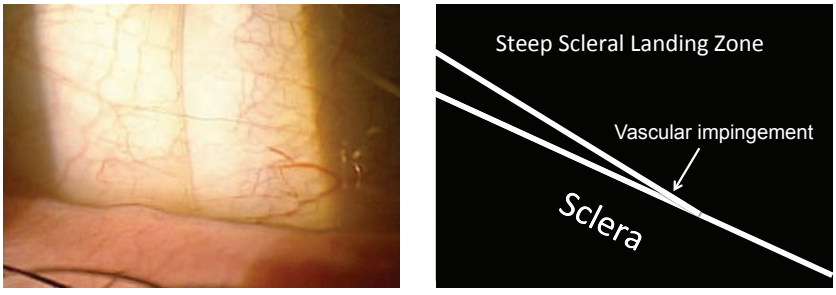
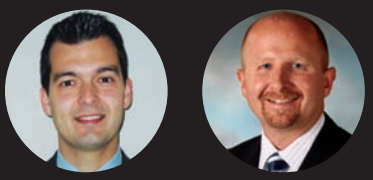


Fig. 2. A clinical photo of impingement. Also shown is a schematic showing a scleral landing zone that is causing impingement.



scleral profile. To resolve this particular challenge, flatten the scleral landing zone. This will allow the lens to more evenly distribute its weight over the conjunctiva, which in turn reduces the localized pressure that causes the conjunctival blanching beneath the edge of the lens.

Because of the obvious pressure on the vascular supply in the underlying conjunctiva, it is important to resolve this fitting challenge as soon as it's seen. Additionally, these patients typically experience significantly higher amounts of debris and clouding under the lens than normal and, as such, require more frequent removal and rinsing of the lens.

Compression results when the proximal portion of the lens's landing zone produces excessive pressure on the bulbar conjunctiva. When initially placed on the eye, patients may experience significant lens awareness; however, this will decrease as the lens settles on the eye. Compression may also result in bulbar hyperemia due to the area of excessive pressure.

As with impingement, this too can be seen at the slit lamp. The appearance of conjunctival blanching in an area under the proximal scleral landing zone is a clear sign of compression (*Figure 3*).

In effect, compression is the converse of impingement: when the scleral landing zone is flatter than the scleral profile, compression results; if the landing is steeper, impingement does. So, it should come as no surprise that the approach to resolution of compression is the opposite of that needed for impingement: steepen the scleral landing zone to achieve a more even lens distribution over the conjunctiva.

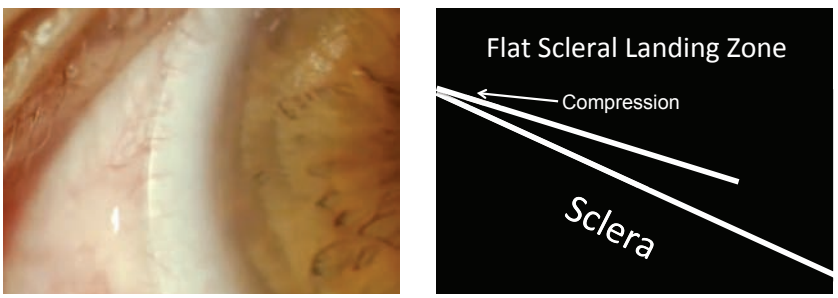
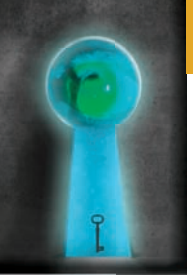


Fig. 3. A clinical photo of compression. Also shown is a schematic showing a scleral landing zone that is causing compression.

It is important to keep these considerations in mind when designing scleral lenses for patients, as it will help to ensure the best possible fit, comfort and visual outcome. These strategies help provide those patients who would benefit from this design the greatest chance of doing so, and will also help to keep individuals in contact lenses who may have otherwise considered discontinuing lens wear. Ensuring your patients are experiencing an ideal lens-to-eye relationship will ultimately help derail dropouts. RCCL



PUTTING SCLERAL LENSES

Commonly reserved only for patients with irregular corneas, sclerals can be an excellent option even for patients with 'normal' ones.

Clinicians have been fitting scleral contact lenses for over a century; indeed, this design marked our first opportunity to correct refractive error without spectacle lenses. Their virtues in vision correction and promotion of ocular surface healing have long been known, but several hurdles made the mainstream viability of scleral contact lenses short lived. The earliest sclerals were made of fragile and potentially harmful glass, which was then succeeded by PMMA—a material that offered poor oxygen transmissibility, leading to the discontinuation of lens wear due to corneal hypoxia. Because these materials required the lenses to be handmade, they were impossible to replicate in the instance of breakage or loss.

Fortunately, the modality has improved in recent years; we now have hyper-oxygen permeable materials, computer-driven lathes and diagnostic imaging to guide fits—making scleral lenses more comfortable and easier to fit than many other options. There is nearly three decades of documentation and hundreds of scientific studies proving the success and benefits of wearing scleral contact lenses.

Thanks to the recent advances in scleral lens designs, patients with irregular corneas and ocular surface disease are now enjoying healthy lens wear and great vision with similar initial comfort to that of a soft contact lens.

However, the rapid advancement of corneal RGP and hydrogel soft lenses (and their silicone hydrogel successors) over the same period relegated sclerals to specialty practices serving niche patient populations. We would argue that this is shortsighted and does a disservice to many patients who might be better served with a scleral design.

REFOCUSING A MINDSET

Over the past three decades, the use of (highly oxygen permeable) scleral lenses for a number of ocular conditions has increased dramatically, and the applications for them continue to grow. Ocular surface disease was the first recognized use for scleral lenses, and remains the only indication currently recognized by Medicare for coverage as a prosthetic device. Patients with corneal ectasia represent a rapidly growing group of scleral lens wearers. Additionally, scleral lenses are restoring vision to patients with neurotrophic and exposure keratopathies, reducing the need for tarsorrhaphies and corneal transplants.

With each passing year, laboratories continue to improve their lens designs to encompass more visual performance needs. For example, scleral lens technology developments made in just the last decade include front surface toric lenses for residual astigmatism and toric peripheral curves for eyes with greater than average scleral toricity. A number of laboratories also offer reverse geometry design lenses and multifocal scleral lenses. There is even technology to precisely customize a lens to the specific shape of an individual's irregular globe. These options allow us to offer customized care for our entire patient population—improving vision, comfort and overall quality of life for habitual and new lens wearers alike.

It's not just the technology and designs of scleral lenses that continue to evolve, however. We're now beginning to use more sophisticated fitting techniques to expand the pool of patients who can be considered candidates for scleral contact lenses. For example, scleral lenses aren't only for patients with irregular corneas; patients with normal corneas are now considered great candidates—especially when their visual needs exceed the typical parameters of soft lenses.

Scleral lens wear in patients who do not have irregular corneas is

ABOUT THE AUTHORS

Dr. Barnett is a Principal Optometrist at the UC Davis Medical Center. She specializes in anterior segment disease and specialty contact lenses.

Dr. Messer practices at the Cornea and Contact Lens Institute of Minnesota. She specializes in fitting specialty contact lenses.

FRONT AND CENTER

By Melissa Barnett, OD, and Brooke Messer, OD

becoming so popular that laboratories are designing scleral lenses made specifically to vault normal corneas. Patients with high astigmatism who desire a multifocal option are no longer restricted to corneal gas permeable lenses—even though, in certain cases (e.g., a patient with ocular surface disease, such as dry eye or refractive error), these designs remain a great option for lens wear.

Adding patients with normal eyes to the scleral lens-wearing population has signaled a major shift in philosophy from years past—and it's continuing to gain popularity. As habitual contact lens wearers reach their forties and contact lens dropout becomes more likely, sclerals can offer us another way to keep patients wearing lenses despite the onset of presbyopia and ocular surface disease that may otherwise be a deterrent.

Overall lens diameter is another aspect of scleral lenses that has seen a significant change. The theory behind lens diameter selection remains the same: the more sagittal depth needed to vault the corneal apex, the larger the lens diameter should be. What has changed, though, is the range of diameters available for scleral lens designs. Now, diameters come as small as 14.3mm, while still maintaining a full corneal and limbal vault, rather than using a corneoscleral fitting technique.

While this design is not appropriate for all irregular corneas, it has been very successful with normal corneas, and a vault of as little as 100 microns is considered acceptable in many cases. These smaller-diameter lenses are less intimidating for some patients and clinicians, easier for patients to handle and, in some cases, may be a less expensive option. In these smaller-diameter lenses, the limbal-scleral curvature is mostly regular and has less interpatient variability near the cornea than the peripheral sclera. As with all scleral designs, limbal clearance must be maintained during lens wear to preserve the health of limbal stem cells.

Table 1. Multifocal Scleral Lenses

COMPANY	LENS
Acculens	Maxim Plus
Acculens	Comfort SL Plus
Art Optical	So2Clear Progressive
Advanced Vision Technologies	AVT
Blanchard	MSD
Blanchard	One Fit
Dakota Sciences	So2Clear Progressive
Essilor	Jupiter Plus
Metro Optics	So2Clear Progressive
Lens Dynamics	Dyna Semi-Scleral
Truform	Digiform Multifocal
Valley Contax	Stable Near

A final change in fitting technique worth noting is the decline in use of fenestrations—a lens alteration used very selectively now, on a case-by-case basis. We have known for 30 years that fenestrating lenses does not increase oxygen transmission or improve tear exchange in any meaningful way. Fenestrations should only be used for easier removal, due to the suction effect. In very rare cases, fenestration may be used to release CO_2 from beneath the lens; however, this is not always successful.

To make the fitting process smoother for practitioners, scleral fitting sets now offer expanded parameters to expedite the process. In addition to numerous base curves, many fitting sets include lenses with different overall diameters, changes to the peripheral curve lifts, different curvatures to contour the limbus and even different specifications in sagittal depth.

NEW PATIENTS, NEW VISION

With all these advances in scleral lens parameters and technology, nearly every patient in your office becomes a scleral lens candidate. The most receptive are likely those who experience frustration with their current soft contact lenses—usually due to the modality failing to adequately meet their vision needs. It's up to the practitioner to ensure every patient is satisfied with their lenses, and it is acceptable to ask your patient whether or not they are satisfied with their quality of vision. Patients often believe their current lenses are the best option

available, so they rarely bother to ask questions regarding new products in the contact lens world. Patients who typically fit this mindset include those with high astigmatism, residual refractive error post-LASIK surgery or presbyopia.

Those who have high astigmatism are especially pleased with scleral lenses, as they can rotate without having an effect on vision. If the astigmatic topography shows limbus-to-limbus toricity, it may extend onto the sclera and produce some lens flexure. As a practitioner, you'll see with-the-rule astigmatism on retinoscopy and the patient may comment on vision fluctuation or reduced acuity with a spherical overrefraction. A spherocylindrical overrefraction and keratometry or topography over the lens will provide some insight on how much flexure is occurring. Typically, increasing the center thickness of the lens by anywhere from 0.05mm to 0.20mm is our first adjustment, but decreasing the overall diameter is another option that may reduce flexure. In our experience, a final option when attempting to decrease flexure is to add toric peripheral curves to the lenses in an effort a better contour to the patient's sclera.

Post-refractive surgery patients have altered corneal geometry and an elevated likelihood of dry eye; they may struggle with vision issues related to the stability of the fit. The oblate-shaped cornea no longer fits the prolate toric soft lenses, which causes patients to become frustrated with lens movement and rotation. Scleral lenses are an excellent option for these patients because the tear lens corrects for corneal astigmatism and helps with dry eye. Occasionally, to maintain an even tear film from limbus to limbus, a reverse geometry lens is needed for an oblate cornea. Many post-LASIK patients want to return to contact lenses when presbyopia becomes a problem. Fortunately, there are a number of well-designed multifocal scleral lens options on the market today. Table 1 lists many examples.

Many well-designed multifocal scleral lenses are on the market today. These lenses are simultaneous vision designs, as these lenses move minimally on the eye. Most designs are center-near, with the exception of the AVT scleral multifocal and Jupiter Plus lenses, which are a center-distance design. The Jupiter Plus lens offers an intermediate-near add, but not full-near add.

MAKING THE SOFT-TO-SCLERAL REFIT

If, following this review, you're eager to find opportunities for fitting new patients in scleral lenses, start by considering those with normal corneas who wear soft lenses for astigmatism or presbyopia who complain of fluctuating vision or poor night vision. To successfully convert our soft lens-wearing patients, we must refit them quickly when problems arise and achieve better results than soft torics or multifocals while maintaining good lens comfort.

First, assess their current frustration level as well as their desire to change modalities and undergo a new fitting procedure. Once the patient has agreed to try new lenses, use revelant anatomical data—their topographies, corneal diameter measurement, palpebral fissure widths—to help select an appropriate lens design. We're all aware that scleral lenses provide better initial comfort when compared to smaller diameter corneal GP lenses, but we need to be sure we select an appropriate design to ensure a good fit in our soft contact lens wearers. In doing so, we provide an excellent first experience, ensuring the patient remains excited about the vision potential offered by this new lens design.

The following tips can help with the education and fitting process:

• ***Lens diameter selection***. The overall diameter of the scleral lens is the first decision you'll have to make. This factor is the primary reason scleral lenses provide more comfort than corneal gas permeable lenses. Diameter is also important because it determines the sagittal depth of the lens. Many patients believe their soft lenses are more comfortable than GP contacts due to the biocompatibility of the material, but we know that it's actually because they have a larger overall diameter and experience less lid interaction and lens movement.

That is an important point to communicate to patients. The larger lenses sit behind both lids, which reduces the interaction between the eyelid and the lens, and promotes excellent comfort and lens stability. Once patients understand this concept, the notion of wearing "hard" lenses is not nearly as intimidating.

When selecting the diameter, do so based on patient factors such as corneal diameter, the sagittal depth required to vault any corneal irregularity or ocular surface disease, scleral factors (e.g., pinguecula, conjunctival chalasis or toricity) and your personal experience with various lens designs. If the cornea is 12mm or more in overall diameter, you may want to begin with a lens that is at least 14.5mm to 15mm, so it can appropriately and comfortably vault both the central cornea and limbus.

An average palpebral fissure width is about 10mm. If a patient has an average sized cornea with a small to average palpebral fissure width, lenses that are 14mm to 15mm in overall diameter will perform well, and the patient will appreciate how easily the lens can

(Continued on page 17)

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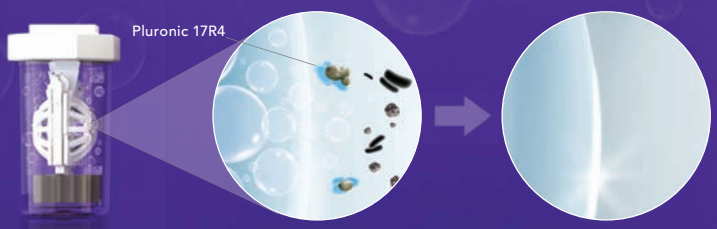

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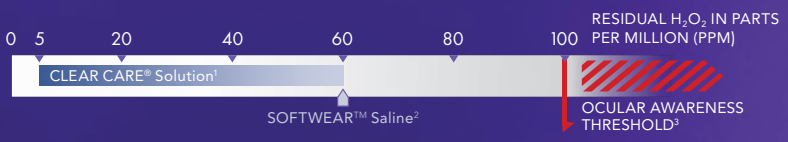

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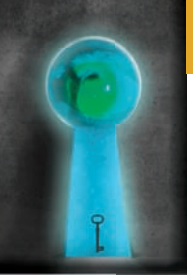

MANAGING

Successfully fitting scleral lenses may seem like a complex task. But understanding a few basic principles of lens curvature will make it simpler than you initially thought.

The best (and most well-paid) pitchers in baseball tend to be those with an excellent command of the curveball, able to throw at high velocity while also ensuring that the ball traces the arc of a curve with the utmost precision. Scleral lens design also relies on precise control of the curve. As in baseball, success stems from a solid foundation in the principles of physics. But scleral lens design is quite a bit simpler—just a matter of adjusting curves and manipulating distances to achieve the desired effects of sagittal depth. This article provides an overview of key facts that can help you master scleral contact lens fitting.

SCLERAL DESIGN 101

There are three main components to scleral lens design: the optic zone, the transition zone over the limbus and the landing zone on the sclera. Each zone is comprised of one or more curvatures, each of which has defined diameters. The shape of the curvatures may vary; they can be spherical, aspheric or a spline (a smooth polynomial function that is more complex than a simple asphere). Each of these zones has a different function and relationship to the ocular surface.

The *optic zone* is the power center of the lens; it is designed to vault the cornea and protect its optical function. The *transition zone* raises and lowers the optical zone relative to the eye, and is also vital to protecting the limbal stem cells. The *landing zone* is the area in which contact between the lens and ocular surface is made. To prevent inflammation, this contact must be done in a very controlled manner.

Scleral lenses are designed to vault both the cornea and limbus entirely and to land solely on the sclera. As such, it is important to understand the ways in which each zone can be manipulated to achieve the desired effect. It really is as simple as asking yourself, "Do I have too much/too little sagittal depth? What options do I have to change it?"

Small-diameter corneal GP lenses are designed to align to the corneal curvature. In these designs, the base curve (BC) has the greatest effect on vault and fluorescein patterns. Scleral lenses differ from these smaller-diameter lenses in that the transition zone is the most important zone for vault determination, followed by the overall diameter.

In scleral designs, the BC, or the back surface optic zone curvature, should be thought of foremost as a power-defining curve, and not entirely as a fit curve. Depending on which transition curves are selected, the BC may be flat or steep—affecting the power of the lens. For example, a -10.00D lens with a BC of 55.00D would be plano with a BC of 45.00D; depending on which transition zone curves are selected in this scenario, each of these BC values may have the same sagittal depth.

Steeper and wider transition curves offer greater sagittal depth, while bigger lenses allow for wider curves. *Figure 1* shows the profile and sagittal depth of a standard geometry 16.1 scleral lens. By increasing the width of the transition zone curves (noted by the red boxes) by 0.5mm the sagittal depth of this lens increases nearly 800 microns (*Figure 2*). Conversely, a 1.8mm change in BC is needed to achieve the same increase in sagittal depth (*Figure 3*).

A reverse curve in the transition zone (i.e., the secondary curve is steeper than the base curve) can also significantly increase sagittal depth—if a change in diameter is not desired (*Figure 4*). In this example, the secondary curve system was steepened by 1.9mm to reach the 800 microns of sagittal depth increase.

ABOUT THE AUTHOR

Dr. Sindt is the Associate Clinical Editor of *Review of Cornea & Contact Lenses*, and of *Review of Optometry*. She is also the Director, Contact Lens Service and an associate professor of clinical ophthalmology and visual sciences at the University of Iowa.

THE CURVE

By Christine W. Sindt, OD

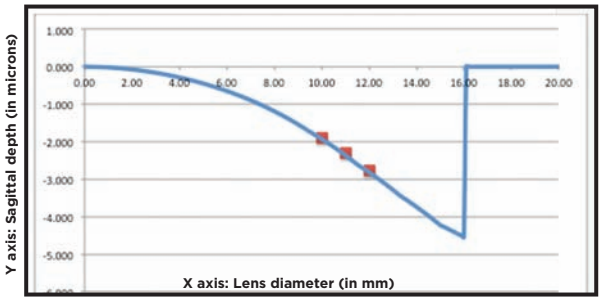

Fig. 1. The profile and sagittal depth of a standard geometry 16.1mm scleral lens.

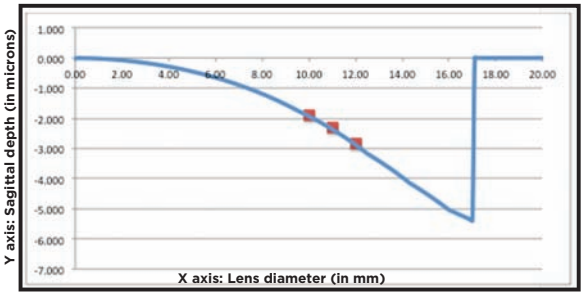

Fig. 2. A 0.5mm increase in transition zone curve width increases sagittal depth nearly 900 microns.

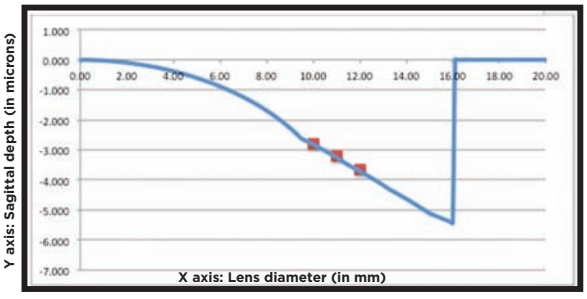

Fig. 3. A 1.8mm change in BC is needed to achieve the same increase in sagittal depth.

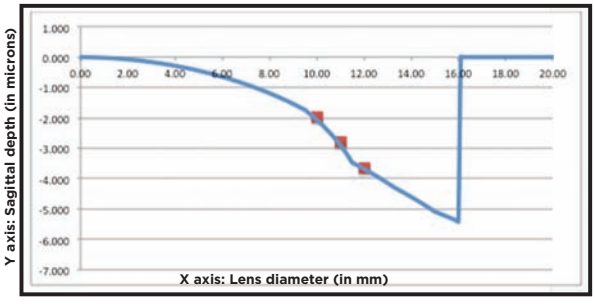

Fig. 4. The secondary curve system was steepened by 1.9mm to gain 800 microns of sagittal depth increase.

FITTING CONSIDERATIONS

There are a number of ocular surface conditions that affect lens design to consider, such as corneal geometry, corneal diameter, limbal geometry and scleral geometry. Lens design is simply a matter of determining the best way to align or vault these different geometries.

For example, post-surgical eyes with elevated grafts will need longer transition curves (*Figure 5*). Conversely, flat, drumhead grafts will need short—but steep—transition curves (*Figure 6*).

The images on the left show the profile of a proud graft with a standard geometry scleral lens. Note the apical touch with transition zone bubble. The fit is improved by widening the transition zone curves, which increases the overall diameter. The figures on the right show a flat drumhead graft; by flattening the BC and making the transition zone curves shorter, the lens is brought closer to the cornea. Steepening the transition curves will help alleviate some of the pressure over the graft/host junction.

Focal changes (e.g., those as a result of keratoconus) will create different sagittal depths across the optic zone (*Figure 7*). For patients with centrally elevated corneas, a steep BC is appropriate, while a flat BC with a steep transition zone (reverse curve) will fit periphery elevations (e.g., pellucid marginal degeneration) more evenly.

Bear in mind that the limbus itself may vary in geometry along different parts of the eye. While the majority of normal eyes will be tangentially aligned from the peripheral cornea to the sclera (*Figure 8*, left side), some limbal areas will have severe curvature changes—as a result of either pathology or surgery (*Figure 8*, right side).

It is necessary to bathe the limbus in fluid to protect the stem cells. Any contact with the limbus may result in inflammation and/or neovascularization of the cornea. If it is necessary to increase sagittal depth over the limbus, the transition zone curves should be widened; shortening the curves will bring the lens closer to the limbus.

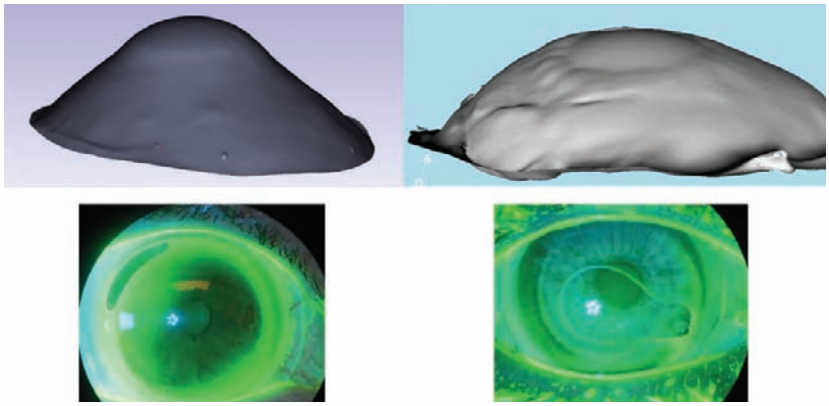

Fig. 5. Different ocular geometries require different lens designs.

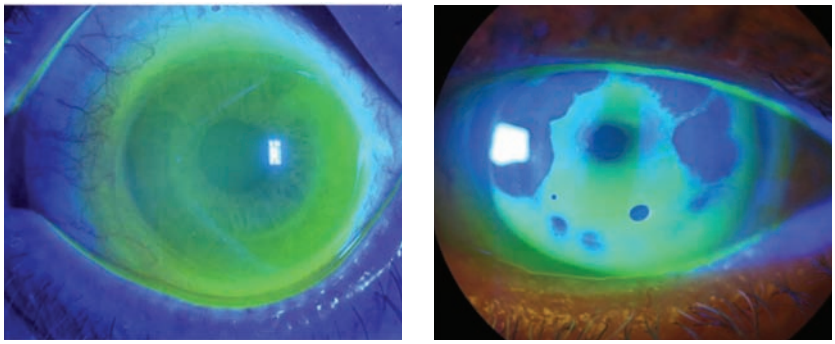

Fig. 6. Altering transition curves and widths can yield dramatic fit changes.

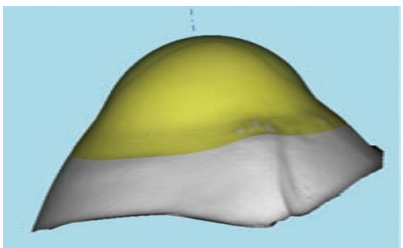

Fig. 7. Keratoconus patients will have different sagittal depths across the optic zone.

The landing zone of the lens should align with the sclera while avoiding localized impingement of both conjunctival and scleral vessels. The narrower the landing zone width, the less area the lens has to land and "float" on the scleral lens surface. If the landing zone is too narrow, the lens may "sink" into the sclera, causing an impression ring (*Figure 9*). If you notice that the lens has an impression ring or rebound hyperemia upon removal, flatter and wider landing zone curves should be ordered.

It is possible for scleral geometry to be entirely different, not just from patient to patient, but also from eye to eye in the same patient, or quadrant to quadrant in the *same* eye. As such, a standardized curvature may not be appropriate for everyone. Changes in scleral landing zone geometry can be frustrating, with localized changes (e.g., pinguecula and pterygium) causing inflammation and discomfort. Even eyes with no scleral pathology present may have significant changes in elevation (*Figure 10*). The nasal quadrant is typically higher and flatter in elevation than the temporal quadrant, resulting in impingement of nasal vessels. For the ultimate scleral design, bitoric, quadrant-specific or independent elevation (patient specific periphery) lenses can be ordered.

Fig. 8. Variations in the geometry of the limbus along different parts of the eye. While the left side of the limbus is aligned from the peripheral cornea to the sclera, note the severe curvature changes due to surgery on the right side of the limbus.

PLAY BALL

Scleral lens design simply comes down to whether a specific area of the lens needs to be closer to or farther away from the ocular surface. Changing curvature widths will have the biggest impact on increasing or decreasing sagittal depth. Using the transition zone to raise and lower the lens allows for flatter base curves and less minus powers. The scleral landing zone, which accounts for focal or quadrant scleral geometry changes, can be manipulated independently from the base curve and transition zone. Wider landing zones prevent the lens from "sinking" into the sclera, so care should be taken that widening the transition curves does not come at the expense of the landing zone width.

Fig. 9. An impression ring due to the lens "sinking" into the sclera.

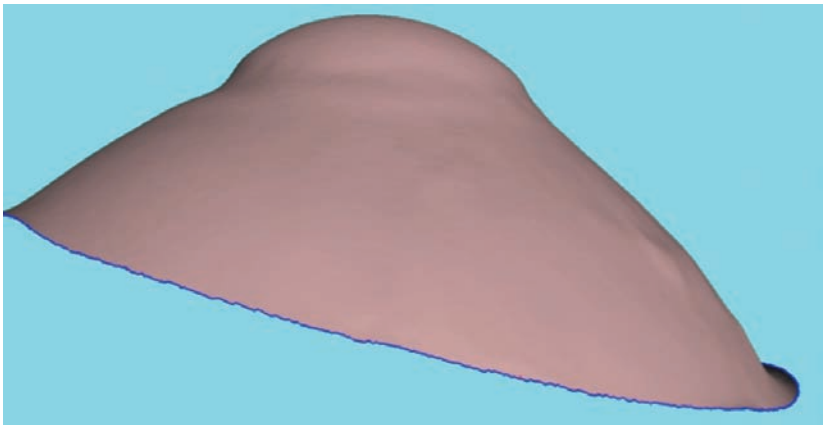

Fig. 10. Elevation changes can occur in both diseased and healthy eyes, as shown in this map of a patient with no scleral pathology.

Remember: for scleral lenses and baseballs alike, it's simply a matter of knowing the simple principles of physics—and you have more control than you think. RCCL

PUTTING SCLERAL LENSES FRONT AND CENTER

(Continued from page 12)

be inserted and removed from the eye. Larger palpebral fissure widths call for a larger lens diameter to ensure the edges of the lens are tucked behind both lids for good comfort. If your patient notes the lens is "a little uncomfortable," it is likely due to lid interaction from lift off or movement. Depending on the situation, the lens may need to be made either bigger or smaller to correct this.

• ***Corneal topography and keratometry readings***. There may be no direct relationship between topographical K readings and scleral lens base curve; however, topographical maps provide presumed information about sagittal depth.[6] Knowing the shape of the cornea can be the deciding factor in lens design selection.

For example, if the topography shows a moderate to large amount of limbus-to-limbus toricity, one might expect the sclera to have a greater than average amount of toricity as well. In this situation, an appropriate lens design may be one from a lab that can produce toric peripheral curves to match the toric sclera. For a scenario in which the corneal toricity is only in the central cornea, a lens with toric peripheral curves is not needed. Topographic readings are also very useful in evaluation of post-surgical corneas.

SOMETHING OLD, SOMETHING NEW

With so many aspects of scleral lenses having evolved in just the past decade, it can be confusing to keep all the information straight. Remember that your lens consultants possess a wealth of knowledge, as do groups like the Scleral Lens Education Society. The introduction of new lens designs means you'll have to learn new techniques, but the principles of patient communication remain the same.

These lenses are comfortable and provide excellent vision correction. The fitting process does require some patience; sclerals are complex in design and need to be ordered custom to your patient's eyes.

With clear communication and guidance from your laboratories, the addition of scleral lenses for normal corneas should serve as a healthy boost toward developing relationships and loyalty with your patients for years to come. RCCL

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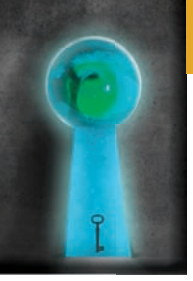


10 DOs and DON'Ts

The use of scleral contact lenses has grown exponentially since 2006.[1] Over the past decade, clinicans have started to consider scleral lens designs as an option for *all* contact lens patients. Improved materials and technology for fitting and manufacturing have helped create the renaissance this modality is currently experiencing.

Scleral lenses offer some distinct advantages, including superb comfort, stability of fit and excellent vision.[2] Despite these advantages, some difficulties can lead to dissatisfaction in your scleral lens wearers. This article will highlight 10 important "do's and don'ts" of scleral lenses.

1. DON'T FORGET TO EXPLAIN THE ENTIRE FITTING PROCESS.

When a patient comes in for a consultation, referral or comprehensive exam, and scleral lenses are found to be the best option for that particular patient, discussing the entire fitting process is critical to their success with scleral lenses. Be sure to inform the patient of just how long each appointment will be, and discuss the schedule of a typical scleral lens patient.

For example, a common schedule may begin with a one-hour diagnostic fitting, followed by a 30-minute dispensing visit, which is then followed by a one-hour training session on insertion and removal techniques. Finally, inform patients that there will be additional follow-up visits after the initial fitting.

Patients new to contact lens wear, and those who have never worn specialty lenses, need to be informed of the complex fitting and follow-up care involved. Detailing this during the first visit eliminates potential patient frustration, and will define their expectations for the scleral lens fitting process appropriately.

2. DO FILL THE LENS BOWL EXCESSIVELY.

Because most scleral lens fittings involve patients who are new to the modality, it is inevitable that there will be some insertion difficulties. This is especially true of patients who have never previously worn any type of contact lenses. Scleral lenses are inserted much differently than conventional soft contact lenses or corneal gas permeable lenses. The patient must tuck their chin into their chest and look down with their nose pointed to the floor. While this may sound strange to most patients, there is a legitimate reason for this: the liquid that fills the scleral lens needs to remain in the bowl.

Filling the lens excessively with non-preserved saline will help prevent insertion bubbles in the case of excessive eye movement, blinking and other errors (*Figure 1*). As some of the fluid will undoubtedly be spilled during the insertion process, excessively filling the lens bowl ensures there will be enough liquid left to still yield an appropriate fit.

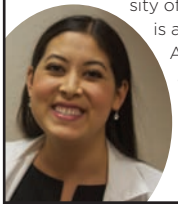
3. DON'T LET GO OF THE INSERTION DEVICE FIRST!

In one of the more common "rookie mistakes," patients will hold their eyelids open, insert the lens, remove their insertion device (e.g., plunger, fingers, plastic ring, etc.) and then release their eyelids. Fortunately, this mistake is also one of the easiest to remedy. After the lens is inserted on the eye, inform patients to release their eyelids first, and then release the insertion device. Releasing the eyelids first allows the lens to become trapped under the lids and onto the eye.

4. DO INFORM YOUR PATIENTS OF SEVERAL WAYS TO INSERT THE LENS.

During the insertion and removal training, be sure to thoroughly explain and demonstrate several insertion techniques (*Figure 2*). For instance, the large plunger may work well for some patients, but many others will find that a scleral ring/orthodontic band/O-ring offers a greater amount of control. Using these devices allows the lens to rest on one finger, freeing the others

ABOUT THE AUTHOR



Dr. Woo graduated from the Southern California College of Optometry and completed a Cornea/Contact Lens residency at the University of Missouri - St. Louis. She is a Fellow of the American Academy of Optometry and a Fellow of the Scleral Lens Education Society. She currently practices at Havasu Eye Center in Lake Havasu, AZ.

Fitting scleral lenses can be a tricky process, but proper preparation can ensure success when fitting this unique modality.

By Stephanie L. Woo, OD, MS

# of SCLERAL LENSES

for lid control. This is particularly useful for patients who have previously worn contact lenses, as using one finger to insert the lens may feel more natural.

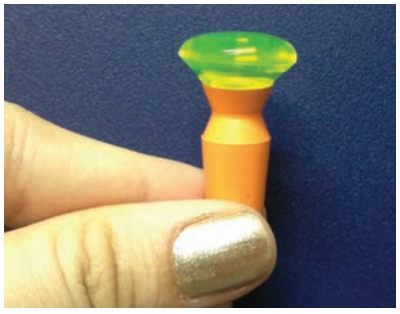


Fig. 1. Fill the lens excessively with non-preserved saline.

Additionally, training your patient on how to insert the lens using a tripod (three-finger) method may be useful for those who do not want to rely on devices to insert the lens. Giving patients a variety of insertion techniques allows them to trial several methods at home to determine which they personally find most comfortable. Simply offering patients a number of insertion options can be a huge factor in their success with scleral lenses.

5. DON'T SEND YOUR PATIENTS HOME WITHOUT RESOURCES!

After the lesson on insertion and removal training, send patients home with multiple resources (e.g., information on scleral lenses, insertion and removal handouts, lens care information, etc.). For example, I have each patient watch a 10-minute video from sclerallens.org on how to properly care for scleral lenses.

Additionally, I always give them a step-by-step guide detailing the process of scleral lens wear (e.g., place the lens on the insertion device, then fill up the lens with non-preserved saline until it is almost overflowing). If a patient forgets something, they can quickly refer to the provided guide. A quick-reference 'scleral lens tip sheet,' (e.g., apply make-up after inserting your lenses, wash your hands with soap that does not contain moisturizers, etc.) can also be a valuable asset for new scleral lens wearers.

6. DON'T ASSUME A LENS BUBBLE WILL DISSIPATE ON ITS OWN.

After inserting a scleral lens, immediately check for bubbles at the slit-lamp. If you see any, the lens must be removed and reinserted. The presence of bubbles is typically due to an error during insertion. Many practitioners think that as the lens settles, the bubble will move and dissipate on its own. This is not the case! The bubble will remain in the tear chamber until the lens is removed and correctly reinserted, and will greatly affect your evaluation of the fit and the over-refraction.

7. DO PERFORM A TEAR EXCHANGE TEST AT THE FOLLOW-UP VISITS.

At any of the follow-up visits, dab a copious amount of sodium fluorescein on the lens surface. Then, approximately 10 minutes later, check to see if any of the sodium fluorescein can be detected underneath the lens. This can help determine whether or not any tear exchange is occurring throughout the day.

If patients complain of red eyes, discomfort, blurred vision or burning upon lens removal, it could be because the lens edge is too tight and is not allowing any tear exchange. This is one of the most common problems seen with scleral lenses. One solution may be to flatten the edge of the scleral lens, which creates greater alignment with the conjunctiva, and allows adequate tear exchange.

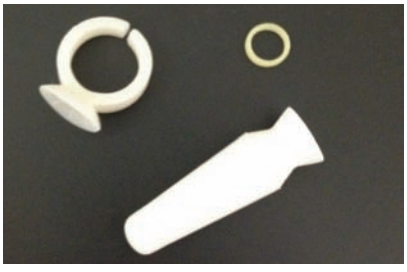
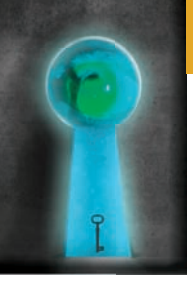


Fig. 2. There are a number of scleral insertion tools and techniques.

8. DON'T FORGET TO ASK THE PATIENT QUESTIONS AT EVERY FOLLOW-UP VISIT.

At a patient's first follow-up visit, lens care and insertion/removal should be detailed. Ask what solution they are using to clean, as well as what they are using to fill the lens. Additionally, ask about insertion and removal to see if they are more proficient in their technique.

(Continued on page 22)



SIMPLIFY

Building a practice that focuses on fitting specialty lenses

BY JOHN RUMPAKIS, OD, MBA

If you'd like to insulate yourself from the commodity-based world of disposable contact lens margin erosion, a specialty contact lens practice is one effective way to do so. Specialty lenses may not get as much attention as other practice-building opportunities, but I believe this area of optometric practice has tremendous potential for growth. Yet it's also a hotbed of frustration for many practitioners—especially given the confusion and apprehension surrounding medical coding and reimbursement.

Generally, when a practitioner considers fitting a patient in a specialty contact lens, it is typically predicated on the presence of a specific medical condition or refractive complication caused by an existing corneal condition. Ocular surface disease (OSD) is an emerging area of both wellness and medical care within many practices today. Building a specialty contact lens practice can be both extraordinarily satisfying and challenging. So, my goal is a simple one: to make coding for and getting reimbursed for specialty contact lenses the easiest part of your very specialized practice.

BACK TO BASICS

Before getting into specific codes, it's necessary to review some basics. In order to know how to properly document your medical record and to use the correct Current Procedural Terminology (CPT) code to describe the appropriate services provided, it is important to understand and keep up to date with the current definitions of the contact lens fitting codes as described in the CPT. Just because you are fitting contact lenses doesn't mean that you can forget or ignore the fundamental concepts of medical necessity, or the requirements of the chief complaint in your medical record.

As mentioned earlier, because you will often be working with a disease process or a medical condition, you must be very familiar with the requirements for the appropriate use of the 920XX and 992XX codes for your office visits that get coded in addition to your contact lens services.

The CPT has the following to say about contact lens fitting: The prescription of contact lens includes specification of optical and physical characteristics (such as power, size, curvature, flexibility, gas permeability). It is not a part of the general ophthalmological services. The fitting of contact lenses includes instruction and training of the wearer and incidental revision of the lens during the training period. Supply of materials may be reported as part of the service of fitting, or may be reported separately using the appropriate supply codes. Follow-up of successfully fitted extended wear lenses is reported as part of a general ophthalmological service (92012).

Now that we've got the basics covered, let's dive into the handful of CPT codes that cover the fitting of contact lenses.

TRADITIONAL CONTACT LENS FITTING CODES[1]

These are the bread-and-butter codes used for routine contact lens services.

- 92310: Contact lens fitting.

This is defined by CPT as the "prescription of optical and physical characteristics of and fitting of a contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia." A 92310 should be charged for the fitting of contact lenses, and also encompasses services up to the point at which you would issue a contact lens prescription. This code does not include contact lens follow-up care after the lenses have been dispensed.

This code is charged every visit in which a new lens is placed on a patient's eye, or when the fit is altered. Incidental revisions, such as power changes without altering the fit, are not billed as a new fitting. Keep in mind that the modifier -52 should be used if fitting only one eye; this is a change that

ABOUT THE AUTHOR

Dr. Rumpakis is currently President and CEO of Practice Resource Management, Inc., a firm that specializes in providing a full array of consulting, appraisal and management services for health care professionals and industry partners. He is also the Clinical Coding Editor for *Review of Optometry*.

YOUR SPECIALIZED CODING

can be both rewarding and challenging. Don't let coding issues prevent success.

was implemented in 2011, replacing the –RT or –LT modifier that was used prior to that date.

- 92311: Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, one eye.
- 92312: Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens for aphakia, both eyes.
- 92313: Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneoscleral lens.

CODES FOR THERAPEUTIC USES OF CONTACT LENS

Use these codes when the service provided includes an element of medical care.

- 92071: Fitting of a contact lens for treatment of ocular surface disease. Please be sure to report materials in addition to this code, using either 99070 or the appropriate HCPCS Level II material code. It is important to keep in mind that this is a unilateral code.
- 92072: Fitting of a contact lens for management of keratoconus, initial fitting. Please report materials in addition to this code, using either 99070 or the appropriate HCPCS Level II material code. This originally was a unilateral code, but in mid-2012 the CMS & AMA opinion stated that this code would be changed from unilateral to bilateral.

When dealing with keratoconic fittings, please keep this specific quotation of the CPT in mind: "For subsequent fittings, please use either the 9921X or 9201X codes." Again, it is important to note that in scenarios such as this you are not following the contact lens; you are following the keratoconic cornea—the contact lens is a treatment option.

REFINING AND/OR MODIFYING YOUR FIT

In most cases, "incidental revision of the lens during the training period" and "with medical supervision of adaptation," are accomplished at the first post-contact lens dispensing visit. Once the proper vision and comfort criteria are met, and you have ordered the final lenses and provided the patient with their contact lens prescription, the patient can now be considered fit for the contacts.

Again, should complications arise, the most appropriate way to bill for office visits is by using the established patient ophthalmologic (9201X) or evaluation and management (9921X) codes. Keep mind that with many (if not most) specialty contact lens fits, you are following a corneal or OSD state—not the contact lens. Many practitioners are giving away thousands of dollars per year by unintentionally including this "free care."

- 92325: Modification of contact lenses. CPT defines this code as "modification of contact lens (separate procedure), with medical supervision of adaptation." This applies when you polish or modify the parameters of an RGP lens using a modification instrument. This is a unilateral service. If done bilaterally, use modifier -50, change your units to two and double your price to indicate it was performed on both eyes.
- 92326: Replacement of contact lens. This covers the professional administrative services for ordering a replacement lens. Also, remember to bill for the lenses separately using the appropriate level II HCPCS V-codes.

Additionally, never consider a fitting fee to be a global, year-long obligation to provide unlimited service to the patient at no charge. If you refit a patient, and it is not just an "incidental revision of the contact lens," then another fee for 92310, 92311, 92312 or 92313 would be an appropriate code to bill, along with the appropriate materials V-code or Healthcare Common Procedure Coding System (HCPCS) code for lens supply.

Additional ophthalmic testing and procedures are often necessary in a specialty contact lens practice. Examples may include:

- Corneal topography (92025): This is probably the best way to monitor progression of keratoconus or other corneal disorders—especially using the change analysis features of the instrument.
- Anterior segment photography (92285): Use this to follow progression of endothelial folds, scarring or other similar complications.

SIMPLIFY YOUR SPECIALIZED CODING

• Endothelial photography and cell count (92286): This is great for following degenerative changes to the endothelial cell layer resulting in therapeutic decisions. Be sure to pay close attention to National Coverage Determination (NCD 80.8) for additional rules and regulations regarding use of this code.

• Pachymetry (76514): This describes the determination of corneal thickness by ultrasound. Use this to monitor progressive thinning of the corneal apex. Keep in mind that the once-a-lifetime limitation associated with this code only applies with respect to the diagnosis of glaucoma and corneal use, and is dependent upon the medical necessity that you establish in the medical record.

"DOES MY INSURANCE COVER THIS?"

Insurance benefits for specialty contact lenses vary greatly. Some managed vision care plans have benefits that their members can purchase that will cover specialty lenses; however, not all policies or benefits are the same. Remember to consult your local carriers' medical policies as well as your provider agreement for specifics on specialty contact lens coverage. Be mindful of patients who haven't purchased coverage for medically necessary contact lenses—you can't "create" coverage if it simply doesn't exist.

So, if there is an exclusion for all contact lenses—or no coverage at all—tell the patient at the initial visit what the total charges will be. Explain to the patient exactly what the fee does and does not cover, including lens exchanges and office visits. Once you've discussed it with the patient, use an Advanced Beneficiary Notice (ABN) form to properly document this disclosure. An ABN is required for Medicare claims (and is accepted by other carriers), and is the best method to inform patients of suspected out of pocket costs.

When completing the ABN form, use the appropriate modifier -GA, -GX, -GY, or -GZ, appended to the CPT or HCPCS code. This will indicate to the carrier that the patient has received appropriate disclosure of personal financial responsibility and has attested to that with their signature on the ABN form.

Building a specialty contact lens practice can be a very rewarding endeavor. Employing all the cutting-edge technology available to us, and our expertise in both optics and the ocular surface, optometry can serve our patients very well by providing the best patient outcomes while keeping our practices safe and profitable. RCCL

1. Current Procedural Terminology (CPT) 2014. American Medical Association, p. 539.

10 DO'S AND DON'TS OF SCLERAL LENSES

(Continued from page 19)

Also ask about quality of vision and comfort. For example, if a patient complains of blurred vision and discomfort upon insertion that progresses as the day goes on, it is likely due to the presence of a bubble. Explaining the need to reinsert the lenses can help the patient to understand why they were having a problem in the first place, and offering a solution will give them more confidence in the product.

9. DON'T "SET PATIENTS FREE" AFTER THEIR ONE-WEEK FOLLOW-UP.

Scleral lens patients need to be monitored more closely than conventional soft contact lens wearers. This is because problems such as lens fogging and tight lens syndrome can arise in scleral lens wearers. If a patient is doing well at their one-week follow-up visit, it would be advisable to see them in about one month, and then three months after that. At each visit, check the lens surface for scratches and build up, then check their tear chamber for clouding before adding sodium fluorescein. Remove the lenses and check their cornea for staining, neovascularization and edema. Regularly checking for complications will help detect issues sooner, and give the patient the perception that their lenses are truly a custom product.

10. DO DEVELOP A CONTRACT FOR SPECIALTY LENS PATIENTS.

Many insurance policies will not reimburse properly for a scleral lens fitting or for the lenses themselves. In such cases, I would advise you to create a scleral lens contract. Be sure to highlight the costs associated with both the fitting and the lenses.

Also, it is important to include a description of what the fitting fee covers (e.g., one-hour diagnostic fitting, one-hour dispense, etc.). The contract should include a section detailing what happens if the lenses don't work for any reason; does the patient get any sort of refund? For example, I keep the entire fitting fee, but I will refund the patient the cost of the lenses—minus shipping and restocking fees. When a contract is written, read and signed, both parties know exactly what to expect.

Fitting scleral lenses can be difficult for both patients and practitioners.These 10 simple tips can help simplify the process and ensure scleral lens success. RCCL

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TREATING THE TEAR FILM: Nutrition is Essential

An often forgotten element of ocular surface health is a balanced diet that includes essential fatty acids.

By Jeffrey Anshel, OD

Dry eye syndrome (DES) goes by many names—*dysfunctional tear syndrome, chronic dry eye, ocular surface disease and keratoconjunctivitis sicca* to name a few—but the approach to management rarely varies. Considering the most recent research into the inflammatory component of this disorder, most authorities are now calling this condition dry eye disease (DED). For many years, the logical treatment has been to supplement the tear film with additional lubrication. But as the science behind tear production has advanced, we now realize that it takes more than simply "adding moisture" to resolve this problem *(Figure 1)*.

A number of new DED treatment methods have emerged, such as enhanced artificial tears (e.g. stabilizers, mucin enhancers, thickeners, etc., to make them last longer in the eye), punctal plugs, lipid layer improvements, tear quality enhancements and epithelial surface treatments. In just the past few years, oral supplementation has given practitioners a new approach to improving, and perhaps resolving, this condition. This article will look at the facts and fiction surrounding the oral treatment of DED, as well as its effects on patient comfort.

ESSENTIAL FATTY ACIDS: 'GOOD' FATS FOR OCULAR HEALTH

Fatty acids (FAs) are important sources of fuel for our bodies because their metabolism yields large quantities of adenosine triphosphate (ATP). A number of different cell types can use either glucose or fatty acids for this purpose. In particular, heart and skeletal muscle prefer fatty acids. FAs are comprised of carboxylic acids that have a long tail, or a chain (*Figure 2*), which can either be saturated or unsaturated. They have an even number chain of carbon atoms, from four to 28, and can be derived from triglycerides or phospholipids. When not attached to other molecules, they are known as "free" fatty acids.

Fatty acids are involved in producing essential life energy in our bodies from food substances and then moving that energy throughout our systems. They govern growth, vitality and mental state. They connect oxygen, electron transport and energy in the process of oxidation.

Some of these FAs are considered "essential," as they are a necessary part of our diet. Essential FAs (EFAs) are also important in oxygen transfer, hemoglobin production and control of nutrients through cell membranes. They have the ability to markedly shorten recovery time from fatigue. EFAs are integral in preventing damage from hard fats, as they are "anti-sticky" and tend to disperse them.[1]

EFAs play a part in almost every function of our body. This discussion will address two essential fatty acids: omega-6 and omega-3.

Omega-6 fatty acids are the most plentiful in our diet. They are found in most everything we eat that contains fat, including meat, most seed and vegetable oils, dairy products and eggs. Omega-3 fatty acids are

ABOUT THE AUTHOR

Dr. Anshel is in private practice in Carlsbad, Calif. He is the president of the Ocular Nutrition Society and is a fellow in the American Academy of Optometry. Additionally, Dr. Anshel serves as a contributing editor to Review of Optometry. He lectures nationally to eye care providers on nutrition and nutritional genomics topics.

found in many seed oils and most cold-water, fatty fish.

A proper balance of these fatty acids is essential to optimum health. The Institute of Medicine recommends a daily intake ratio of 4:1—four times as many omega-6 fatty acids as omega-3 fatty acids.[2] Despite this recommendation, it is currently estimated that the average American diet maintains a ratio of 25:1.

Fatty acids are stored in every cell membrane of our body. They have two primary functions. First, they act as sentinel gatekeepers for every cell, ensuring cellular fluidity. They do this by allowing vital nutrients to enter the cell, while forcing out destructive free radical debris. Second, both omega-6 and omega-3 fatty acids can be converted into

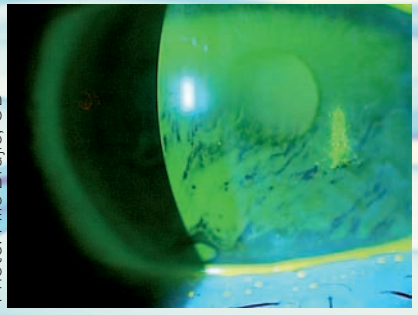

Photo: Mile Brujic, OD

Fig. 1. Staining in chronic dry eye. Long-term management may benefit from oral supplementation.

three different types of active molecules, called prostaglandins.

The three site-specific types of prostaglandins are known as PGE1, PGE2 and PGE3. Nutrient co-factors such as vitamin C, vitamin B6, zinc and magnesium help our bodies produce enzymes that convert dietary omega-6 and omega-3 fatty acids into these three types of prostaglandins.

PROSTAGLANDINS

PGE1 reduces inflammation and inhibits blood clotting. In addition, PGE1 is also capable of reducing pain, swelling and redness associated with inflammation, particularly in mucosal tissues, which includes the eyes. Many doctors don't realize the important fact that this particular type of prostaglandin can only be produced by omega-6 fatty acids.

PGE2s are the opposite of PGE1s, but can also only be produced by omega-6 fatty acids. These pro-inflammatory prostaglandins constrict blood vessels, increase body temperature and encourage blood clotting. These events are life-saving when the body suffers a wound or injury, for without PGE2 a person could bleed to death from the slightest of cuts, or succumb to a viral or bacterial attack. However, in excess, this type of prostaglandin is harmful because it can lead to a chronic inflammatory condition in the body.

PGE3s are available from omega-3 fatty acids. Omega-3 FAs, particularly docosahexaenoic acid (DHA), help keep brain cells healthy. These fatty acids also keep the rods and cones working properly. The brain and retinal cells contain more DHA than any other cell in the body. The other omega-3 FA, eicosapentaenoic acid (EPA), also plays an important anti-inflammatory role. It appropriately blocks the release of omega-6 arachidonic acid, which is necessary for the production of pro-inflammatory PGE2.

Without sufficient omega-3s in the diet, chronic inflammation can occur; this status is linked to many degenerative diseases of the eye, including macular degeneration, glaucoma and diabetic retinopathy. As with all dietary intakes—including vitamins, minerals and plant-based antioxidants—proper balance of essential fatty acids is the key to good health. Most scientists agree that a diet which includes cold-water fish two or three times a week, or EPA/DHA supplementation, helps the body maintain the proper balance of essential fatty acids it needs (*Table 1*).

ROLE OF INFLAMMATION

PGE1 reduces ocular surface inflammation and also the inflammatory process associated with meibomitis and reduced lacrimal gland aqueous output.

Omega-6 fatty acids have been given a bad rap by many medical writers. Of course, it is true that the typical American diet is overloaded with omega-6 linoleic acid (LA) from vegetable oils such as sunflower, safflower, corn, cottonseed and soybean oils, which are added to nearly all processed foods. A great number of American pantries are far too full of overly processed crackers, chips, cookies and cakes—and thus the omega-6 oils that oxidize too

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Goal Statement: Ocular surface comfort and contact lens success depend on many factors, and a fully functional tear film is an important contributor to clinical outcomes. This course will review the influence of nutrition on tear film integrity, especially the role of essential fatty acid intake.
Faculty/Editorial Board:
Jeffery Anshel, OD

Credit Statement: COPE approval for 1 hour of CE credit is pending for this course. Check with your state licensing board to see if this counts toward your CE requirements for relicensure.
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Disclosure Statement: The author has no financial relationships to disclose.

quickly and become pro-inflammatories (*Table 2*).

However, good health also depends on omega-6 gamma linolenic acid (GLA), a downstream metabolite of omega-6 linoleic acid that can be found in sources such as black currant seed oil, borage oil and evening primrose oil. This compound is a necessary component in the downstream metabolism of omega-6 fatty acid to the PGE1s, which are associated with healthy tear film. The human body is incapable of metabolizing omega-3 fatty acids to these specific anti-inflammatory prostaglandins.

metabolites are present in the body. Adequate amounts of nutrient cofactors in the body—including magnesium, vitamins A, C and B6, zinc and gamma tocopherols—help to stabilize both omega-6 and omega-3 fatty acids and enhance the delta-6-desaturase enzymatic conversion of omega-6 fatty acid from LA to GLA to DGLA to the anti-inflammatory PGE1. They also enhance the delta-6 and 5-desaturase enzymatic conversion of the short chain omega-3 alpha-linolenic-acid (ALA) to EPA/DHA, and eventually the anti-inflammatory PGE3. This could possibly explain the benefits attributed to omega-3 fatty acids.

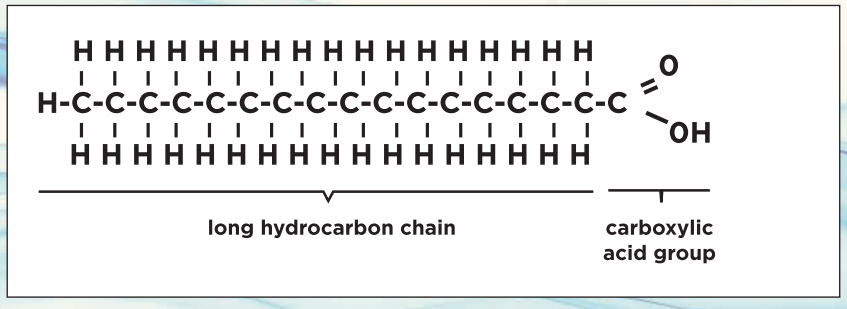

Fig. 2. Fatty acids are made of carboxylic acids that have a long tail, or a chain.

Most omega-6 fatty acids in our diet are consumed in (polyunsaturated) vegetable oils as linoleic acid (LA). Excessive intake of LA is unhealthy, as it can promote inflammation if it is not properly metabolized. In contrast, omega-6 fatty acids that are successfully metabolized, or those that have the metabolic advantage of containing GLA, reduce inflammation after further metabolizing to dihomo-gamma-linolenic acid (DGLA), which also blocks, when appropriate, the pro-inflammatory arachidonic acid conversion.[3]

Successful DGLA downstream metabolism of omega-6 to the anti-inflammatory PGE1 is secured by omega-3 EPA, which should preferably come in the form of fish oil, and blockage of arachidonic acid, if those particular omega-3

Doctors who simply recommend fish oils for treatment of dry eye conditions are really only treating one aspect of the disorder. The DHA/EPA in fish oil will effectively increase the production and quality of the meibomian glands secretions, which leads to the increased stability of the anterior surface of the tear film. However, fish oil alone will take much more time to be effective, and will not address the other structures that can contribute to dry eyes, specifically the watery and mucin layers of the tears and the anterior epithelium of the cornea. These structures require additional nutrients to support their stability and function.

The omega-6 fatty acids in flaxseed oil do not include any GLA; therefore, using flaxseed is totally dependent on the unpredictable delta-6 enzymatic conversion of its LA to GLA. As an omega-3 fatty acid, flax does not contain EPA/DHA either, and as such, it is totally dependent on both the delta-6 and delta-5 enzymatic conversion of its high-content alpha-linolenic-acid (ALA) to EPA/DHA, which is required to produce the anti-inflammatory prostaglandins PGE3.[4]

This conversion is poor at best, being about 7-10% in women and only about 1% in men. All fatty acids compete for the same metabolic desaturase, so for good health, the goal should be to consume fewer trans fat omega-6s, and to consume more GLA omega-6s and DHA/EPA omega-3s. In addition, the conversion from ALA to DHA/EPA is diminished as we age, which is yet another reason that aging patients may experience chronic ocular dryness.

THE KITCHEN AS CLINIC

The body requires all of the essential fatty acids for optimal health. They are particularly important for the contact lens patient with dry eye, because PGE1s from omega-6 interrupt the inflammatory loop associated with chronic DES. The PGE1s also increase the anti-inflammatory immunosuppressive effects of cyclosporine.[5] If a practitioner is determined to use a cyclosporine agent to treat DES, using an oral supplement will actually serve to enhance this action.

A good nutritional supplement should address many of the underlying inflammatory processes associated with dry eye syndrome.[6] Oral administration of specific omega-6 EFAs that contain sufficient amounts of GLA are suggested to stimulate the natural

Table 1. Cold-water Fatty Acid Sources

EPA and DHA have been consistently shown to be the most beneficial fatty acids in thousands of published studies. The following table exhibits the typical values of EPA and DHA in various forms of non-concentrated fish oil.

Fish Source	EPA	DHA
Anchovies/Sardines	18%	12%
Cod Liver Oil	9%	14%
Salmon	9%	10%

production of PGE1.[7] Black currant seed oil is an excellent source of omega-6 GLA because it is more stable than either borage oil or evening primrose oil.[8] Many anecdotal stories abound regarding the use of flaxseed oil; however, it is the most unstable of the essential fatty acid oils, and it does not contain GLA. Flax stability issues keep it from easily converting to GLA, which it must do in order to produce PGE1.

Pharmaceutical grade cold-water fish oil as a source of omega-3 EPA/DHA is germane to a good formulation. It serves as a metabolic gateway boost to the downstream conversion of the omega-3 to the anti-inflammatory PGE3, while at the same time preventing inappropriate omega-6 arachidonic acid production. Vitamin E, specifically gamma tocopherol, is suggested to prevent oxidation by stabilizing the EFAs and inhibiting COX2 enzyme activity that promotes inflammatory response.

While many tear enhancement options do exist, one must look at the underlying cause of DED. In some (perhaps many) cases, it's possible that DED is a manifestation of an essential fatty acid deficiency! Ask your dry eye patients how many times a week they eat fatty fish—you'll be amazed at how infrequent it is. As a result, it is not uncommon that supplementation is required. So, when managing patients who present with DED, don't forget to address nutrition! Be a clinician of the kitchen. RCCL

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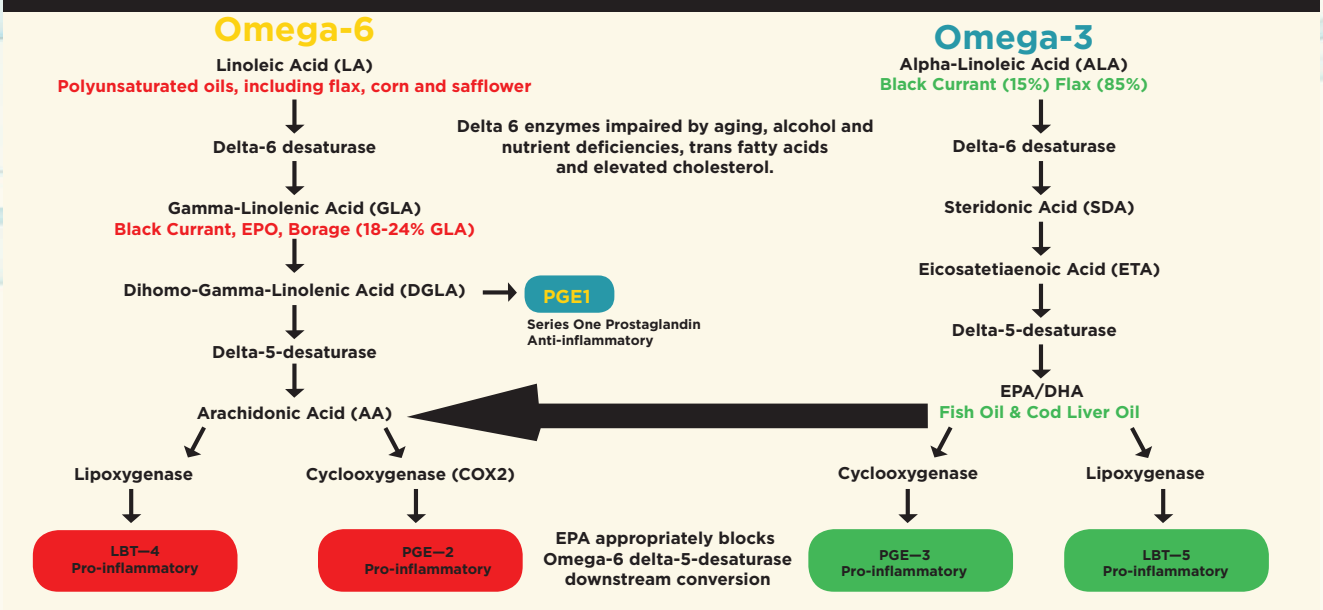
Table 2. Metabolic Pathways of Omega-3 and Omega-6 Fatty Acids



TREATING THE TEAR FILM

CE TEST

1. Which of the following is not a source of GLA?
a. Black currant seed oil
b. Evening primrose oil
c. Flax seed oil
d. Borage oil

2. Fatty acids that are required to be a part of the diet are termed:
a. Required fatty acids
b. Essential fatty acids
c. Endogenous fatty acids
d. Exogenous fatty acids

3. Which nutrients are important co-factors in Omega EFA conversion?
a. Vitamins C and B6
b. Zinc
c. Magnesium
d. All of the above

4. Which of these nutrients produce prostaglandin E1?
a. Alpha-linolenic acid
b. Dihomo-Gamma-linolenic acid
c. Eicosapentaenoic acid
d. Docosahexaenoic acid

5. Prostaglandin E1 is most responsible for:
a. Anti-inflammatory mucins
b. Pro-inflammatory cytokines
c. Pro-inflammatory mucins
d. Pro-inflammatory lipoxgenase

6. The fatty acid that directly leads to pro-inflammatory prostaglandin E2 is:
a. Docosahexaenoic acid
b. Eicosapentaenoic acid
c. Linoleic acid
d. Arachidonic acid

7. The conversion of alpha-linoleic acid to EPA/DHA is:
a. About 100% in adults
b. About 10% in men
c. About 10% in women
d. About 1% in women

8. The best balance of omega-6 to omega-3 essential fatty acids is:
a. 10:1
b. 15:1
c. 75:1
d. 4:1

9. DHA is most abundant in which tissues?
a. Joints
b. Brain and retina
c. Collagen
d. Skin

10. Flax seed oils can be problematic in treating dry eye because:
a. They are highly unstable
b. The contain too much omega-3
c. The contain too much omega-6
d. They come from a vegetable source

Examination Answer Sheet

Valid for credit through April 1, 2017

This exam can be taken online at www.reviewofcontactlenses.com.
Upon passing the exam, you can view your results immediately.
You can also view your test history at any time from the website.

Treating the Tear Film: Nutrition is Essential

Directions: Select one answer for each question in the exam and completely darken the appropriate circle. A minimum score of 70% is required to earn credit.

Mail to: Jobson - Optometric CE, PO Box 488, Canal Street Station, New York, NY 10013

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This course is joint-sponsored by the Pennsylvania College of Optometry

There is an eight-to-10 week processing time for this exam.

1. Ⓐ Ⓑ Ⓒ Ⓓ
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10. Ⓐ Ⓑ Ⓒ Ⓓ

1 = Excellent 2 = Very Good 3 = Good 4 = Fair 5 = Poor

Rate the effectiveness of how well the activity:

11. Met the goal statement: ① ② ③ ④ ⑤
12. Related to your practice needs: ① ② ③ ④ ⑤
13. Will help you improve patient care: ① ② ③ ④ ⑤
14. Avoided commercial bias/influence: ① ② ③ ④ ⑤
15. How would you rate the overall quality of the material presented? ① ② ③ ④ ⑤
16. Your knowledge of the subject was increased:
○ Greatly ○ Somewhat ○ Little
17. The difficulty of the course was:
○ Complex ○ Appropriate ○ Basic

How long did it take to complete this course?

Comments on this course:

Suggested topics for future CE articles:

Please retain a copy for your records. Please print clearly.

You must choose and complete one of the following three identifier types:

① SS # ___ - ___ - ___

Last 4 digits of your SS # and date of birth

② ___ - ___

State Code and License #: (Example: NY12345678)

③ ___

First Name

Last Name

Email

The following is your: ☐ Home Address ☐ Business Address

Business Name

Address

City State

ZIP

Telephone # ___ - ___ - ___

Fax # ___ - ___ - ___

By submitting this answer sheet, I certify that I have read the lesson in its entirety and completed the self-assessment exam personally based on the material presented. I have not obtained the answers to this exam by any fraudulent or improper means.

Signature _____ Date _____

Lesson 109885 RO-RCCL-0414

Meeting the Cornea's Critical Oxygen Needs

The Rose K2 XL™ lens made with Menicon Z material delivers maximum oxygen to the cornea.

Paul Rose, DipOpt, BSc, FNZSCLP

Oxygen availability to the cornea with contact lens wear is one of the most important factors to consider for long-term corneal health and to reduce the risk of infection, as studies have shown that corneas deprived of oxygen are more susceptible to infection.[1] Ongoing material research continues to provide contact lens practitioners with higher-Dk materials with good wetting angles that easily meet the Holden-Mertz criteria for critical oxygen transmission for daily wear. In addition, some hyper-Dk materials meet extended-wear criteria, allowing overnight wear.[2] Laboratories also endeavor to keep GP corneal lenses to a minimum center thickness to reduce lens bulk and maximize Dk/t to ensure the lens transmits sufficient oxygen to the cornea.

The growing popularity of scleral and semiscleral lenses raises a concern that oxygen availability to the cornea has been largely ignored. Combine this with reduced tear exchange, as is the case with scleral lenses, and we have the potential to adversely affect long-term corneal health.

Total scleral system

GP corneal lenses typically have center thicknesses of 0.1 mm to 0.16 mm, depending on the power, whereas most scleral and semiscleral lenses are significantly thicker, anywhere from 0.25 mm to 0.7 mm. This dramatically increases the bulk of the lens, thus reducing the flow of oxygen to the cornea. Oxygen transmission was an important consideration when I designed the Rose K2 XL corneoscleral lens. I wanted to ensure that a lens that covered the cornea and had considerably less tear flow than a corneal lens would maximize oxygen transmission to avoid long-term corneal complications created by anoxia. With the tear film having a Dk of about 80, the tear layer thickness under the lens must be considered when addressing oxygen availability to the cornea, as this layer also becomes a potential barrier to oxygen reaching the cornea.

Michaud and colleagues[3] looked at oxygen at the cornea, taking into account the Dk of the material, the thickness of the lens and the thickness of the tear layer under the lens. By applying the formula:

$$\frac{Dk}{t_{scl}} = \frac{1}{(t_1/Dk_1) + (t_2/Dk_2)}$$

where Dk/t_1 refers to the lens and Dk/t_2 refers to the tear layer, it is possible to calculate the overall oxygen permeability of the total scleral system (Dk/t_{scl}). We can calculate this number for any lens with a center thickness of 250 microns (0.25 mm) to 500 microns and a tear layer (clearance) from 100 microns to 400 microns (see Table 1). Considering that most semiscleral designs require 200 microns of tear layer under the lens, none of the lenses with center thicknesses of 250 microns or more meets the minimum Holden-Mertz requirement of 24 $x10^{-9}$ for daily wear.

Triple the minimum requirement

Let's now consider the Rose K2 XL lens, using Menicon Z (tisilfocon A) with a Dk of 163 (ISO/Fatt method). Assuming a tear layer that results from a minimum corneal clearance over the highest part of the cornea of 20 microns, and a center thickness of 140 microns (0.14 mm), we can calculate the total scleral system (Dk/t_{scl}) is 81.8 $x10^{-9}$, which is more than three times the minimum requirement for daily wear.

When you combine these factors with a lens design that has most of the bearing zone on the cornea and some movement to prevent binding, it is apparent that this goes a long way toward ensuring some tear exchange from behind the lens.

Ensuring that high levels of oxygen are available to the cornea is important for the long-term success of patients who wear semiscleral or scleral lenses. The Rose K2 XL lens goes a long way toward meeting these requirements.

Table 1

Dk=100	Minimum Corneal Clearance (μm)						
Lens thickness (μm)	100	150	200	250	300	350	400
250	26.7	22.8	20.0	17.8	16.0	14.5	13.3
300	23.5	20.5	18.2	16.3	14.8	13.5	12.5
350	21.1	18.5	16.7	15.1	13.8	12.7	11.7
400	19.1	17.1	15.4	14.1	12.9	11.9	11.1
450	17.4	15.7	143	13.1	12.1	11.3	10.6
500	16.0	14.5	13.3	12.3	11.4	10.6	10.0

: satifies HM criteria

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By Elyse L. Chaglasian, OD, and Tammy Than, MS, OD

FQs: The Secret of Our Success

These popular drugs are essential to the care we provide. Why have fluoroquinolones become such workhorse drugs? Where might they be headed? Let's find out.

Topical antibiotics revolutionized the way eye doctors care for patients with at-risk corneas. The ability to target infectious organisms with a site-specific therapy limited to the anterior segment of the eye improved clinical outcomes by orders of magnitude. Systemic medications would be impractical and ineffective in most ocular infections. Without topical therapies, many patients would suffer long-term visual and ocular health consequences.

Fluoroquinolone eye drops are now routinely and confidently prescribed as first-line therapy for a number of acute and chronic ophthalmic conditions, such as bacterial conjunctivitis, blepharitis and corneal disorders (e.g., abrasions, infiltrates, ulcers). They are also used routinely for prophylaxis, both pre- and post-ocular surgery.

Lest we take these workhorse drugs for granted, it's important to review the history of the fluoroquinolone class and how each 'generation' has surpassed the previous one, then look to what's ahead.

IT BEGAN BY ACCIDENT

Prior to the introduction of fluoroquinolones, we simply had quinolones. These were the first antimicrobials to be developed in a lab. The first quinolone, nalidixic acid, was accidentally discovered in 1962 during the manufacture of the antimalarial compound chloroquine. It was used systemically for the treatment of urinary tract infections, but the agent had little effect on gram-negative organisms. Alterations to its structure led to the development of second-generation products, such as oxolinic acid and clinoxacin. The use of these agents was also limited, due to poor systemic bioavailability and renal toxicity.[1,2]

The addition of fluorination to quinolones gave rise to the then-new class known as fluoroquinolones. The improved gram-positive activity, combined with solubility in ophthalmic solutions, expanded the clinical use of these drugs to the ocular field.[3] The first fluoroquinolone, norfloxacin, introduced in 1978, resulted from the addition of fluorine at the C-6 position. It was the first fluoroquinolone to be used in the treatment of an ocular condition—namely, bacterial conjunctivitis. While norfloxacin exhibited excellent activity against gram-negative organisms, it proved to be largely ineffective against gram-positive bacteria.

HOW THEY WORK

So, what exactly is the mechanism of action of the fluoroquinolones? Put simply, it is a bactericidal effect. Fluoroquinolones act in a unique manner: directly inhibiting DNA synthesis. This effect is mediated through the formation of a complex between the drug, the bacterial DNA and two essential bacterial enzymes (i.e., DNA gyrase and topoisomerase IV).[4]

DNA gyrase is an essential enzyme for DNA replication and transcription, while topoisomerase IV separates the interlocking of daughter DNA strands. If either of these processes is prevented, DNA and RNA synthesis and cell growth are blocked, which ultimately leads to cell death. Second- and third-generation fluoroquinolones preferentially inhibit one or the other, while the fourth-generation agents have the ability to exhibit balanced inhibition of both enzymes.[5]

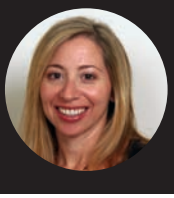
In the early 1990s, the addition of a cylopropryl ring at the R1 position led to the development of the second-generation fluoroquinolone, ciprofloxacin, which had increased antibacterial activity against gram-positive and gram-negative pathogens.

Adding a pyridobenoxazine ring between the R1 and R8 positions led to the creation of another second-generation drug, ofloxacin.[3] While many consider levofloxacin a third-generation fluoroquinolone, it's really just a levo-isomer of ofloxacin and not a truly new molecular structure. In reality, its designation as third-generation fluoroquinolone is mostly due to timing: it was introduced nearly a decade after its most immediate predecessors.

A number of studies have demonstrated that, although these older-generation fluoroquinolones can provide coverage against the most frequently encountered gram-positive and gram-negative pathogens, there is increasing resistance to these agents—especially in gram-positive organisms, such as *Staph. aureaus*.[6-8]

TODAY'S PRACTICE

The fourth-generation drugs, primarily used in modern clinical practice, are gatifloxacin and moxifloxacin. These entries are known for their enhanced activity against




gram-positive organisms and atypical mycobacteria, improved drug delivery in the anterior segment and lower predisposition for selecting bacterial strains.[9]

The most recent entry to the fourth-generation class, besifloxacin, was introduced in 2009. This is the first product developed specifically for ocular use, with no systemic use to speak of; this is often cited as a beneficial hedge against the risk of antibiotic resistance. It is an entirely new chemical entity known as a chloro-fluoroquinolone, and appears to offer excellent potency against gram-positive and resistant strains. Unlike other fluoroquinolones, which are manufactured in aqueous vehicles that are rapidly eliminated from the tear film, besifloxacin is a 0.6% suspension, formulated in a base designed to improve drug delivery in the tear film and prolong retention time on the ocular surface.[10]

The structural changes in the fourth-generation drugs confer less resistance potential than the earlier compounds.[5,9] Additionally, these changes increase ocular tissue concentrations relative to organism minimum inhibitory concentration (MIC) to inhibit bacterial growth.[5,9] Fourth-generation fluoroquinolones have been shown to be less prone to resistance to single-step mutations (which occur within genes encoding for one of the two principal target enzymes) that produce low-level resistance.[11] This is accomplished by maintaining high mutant prevention concentration that is generally several fold higher than the MIC.[11] Because these agents can inhibit both DNA gyrase and topoisomerase, they are unlikely to develop higher level, multi-step resistance.

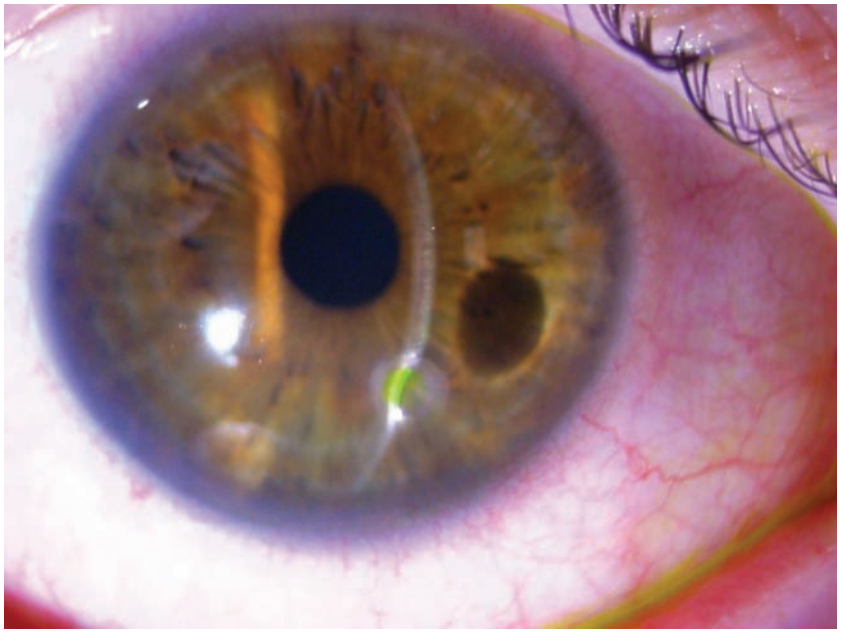


Photo: William Townsend, OD

A small, peripheral corneal ulceration. Fluoroquinolones are frequently prescribed to treat conditions such as corneal ulcers.

TOMORROW'S POTENTIAL

Fourth-generation fluoroquinolones are safe, effective antibiotics that have greatly improved upon the capabilities of their predecessors. But further advances can still be made to future generations of these popular agents. A typical 'wish list' might include the following:

- improved bioavailability
- reduced dosage frequency to improve patient compliance
- reduced costs to insurers and patients
- the ability to eradicate infection faster than previous generations
- a lower potential risk of developing resistance

Given the improvements from the third to the fourth generation, it's exciting to consider what the fifth generation may have in store! RCCL

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Dust Off Those Diagnostic Lenses

While empirical fitting is becoming the norm, patients presenting with irregular corneas require a more specialized lens fitting approach.

Fitting patients with diagnostic hard or gas permeable lenses was almost a necessity when both of these modalities first became available on the market. Practitioners relied on diagnostic lens sets and would routinely fit the patient with several lens options in-office to determine the appropriate fit and power for each patient. The process was tedious—for those on both sides of the slit lamp.

It has been a great boon to GP lens practice that nowadays most labs can simply create a lens based on the patient's keratometry values and refraction. Even more complex lenses, such as bitorics and GP multifocals, can be ordered empirically—eliminating the need for a diagnostic fit.[1] Empirical fitting offers the potential to reduce the chair time of every patient. "Think of it as ordering a custom diagnostic lens for every patient," says Doug Benoit, OD.[1] While empirical fitting works very well in most cases, certain patient scenarios will still require diagnostic lens fitting.

This technique is particularly helpful in observing the lens-to-cornea relationship and lid interaction.[2] These fits can be especially useful for patients who present with irregular corneal astigmatism due to keratoconus, pellucid marginal degeneration or corneal surgery (e.g., transplant, RK, LASIK). And because lens/eye dynamics are also compromised by ocular surface disease, such patients can benefit from diagnostic lens fitting as well. Scleral lenses are almost always fit using a diagnostic lens kit, due to factors such as total corneal clearance, scleral contour and lens settling.

MAINTENANCE

Diagnostic lenses can be stored either wet or dry. Wet diagnostic lenses have excellent wetting capabilities and are ready for immediate use—there's no need to clean or condition them before use. Keep in mind, however, that when lenses are stored wet they must have their solution replaced every 30 days to ensure appropriate disinfection.[3] Because this can be a time-consuming process, storing diagnostic lenses dry is the standard practice for most doctors.

Such lenses need to be cleaned and conditioned before being applied to a patient's eye.

The lenses should be cleaned with an approved GP lens cleaner, such as Boston Simplus/Original/Advanced (Bausch + Lomb) or Optimum (Lobob). Cleaning the lenses thoroughly ensures a smooth surface free of debris, so spend at least 30 seconds cleaning the lens (*Figure 1*). Once cleaned, it will need to be conditioned; this will ensure the lens wets well. GP conditioning agents such as Boston Conditioning solution and Boston Simplus work very well for this purpose. Additionally, an off-label use of Biotrue can aid in wetting. Biotrue contains hyaluronan, which binds to the lens surface and can help stubborn, non-wetting GP lenses (*Figure 2*). Adding Biotrue to the conditioning process may help GP lenses to wet more easily.

Following the trial fitting, the lenses must be cleaned and disinfected. The CDC suggests using ophthalmic grade hydrogen peroxide 3% to disinfect rigid lenses. According to the CDC, "Contact lenses used in trial fittings should be disinfected after each fitting by using a hydrogen peroxide contact lens disinfecting system for 10 minutes."[3-4]

Once the lenses have been successfully disinfected, they should be stored dry. Be sure to take extra care to ensure all liquid is removed from the lens case, as well as the lens itself. If there is even one drop of liquid, the lens may bind to the case, potentially causing the lens to break as it is being removed from the case when reused at a later date.

TOPICAL ANESTHETICS

The use of a topical anesthetic may be helpful during a diagnostic GP fitting. If a patient has never worn GP lenses, instill one drop of anes-

Hyper-Dk Lens Care

For lens materials with Dk values over 100, such as Boston XO (Bausch + Lomb), Boston XO2 (Bausch + Lomb) and Menicon Z (Menicon), Boston Advanced may be too abrasive for the lens surface. This can cause the material, which is softer and more pliable, to break down faster and scratch more easily. If your patient wears a lens made of a hyper-Dk material, consider recommending other GP care products such as Boston Simplus or Optimum by Lobob.

Fig. 1. Diagnostic GP lens being cleaned with Optimum. Notice the foamy lather it creates.

Fig. 2. The use of Biotrue during the contact lens conditioning step can aid in the wetting of a GP lens.

Fig. 3. The use of a topical anesthetic during diagnostic GP fitting can aid in patient comfort.

thetic in each eye prior to applying the lens (*Figure 3*).[5] This helps to increase patient comfort during the fitting process—especially if they will be trying multiple lenses. A topical anesthetic can also help to inhibit excessive tearing, which will make the evaluation of the fit significantly easier.

While most practitioners will agree that topical anesthetic is useful when fitting corneal lenses, how do they feel about using it when fitting scleral lenses? Sclerals are very comfortable and already feel much better than corneal GP lenses. So, is it really even necessary to use a topical anesthetic?

The debate on this topic is split; unfortunately, there is no clear-cut answer. Some practitioners will argue that a scleral lens is so comfortable that there is no need for any topical anesthetic. Others, by contrast, maintain that instilling a topical anesthetic is still useful for scleral lens fittings—especially in patients who have never worn any type of contact lens in the past, rigid or soft.

Personally, I agree with using anesthetic during a scleral lens fit. Many patients presenting with irregular corneas have never previously worn contact lenses, so they exhibit some apprehension about wearing any type of contact lens. Additionally, because scleral lenses are quite large when compared to a corneal GP lens, patients begin to feel even more nervous when they see the larger lenses. In my experience, I have found that using topical anesthetic on all my GP diagnostic fittings has worked quite well. This technique allows me to quickly apply and remove several different lenses until I find the appropriate fit, while the patient remains very comfortable during this process.

While the trend favoring empirical fitting continues to expand every day, diagnostic lens fitting is still important in any practice—especially in patients with irregular corneas. Exercising proper care for the diagnostic lenses and using a topical anesthetic during the fitting process can help you become successful with all of your diagnostic fits! RCCL

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"You Don't Know *My* Staff"

Staff problems often begin at the managerial level. Leading in a fair but firm manner will create a more successful practice.

As the old saying goes, if I had a nickel for every time I heard a doctor tell me that I didn't know his or her staff, I'd have a *lot* of nickels.

That remark is usually the culmination of a doctor telling me something along these lines:

"At our last office meeting, we discussed that patients need to be called the same day their contact lenses come in. I've outlined this protocol to my staff repeatedly, but they only follow it for a few days before reverting to doing it only occasionally. It's so frustrating."

After hearing that I'll ask, "On a scale of one to 10, how important is it that your staff do this consistently?"

"It's extremely important—it's like a 12! That's why I continue to ask them to do it!"

"Well, you need to sit your entire staff down at your next meeting and make it clear that it's a 12. If they can't get it done, and there isn't a good reason—not an excuse, but a legitimate reason—why they can't, then they'll have to seek work elsewhere."

"What? Are you actually telling me that if my staff doesn't do what they're supposed to do, I'm supposed to fire them?"

"Yes, I am."

"But, Gary, you don't know *my* staff. They'll find 100 reasons for why my idea is a bad one or 200 excuses for why they can't get the task done."

And round and round the conversation goes.

IT'S UP TO YOU

The essence of most "staff" problems isn't truly a problem with the staff at all. Instead, these problems are often due to a lack of two things repeatedly seen by our consultants in the majority of offices with which we work.

First, there are no clear systems or processes in place that spell out exactly how and when specific tasks must be completed. In this case, calling the patient when their lenses arrive should be connected to opening the box of contact lenses. If this is already the procedure and the task is still not being done consistently, then we have arrived at the second most common observation—a lack of leadership.

Being a leader doesn't solely mean being a hatchet man or woman and firing people who don't do what they should. It means that you have to possess the ability to clearly communicate what needs to be done, and why those tasks must be done. In this case, notifying patients should be tied to your practice's mission of providing exemplary customer service.

If that's something in your practice's DNA and a part of every fiber of everything your staff does, you have a greater likelihood of successfully completing any task. It also forces you to make sure that tasks that you are assigning to your staff are aligned with your practice's vision and values, and not solely there because you thought to yourself, "Well, I guess that seems like a good idea."

Next, you have to decide and believe that the task at hand is really a "12." If so, and it's consistently not being done, your next job as a leader is to determine whether your staff's reasons (or, in many cases, excuses) for not completing tasks are valid. If the reasons are in fact legitimate, and the task is really important to you, clear any obstacles that may prevent your staff from succeeding.

Once you've done that, if things are *still* not being completed, then it's time to wield the hatchet. I know, it's uncomfortable, but if what you're asking to be done is highly important and aligned with your values, you are left with two choices: continue stressing and complaining about it or hire someone else who can get the job done.

I FEEL YOUR PAIN

I *do* know your staff. I've been there, done that and have the experience and scars to prove it. Lead your staff consistently, firmly and fairly—it'll create a far more enjoyable and successful environment for everyone involved. RCCL

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