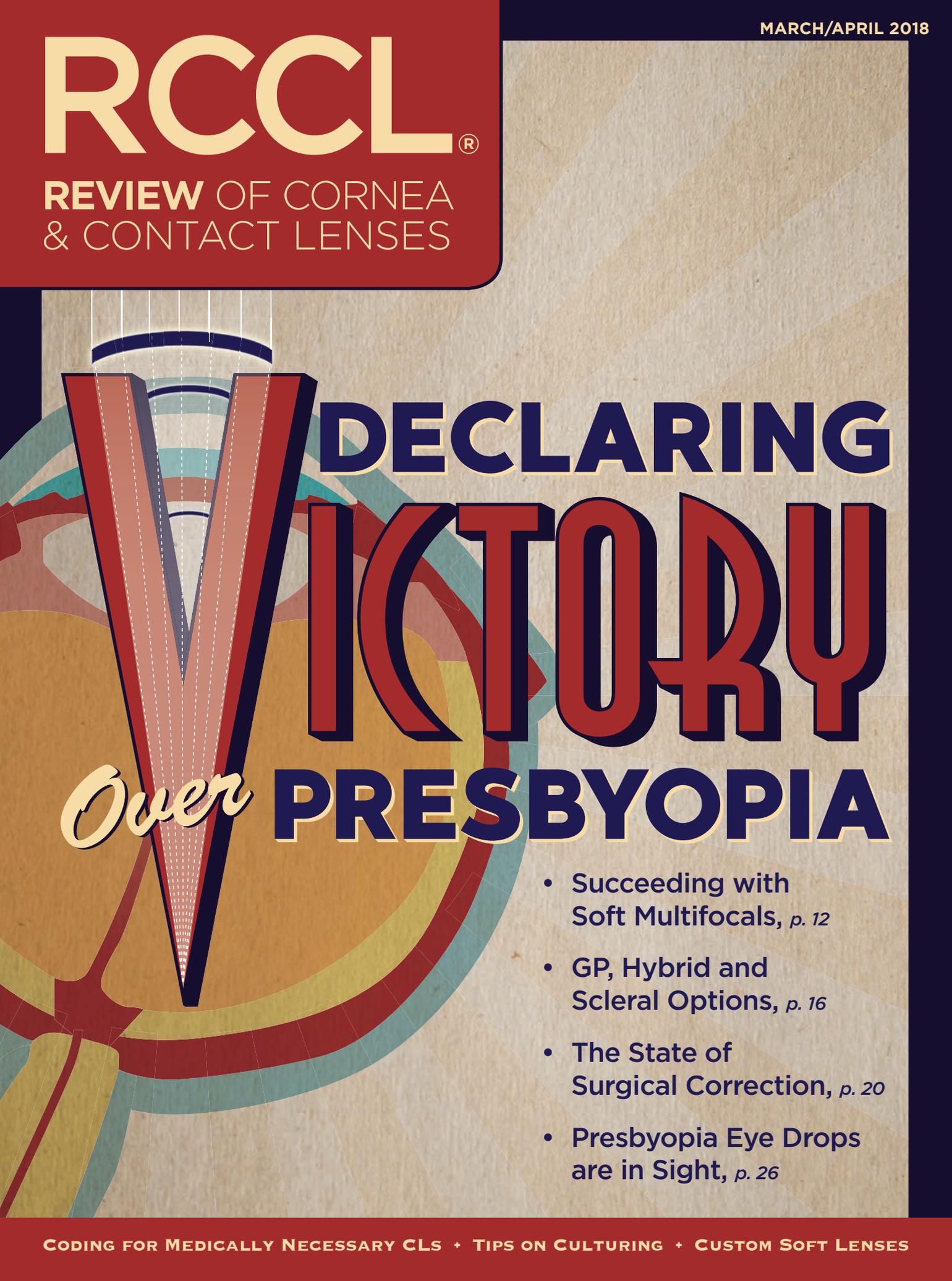


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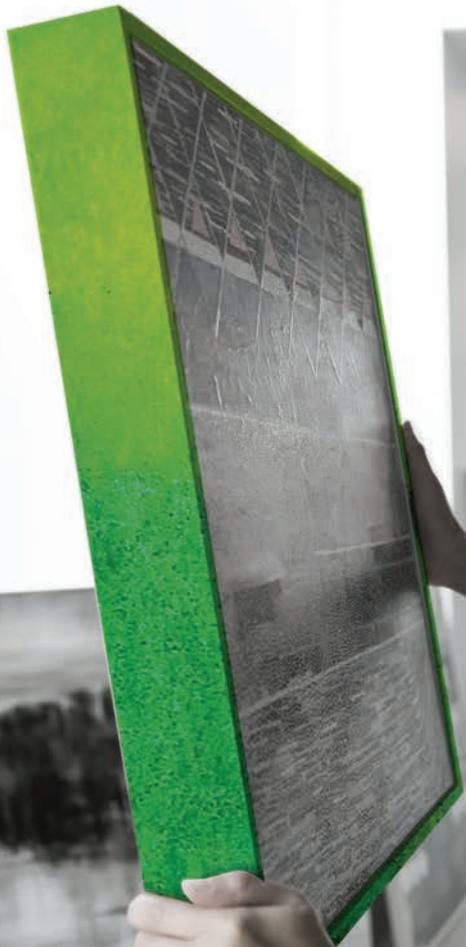
REVIEW OF CORNEA
& CONTACT LENSES

A stylized, colorful illustration of a human eye with a contact lens. The eye is rendered in shades of blue, green, and yellow, with a large, dark blue 'V' shape superimposed over it. The 'V' is filled with a gradient from red to yellow. The word 'VICTORY' is written in large, bold, red letters with a blue outline, and 'PRESBYOPIA' is written in large, bold, blue letters with a yellow outline. The word 'Over' is written in a cursive, yellow font. The background is a textured, light brown color with a grid pattern.

DECLARING VICTORY *Over* PRESBYOPIA

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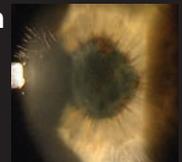
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IN BRIEF

■ A new study suggests soft contact lens (SCL) wearers with **meibomian gland dysfunction and dry eye symptoms** may find **relief** after a 12-minute treatment with **thermal pulsation**. The study, sponsored by TearScience, found SCL wearers who underwent treatment with the Lipi-Flow system (TearScience/Johnson & Johnson Vision) had improved meibomian gland secretions, reduced dry eye symptoms and increased contact lens wear time of roughly four hours a day—all of which lasted through the three-month follow up.

Blackie CA, Coleman CA, Nichols KK, et al. A single vectored thermal pulsation treatment for meibomian gland dysfunction increases mean comfortable contact lens wearing time by approximately 4 hours per day. *Clin Ophthalmol*. 2018 Jan 17;12:169-83.

■ Researchers recently found a **high level of mild meibomian gland atrophy** in a **pediatric population**. In the study, meibography was performed on 99 subjects from ages four to 17, and results showed that **42% of subjects** had evidence of meibomian gland atrophy. According to those involved, this may mean it's time to reassess our current understanding of baseline gland architecture and perhaps start examining younger patients for meibomian gland atrophy and dysfunction.

Preeya K, Gupta MD, Madelyn N, et al. Prevalence of meibomian gland atrophy in a pediatric population. *Cornea*. December 1, 2017. [Epub ahead of print].

■ In a recent study of **corneal biomechanical properties** and anterior segment parameters in patients with **obstructive sleep apnea syndrome (OSAS)**, findings suggest that, as OSAS severity increases, biomechanical **changes may occur** in corneas **without topographical changes**. The study looked at 54 OSAS patients and 20 healthy controls; results showed that those with severe OSAS had significantly lower corneal hysteresis and corneal resistance factor results. However, none of these patients showed any noteworthy findings on corneal topography.

Dik kaya F, Yildirim R, Erdur SK, et al. Corneal biomechanical properties in obstructive sleep apnea syndrome. *Eye Contact Lens*. February 7, 2018. [Epub ahead of print].

An Update on Ortho-K

Several recent studies have addressed orthokeratology (ortho-K) and its effects on ocular physiology.¹⁻⁴

A pair of studies out of Spain looked at the short- and long-term effects of ortho-K on corneal sub-basal nerve plexus (SBNP)¹⁻² While there were few changes in the short-term, long-term results showed a reduction in SBNP linked to changes in corneal nerve tortuosity. Also, this effect did not reverse in the first month after treatment was stopped, meaning these changes may be slow to return to baseline.

In another study from Spain, researchers found higher tear film osmolarity values in ortho-K lens wearers than in non-contact lens wearers.³ After the ortho-K lenses were removed, the tear film osmolarity values returned to normal. These results indicate that ortho-K lens wear can lead to increased tear film osmolarity, it also appears to be reversible, researchers conclude.

Another recent study explored the effect of ortho-K on axial length growth in juvenile myopic anisometropes.⁴ Findings revealed that axial length elongation was significantly slower in eyes treated with ortho-K than in contralateral eyes.

Additionally, 16 of the study's 25 patients developed myopia in their contralateral eyes, which were not myopic at the start of the study.

"This study is interesting because it compares the axial length growth rate before and after ortho-K treatment in the less myopic eye after it became myopic," says Karen Yeung, OD, senior optometrist at the Arthur Ashe Student Health & Wellness Center at the University of California Los Angeles. Ortho-K

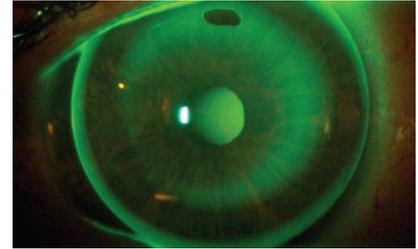


Photo: Daddi Fadel / iDopium

Ortho-K's effect on eye physiology may not always be desirable.

treatment in those eyes also slowed axial length growth.

Dr. Yeung says she is discontinuing ortho-K in more and more patients these days for reasons including irregular sleep and dry eye. "These patients just want one pair of glasses that they can see out of at any time," she says. This leads her to wonder whether multifocal contact lenses or atropine for myopia be better options for myopia control.

One recent study looked at the efficacy of extra low-dose atropine (0.01%) in addition to ortho-K for myopia control in a pediatric population.⁵ While this reduced disease progression in patients with low and moderate levels of myopia, it didn't impact disease progression in high myopes. As such, the researchers warn that atropine will not always be effective against myopia, but they note that a positive effect exists.

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Making Waves in Myopia

New research—slated for discussion at this year’s Association for Research in Vision and Ophthalmology (ARVO) meeting—suggests early age of myopia onset and fast progression rates are important factors of high myopia in adulthood.¹ The researchers found 20% of their test subjects diagnosed with myopia before age 10 had high myopia by age 25. Such stark numbers emphasize the need for early—and effective—therapies. Clinicians planning to attend ARVO may get a sneak peek at what tomorrow’s myopia management may look like:

Contact lenses. While researchers are well versed on the benefits of exposure to violet light (360nm to 400nm wavelength) for patients with myopia, less is known about the violet light transmittance of contact lenses and its effect on myopia control. Researchers from Japan found that children who wore contact lenses with more violet light transmittance had less axial length elongation. If the results of this study are confirmed with future prospective clinical trials, the light transmittance of contact lens materials might become germane to the decision-making process surrounding myopia control efforts.²

In another ARVO abstract, a company-led case series analysis of NaturalVue Multifocal lenses (Visioneering Technologies)—a distance-center, extended depth-of-focus design—found myopic patients who switched to this lens had clinically significant reduction in progression and axial elongation. Though a small study of only one lens, the results are encouraging.³

Exercise. A recent retrospective, observational study at Kaiser

Permanente Southern California found 41.9% of 60,789 patients had myopia. While the researchers were expecting the rate of myopia to increase with age, they were surprised to note that at least 60 minutes of self-reported daily exercise was associated with lower risk of myopia. The researchers believe exercise is an important modifiable risk factor clinicians should discuss with all at-risk patients.⁴

In addition, a recently published study of Canadian children found outdoor time positively impacted myopia, and one extra hour of outdoor play each week lowered the odds of myopia by 14.3%.⁵

Atropine. Yet another study shows once nightly low-dose atropine (0.05%, 0.025%, 0.01%) was effective in slowing myopia progression compared with a placebo group. The study also found atropine 0.05% had better efficacy while maintaining a safer treatment profile than other groups.⁶

Research has a long way to go before we fully understand myopia and how to combat it, but these findings are a step in the right direction and are poised to make waves in future treatment protocols. **RCCL**

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The Prospect of Antimicrobial Lenses

These could save contact lens wearers a lot of trouble, and research shows some promise.

Scientists, manufacturers and clinicians are always looking for ways to minimize the occurrence of infection in contact lens wearers. One initiative that receives attention from time to time is the use of antimicrobial surfaces on contact lenses and lens cases to reduce the risk of microbial keratitis.

The concept of using an antimicrobial surface such as a heavy metal coating is not new; antimicrobial coatings have been employed in orthopedic implants, urinary catheters and wound dressings for decades.¹ For contact lens wearers, preventing bacterial adhesion and its resulting colonization would minimize biofilm deposition—likely preventing (or at least minimizing) the chance for infection and reducing inflammation.^{1,2}

Researchers are constantly examining antimicrobial agents suitable for contact lenses and lens cases as viable protective mechanisms against potential risk for microbial keratitis secondary to contact lens wear. Strategies include using cationic metals such as silver and peptides, selenium, furanones, chitosan, quorum-sensing inhibitors and various biocidal and non-cidal agents such as polyquats.^{1,2} Also, several animal studies support biocompatibility and safety of lenses coated with antimicrobial peptides.³

A NEW CONTENDER

Melimine, a cationic peptide, has broad-spectrum activity and is part of the innate immune system of all multicellular organisms. It also has the ability to inhibit microbial growth.³ Melimine's

proven effectiveness against bacteria and non-bacterial pathogens has caught researchers' attention. This coating does not alter the physical dimensions of the lens and is even heat stable.³ Might it be the best option so far?

The goal is to develop lenses with an ideal surface coating or an infused material: non-toxic with significant antimicrobial activity. In addition, it should have minimal impact on normal ocular flora or the innate immune system responsible for warding off and responding to possible infection.^{1,3} Researchers hope lenses with melimine will inhibit microbial adhesion and consequently reduce adverse events—including microbial keratitis.

Keep in mind that our bodies have robust anti-infective defenses that naturally provide surveillance through neutrophils and macrophages.⁴ Small peptides called defensins have naturally occurring anti-infective properties. Additionally, lactoferrin is found in mucous membrane secretions along with other tear film components and may actually prevent adherence of bacteria to the lens surface and block biofilm development.^{1,4}

UPHILL BATTLE

Literature has yet to uncover what happens to the elaborate innate defense system when a lens with surface coating is introduced to the ocular surface, and blocking any of the inflammatory mechanisms may not serve a desirable purpose. Only clinical trials can fully assess whether antimicrobial lenses (and cases) induce resistance. According to Mark Willcox, PhD, of the

University of New South Wales, laboratory tests have reported that bacteria have trouble becoming resistant to antimicrobials such as silver, selenium and melimine.

Unfortunately, several impediments to the development of effective antimicrobial lens surfaces exist. First, the cost of production poses limitations, especially with single-use lenses. In addition, there have been concerns about unintended effects on the whole tear film ecosystem when blocking or killing off normal flora. Surprisingly, the biggest hurdle may be the regulatory approval process. According to Dr. Willcox, you may actually need to prove reduction in microbial keratitis, and that likely poses some study design problems. Lastly, there is the question of the proposed agent's compatibility with current accoutrement.¹

Fortunately, microbial keratitis with subsequent vision loss is rare. But wouldn't it be nice to make it exceedingly rare? The notion of producing lenses with antimicrobial surfaces or polymers (with similar qualities) has been investigated for decades with little progress, but there's motivation to reduce the rate of infection in lens wear. Will melimine or another agent be the answer in the near future? **RCCL**

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HIGH PATIENT AND ECP PREFERENCE FOR AIR OPTIX® PLUS HYDRAGLYDE® CONTACT LENSES



Melissa Barnett, OD, FAAO, FSLC
Sacramento, California

Dr. Melissa Barnett was compensated by Alcon for her authorship of this advertorial.

The daily lives of contact lens wearers are full of obstacles to comfortable lens wear, including dry or smoky air, digital device use and long days of lens wear. These obstacles have their impact: in a survey, 2/3 of contact lens wearers said they experience dryness/discomfort with their current lenses.¹

At my practice, my goal is to provide contact lenses with improved technologies that promote patient comfort, healthy eyes and contact lens compliance. Studies show that monthly and daily replacement lenses promote better replacement compliance than 2-week lenses.^{2,3} Patients and ECPs agree that AIR OPTIX® plus HydraGlyde® monthly replacement contact lenses, combined with a nightly lens care system that contains HydraGlyde® Moisture Matrix technology, provide a positive wearing experience.¹

I participated in a survey of contact lens satisfaction in habitual wearers of 2-week or monthly replacement contact lenses (N = 229). We surveyed our patients about their habitual brand, and then about AIR OPTIX® plus HydraGlyde® contact lenses after a 1-month trial.¹ Patients used CLEAR CARE® PLUS Cleaning and Disinfecting Solution or OPTI-FREE® PureMoist® Multi-Purpose Disinfecting Solution for daily lens care. Both of these lens care products feature HydraGlyde® Moisture Matrix. At the end of the trial period, patients surveyed expressed strong satisfaction with AIR OPTIX® plus HydraGlyde® contact lenses: more than 9 out of 10 patients surveyed agreed these lenses felt comfortable upon insertion each day,¹ and four times as many agreed (vs disagreed) that AIR OPTIX® plus HydraGlyde® lenses felt comfortable through the end of the day.¹ Finally, four times more patients surveyed preferred AIR OPTIX® plus HydraGlyde® contact lenses (plus daily HydraGlyde® lens care), over their previous lenses, after wearing them for 1 month.¹

Among the eye care professionals who participated in the survey (N=20), three out of four agreed** that AIR OPTIX® plus HydraGlyde® contact lenses will be the preferred monthly replacement lens in their practices. The same ratio also agreed¹ they would proactively recommend their 2-week and monthly replacement wearers switch to AIR OPTIX® plus HydraGlyde® contact lenses.¹

The outstanding experience reported by patients and eye care professionals is supported by a combination of two proprietary technologies. SmartShield® Technology is the permanent surface treatment used in all AIR OPTIX® brand lenses. SmartShield® Technology is an ultra-thin permanent protective

shield that is bonded to the outer surface of the lens, minimizing the amount of exposed silicone.⁴ This proprietary surface treatment helps the lens resist lipid deposits,⁵⁻⁷ supports tear film stability,^{7,8} and helps maintain outstanding wettability.^{9,10} HydraGlyde® Moisture Matrix is a proprietary wetting agent that creates an envelope of long-lasting lens surface moisture.¹⁰

Recent studies demonstrate the wettability of AIR OPTIX® plus HydraGlyde® contact lenses. In one, placido rings were projected onto surfaces of several lenses.¹¹ A wet surface reflects a stable image of the rings, but as the surface dries, the reflections become distorted. Directly out of pack, AIR OPTIX® plus HydraGlyde® contact lenses showed more stable reflections at 2 minutes than several competitive lenses ($P < 0.01$), demonstrating excellent lens surface moisture retention. In another study, time to lens surface moisture breakup (the time it takes for the first “spot” of dryness to appear on the lens) was measured after soaking lenses in PBS solution for 16 hours.¹² The time to lens surface moisture breakup of AIR OPTIX® plus HydraGlyde® contact lenses was longest (19 seconds), indicating lasting lens surface moisture. (Figure)

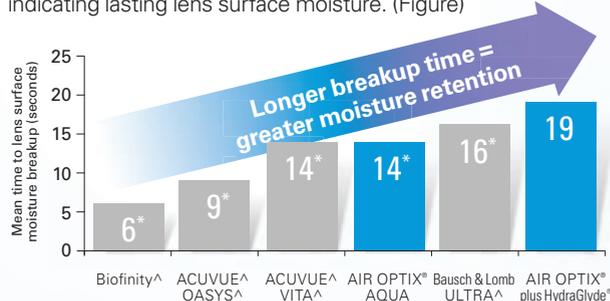


Figure: AIR OPTIX® plus HydraGlyde® Contact Lenses Provide Long-Lasting Lens Surface Moisture Retention After 16 Hours of Simulated Wear¹²

Mean time to lens surface moisture breakup after 16-hour soak in phosphate-buffered saline solution. Ten lenses per brand were analyzed. * $P < 0.05$ vs AIR OPTIX® plus HydraGlyde® contact lenses. ^Trademarks are the property of their respective owners.

Recommend lens care solutions with HydraGlyde®—CLEAR CARE® PLUS with HydraGlyde® or OPTI-FREE® PureMoist®—as the perfect combination with AIR OPTIX® plus HydraGlyde® contact lenses to keep outstanding comfort going all month long,¹ so your patients can see, look and feel their best!



¹Based on ECPs who “agreed” or “somewhat agreed” with the statement: “AIR OPTIX® plus HydraGlyde® contact lenses will be the preferred monthly replacement lenses in my practice.”
²Based on ECPs who “agreed” or “somewhat agreed” with the statement: “I plan to proactively recommend to my 2-week and monthly contact lens wearers that they switch to AIR OPTIX® plus HydraGlyde® contact lenses.”
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Important information for AIR OPTIX® plus HydraGlyde® (lotrafilcon B) contact lenses: For daily wear or extended wear up to 6 nights for near/far-sightedness, presbyopia and/or astigmatism. Risk of serious eye problems (i.e., corneal ulcer) is greater for extended wear. In rare cases, loss of vision may result. Side effects like discomfort, mild burning or stinging may occur.

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



Our passion is to help your patients see, look and feel their best.



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A Hidden Opportunity

Pay attention to the eyelids—they can help us improve contact lens wear for our patients.

As eye care practitioners, we fit all types of patients for contact lenses. They can range from standard spherical prescriptions to the most complex corneas—and the road to successful lens wear is not always smooth.

Currently, the main reasons a patient will discontinue lens wear are discomfort and dryness.¹ Over the years, manufacturers have made much headway in modalities, designs and surface chemistry to make contact lenses more comfortable. So, why do so many lens wearers become uncomfortable in their lenses?

The ocular surface is a major contributor to contact lens comfort. A healthy ocular surface gives our patients the best chance for successful lens wear, and a compromised ocular surface can play a big part in a patient's unsuccessful lens wear. Also, as contact lens wearers age, they generally complain of contact lens discomfort more often.² To improve contact lens comfort, we must find strategies to optimize the ocular surface; based on recent reports, the eyelids might be a good place to start looking.

A DEEPER DIVE

Studies indicate that the bacterial load on the lid margins is normally present in low concentrations, often referred to as the normal flora.³ The two most common bacteria that can inhabit the eyelids are *Staphylococcus epidermidis* and *Staphylococcus aureus*. The normal flora lives in a biofilm that allows adequate amounts of bacteria to live

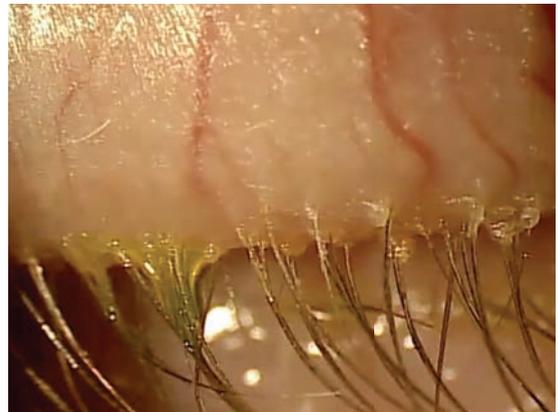
in harmony with the host. When imbalances in the local environment occur, over-colonization can lead to greater concentrations of microbes. Bacteria can sense the increased concentration, and when it achieves a certain quorum, it activates dormant genes. These are responsible for producing proteins that cause a wide array of virulence factors and, ultimately, inflammation in the tissue. This occurs over decades and is believed to be the underlying cause for many of the signs and symptoms we see in our dry eye patients.

The report's authors propose a new term for this, dry eye blepharitis syndrome (DEBS), and four stages in which it manifests from the over-colonization of bacteria on the lid margin:

Stage 1 involves the lash follicles. There is a potential space between the lash and the surrounding follicle that allows the biofilm to extend. Overpopulation of this region initially creates a subtle edematous follicular tissue that extends around the lash. Scurf or debris at the base of the lashes is simply the overpopulation of bacteria in the follicle. Take into consideration the natural growth of the lash and you can understand why at times this scurf

is seen clinically at different levels along various lashes. When this occurs over decades, we may not see as much scurf at the lash margin, possibly because the lash bulb may be so badly damaged that the lash is growing at a significantly slower rate, if at all. Without normal growth, the lash is unable to push bacteria out of the lash margin. All of this can also lead to lash loss.³

Stage 2 includes the meibomian glands as well as the lash follicles. In a normal state, the meibum is constantly flowing out of the nar-



At top, mild signs of blepharitis with some debris noted at the base of lashes. At bottom, severe blepharitis with more debris noted at the base of the lashes.



row ductule, impeding the bacteria's ability to overpopulate the gland. As the biofilm extends toward the meibomian glands, it can slowly begin lining the orifice and entering the glands. Over time, this creates distension and affects the glands' ability to produce secretions.³

Automated heat and expression procedures such as LipiFlow (Tear Science) can remove the contents of the glands and, ultimately, the source of the virulence factors and inflammation within the gland.³

Stage 3 involves the accessory glands of Krause and Wolfring. These glands produce basal levels of aqueous for the ocular surface, and their anatomical location makes them less accessible to the biofilm on the surface of the eye. This also helps explain why we often see the meibomian glands as greater contributors to dry eye in non-Sjögren's forms of dry eye.³

Stage 4 describes the structural integrity of the lid margin becoming compromised because of the prolonged exposure to inflammation. Lid laxity, entropion, ectropion, madarosis and trichiasis may all be manifestations of extended inflammation.³

PUTTING IT ALL TOGETHER DEBS can help explain why the tear film quality of some patients may constantly degrade over time. It can also give us a new appreciation for the bacterial biofilm and what can happen when bacteria densities increase above normal ranges, along with inflammation. More importantly, from a clinical perspective it provides us guidance

on what we can do to prevent these long-term chronic changes from occurring.

In theory, reducing the bacterial bioload on the lid margin should improve signs and symptoms of dry eye. Some studies have shown improvement in dry eye signs and symptoms after the use of microblepharon exfoliation.^{4,5}

LOADED LIDS

Recently, researchers in Australia investigated the influence of the eyelids on contact lens comfort in 30 patients and randomly split them up into groups treated with either microblepharon exfoliation treatment using BlephEx (Rysurg) or a lid hygiene product.⁶

Results show that the bacterial load on the eyelids was significantly greater in patients who were symptomatic for contact lens discomfort than those who were comfortable in their contact lenses.⁶ After microblepharon exfoliation treatment, the bacterial load on the eyelids was significantly reduced.

Additional eyelid findings, including gland orifice capping and quality of meibum secreted, were also improved after this treatment. In one compelling statistic, of the 17 patients who were symptomatic lens wearers prior to treatment, 10—or 59%—were asymptomatic after microblepharon exfoliation treatment.

In the lid hygiene group, the lid margin microbial load was also measurably reduced, but there was



Chronic blepharitis showing eyelash loss and misdirected lashes.

no improvement in the additional eyelid findings that improved in the BlephEx group.⁶

Because the eyelids and the bacterial bioload they carry may affect the health of the ocular surface, understanding them could help us uncover reasons for contact lens discomfort. By being cognizant of the effects of the lid margin and incorporating strategies to improve its health, we can enhance lens wear for our patients and ultimately keep more of them wearing lenses. [RCC](#)

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Burning Questions

Severe alkali exposure wreaks havoc and demands a swift response to preserve vision.

This 54-year-old man—an industrial worker—experienced an alkali burn while lowering a stainless steel die coated in aluminum particles into a tank containing sodium hydroxide. Though he was wearing safety glasses at the time, some of the liquid splashed into his right eye. He rinsed the affected eye for five to 10 minutes at a safety workstation, then returned to work despite having immediate pain and diminished vision; he sought care the following afternoon.

The local optometrist noted a pH

of about 8 to 9, hand motion vision, two areas of symblepharon, a corneal epithelial defect and 4+ anterior chamber cell. The conjunctival adhesions were broken with a cotton-tipped applicator, atropine was instilled and a pressure patch was applied. He was seen on follow-up the next afternoon and had 5/200 vision with additional symblepharon formation, 3+ anterior chamber cell and a total corneal epithelial defect. His pH was rechecked and found to be about 7 to 8. He was referred to the hospital that day.

Upon arrival, his vision in the

right eye was 20/40 and the tear film pH was 9. Slit lamp exam showed a total corneal epithelial defect and diffuse conjunctival injection and chemosis. The conjunctiva looked somewhat devascularized and white near the inferior limbus. The inferior conjunctival fornix was markedly shortened with a broad symblepharon stretched medially to the plica. The corneal stroma was slightly hazy. The anterior chamber was notable for 1+ cell and his intraocular pressure (IOP) was 25mm Hg by Tonopen.

A small metallic particle was





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removed from the inferior fornix at the slit lamp. The patient was placed in a supine position, anesthetized with tetracaine and the conjunctival fornices were swept with a glass rod. No additional foreign bodies were seen as a result.

To aid irrigation, a Morgan lens was placed on the eye; the ocular surface was then bathed in six liters of saline. The final pH was approximately 7. As this level was considered stable, an amniotic membrane was placed the following day. His vision at this point was 6/500.

He was started on an aggressive course of medications OD:

- Prednisolone acetate 1% ophthalmic suspension Q2h
- Medroxyprogesterone 1% ophthalmic suspension Q2h
- Ascorbic acid 10% ophthalmic solution Q2h
- Sodium citrate 10% in Celluvisc ophthalmic solution Q2h
- Ofloxacin 0.3% ophthalmic solution QID
- Scopolamine 0.25% ophthalmic solution BID
- Doxycycline 100mg PO BID
- Sodium ascorbate 2,000mg PO BID

The patient was seen daily for a week, then monthly for IOP checks after his epithelium healed. He was lost to follow up at one year.

FIGHTING FIRES ON MANY FRONTS

Chemical burns represent 7% to 19% of all eye injuries, with about 15% to 20% of facial burns involving at least one eye.¹ They can jeopardize many anterior segment structures, as well as the ocular ad-

nexa, simultaneously. Alkali burns are considered the most dangerous, since they can penetrate deep into the eye, causing saponification of the cells. The damaged tissue in return releases proteolytic enzymes during an inflammatory response. There may be an acute IOP rise, as well as long-term IOP problems. Damage to the limbal stem cells will lead to vascularization of the cornea. Conjunctival damage causes scarring, fornix shortening, loss of goblet cells with associated ocular surface dryness and lid malposition.

Acute treatment includes copious irrigation with 20 or more liters of saline until pH reaches normal levels. It should continue to be checked every several hours to be sure it is stable. Ascorbate is added (oral and topical) to increase aqueous levels and reduce the incidence of corneal thinning and ulceration. Medroxyprogesterone is used to prevent deep ulceration and perforation of the cornea in severe alkali burns.² While steroids reduce inflammatory cell infiltration and stabilize cell membranes, the clinician should remain vigilant for corneal melts. Antibiotics are necessary on a cornea with epithelial defects, and antiglaucoma drops are prescribed if necessary.

Prognosis largely depends on the alkali material's depth of penetration into the tissue. Patients should be monitored for stem cell dysfunction, glaucoma and dry eye-associated goblet cell dropout. **RCCL**

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Succeeding with *Soft Multifocals*

Thanks to enhanced materials and designs, these lenses remain the first-line option for today's presbyopes.

By Jane Cole, Contributing Editor

In just two years, the number of presbyopes in the United States is expected to climb to 123 million, or approximately three times the current population of California.¹ This means that by 2020, an even greater population of fortysomethings will likely be sitting in your chair. While the list of treatment options for presbyopic patients continues to expand, soft multifocal contact lenses remain a top choice for many doctors.

Today's multifocal designs are much improved from earlier generations, in part because the latest lenses are comprised of upgraded materials that don't dry out by the end of the day. According to Justin Bazan, OD, of Park Slope Eye in Brooklyn, NY, dehydration routinely diminished optics in earlier multifocal designs.

Additionally, most of today's

multifocal lenses are available in single-use options, and their optics have been revamped to provide better vision based on how patients use their eyes, specifically with digital device use.

"Practitioners need to get excited about multifocal contact lenses and drop their baggage," Dr. Bazan says. "Make multifocals a first option—and stick with the latest round of lenses—and you are going to be successful."

NEAR OR FAR

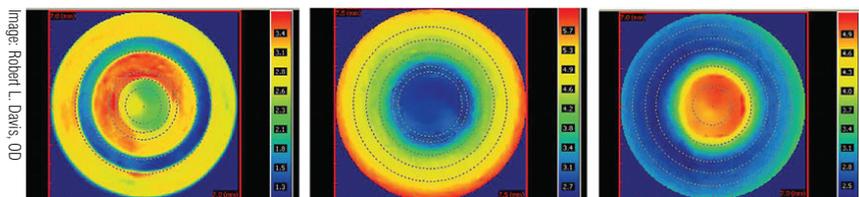
Many of today's popular multifocal soft contacts feature center-near designs, with the near focal power located in the middle of the lens and distance in the periphery.

Some available center-near designs include: Bausch + Lomb's Ultra for Presbyopia and Biotrue OneDay for Presbyopia; Alcon's

Air Optix Aqua Multifocal and Dailies Total1 Multifocal; Johnson & Johnson Vision's 1-Day Acuvue Moist Multifocal; and CooperVision's Biofinity Multifocal (with the center-near design option).

Other soft multifocal lenses are based on a center-distance design. Here, the distance power is located in the middle of the lens and the near power is on the periphery. Common lenses with these designs include CooperVision's Biofinity Multifocal (with the center-distance design option) and NaturalVue Multifocal 1 Day from Visioneering Technologies.

"In both lens designs, there is often a significant amount of asphericity, which allows them to have a smooth transition between each focal distance," says Dave Anderson, OD, of Miamisburg Vision Care in Miamisburg, Ohio. "The biggest difference among all these lenses has to do with the emphasis on near or distance, as some perform better up close and some better at distance. Knowing this, I can choose what lens best suits the needs of each specific patient depending on their visual demands and their daily routines."



At left is a simultaneous vision multifocal lens, which alternates between near and distance zones. In the center is a distance-center multifocal lens. At right is a near-center multifocal lens.

The Duette Progressive Center Distance lens by SynergEyes—a hybrid design with a GP center and a soft lens “skirt”—is another newly available center-distance lens, with zone sizes ranging from 1.8mm to 4mm. According to the company, the lens is designed for patients experiencing challenges with distance vision and is also available in a near-center design.

While today’s simultaneous multifocal lens designs tout clear vision in all zones, they generally still impact distance vision to some degree, according to Brian Chou, OD, of EyeLux Optometry in San Diego. “I’m up front with my patients that this happens, but for many, multifocal contact lenses are still desirable because it gives them the benefit of improved near vision,” he says.

TIPS FROM THE TRENCHES

According to Robert L. Davis, OD, of Davis Eye Care Associates in Oak Lawn, IL, certain clinical pearls can help practitioners arrive at a particular lens design faster than a trial-and-error method. For example, if a patient is younger than 50 years old, Dr. Davis finds a distance-center lens often works better. Meanwhile, his patients 50 and older often do better in a near-center lens.

“If distance is in the center of the lens, then it is going to take real estate to get out to the necessary add power someone who is older is going to need,” he says. “If you use a near-center lens, the total near power is in the center, so you can control where the distance zone starts and make sure it is shorter than the pupil size.”

Today’s soft multifocal lenses can be customized, which can increase their success rate, Dr. Davis says. Some lens designs are available in multiple powers, and base curves,

diameters and center and distance zones can be tailored to fit the patient’s needs.

According to Dr. Davis, the key to a successful fit is not the lens, but the patient. “What is controlling the patient’s ability to see is their pupil size,” he says. “You can try any lens design, but if there is a mismatch between the pupil size and the design, the patient isn’t going to be successful.”

For example, if a distance-center lens is 3mm in the center and everything outside of 3mm in near—and the patient’s pupil size is 2.5mm—the patient won’t be able to read up close because the pupil is smaller than where the reading zone starts.

“I’m asked all the time, ‘Is there one best lens?’ and my answer is, ‘If there was one best lens, there would be no others,’” Dr. Davis says. “Unless you use all the lenses, you’re going to limit your success because there is a place for them all. It’s just trying to find the match between the lens type and the patient.”

It is also prudent to read the patient’s reaction when they try on a soft multifocal lens, Dr. Davis says. “If a patient says to me, ‘I can’t see a thing in distance after I put a lens on,’ then I know I will need to increase the distance zone or decrease the near zone. Or if they say, ‘My distance is perfect, but I can’t read a thing close up,’ it’s not about power since I’ve already examined them—it’s about the real estate designated for near vision versus distance vision.”

Mile Brujic, OD, of Premier Vision Group in Bowling Green, Ohio, routinely takes topography readings over the surface of a multifocal lens after it has been placed and centered on the eye. This gives him the ability to see where the optical zones are lined up over the patient’s physical line

THE PERFECT FIT

Want to master your multifocal fitting? Dr. Brujic offers up these tips:

1. Make sure the patient isn’t over-minused.
2. Test for ocular dominance. If you’re fitting a multifocal patient and something isn’t going as planned, you may need to troubleshoot, and determining the dominant eye is key. Be sure to test for sensory dominance as opposed to sight dominance, Dr. Brujic says. Have the patient look at a target with both eyes open and place a +1.50 lens in front of each eye in succession (not simultaneously) to blur their vision, and ask which is better. The eye that doesn’t have the lens over it when the patient says they feel it’s better is the sensory-dominant eye.
3. Identify the patient’s goal. Dr. Brujic first asks the patient what he or she wants to achieve with a multifocal lens. “And ‘seeing up close’ isn’t specific enough,” he says. “If a patient responds they would like to see their cell phone better, that’s a specific goal.” Next, ask if there are other things the patient would like to be able to do better. “They might answer, ‘Yes, at work I want to be able to see my computer.’ Then we can ask, ‘How far is your computer away from you at work?’ so we know what type of distance we’re dealing with.”
4. Explain to the patient how and where multifocals will improve their vision—and when they might fall short.
5. Dive in and get lenses on the eyes. The sooner the conversation moves from concepts to trial fitting, the better.

SUCCEEDING WITH SOFT MULTIFOCALS

of sight, he says. “Prior to using topography over the surface of these lenses, there were some patients who did well and some who didn’t, and we really didn’t know why some were successful and others weren’t.”

Manufacturer fitting guides can also be helpful when fitting these patients. “It behooves all practitioners to put their egos aside and pull up the fitting guides,” says Dr. Bazan. “These are going to give you the best way to ensure your patient’s ideal outcome.”

TAKE A TEST DRIVE

Patient misconceptions about multifocal contact lenses can be a barrier to finding the right lens, but putting on a trial lens during the exam can change patient perceptions, Dr. Davis says. Recently, after examining a 48-year-old female patient who wore a single vision distance disposable lens, Dr. Davis realized she needed a bifocal.

“Many of these patients don’t want to wear a bifocal because it’s a reminder they are getting older, and they don’t want any reminders,” says Dr. Davis. In this case, he put a multifocal trial lens on the patient without mentioning what it was, and the patient responded to her sharpened near and distance vision by calling Dr. Davis “a miracle worker.” Once the patient realized she could now

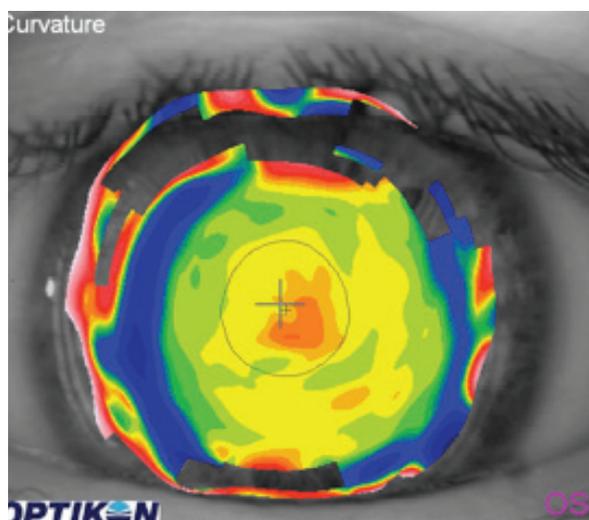
see her phone and the letters on the distance acuity chart, Dr. Davis mentioned the lens he put on was a multifocal. “The patient then asked if she had to look at a particular spot, up or down, and I told her, ‘No, the lenses are center surrounding.’ Most patients think multifocal contacts are like spectacle multifocals, where distance is on top and reading is at the bottom of the lens.”

BEST CANDIDATES

Patient personalities—and expectations—should come into play when considering a fit for soft multifocal contacts. Listening to the patient’s needs and expectations is the most valuable indicator of success when fitting multifocals, says Glenda Secor, OD, of Huntington Beach, CA.

Additionally, she says all presbyopic patients should be informed of the multifocal options including contact lenses. “Highly motivated patients are the easiest. Early presbyopes and hyperopes are generally great candidates.”

It’s also important to remember



A topography reading over a soft multifocal lens. The line of sight (represented by the cross) is located nasal to the near-center portion of the lens.

the goal of using a multifocal lens is not to get the patient crystal clear vision, but functional vision, says Dr. Chou. “The OCD patients who are comparing the vision in their right eye with their left eye are generally not the types of patients to get into a multifocal contact,” he says.

Additionally, you may want to reconsider perfectionist patients who will compare their multifocal contact lens vision with the most updated progressive glasses, Dr. Chou adds. Instead, the best patients are the ones who will benchmark their vision through a multifocal contact lens against their uncorrected vision. “I tell patients that their vision with a multifocal lens is going to be way better compared with their naked eye, but it’s not going to approach what they would get with updated glasses, which is honest,” says Dr. Chou. “It’s always better for practitioners to under-promise and over-deliver.”

For Dr. Anderson, the selection process for current contact lens wearers begins with understanding what a patient does with their eyes



Various multifocal zone sizes within a pupil.

Image: Mike Brulic, OD

Image: Robert L. Davis, OD

and how much of an issue the near is for them. “If someone is noticing a slight blur at the end of the day on medicine bottles in low light, I will tell them they are going to need a multifocal lens in the near future,” he says. “For current wearers who have just started trying over-the-counter readers or those who are noticing their phones are always blurry, I will nearly always push towards a multifocal contact lens.”

When evaluating prospective new wearers, Dr. Anderson focuses almost entirely on what they do with their eyes. If a patient does mostly distance tasks, they may be quicker to notice the flaws of multifocal contacts, but if they work up close all day, they will be quicker to notice the benefits.

ACCENTUATE THE POSITIVE

Managing patient expectations doesn't end after the initial fit, however.

Something as simple as word choices can make a difference in patient perception. Dr. Chou refers to the second office visit as a “progress visit” rather than a “follow-up.” This reinforces the value of the appointment for the patient. Often, practitioners with lower success in prescribing multifocal lenses treat subsequent appointments like medical visits, Dr. Chou adds. “The first question they ask is, ‘Are you having any problems?’ The better questions is, ‘How are you enjoying your freedom from glasses?’”

Practitioners who adopt the medical model for multifocal lens visits generally also make the mistake of checking each eye individually first, and then having the patient read the smallest letter on the screen to get to the measurement endpoint as quickly as possible, Dr. Chou says. “That

psychologically puts doubt in the mind of the patient because multifocal patients usually don't see the 20/20 line crystal clear.” Instead, he believes practitioners should ask positive questions, check visual acuity first binocularly with both eyes open and start with one of the largest letters that the patient couldn't see uncorrected prior to the treatment.

ON THE HORIZON

One promising multifocal working its way through the pipeline is an accommodating contact lens from the Vistakon division of Johnson & Johnson Vision.^{2,4} “It sounds remarkable,” says Dr. Chou. “The lens would change focus like an autofocus camera.”

In a similar vein, Verily and Alcon are working to develop a smart, accommodating soft contact lens that contains tiny integrated circuits, sensors and wireless communication capabilities for self-contained wireless sensing on the surface of the eye.⁵

Improvements more likely in the near-term will expand the range of candidates who can try multifocal lenses. “While our spherical patients have a plethora of options currently out on the market, our astigmatic patients do not enjoy such options,” Dr. Bazan says. “However, there are innovations in multifocal technology coming up and in a couple of years they will have some.”

Overall, soft multifocal contact lenses have come a long way since their introduction, and that should encourage doctors to embrace these designs when dealing with presbyopic patients. “Everyone's a potential candidate,” Dr. Bazan stresses. “Follow the fitting guides and drop your baggage. The new lenses are awesome.” 

WHAT TO CHARGE?

There are two schools of thought here. “In the past, because multifocal lenses were a crapshoot, you didn't know if it was going to be one visit or five visits, so we would set the fees higher to account for that,” says Dr. Bazan. “Now, because most of my multifocal fits are the same as my spherical and toric fits, I set them at the same fee.” That covers patients for the initial visit and one follow up. For additional visits, Dr. Bazan raises the fee to a level 2 contact lens fit. “But I can't tell you the last time we've had a level 2 contact lens fit for a multifocal,” he adds.

On the other hand, Dr. Brujic advises practitioners to set multifocal fitting fees higher than spherical lens fitting fees. “It takes more knowledge from the practitioner to be able to effectively and efficiently fit these lenses,” he says. Dr. Anderson agrees, citing the additional time and effort required to successfully fit multifocal lenses. “I charge accordingly, and this is typically 2.5 times what I base my spherical contact lens fees on,” he says. “Not only do they require more follow up typically, these patients also need more coaching while wearing the lens.”

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Freedom on Your Fingertip: GP, Hybrid and Scleral Multifocals

These options offer crisper vision than soft lenses and custom-tailored solutions that can satisfy even the most dubious patients.

By Cory Collier, OD

With a dual focus on both medical and refractive eye care, optometrists are uniquely positioned to provide patient-specific vision solutions to each and every patient. While ODs are successfully meeting the needs of most patient populations, many continue to under-deliver for those patients in need of presbyopic contact lens correction.

Not a day goes by without a presbyopic patient in my chair telling me they have either tried and failed or never even pursued contact lenses because they thought they were a poor candidate. They list any number of perceived complications such as too much astigmatism, a too high or too low prescription, or dry eye, to name a few.

These patients represent a tremendous opportunity for us to look beyond the soft lens fitting sets in our offices to find a customized and highly satisfying vision solution: gas permeable (GP) multifocal lenses.

Multifocal GP lenses are available in three modalities: corneal, hybrid and scleral lenses. While each provides its own unique advantages and disadvantages, two key concepts, translation and simultaneous vision, are fundamental to multifocal GP lenses. Let's take a look at the mechanics behind these lenses, and the variety of multifocal designs available today.

TRANSLATION

The physical movement of a lens on the eye allows gaze-specific positioning of a desired optical portion of the lens in front of the pupil. A translating design, used for bifocal or trifocal corneal GP lenses, is a segmented corneal lens with the top of the lens containing the distance prescription and the bottom containing the reading addition. A correctly fit lens positions the distance correction in front of the pupil on primary gaze with the segment resting at or just below the inferior pupil margin, providing the patient access to the add in downgaze. These designs are only available in corneal GP lenses, as other modalities have inadequate movement.

Advantages include crisp, dedicated distance and near optics. Candidates for this type of lens are those unwilling to compromise distance visual acuity or those who have highly precise near vision requirements. This mode of correction comes with the caveat that range of vision will be compromised, as the patient is typically limited to two focal distances. Also, gaze positioning is critical: patients expecting to see near objects at or near primary gaze or overhead will not be successful with this design.

Lid anatomy is another essential factor with translating designs. Ideally, the upper lid will be positioned near or above the superior

limbus with the lower lid 1mm to 2mm above the inferior limbus. This upper lid position discourages lid attachment, which can inadvertently pull the bifocal segment too high in primary gaze. The high lower lid provides the necessary ledge to position the inferior edge of the lens against. To exploit this relationship, most translating designs have a truncated lower edge, creating a flat inferior lens surface to rest against the flat inferior lid margin, further aiding in stability in primary gaze and translation in downgaze. These designs should be avoided in patients whose inferior eyelid is positioned below the inferior limbus.

Because translation and lens positioning on the eye are key, a diagnostic fitting is integral to success with bifocal lens designs. Important fitting characteristics include an inferior to inferior-central lens position with the lower edge resting on the inferior eyelid, segment

ABOUT THE AUTHOR



Dr. Collier is a partner at Artisan Eye in Lakewood Ranch, Florida. Prior to opening Artisan Eye, he practiced at Bascom Palmer Eye Institute, where he focused on specialty contact lenses for refractive and therapeutic patients. He is a fellow of the American Academy of Optometry and the Scleral Lens Education Society.

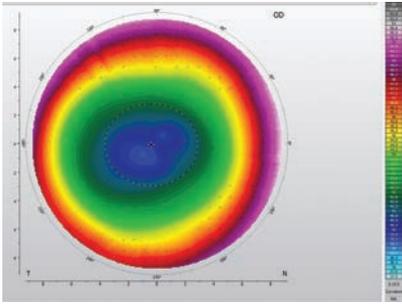


Fig. 1. The topography of a center-distance aspheric corneal GP shows the increasing power gradient from center to periphery.

height at or slightly below the pupil margin, fast lens movement with each blink that quickly re-settles so as to not impact distance vision and at least 2mm of translation on downgaze. Because of their thickness and positioning on the eye, these lenses tend to create more initial lens awareness. This, combined with limited focal distances, render translating designs a niche lens modality.

SIMULTANEOUS VISION

These lenses position distance and near optics in front of the pupil at the same time—the same design as soft multifocal lenses.

Concentric. Distinct distance and near rings are used to create a simultaneous vision correction with this design. The central portion of the lens is typically dedicated to distance vision with alternating rings of near and distance power moving from the center to the periphery of the lens. These lenses are less commonly used today due to advances in aspheric lenses.

Aspheric. This lens design uses gradual curvature changes within the optic zone to create a power gradient. The resultant optic zone contains distance, intermediate and near optics, providing patients with variable vision demands with access to the right correction for the right distance. Aspheric lenses commonly

employ a center-distance zone that gradually increases in power to a near peripheral zone (*Figure 1*). Although this is typical, many designs are available in center-near as well, allowing flexibility and customization for each patient.

The aspheric curvature can be placed on the front or back surface of the lens. Originally, back surface aspheric lenses were used more frequently, as they employ a highly steep central curvature and provide an opportunity for significant central plus power. Although this helps clinicians attain high reading additions, the fitting relationship can cause corneal molding and resultant spectacle blur.

In contrast, when the aspheric curve is placed on the front surface of the lens, the back surface of the lens can remain spherical. This provides an easy-to-fit lens that behaves similarly to a standard spherical back surface lens when on the eye. Although higher add powers are achievable with today's front surface designs, the more advanced presbyope may still struggle to reach their full add requirement with front aspheric optics alone. In this situation, combining front and back surface aspheric optics or binocular strategies such as over-plussing the non-dominant eye can provide more reading power.

Aspheric designs are ideal for the emerging presbyope, the patient with matching refractive and corneal astigmatism, as well as the successfully fit single-vision GP patient who is ready to transition into multifocal lenses. In the latter case, an aspheric front surface may be added to the patient's habitual well-fitting spherical lens, allowing for a simple transition and fitting process. Factors to consider in patient selection for aspheric corneal lenses are patients seeking regular or full-time daily wear and a superior lid positioned 1mm to 2mm below the superior limbus to encourage a comfortable, lid-attached, well-positioned lens. For those who do not satisfy the above requirements, consider hybrid or scleral aspheric lenses, as they operate essentially independent of lid position and can be more comfortable for those who only wear lenses occasionally.

While aspheric lenses employ simultaneous optics, corneal aspheric lenses have the added benefit of translation, allowing for controlled positioning of near add power when reading. For center-distance corneal aspheric lenses, the properly fit lens shifts up as the patient looks down to read, positioning the pupil into the periphery of the lens. This helps the patient reach the portion of the lens that contains their full reading

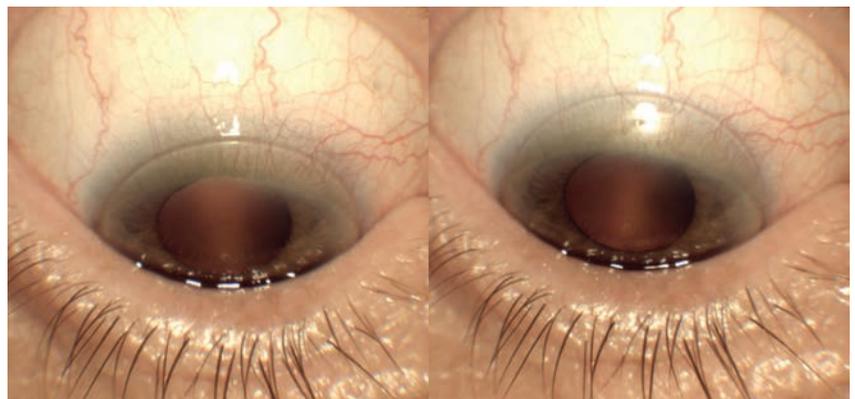


Fig. 2. These images show the difference between inadequate translation, at left, and proper translation, at right.

FREEDOM ON YOUR FINGERTIP: GP, HYBRID AND SCLERAL MULTIFOCALS

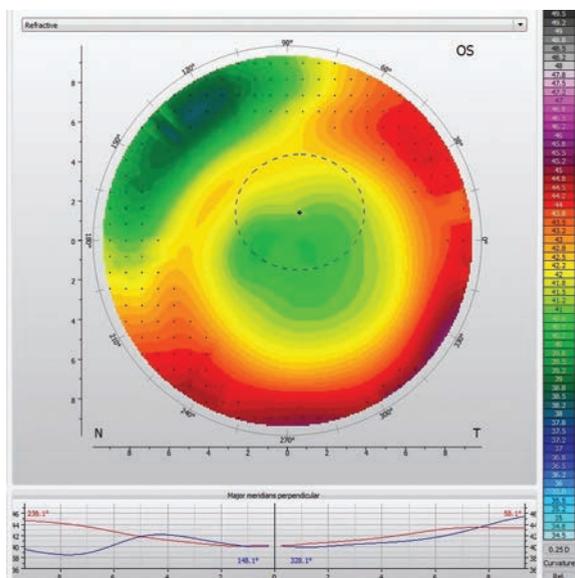


Fig. 3. The topography of this center-distance scleral lens demonstrates inferior-temporal decentration. Note the high degree of varying power in front of the pupil (dotted black circle).

prescription (Figure 2). In addition, this principle allows a larger central portion of the lens to be dedicated to distance vision, maintaining crisp distance vision and reducing the inherent issues of simultaneous multifocal optics such as reduced distance contrast, glare and halos. In higher add powers, or lens designs incapable of translation, center-near optics may be employed due to the natural miosis associated with near tasks. Center-near designs will often positively impact near visual acuity at the expense of decreased distance visual acuity or increased distance symptoms of glare and halos.

MODALITIES

The three GP multifocal lens modalities currently available—corneal, hybrid and scleral—each have their own unique properties that make them ideal for different patients:

Corneal GP lenses are available in translating, concentric and aspheric lens designs. As with single vision corneal GP lenses, multifocal corneal GP lenses benefit from nearly endless customization for

both fit and optics. Parameters include a wide range of distance prescriptions and add powers in 0.25D increments or smaller. In addition, many designs are available with variable center-distance or near zones.

The overwhelming visual advantage of corneal GPs is their on-eye movement. Movement provides not only translation, but also pumps tears under the lens, providing hydration to the cornea and improved oxygen

availability. Despite these advantages, movement also contributes to an increased initial lens awareness, creating a longer adaptation period.

Factors to consider in patient selection are refraction, wear schedule and vision demands. Corneal GP multifocals allow for the correction of both corneal and residual astigmatism, making them a great option for patients whose corneal and refractive astigmatism do not correspond. Patients who commonly find success with lens adaptation and comfort are those who wear their contact lenses as their primary vision correction. Finally, corneal lenses may be the best option for those with high vision demands at both distance and near due to their ability to translate.

Hybrid lenses, with their GP center and soft skirt, can provide patients with the best of both worlds. GP optics are often superior to their soft lens counterparts and allow for the correction of corneal astigmatism. The skirt provides improved initial comfort compared with corneal GP lenses and helps center the

optics over the pupil. This centration is key, as the currently available multifocal hybrid lens options are center-near aspheric designs.

The disadvantages of a hybrid lens include limited physical and optical customization, a lack of translation and handling difficulties. Only one diameter is available, so patients who vary significantly from standard horizontal visible iris diameter (less than 11.6mm or more than 12.0mm in my practice) may struggle to achieve a healthy and comfortable fit. In addition, limited add power options and an inability to alter the size of near and distance zones hinders the customization some patients require. A complete reliance on simultaneous vision with a lack of translation may also decrease the overall clarity of vision compared with corneal GPs. With these lenses, patients may note difficulty with removal, as a specific inferiorly positioned and close finger pinch technique with dry fingers is required to remove the lens.

With their ability to address corneal astigmatism, hybrid lenses can offer presbyopic patients improved clarity compared with soft lenses, in addition to less initial lens awareness than corneal GP lenses.

Scleral lens designs, due to their lack of movement on the eye, employ simultaneous vision. The properly fit scleral lens moves minimally, if at all, on the eye, distributes its weight on the relatively insensitive conjunctiva and provides nearly no edge awareness—adding up to a highly comfortable lens with minimal initial lens awareness.

Depending on the specific design, center-near, center-distance or both are usually available. Some designs take advantage of the binocular system by matching the dominant eye with center-distance and non-dominant eye with center-near, or employ larger or smaller distance

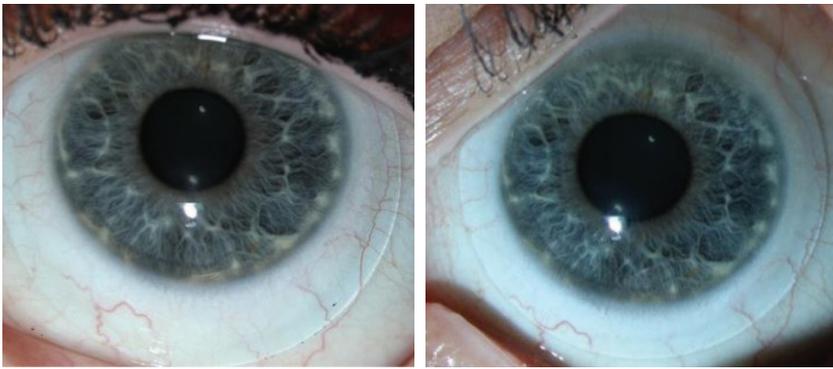


Fig. 4. These images show an inferiorly decentered scleral lens, at left, vs. a well-centered scleral lens, at right. This improvement in centration was accomplished by decreasing the diameter of the lens.

and near zones in the dominant and non-dominant eye. As with corneal GPs, customization abounds for most designs with add powers ranging from +1.25D to more than +3.00D—many available in 0.25D steps—and variable center-near and -distance zones to account for pupil size variation.

Many of the commonly fit scleral lens designs are now available with multifocal optics, and clinicians can fit the patient from their existing diagnostic fitting set. When placing the order, simply incorporate the multifocal optics, commonly based on a combination of add power, eye dominance and pupil size.

Scleral lenses can help clinicians address vision and comfort, both of which are key contributing factors to the increased contact lens drop-out rate in patients older than age 45.¹⁻³ The post-lens tear reservoir of a scleral lens can be advantageous when addressing both vision and comfort, whether neutralizing irregular or regular corneal astigmatism, providing relief for ocular surface dryness or, more commonly, a combination of all three.

Neutralizing corneal astigmatism may improve the clarity of vision in presbyopic patients with matching corneal and refractive astigmatism. This, combined with precise add customization and the ability to

match pupil size with distance/add zones, provides scleral lenses a distinct advantage over soft multifocal lenses for some patients.

In addition, scleral lenses can be exceptionally comfortable. The tear reservoir also helps to provide constant hydration to the corneal surface—a great feature for patients experiencing dry eye or those who could be pushed into a symptomatic state with contact lens wear.

Although an excellent option for many, patients unwilling to compromise their distance or near vision may be more successful in corneal GP designs that allow for translation. Some patients may struggle with insertion and removal of scleral lenses, and all patients should be well educated upfront on the particular handling requirements. Finally, patients with endothelial cell dysfunction or those who demand exceptionally long wear schedules (exceeding 16 hours a day of lens wear) are typically better served in corneal lens designs due to the relatively decreased oxygen availability of scleral lenses.

Multifocal scleral lenses are fit with the same philosophy as other indications for scleral lens wear. One common obstacle in fitting multifocal sclerals can be centration. We know that scleral lenses typically decenter inferior and tem-

poral, which, combined with the natural tendency of the pupil to be minimally decentered superior and nasal, results in a mismatch (*Figure 3*). Clinicians should employ every strategy to improve centration, including adding toric or quadrant specific haptics, decreasing lens thickness, minimizing central and limbal clearance and decreasing diameter (*Figure 4*).

WHERE TO START?

When a presbyopic patient is interested in multifocal contact lenses, you should begin with what you know and are comfortable fitting. For the majority of multifocal lens designs, the physical characteristics that lead to success are comparable with their single vision counterparts. If you are already comfortable with corneal GPs, start with a front aspheric design, which can be easier to fit with its spherical back surface. If you are happy with hybrids, impress a patient with matching refractive and corneal astigmatism with the sharpness they were never able to achieve with their soft multifocals. If scleral lenses are your new passion, fit the patient similarly to your other scleral lens patients (focusing on centration) and then dial in the multifocal optics.

With an understanding of GP multifocal basics and the drive to help your patients find their clearest and most comfortable vision correction, you are on your way to broader multifocal lens fitting success. **■**

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PRESBYOPIA:

The State of Surgical Correction

As IOL options continue to evolve, procedures targeting the cornea and even the sclera open up new frontiers for surgeons.

By David Geffen, OD

An effective solution to presbyopia is the brass ring that eye care practitioners and manufacturers have been reaching for our entire careers. While many patients are content to wear spectacles or contact lenses, increasingly our patients seek a more natural and persistent correction, one that feels akin to the vision they remember from their younger years. By 2020, the global number of presbyopes is expected to rise to 1.4 billion.¹ Because these patients have a variety of other eye issues such as cataracts, macular degeneration, glaucoma and diabetic retinopathy, our practices will be busier than ever.

Our patients are working much later in life than generations past and using digital devices at high rates, so the visual demands of the older population are greater than ever before. Even in retired patients, near vision demands have never been greater. On top of this, today's presbyopes want to maintain a youthful appearance, leading to a race among manufacturers to provide more permanent options to correct near vision than conventional glasses or contact lenses.

Many feel traditional surgical options are too invasive, do not consistently produce high quality vision and could potentially cause optical and visual distortions

as well as other complications.² Monovision has been the most common surgical correction for presbyopia to date, performed using laser-assisted *in situ* keratomileusis (LASIK) or photorefractive keratectomy (PRK) as part of a correction for refractive error. These have their drawbacks, however.

In my practice, I have found the most common complaint associated with monovision is slight distance blur. Moreover, most patients cannot tolerate too much of a difference between their two eyes, limiting the amount of near correction practitioners can provide. Presbyopic LASIK, and multifocal LASIK techniques more specifically, have yielded poor results and most surgeons no longer use them.

The shortcomings of current techniques have made many doctors skeptical of any new technique for presbyopia correction. Despite this, several newly approved options show potential to earn back their trust. Although practitioners have been hesitant to mention new techniques to their patients, this mindset could be problematic. If a patient learns about a new technology from a friend or "Doctor Google," they may assume you don't know about the technology and seek out their friend's practitioner for information. For this reason, it is always advisable to

educate patients about new technologies and explain the benefits and risks if they are interested.

INTRAOCULAR LENSES

For two decades, cataract patients have had the option to choose an intraocular lens (IOL) implant that not only remedies their aphakia but also improves near vision. The category has yet to achieve mainstream success, however, mostly due to concerns about glare, halos and inadequate near vision correction. But properly educated patients with realistic expectations can come away with greater visual independence that translates into satisfaction with the experience.

This option has also become a beneficial alternative for older presbyopes and higher hyperopes. While many feel IOL implantation in the absence of cataracts is too invasive, more surgeons are talking to patients 55 years and older about clear lens extraction, in which the crystalline lens is

ABOUT THE AUTHOR



Dr. Geffen is the director of Optometric and Refractive Services at the Gordon Schanzlin New Vision Institute of TLC Laser Eye Centers in San Diego, California. He is the current past president for the Optometric Cornea and Cataract Refractive Society.

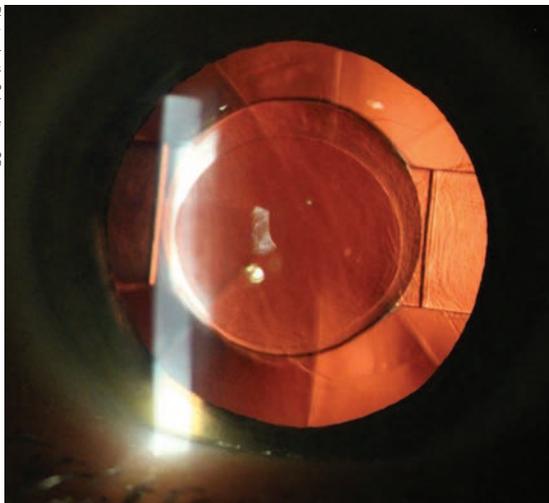


Fig. 1. The Crystalens AO accommodating IOL avoids the glare and halos of multifocals.

removed before there are sufficient changes for the patient to qualify for covered cataract surgery.³

In our practice, we typically offer clear lens extraction as well as LASIK or PRK to these patients. Here, it is important to review the pros and cons of each option with patients and make sure they understand that if they have LASIK at this age, the lens will change over time. IOLs also open patients up to options for multifocal, extended depth of focus or accommodating lenses, providing some amount of near vision. Three types of IOLs are used today:

Multifocal IOLs create several focal points with concentric zones of varying optical power.⁴ Since the aperture of each zone differs, image quality depends on pupil size and reactivity to light and accommodation. Multifocal IOLs, which now can include a toric option, are growing in popularity and new, lower-add multifocal lenses help reduce the size of potential halos. These IOLs are often better tolerated than older generations with 4D-add lenses and thus far have shown success in our practice.

Extended depth of focus IOLs, a new category, seek to overcome the shortcomings of multifocal IOLs by using diffractive optics to elongate the focal length and correct for chromatic aberration (the light dispersion that occurs between colors of different wavelengths). The aim is to improve near and intermediate vision while reducing the likelihood of glare and halos.

Accommodating

IOLs attempt to mimic the reshaping of the crystalline lens. This eliminates the risk of glare and halos that may accompany multifocal or diffractive optics, but creates its own shortcomings such as inadequate near vision and the general difficulty of replicating a dynamic physical process.

One commonly used example of an accommodating IOL is the Crystalens AO (Bausch + Lomb) (Figure 1). In theory, the lens moves back and forth to add near power. However, many feel that the lens actually flexes slightly to create a near effect. In our practice, we have found that we can typically achieve about 1D to 1.5D of near power when using this option.

Accommodating designs fall into two categories:

- **Single-optic IOLs** alter image focal points through anterior movement of the IOL and changes in the lens architecture.⁴

- **Dual-optic IOLs** use two lenses to enhance the range of accommodation: an anterior high plus lens coupled with a posterior minus lens. As the distance between the two lenses changes, optical power is altered.⁴

NEW AND EMERGING IOL OPTIONS

The Tecnis Symphony IOL (Abbott Medical Optics) has gained wide acceptance in the United States over the past year. It uses an extended range of focus to achieve good distance and intermediate vision, as well as some near (Figure 2). Another option, the Restor 2.5D (Alcon) multifocal lens with active focus, provides similar vision to the Tecnis Symphony IOL. Additionally, both companies have higher-powered IOLs for better near vision with slightly less intermediate vision, although these have also shown a higher rate of associated patient symptoms such as glare and halos. These lenses now are also available in a wide range of astigmatic powers.

Other options for these patients are bioptic procedures, in which the surgeon combines an IOL with

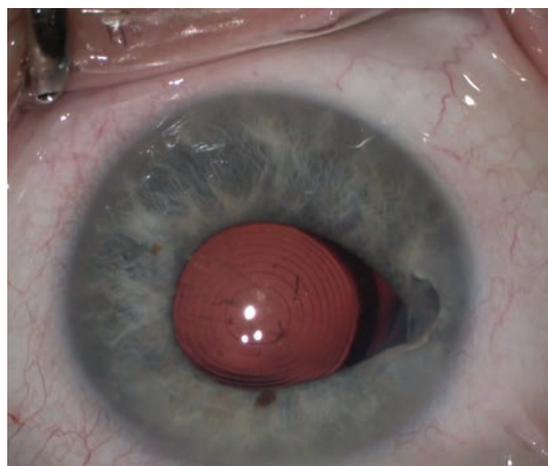


Fig. 2. The Symphony IOL uses refractive echelettes that appear similar to the concentric rings of a multifocal but diffract rather than split the light entering the eye.

PRESBYOPIA: THE STATE OF SURGICAL CORRECTION

LASIK to correct for residual astigmatism. However, one issue with bioptics is that many cataract surgeons do not have access to a laser, forcing them to charge patients a significant amount beyond the standard cataract procedure cost.

The Light Adjustable Lens (RxSight) is the latest entry into the premium IOL market. While its current form does not address presbyopia, its technology could be used to help presbyopes in the future.

This lens is implanted in a fairly simple surgical procedure that does not need to employ intraoperative aberrometry, as with some premium IOL implants. With a special laser, the practitioner can adjust the power of the IOL after surgery, leading to more accurate postoperative refractive outcomes. Its initial approval covers astigmatism up to 0.75D. Because ultraviolet (UV) light is used to adjust the lens power until the final power is permanently set, patients must avoid any exposure to UV light in the immediate postoperative period or the lens will not be adjustable.

In the future, this lens could

open up post-surgery optic adjustments for many types of patients, including coverage of greater astigmatism and multifocal designs. For example, if a patient were unhappy with their multifocal effect, practitioners would be able to adjust the optics to a more acceptable design after surgery.

CORNEAL INLAYS

First approved in the US in 2015, corneal inlays have several advantages over other refractive procedures.⁵ They are an additive technology that can be removed in the event of patient dissatisfaction, complication or onset of other conditions. The procedure does not remove tissue, so patients can still potentially undergo future surgical solutions. In fact, the procedure is considered less invasive than lens surgery. And depending on the inlay, near correction often remains effective as presbyopia advances.

Three styles of corneal inlays exist, all designed for monocular implantation in the non-dominant eye: corneal reshaping inlays, refractive inlays and small-aperture inlays. Currently, two corneal inlays have been FDA approved, but one of those companies recently went out of business, leaving only one on the market. Additionally, a third corneal inlay option is in Phase III trials and a fourth is in development.

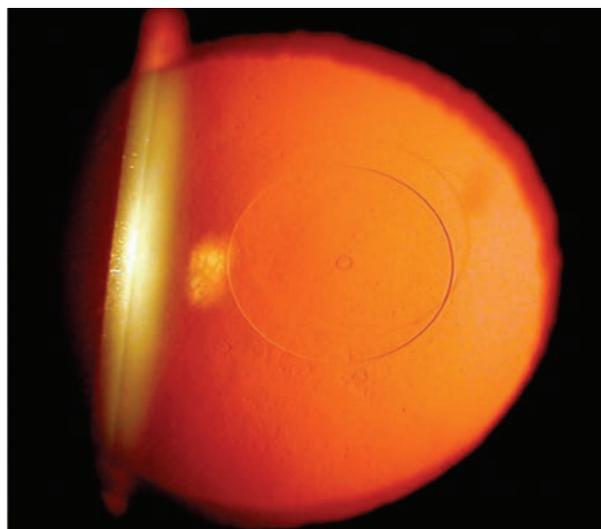


Photo: Clark Chang, OD

Fig. 4. The Flexivue Microlens, which is currently in FDA trials, functions similar to a multifocal contact lens, using concentric rings of increasing add power.

Kamra Near Vision Inlay

(AcuFocus). This small-aperture (5 μ m) inlay is placed in a pocket in the stroma to increase depth of field and improve near vision while only minimally impacting distance vision (*Figure 3*).⁶ The opaque ring is 3.8mm wide with a 1.6mm aperture, and the inlay—which houses 8,400 laser holes to improve oxygen and nutrient transfer through the cornea—is placed in the non-dominant eye. Near light rays coming through the pinhole are focused clearly on the retina. As a result of this process, distance vision is often slightly decreased, typically by two to three lines. If a patient is unhappy with their results, the surgeon can remove the inlay and vision should return to close to what it was before the procedure.

The Kamra is indicated for presbyopic patients between the ages of 45 and 60 with cycloplegic refractive spherical equivalents of +0.50D to -0.75D and ≤ 0.75 D of refractive cylinder. These patients do not need glasses or contact lenses for clear distance vision, but for near correction they require

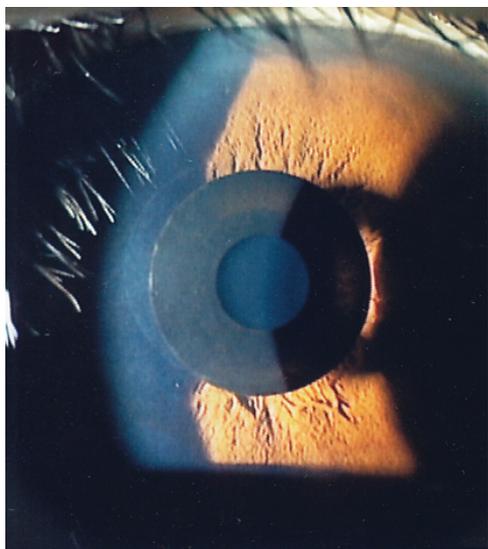


Photo: Minou Tomita, MD

Fig. 3. The Kamra Near Vision Inlay is designed to increase depth of field and improve near vision.

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PRESBYOPIA: THE STATE OF SURGICAL CORRECTION

+1.00D to +2.50D of reading add. The ideal patient has slight myopia but good distance vision.

Flexivue MicroLens (Presbia). Currently in Phase III FDA trials, this hydrophilic acrylic refractive inlay has a 3mm diameter, 0.015mm/15µm edge thickness and a plano central zone with increasing rings of higher power (Figure 4). It functions similarly to a multifocal contact lens and comes in powers ranging from +1.5D to +3.5D in 0.25D increments. The lens is inserted under a flap or in a pocket in the non-dominant eye, and the surgeon can remove and replace it with a higher power inlay as the patient becomes more presbyopic.

Icolens (Neoptics). Still in the early stages of development, this hydrophilic copolymer inlay is 3mm in diameter and has an edge thickness of <15µm (depending on refraction). For presbyopia, it offers powers ranging from +1.5D to +3D in 0.5D steps. Since it has no power in the center and positive refractive power in the periphery, powers can be exchanged as presbyopia progresses.

Raindrop Near Vision Inlay

(**ReVision Optics**). Although this corneal reshaping inlay was approved by the FDA in June 2016, ReVision Optics announced in January 2018 that it was closing its doors, taking the Raindrop off the market.⁸ This came as a result of poor sales and insufficient funding.

In general, the inlay market has yet to meet sales expectations, at least in part because surgeons have not embraced the technology. For this category to continue moving forward, more surgeons will need to start incorporating this technology into their practices and testing the benefits.

SCLERAL INSERTS

A new concept entails inserting bands in the sclera to increase tension on the zonules in hopes of preserving the patient's accommodative ability. As we age, the crystalline lens increases in size, limiting the amount of tension the ciliary muscle can create to change the eye's focus.

The VisAbility Micro-Insert (Refocus Group) places four PMMA inserts into the sclera just beyond the limbus; FDA trials are underway (Figure 5). By increasing

the space between the lens and ciliary body, this procedure improves the ciliary muscle's ability to refocus the natural lens. This procedure would be targeted for emmetropes and may end up being combined with another procedure to first correct a patient's distance vision.

SUCCEED NOW

The perfect solution to presbyopia still eludes us. But thanks to the wide array of technologies currently available, we can help satisfy many people today. Educating our patients and knowing how they use their eyes is paramount to success. Too often, we judge success as sharp 20/20 vision, but with refractive surgery many patients are better off if we aim for 20/happy. We need to change our thinking so we can find the best available solutions for our patients.

Patients with a long history of multifocal contact lens wear are generally good candidates for a clear lens extraction with one of the new IOLs available, and cataract patients are better served by today's lenses as well. Patients who are close to emmetropia but can adjust to slight monovision could be good corneal inlay candidates. Those who cannot tolerate any blur might be good VisAbility implant patients.

Surgical correction of presbyopia in 2018 is more robust than ever, and motivated patients can achieve success. However, always be sure to under-promise and over-deliver. **RCCL**

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Photo: Refocus Group

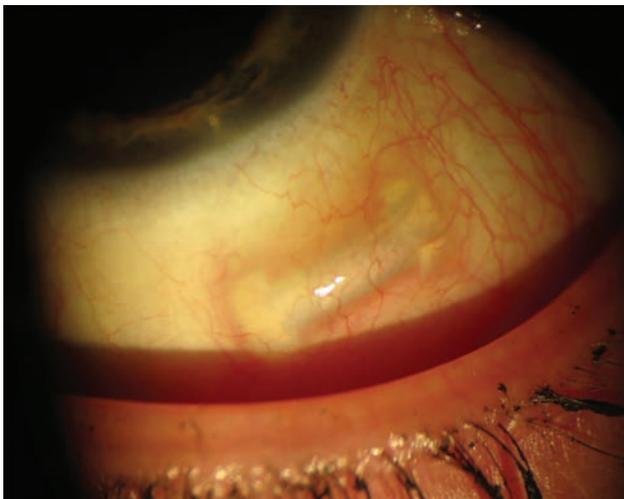


Fig. 5. The VisAbility represents a new concept in presbyopic surgery: scleral inserts. It is currently undergoing FDA trials.

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Presbyopia Eye Drops

are in **SIGHT** The future looks bright for topical presbyopia treatment.

By Brian Chou, OD

At a glance, it might seem like a fake news headline shared on social media: “Eye drops get rid of reading glasses.” However, the prospect of topical treatment for presbyopia is real and on the horizon. Two domestic efforts are in the pipeline—Liquid Vision (Presbyopia Therapies) and UNR844 (Novartis)—and several efforts from abroad are in the wings. This article reviews the latest in this emerging treatment category, along with the implications for patients and our profession.

A NEW OPTION

Presbyopia affects nearly 1.7 billion people worldwide today, and that figure is expected to reach 2.1 billion by 2020, according to one industry estimate.¹ While eyeglasses, contact lenses and surgery each play a role in treating presbyopia, the global need for improved treatment is still large and growing. Pharmacologic topical therapy is an emerging class of treatment with presbyopia in its crosshairs.

The etiology of presbyopia is still under debate, and the relative contributions of lenticular sclerosis, reduced capsular elasticity, increasing lenticular circumferential diameter,

reduced zonular tension and loss of ciliary body movement are not clear. Most eye drops proposed for presbyopia are a mixture of two or more drugs that stimulate pupillary constriction and accommodation for a few hours.²

PINHOLE EFFECT

With Liquid Vision, Presbyopia Therapies set out to commercialize a binocularly instilled drop that, unlike pilocarpine, produces a pinhole effect without inducing significant ciliary body spasm, thereby avoiding brow ache and any myopic shift that would disturb distance vision.

According to company CEO Jim McCollum, the drops were created by combining the miotic agent aceclidine and the cycloplegic agent tropicamide, with the intent of producing strong miosis with negligible accommodation, improving both distance and near vision (*Figures 2 and 3*). In other words, the dosage of tropicamide is calibrated to counteract the accommodation and ciliary body contraction stimulated by aceclidine, while the miosis from aceclidine helps moderate the dilatatory effect of tropicamide. The key is in the ratio and balance of the drugs working together.

Onset of action for the drops is approximately 30 minutes, creating a stable pupil below 2mm in diameter, and their effect is estimated to last at least four hours.³ Mr. McCollum says the fast onset will also allow practitioners to sample the drops therapeutically during routine visits, and that a second dosing could allow for a full day of vision correction.

Another major benefit of Liquid Vision, according to McCollum, is that it is a complement to existing presbyopia treatments such as glasses and contact lenses rather than a permanent replacement. In one preliminary trial for this eye drop, patients ranging in age from 46 to 63 reportedly experienced improved near visual acuity from three to seven lines on the Jaeger scale without compromising distance vision.³ Some patients reported a dimming effect, but it resolved after the first few days.

According to Mr. McCollum, the FDA conducted a Phase IIa

ABOUT THE AUTHOR



Dr. Chou practices in San Diego, where he directs a referral-based keratoconus clinic and serves as an expert witness for litigation involving optometric standard of care.

proof of concept trial for dosing, safety and efficacy in 2016, and results showed improvement in uncorrected near visual acuity compared with placebo at multiple near distances and time points following a single dose. Additionally, the drug was well tolerated, with no serious adverse events. Mr. McCollum says an FDA Phase IIb trial is underway to evaluate a potentially more powerful formulation with enhanced protocol; data should be available at the end of 2018's second quarter. He hopes the drug will be commercialized by 2022.

MIOSIS

One presbyopia study looked at use of 3% carbachol combined with 0.2% brimonidine in the non-dominant eye.⁴ Carbachol stimulates the parasympathetic innervation, the muscarinic and nicotinic receptors on the iris sphincter muscle, leading to miosis and increased depth of



Fig. 1. Eye drops for presbyopia could reach commercialization in the not-too-distant future.

focus. Brimonidine, meanwhile, binds to alpha-2 receptors on the presynaptic nerve endings of the dilator muscle, inhibiting release of neurotransmitters and reducing activity of the dilator muscle to facilitate miosis.

In one prospective, randomized clinical trial of 10 naturally emmetropic and presbyopic subjects between ages 42 and 58, the combined drop treatment showed statistically significant improvement in mean near visual acuity in all subjects compared with those who received separate forms of carbachol or brimonidine alone.⁴ This was also accomplished without any change to binocular distance acuity. However, the study does not indicate what happened to the visual acuity of the treated eye. Interestingly, none of the subjects reported symptoms of reduced depth perception from the difference in retinal illuminance (i.e., the Pulfrich effect).⁴

DYNAMIC PSEUDOACCOMMODATION

Colombian ophthalmologist Luis Felipe Vejarano, MD, has developed a combination eye drop for binocular twice-daily use called FOV Tears. According to Dr. Vejarano, the onset of action is five to 10 minutes for 70% of users by the third month of use, and the

Business Impact

To appreciate the potential business opportunity here, suppose that an elective prescriptive therapy for presbyopia costs \$83.33 per month for ongoing use, the equivalent of \$1,000 per year. If just one million users out of the more than 110 million presbyopes in the United States (less than 1% market penetration) elected to start up with the therapy, it would stand to generate \$1 billion in annual revenue.¹

duration of effect is approximately four to five hours initially but extends to approximately eight hours with continued use. The drops contain pilocarpine 0.247%, phenylephrine 0.78%, polyethelenglycol 0.09%, nepafenac 0.023%, pheniramine 0.034% and naphazoline 0.003%. The rationale behind this formulation, Dr. Vejarano says, is to allow for what he calls “dynamic pseudoaccommodation,” in which the predominant improvement in near vision comes from real accommodation rather than the pinhole effect. The benefit is that the maintenance of physiological pupil diameter variation prevents indoor vision dimming. The pilocarpine provides

Release Date: February 23, 2018

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Goal Statement: Major headway has been made in the development of topical treatments for presbyopia. Currently, two domestic efforts—Liquid Vision (Presbyopia Therapies) and UNR844 (Novartis)—and several international efforts show promise. With a strong working knowledge of upcoming options for topical presbyopia care, ODs should be able to confidently and efficiently incorporate these treatments into their practices. This article reviews the options in this new treatment category, as well as the implications for ODs and their clinical practices.

Faculty/Editorial Board: Brian Chou, OD

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PRESBYOPIA EYE DROPS ARE IN SIGHT

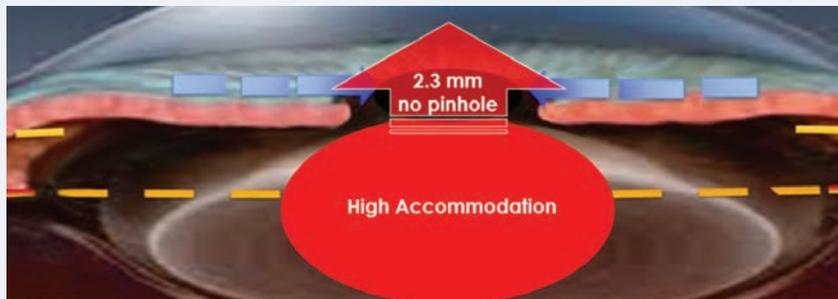
both miosis and accommodation. Meanwhile, the phenylephrine, nepafenac, pheniramine and naphazoline counteract ciliary muscle spasm, vascular congestion and hyperemia induced by the pilocarpine, and help to avoid excessive pupillary constriction. Finally, polyethelenglycol is a lubricant that improves drop tolerance upon instillation.

In a pilot study published in 2016, researchers describe the results of 14 presbyopic subjects aged 41 to 55 using the FOV Tears formulation.⁵ The results showed a mean improvement in uncorrected near visual acuity about two to three lines in each eye and binocularly from a baseline mean of about J3.5 to about J1.5 with an improvement ≥ 3 lines until four hours for seven patients (50% of the subjects). None of the patients experienced a loss in unaided distance visual acuity, either monocularly or binocularly, and there were no adverse events reported.

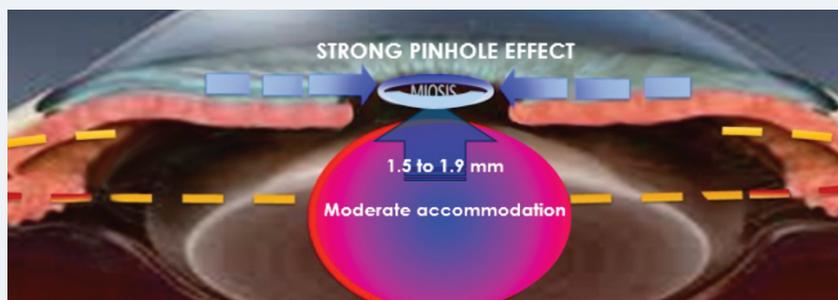
According to Dr. Vejarano, results will soon be published from a study of FOV Tears on more than 300 presbyopes in two groups, one of natural emmetropes and the other of emmetropes following LASIK. Additionally, he says a trial involving 60 patients in Europe will begin soon. Currently, FOV Tears is only available in Colombia.

PROLONGED EFFECT

Claes Feinbaum, MSc, PhD, a professor emeritus of optometry at Ben Gurion University of Negev in Israel uses a combination oil-based eye drop for bilateral therapy with an undisclosed parasympathomimetic to stimulate miosis and accommodation, along with a nonsteroidal anti-inflammatory drug (NSAID) to prolong the effect of the parasympathomimetic. Dr. Feinbaum reports the duration of



Figs. 2 and 3. Above, pilocarpine, a traditional miotic drug, does not provide a pinhole effect, according to Presbyopia Therapies. Below, Liquid Vision drops use aceclidine to create a strong pinhole effect, while tropicamide regulates accommodation. The combination and ratio of drugs aids both near and distance vision.



effect is up to 12 to 14 hours.

Favorable results of the combination were initially presented at the 2013 European Society of Cataract & Refractive Surgeons meeting in Amsterdam when the formulation was referred to as Presbyeyedrops, a name that has since become PresbiDrops (CSF-1, Orasis Pharmaceuticals).⁶

In another study of the combination drops, this one featuring 81 patients, one to two drops of the PresbiDrops formulation in both eyes caused mean pupil diameter to decrease significantly from 3.77mm to 2.63mm.⁷ Additionally, patients experienced significant improvements in mean unaided distance visual acuity, from 0.932 (20/21 Snellen chart equivalent) to 1.141 (20/17), and unaided near visual acuity from 0.356 (20/56) to 0.649 (20/31). Three-fourths of the patients experienced no adverse reaction, while four patients experienced nausea immediately after instillation that

quickly resolved, and another four patients developed headaches that gradually disappeared over 10 to 15 minutes. There were also two cases of dryness or burning, four cases of stinging and four cases of blurry distance vision, all of which dissipated over five minutes.

PresbiDrops is currently in the process of completing FDA regulatory approval, where it will soon start Phase IIb.⁸

MODIFIED LENS SHAPE

The late Argentinian ophthalmologist Jorge Benozzi, MD, developed a presbyopia treatment that combines different concentrations of pilocarpine and diclofenac.⁹ The rationale of using pilocarpine is the same as with other strategies for using a parasympathetic agonist for presbyopia—stimulating ciliary muscle contractions to modify the shape and position of the lens. While the associated ciliary body contraction and accommodation can negatively impact distance

Images: Presbyopia Therapies

vision, diclofenac, an NSAID, is intended to moderate the full amount of miosis and ciliary body contraction.⁹ The NSAID also is intended to prevent uveal tract inflammation from chronic dosing of pilocarpine, which can otherwise lead to posterior synechiae and a fixed pupil (Figure 4).⁹

In a study of this method, researchers treated both eyes of 100 patients for five years.⁹ All patients showed near vision of J1 and distance vision of 20/20 when the drops were instilled at six-hour intervals daily. Some side effects reported in the study include ocular burning and discomfort after drop instillation in 20 patients, with one abandoning treatment as a result. Another four patients also discontinued treatment due to fear of chronic drop instillation.

Now known as Benozzi Method, the treatment has been available in Argentina since 2009 and, according to Giovanna Benozzi, MD (Dr. Benozzi's daughter), 25,000 patients have been successfully treated.¹⁰ "We use different combinations depending on each patient, restoring accommodation binocularly at all distances over time," she says. "We have found no important adverse effects in all the years of treatment."

PRESBYOPIA POST-LASIK

Another proprietary drop, PresbiPlus, includes a mixture of two parasympathomimetics with one parasympatholytic. It is instilled bilaterally twice daily to stimulate accommodation and pupillary constriction. A clinical trial that followed patients for one year showed that 90% could see J4 to J1 after using the drops with no adverse reactions.¹¹

According to Roberto Pinelli, MD, scientific director of Switzerland Eye Research Institute

and the developer of PresbyPlus, "I currently use PresbyPlus for my patients after femtosecond PresbyLASIK to maintain accommodation. While most of my current research is directed towards femtosecond PresbyLASIK, development of PresbyPlus remains active and ongoing." Dr. Pinelli also says that topical pharmacologic treatment of presbyopia holds promise for ODs in expanding their role in comanagement following LASIK.

RESTORING THE LENS

Unlike eye drops that attempt to stimulate miosis or accommodation, UNR844 uses a completely different treatment approach for presbyopia. Previously called EV06 ophthalmic solution (lipoic acid choline ester or LACE, 1.5%), UNR844 is now set to go through Phase II and III development. According to Novartis, the drug "is being studied for topical administration to restore the natural flexibility and accommodating power of the lens."

This prodrug is designed to penetrate the cornea and then break down into lipoic acid and choline, two naturally occurring substances.^{13,14}

Lipoic acid is then metabolized into dihydrolipoic acid within the crystalline lens fiber cells, where it reduces protein disulfide bonds to soften the lens and restore accommodative amplitude.

Phase I-II study of UNR844 in 75 patients (50 using LACE 1.5% and 25 using placebo)

over 90 days showed that the drug was safe and well tolerated with no treatment-related study discontinuations. Additionally, all patients showed improvement in distance-corrected near vision acuity (DCNVA) efficacy measures starting at day 15.¹⁴ By day 91, 82% of patients had 20/40 DCNVA or better in the LACE group compared with 48% in the placebo group, with baseline values of 30% and 28%, respectively. Similarly, 60% of LACE-treated subjects had 20/32 DCNVA or better at day 91 compared with only 24% in placebo; the baseline value for this measure in both groups was 8%. Finally, 36% of LACE-treated subjects had 20/20 and 20/25 DCNVA at day 91 compared with 16% in placebo, with the baseline value for this measure in both groups at 0%.

UNR844 is expected to be used for bilateral therapy with twice daily instillation. Novartis plans to file for marketing approval in 2021.¹²

Eventually, LACE or a similar preparation may also help slow or even reverse nuclear sclerosis, which is thought to result from the same chemical process underlying presbyopia, according to Richard

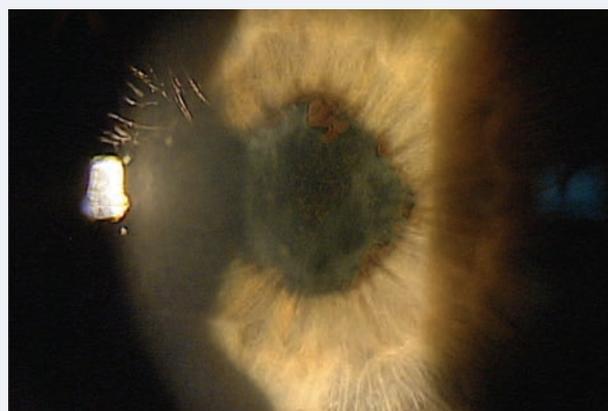


Fig. 4. According to Giovanna Benozzi, MD, chronic dosing of pilocarpine alone may lead to posterior synechiae and a fixed pupil, as shown here. Diclofenac, used in Benozzi Method, is intended to prevent this complication.

Photo: Walt Whitley, OD, MBA, and John Sheppard, MD, MMSc



PRESBYOPIA EYE DROPS ARE IN SIGHT

Lindstrom, MD, a board member and equity owner of Encore Vision, which developed EV06 prior to acquisition by Novartis.¹⁵

THE IMPLICATIONS

The many efforts to develop eye drops for presbyopia foreshadow the likelihood of a safe and effective treatment within the next few years to complement eyeglasses, contact lenses and surgery. This is wonderful news for the growing presbyopia population.

The consumer demand for an eye drop for presbyopia is high enough that it has supported the sale of non-prescriptive drops that allegedly fix this issue, such as Bright Eyes Drops (The Ethos Group) and Blur Relief (The Relief Products) homeopathic eye drops, which sell for \$99.97 and \$10.99 per bottle, respectively.^{16,17} While the evidence-based support for homeopathic drops in treating presbyopia is not at a level that most eye care professionals require, the pharmacologic treatments under development, with regulatory approvals demonstrating safety and efficacy, will likely earn the favor of many eye doctors.

For ODs, the commercialization of viable topical drops for presbyopia may provide a way to increase demand for their prescribing services and offset eroding contact lens and eyeglasses sales. They could provide patients with therapeutic samples of the combination drops for presbyopia even during routine examination due to the rapid onset of action and the fact that the effect will wear off within a day. This would be unlike therapeutic sampling of topical antibiotics for bacterial conjunctivitis, where the sample alone may achieve resolution without the need to fill a written prescription. Instead, patients would simply get

a preview of the drops' efficacy before deciding whether it would be worthwhile to fill the prescription. The combination drops would also largely serve as an adjunct to existing treatment for presbyopia rather than a replacement, preserving the existing roles for glasses, contact lenses and surgery.

In addition to improving near vision, topical presbyopia drops may also address aberrations dependent on pupil size, including mild levels of myopia, hyperopia and astigmatism. Likewise, they may help patients with symptomatic higher-order aberrations, including those arising from past refractive eye surgery.

ODs will need to check their state therapeutics laws to be sure they will have the authority to prescribe eye drops for presbyopia. If there is ambiguity or no provision to allow their prescribing, now is the time to act so therapeutic privileges can be amended to encompass this future pharmaceutical category.

As an example, while Latisse (bimatoprost 0.03%, Allergan) received FDA approval in December of 2008, California ODs with therapeutic certification were not given explicit privileges to prescribe a drug for hypotrichosis. That finally changed on January 1, 2018 with Assembly Bill 443 going into effect. Moving forward, this same bill allows therapeutically certified ODs in California to prescribe non-controlled medications and use non-invasive medical devices as they are invented for conditions they already treat. This means that pharmacologic treatment for presbyopia will be within the prescribing privileges of certified California ODs upon approval. Hopefully, other states without provisions for optometric privileges in pharma-

cological presbyopia treatment can avoid a similar situation California ODs experienced with Latisse. The possibility of presbyopia eye drops hitting the market in the not-too-distant future is an encouraging sign for eye care providers the world over. **RECL**

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CE TEST ~ MARCH 2018

1. If 10% of all presbyopes in the United States regularly used a topical drop for presbyopia at an out-of-pocket cost of \$83.33 per month, what is the expected annual revenue generated?
 - a. \$114 million.
 - b. \$1 billion.
 - c. \$10 billion.
 - d. \$114 billion.
2. Which of the following is not identified as a potential cause for presbyopia?
 - a. Lenticular sclerosis.
 - b. Reduced elasticity of the capsule.
 - c. Reduced zonular tension.
 - d. Paresis of the levator palpebrae superioris muscle.
3. Which of the following is currently not a proposed pharmacologic mechanism of action to treat presbyopia?
 - a. Pupillary miosis.
 - b. Parasympathomimetic induced accommodation.
 - c. Reduction of disulfide bonds in lenticular proteins.
 - d. Liquefaction of the lens nucleus.
4. Which of the following statements is false about Liquid Vision eye drops?
 - a. The miosis produced by aceclidine in the formulation exceeds the dilation effect of tropicamide.
 - b. Clinical data shows that patients regularly experienced the Pulfrich effect.
 - c. Onset of action is approximately 30 minutes after instillation.
 - d. The drop is intended as an adjunct rather than replacement to existing presbyopic treatment.
5. Which of the following drops was used for unilateral instillation?
 - a. Liquid Vision.
 - b. 3% carbachol with 0.2% brimonidine.
 - c. FOV Tears.
 - d. PresbyPlus.
6. Which of the following combination formulations is comprised of the greatest number of different individual drugs?
 - a. Liquid Vision.
 - b. FOV Tears.
 - c. PresbiDrops.
 - d. PresbyPlus.
7. Which of the following does not have an NSAID as an active drug?
 - a. Liquid Vision.
 - b. FOV Tears.
 - c. Drops used in Benozzi Method.
 - d. PresbiDrops.
8. What is the proposed mechanism of action of UNR844?
 - a. Miosis causing a beneficial pinhole effect.
 - b. Ciliary body spasm causing tonic accommodation.
 - c. Reduction of disulfide bonds in lenticular proteins, softening the lens.
 - d. Crosslinking of the zonular proteins, increasing zonular tension.
9. The combination topical pharmacologic treatments for presbyopia are likely conducive to therapeutic sampling because:
 - a. They have a rapid onset, within one hour.
 - b. They have a limited duration of effect that requires daily or twice-daily dosing.
 - c. These drops serve as an adjunct to the traditional role of glasses and contact lenses for presbyopia, rather than an outright replacement.
 - d. All the above.
10. Which of the following is false about pharmacological treatments of presbyopia?
 - a. There are international efforts to develop these treatments.
 - b. They may also help treat selected cases of mild myopia, astigmatism and hyperopia.
 - c. They may improve vision for patients with elevated higher-order aberrations after LASIK.
 - d. Each of the combination drops for presbyopia can also reverse cataracts.

EXAMINATION ANSWER SHEET

Presbyopia Eye Drops are in Sight

Valid for credit through February 23, 2021

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

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 Medical Information, Dept.: Optometric CE, 440 9th Avenue, 14th Floor, New York, NY 10001.

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

- Answers to CE exam:**
- | | | |
|------------|------------|-------------|
| 1. A B C D | 4. A B C D | 7. A B C D |
| 2. A B C D | 5. A B C D | 8. A B C D |
| 3. A B C D | 6. A B C D | 9. A B C D |
| | | 10. A B C D |

Post-activity evaluation questions:

Rate how well the activity supported your achievement of these learning objectives:

1=Poor, 2=Fair, 3=Neutral, 4=Good, 5=Excellent

- | | | | | | |
|---|---|---|---|---|---|
| 11. Better understand the different options of presbyopia eye drops being developed. | ① | ② | ③ | ④ | ⑤ |
| 12. Better identify the financial opportunity presbyopia eye drops bring to optometric practices. | ① | ② | ③ | ④ | ⑤ |
| 13. Improved my ability to educate patients about the potential options for presbyopia eye drops. | ① | ② | ③ | ④ | ⑤ |
| 14. Better understand how the different potential presbyopia eye drop options work. | ① | ② | ③ | ④ | ⑤ |
| 15. Increase my understanding of the clinical impact presbyopia eye drops would have. | ① | ② | ③ | ④ | ⑤ |
| 16. Improve my knowledge of potential problems associated with topical presbyopia treatment. | ① | ② | ③ | ④ | ⑤ |

Rate the quality of the material provided:

1=Strongly disagree, 2=Somewhat disagree, 3=Neutral, 4=Somewhat agree, 5=Strongly agree

- | | | | | | |
|--|-------|---|---|---|---|
| 17. The content was evidence-based. | ① | ② | ③ | ④ | ⑤ |
| 18. The content was balanced and free of bias. | ① | ② | ③ | ④ | ⑤ |
| 19. The presentation was clear and effective. | ① | ② | ③ | ④ | ⑤ |
| 20. Additional comments on this course: | _____ | | | | |

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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 fraudulent or improper means.

Signature: _____ Date: _____

Please retain a copy for your records.

LESSON 116188, RO-RCCL-0318

Coding for *Medically Necessary* Contact Lenses

The current healthcare coverage landscape can be tricky to navigate. Knowing these essentials can help. **By John Rumpakis, OD, MBA**

The dichotomy of today's healthcare environment can be both exciting and frustrating. Point-of-care innovations are at an all-time high, but the associated coverage is confusing and constantly changing. New technologies we would like to offer our patients may be out of reach due to blurred lines between medical coverage and refractive coverage, carrier coverage policy decisions and shifts in payer policy—all of which force the consumer to take on a larger share of the cost through higher deductibles and copays.

This conundrum is best exemplified with the billing and coding of medically necessary contact lenses.

NO CONSENSUS

The definition of medically necessary contact lenses should be clear by now, yet it continues to be parsed, segmented and redefined by third party carriers. Practitioners may have to bear part of the blame for this as well, as some fall short in establishing and documenting true medical necessity for a contact lens fit with respect to specific pathologies. From the payer perspective, some waste and abuse has occurred, resulting in greater scrutiny and tightening of payer policies. Because of this, medically necessary contact lenses have different definitions based upon the

carrier providing the benefits. Here are a few examples:

EyeMed:¹ “Contact lenses are defined as medically necessary if the individual is diagnosed with one of the following specific conditions:

- Anisometropia of 3D in meridian powers.
- High ametropia exceeding -10D or +10D in meridian powers.
- Keratoconus when the member's vision is not correctable to 20/25 in either or both eyes using standard spectacle lenses.
- Vision improvement other than keratoconus for members whose vision can be corrected two lines of improvement on the visual acuity chart when compared to the best corrected standard spectacle lenses.
- All requests for medically necessary contact lenses must be submitted by network provider for review and approval by our medical director before a claim will be processed for the service.”

VSP:² “There are certain eye conditions that can only be corrected by contact lenses. Non-elective contact lenses, also called medically necessary contact lenses, are prescribed by your optometrist to correct these types of eye problems, whereas elective contacts are chosen by the patient to correct an eye issue that eyeglasses or sometimes

laser surgery can also correct. Your eye doctor will let you know if you need non-elective contact lenses.”

Other carriers with well-defined definitions based on the specific clinical conditions observed in the patient include Aetna, HealthNet and Excellus BCBS Medicaid.³⁻⁵ These definitions have both commonalities and disparities, often making the correct use of medically necessary contact lenses quite carrier-specific.⁶

Providers must be familiar with the carrier-specific definitions and payer policies to properly prescribe and advocate for a non-elective contact lens prescription. Due diligence is critical in these cases to avoid any compliance issues.

CRACKING THE CODE

According to the CPT section covering contact lens fits: “The fitting of contact lenses includes instruction and training of the wearer and incidental revision of the lens during the training period.”⁷ The

ABOUT THE AUTHOR



Dr. Rumpakis is president and CEO of Practice Resource Management, Inc., a firm that specializes in providing consulting, appraisal and management services for healthcare professionals and industry partners. He is also *Review of Optometry's* clinical coding editor and authors the monthly Coding Connection column.

following codes describe the fit if performed by the physician according to the CPT:

- 92310: “Prescription of optical and physical characteristics of and fitting of contact lens, with medical supervision of adaptation; corneal lens, both eyes, except for aphakia.”
- 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.”

Note: While the 92313 code description does not specify unilateral or bilateral, the Centers for Medicare and Medicaid Services (CMS) indicate that it should be considered a unilateral fit.

Other important codes include:

- 92071: Fitting of contact lens for treatment of ocular surface disease. (This is considered a unilateral code.)⁸
- 92072: Fitting of a contact lens for management of keratoconus, initial fitting.⁸ Because this is a bilateral code, make sure to report materials in addition to this code using either 99070 or the appropriate Healthcare Common Procedure Coding System (HCPCS) Level II material code. According to the CPT, “For subsequent fittings, report using evaluation and management service or general ophthalmological services.” For every follow-up visit, use a 9921X or 92012 code

to follow the keratoconic cornea—remember, you are following the keratoconic cornea, and the contact lens is just the treatment paradigm.

REFINE AND MODIFY

In many situations, “incidental revision of the lens during the training period” and “with medical supervision of adaptation” are both accomplished during the first post-contact lens dispensing visit. Once the proper vision and comfort criteria are met and you have either ordered the final lenses or have provided the patient with their contact lens prescription, the patient can be considered fit for the contact lenses and the service period for that particular code is over. Should complications arise, the best way to bill for office visits is by using the established patient ophthalmologic (9201X) or evaluation and management (9921X) codes because you are following or managing an ocular condition, not performing a contact lens check.

Practitioners must remember to code properly for the materials. These HCPCS Level II codes specifically describe a scleral lens, followed by the 2018 CMS National Average reimbursement amount:

- V2530: contact lens, scleral, gas impermeable, per lens (\$211.81)
- V2531: contact lens, scleral, gas permeable, per lens (\$555.28)

Other material codes that may be applicable, depending on the technology, include:

- V2599: contact lens, other type (N/A)
- V2627: scleral cover shell (\$1,501.39)

These are all based on a per-lens reimbursement amount, and the lens type and V codes used must match. Many carriers now request



Scleral lenses are often medically necessary for patients with irregular corneas, as seen here.

invoices as well.

Finally, make sure not to confuse coverage with reimbursement or fees. Your fees should be based on a consistent methodology across the patient spectrum without bias or discrimination. Remember the “golden rule”: one fee per CPT code, no matter who is paying. A patient’s benefits for materials as paid by a third party and your fees are two separate issues.

THE NOTIFICATION SYSTEM

The US healthcare system is designed to allow a physician to be paid 100% of the time for 100% of the services and materials they provide if the physician and their staff do their jobs correctly. While you may not get paid 100% of your customary fees, if you do what you are supposed to do, you should never be in a situation where you have to write off a service or material fee in its entirety.

To eliminate write-offs, start by exercising proper use of an Advanced Beneficiary Notice (ABN). While an ABN is specifically designed for Medicare Part B patients, it can be modified for commercial carriers. If you are providing care for a Medicare Part C (Medicare Advantage) patient, an ABN generally does not apply. Be sure to check each of your carrier’s website or provider manual and

CODING FOR MEDICALLY NECESSARY CONTACT LENSES

use the specific waiver of liability form they provide.

An ABN is a written notice a provider gives to a Medicare Part B beneficiary before providing items or services when the provider has reasonable knowledge that Medicare will not pay for some or all of the items or services. This is not a general or long-standing form, but rather a per-occurrence, per-procedure form and must be completed prior to providing the patient with services. The patient must sign the ABN form, and you must include it in your electronic health records and make it a permanent part of the patient's medical record.

The ABN requires that you explain what services or materials you are proposing to provide, why they may be denied by the carrier and the costs of the specific service or materials. This allows the patient to make an informed decision about the services or materials and make sure they're aware that they may have to bear financial responsibility. The ABN provides three options for patients:⁹

Option 1: I want the _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

Option 2: I want the _____ listed above, but do not bill

Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.

Option 3: I don't want the _____ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

If you are adapting an ABN for a commercial carrier, create a new form and substitute the word Medicare with your insurance carrier. In each option listed, you can get paid on the date of service rather than waiting for the carrier to make a coverage decision. It is always preferable to write a refund check to the patient than to manage the accounts receivable situation created by not collecting at time of service.

Because an ABN form or its derivative for commercial carriers is never submitted to the carrier, you must use modifiers to let them know you have properly completed the ABN form. Four common modifiers can be appended to the CPT codes for procedures that may be denied by the carrier. Depending on the service provided and the specific circumstances, the modifier can be either required by Medicare

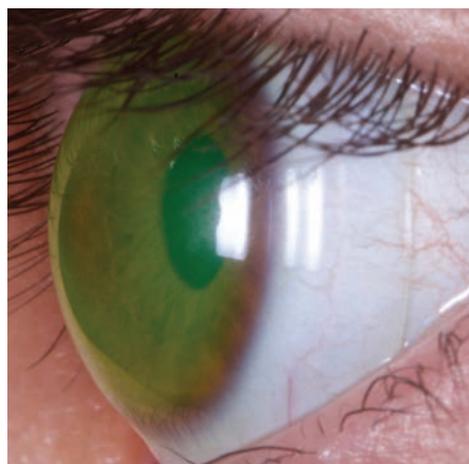
or voluntarily appended to the CPT code. Here are Medicare's definitions for each modifier:

Modifier GA: *Waiver of liability statement issued as required by payer policy, individual case.*

When this modifier is appended to a CPT code, it reports that you issued a required ABN for a service and is on file. CMS will assign financial liability to the beneficiary should the services be denied. The financial liability will be legally transferred to the patient, and you can bill the patient for this service.

Modifier GX: *Notice of liability issued, voluntary under payer policy.* When you append this modifier to a CPT code, it reports that you issued a voluntary ABN for a service that is statutorily excluded from Medicare reimbursement. Medicare will reject non-covered services appended with GX and assign liability to the beneficiary. Since this is a voluntary ABN, the patient always has financial responsibility for the service.

Modifier GZ: *Item or service expected to be denied as not reasonable and necessary.* When you use this modifier, it reports that you did not issue an ABN for a particular service. CMS will automatically deny the service and indicate



These images show a keratoconus patient before, at left, and after being fit with a medically necessary scleral lens.

Photos: Tom Arnold, OD

the beneficiary is not responsible for payment. Because you did not obtain an ABN prior to performing the service, you are not allowed to bill the patient.

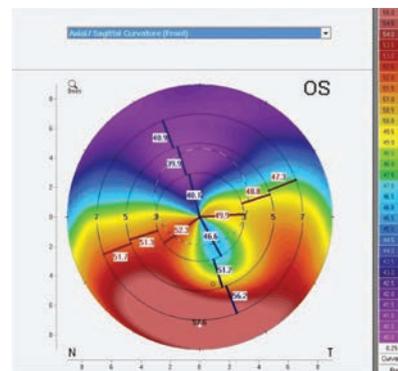
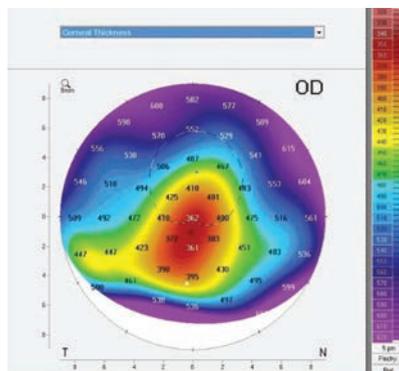
Modifier GY: *Item or service statutorily excluded or does not meet the definition of any Medicare benefit.* When this modifier is appended to a CPT code, it reports when a service is specifically excluded by Medicare, and you did not issue an ABN to the beneficiary. CMS will deny these claims and the beneficiary will be completely responsible for all financial liability.

Modifiers GA and GZ are often used if a procedure does not meet medical necessity as determined by a Medicare Local Coverage Determination or National Coverage Determination. Modifiers GX and GY, on the other hand, are used for items or services statutorily excluded from the Medicare program. Here, the use of an ABN is optional and informational only, but provides proof the beneficiary understands he will be liable for payment for these services. When using either modifier, the provider should bill the patient for the services provided.

REIMBURSEMENT

When you are a contracted provider with a specific carrier, you are generally bound by the provider agreement to accept the maximum allowable reimbursement for services or materials provided to the patient, as long as your customary fees are equal to or higher than the carrier-stated maximum.

Most carriers do not allow you to bundle or unbundle your services and materials for financial gain. Additionally, most carriers do not allow you to bill the patient the difference between the carrier's stated maximum allowable and



Photos: Tom Arnold, OD

Topography can be instrumental when fitting medically necessary contact lenses for patients with conditions such as pellucid marginal degeneration.

your customary fees. As a result, you must accept what the carrier allows for covered services and materials. Generally, the only way to avoid continued underpayment is to terminate your provider agreement with the carrier.

In some situations, the carrier may not be aware of a new lens technology, and the reimbursement may be lower than the cost of the material. Here, establishing a line of communication with the carrier's provider relations department is often beneficial. If you can provide documentation such as invoices, product descriptions and statements of medical necessity explaining why you feel patient outcomes would be enhanced with the new technology, the carrier may adjust payment policy to accommodate the new lens option.

Today, many of these services and materials are excluded from patient coverage, making patients fully responsible for payment. If you are considering discounting your professional services or materials, please be aware of applicable rules and regulations surrounding your discounting policies. Generally, a discount should not exceed 10%, and the net discounted amount should never be less than what you are accepting from Medicare as payment in full. You would not want to jeopardize your

established reimbursement pattern with carriers by violating a discount policy.

As new contact lens technologies come to market and provide patients with greater benefits with medically necessary contact lenses, it is essential we prepare our practices accordingly. Ensure profitability and peace of mind by establishing internal controls and policies to match your increased clinical offerings. When you achieve good compliance, you will be able to enjoy peace of mind despite a highly scrutinized coverage environment. **RCCL**

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Avoid the Near Miss

Understanding GP multifocal lens designs and how the patient's anatomy influences the choice can help you provide spectacle independence for both reading and distance acuity.

In this age of digital devices, near vision demands have never been greater. For patients reaching presbyopia, the impairment of visual function during near tasks can be highly frustrating. Fortunately, advances in multifocal contact lens technology gives most patients the opportunity to meet their visual needs while maintaining freedom from spectacles.

Despite the arsenal of multifocal options available, many practitioners are still hesitant to fit them, instead recommending over-the-counter readers or monovision. However, studies show patients prefer the vision they get with multifocals to monovision.¹

Gas permeable (GP) multifocals in particular can provide superior vision compared with their soft lens counterparts.² And while fitting GP multifocal lenses can seem intimidating, understanding these concepts can help you get started on a path to success.

LENS DESIGNS

Presbyopic corneal GP lens designs are divided into two categories:

Non-segmented multifocals include aspheric and concentric designs, with the vast majority of contemporary multifocals being aspheric lenses.

Aspheric multifocals use a change in curvature on either surface of the lens to provide an increase in plus power. As the eccentricity (or rate of flattening) increases, greater effective add powers can be achieved. Aspheric multifocals are considered simul-

taneous vision designs, meaning both distance and near light rays are presented to the pupil simultaneously. This forces the brain to choose which light rays to accept. Although the transition between zones is generally smooth, higher add powers may still produce aberrations that affect distance vision. Accordingly, aspheric multifocals may perform better for low to medium adds.

Back-surface aspheric multifocals are center-distance designs with increasing add power as you move to the periphery of the lens. If back-surface asphericity alone does not provide sufficient near vision, additional asphericity or a concentric annular zone can be added to the front surface of the lens to increase add power. However, patients with a nearly spherical cornea may achieve a better fit with a front surface-only aspheric design, reducing the chances of corneal molding, which can occur with higher eccentricity back-surface aspheric lenses.

Segmented multifocals, also known as translating multifocals, have distinct areas of distance and near optics separated by lined or crescent shaped segments, allowing for crisp, uninterrupted vision at both distances. If intermediate vision is required, a smaller trifocal segment can be included as well. In primary gaze, the segment should be positioned at the inferior pupil margin so the near optics do not interfere with distance vision. Here, the inferior

lens edge rests on the lower eyelid like a shelf. On downgaze, the eyelid then pushes the lens upward to move the near optics in front of the visual axis.

In addition to base curve, translating lenses use prism ballasting and truncated edges to help center the lens and stabilize rotation.

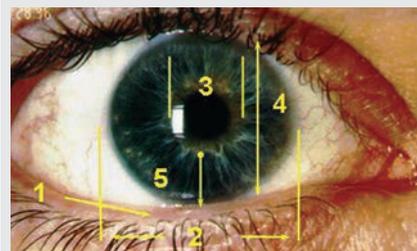
PATIENT EVALUATION

The patient's periocular and ocular features may dictate which GP multifocal lens you end up choosing. For example, the lid anatomy may immediately exclude some patients from a translating design. Proper lens translation requires a lower lid at or within 1mm of the lower limbus. Additionally, there should be good tonicity to allow the lens to rest on the lower lid without sliding between the lid and the globe. Smaller palpebral fissure size may

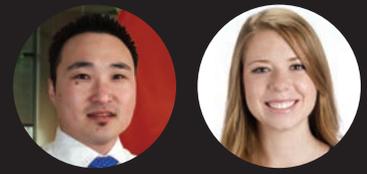
ANATOMICAL CONSIDERATIONS

Evaluate these six anatomical features when sizing up a presbyope for GP lenses:

1. Lid position.
2. Corneal diameter.
3. Pupil size and dynamics.
4. Fissure width.
5. Lower lid pupil edge.
6. Location/amount of astigmatism.



Information and photo: Edward Bennett, OD, MSED, and David Hansen, OD



Photos: Thuy-Lan Nguyen, OD

also exclude translating lenses, which tend to ride high if the lower lid is above the limbus.

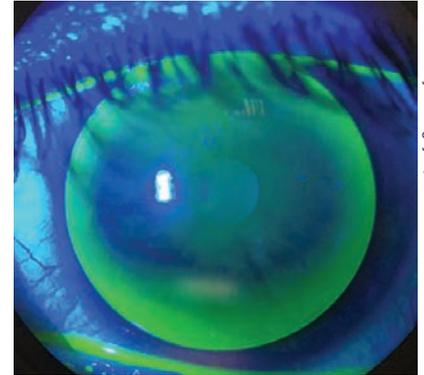
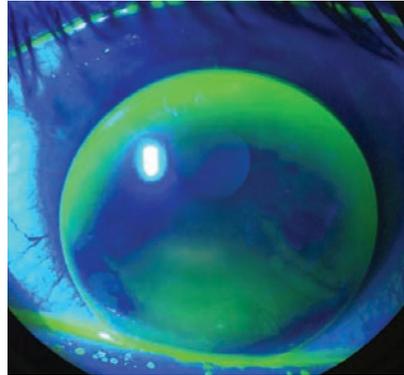
With aspheric lenses, the upper lid is of more importance for dictating lens diameter. If the upper lid is near the upper limbus, you can easily achieve a lid-attached fit using an average-to-larger diameter lens. Upper lids above the upper limbus may require a smaller diameter to achieve an interpalpebral fit.

As patients age, their pupil sizes typically decrease. For those with larger than average pupils, aspheric designs may yield ghosting or halos. Translating designs often work better in these cases, as large pupils allow for an easier transition from distance to near optics. Conversely, miotic pupils may have difficulty achieving the full power range towards the periphery of an aspheric design.

Lens centration is also critical for success with multifocals. Aspheric multifocals are commonly fit steeper than flat K. By using a fitting nomogram based on the patient's K readings, you can fit aspheric lenses empirically with success.³ Translating lenses, on the other hand, are better fit diagnostically so you can evaluate the movement on eye. These lenses are typically fit flatter than K and perform better on flatter corneas.

SETTING EXPECTATIONS

The best candidates for GP multifocals live balanced lifestyles without demanding perfect vision. Although many patients desire crisp vision at all distances, defining success with



An inferiorly decentered multifocal GP with excessive movement, at left, will cause blurred, fluctuating vision and discomfort. To improve fit and vision, steepen the base curve and increase the overall diameter, at right.

them ahead of time will help set proper expectations. Discussing the 80/20 rule with patients can also be helpful. Under this rule, a goal of 80% of daily activities should be achieved without any second thought, while the other 20% of the day may include mild difficulty at either distance or near. Make sure they understand that occasional use of magnification, illumination or over-glasses is not equivalent to failure.

Additionally, unlike single-vision lenses, it can take several weeks for the brain to adapt to the optics of multifocal lenses. During this time period, changes to the lens may be required to improve the fit or vision. Patients should expect at least one change to the lenses during the initial fitting.

The other main concern is that new wearers will not tolerate GP lenses in terms of initial comfort. Building up wear time is essential, similar to breaking in a new pair of dress shoes. It can be easy to underestimate a patient's motivation and ability to adapt to GPs;

however, a properly fit lens that provides great vision can make the process much easier.

Although less popular than soft multifocals, GPs can provide high quality vision at both distance and near for presbyopic patients. As with soft multifocals, determining patient needs and setting expectations is essential for success. Once you choose a design, you can use both diagnostic and empirical fitting methods with good success. When ordering empirically, corneal topography is a useful tool for both keratometry measurements and pupil size. If you need troubleshooting, lab consultants are a great resource to provide assistance. **RCCL**

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Back at Square One—With a Twist

Clinicians should consider specialty soft contact lenses for patients who struggle with adaptation to rigid lens designs.

When an irregular cornea patient no longer achieves optimal vision with standard soft contact lenses, it's time to take a step back and consider all of the options, including rigid gas permeable (RGP), scleral and specialty soft lenses.

However, long-time soft lens wearers can sometimes be difficult to convert to RGP lenses. They can often struggle with the adaptation period, given that conventional soft lenses are comfortable from the start. This case highlights the challenges of converting a soft lens wearer with pellucid marginal degeneration (PMD) to a rigid lens modality—and what to do when the patient simply can't adapt.

THE CASE

A 44-year-old male with PMD was referred to the clinic with complaints of poor vision with his soft toric contact lenses. According to his records, he tried both RGPs and a piggyback system 10 years ago, both without success. Two months ago, his optometrist tried to refit his soft lenses with an updated prescription, but could not get good results. His previous contact lens Rx provided him the best vision, but it was still unsatisfactory.

His presenting contact lens Rx was toric 8.4/-0.50 -4.00x070/14.5 OD, which provided a visual acuity (VA) of 20/30, and toric 8.4/-0.50 -4.75x090/14.5 OS, with a VA of 20/25-. His manifest refraction was -7.00 +6.25x175 (20/20-) OD and -8.75 +7.00x008 (20/25-) OS.

Slit lamp exam revealed clear lids, lashes and conjunctiva and deep and quiet anterior chambers OU. Inferior central corneal thinning was noted OU. The iris was normal with clear lenses OU. Intraocular pressures (IOPs) were 10mm Hg OD and 11mm Hg OS. Topographical imaging revealed a “kissing dove” pattern characteristic of PMD with simulated K readings of 46.01/42.54D OD and 47.78/45.56D OS (*Figure 1*).

I discussed the contact lens options available, and the patient said he would try whatever lens would provide him the best vision and comfort. I first chose scleral lenses and started with a 45/-1.50/16.0 Europa (Visionary Optics) lens on the patient's right eye and a 46/-2.00/16.0 lens for the left. Centrally, the right lens exhibited 200µm of clearance estimated using an optic section through slit lamp, and the left exhibited 250µm of clearance. Both lenses had minor limbal touch 360° OU. Blanching was noted on the landing zone of both scleral haptics. An over-refraction of -4.00 gave 20/20 OD and -3.75 gave 20/20 OS. The patient was thrilled with the comfort and the vision. The following lenses were ordered:

- 45/-5.50/16.2 1 flat edge OD
- 45/-4.75/16.2 1 flat edge OS

The lenses were ordered with a larger diameter to vault the limbus. Because increasing the diameter also increased the apical clearance, the base curve of the left lens was adjusted to lower the vault, and the landing zone was flattened one step in both lenses.

DISPENSING VISIT

When the patient returned for the lenses, he had a difficult time inserting them. On both eyes, the lenses exhibited an optimal fit: 250µm of apical clearance, 360° limbal clearance and lens alignment with the conjunctiva with no blanching. His vision was 20/20 OU. The patient was able to remove the lenses easily, but because he was not used to inserting lenses face down with fluid and could not keep his eyes open, insertion remained a challenge. As he had no problems with removal, he was sent home to practice.

WEEK ONE FOLLOW-UP

The patient presented with complaints that he was not able to wear the lenses. He had a busy schedule and couldn't find the time to sit and practice insertion and removal. He declined more training. He came to return the lenses and discuss other options. He already had a history of RGP and piggyback lens failure due to inability to adapt to the lenses, and he was opposed to hybrid lenses because of their similar insertion method to sclerals. That left us with specialty soft lenses. After discussing the modality, the patient decided to move forward with that option for its ease of insertion and adaptability.

FITTING, ROUND TWO

I started with a NovaKone (Alden) diagnostic set. Using the fitting guidelines, I put a 8.2/8.6/-5.00/15.0, increased thickness (IT) factor 1 lens on the patient's right eye. I performed manual keratometry over the lens, and the mires were not distorted. An over-refraction of



plano +3.50x178 brought the vision to 20/20-.

With the same lens on the left eye, manual keratometry revealed distorted mires -5.00. A lens with the same parameters but with an IT of 2 exhibited more distinct and clear mires. An over-refraction of -1.50 +4.75x007 brought the vision to 20/20-.

Both lenses exhibited good movement and centration with clearance over the apex of the cone. The following lenses were ordered:

- 8.2/8.6/15.0, -1.25, -3.75, 088, IT:1 OD
- 8.2/8.6/15.0, -1.50, -4.75, 097, IT:2 OS

SOFT LENS DISPENSE

When the lenses were placed on the patient's eyes and evaluated, they exhibited good movement and centration. Vision measured 20/20- OU with no over-refraction. The patient was happy with his vision, but he felt the thickness of the lens was uncomfortable. He was advised to build wearing time and see how the lenses felt in a few weeks.

TWO WEEKS LATER

The patient presented with no complaints, though it took him a week to adjust to lens wear. He also said his vision was not as clear as with the scleral lenses, but was significantly better than the vision provided by his initial soft toric lenses.

DISCUSSION

Patients with an irregular cornea—caused by keratoconus or PMD, for example—who correct relatively well in spectacles (e.g., about 20/30)

can often benefit from specialty soft lenses. Although standard toric lenses can sometimes help irregular cornea patients with good spectacle acuity, the final lens power parameters can be difficult to predict through a spectacle Rx due to the draping effects over the irregular corneal surface.

For irregular cornea patients used to standard soft lens who want better vision but are hesitant to convert to an RGP, specialty soft lenses are a good option. Depending on the brand, these lenses have additional parameters such as thickness or size to drape over the cornea to mask irregular astigmatism. They are also more customized than a soft toric lens, providing more control of the way the lens fits over an irregular surface and often leading to slightly more predictable vision. Diagnostic fitting sets and spherocylindrical over-refractions are quite valuable in these cases.

While beneficial in many instances, specialty soft lenses come with a few concerns to be on the lookout for. For one, clinicians must consider the wearing time of these lenses, as they do not provide the same high oxygen permeability as standard soft lenses. Many manufactur-

ers use lens thickness to compensate for the lack of lens rigidity, which can make adaptation more challenging for patients. The higher the IT factor, the thicker the lens: an IT of 0 is 350µm thick, while a lens with an IT of 4 is 750µm. This, combined with a lens material with a dk of 21, can lead to hypoxia if the lens is overworn.¹ Patients should be advised to limit their wearing time to prevent corneal neovascularization. This is especially important for patients with keratoconus or other thinning disorders with irregular astigmatism who may one day need a corneal transplant.²

The easy adaptation and superior optics of scleral RGP lenses has made them the go-to choice for hard-to-fit patients. However, one type of lens does not fit all. Every patient is different, and contact lenses must be tailored to their lifestyle and visual needs. In this case, while vision was superior with an RGP lens modality, the patient was happier with a specialty soft lens that was easier to insert and remove, despite slightly reduced vision. **cccl**

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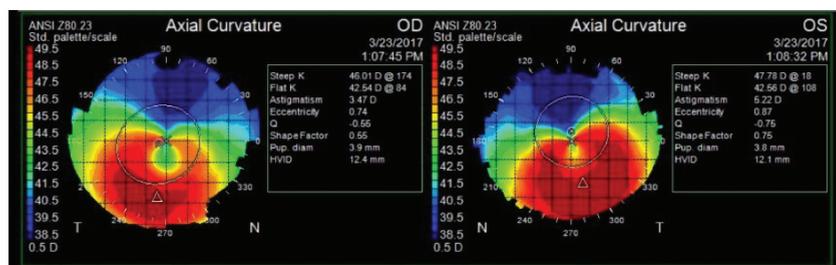


Fig. 1. The patient's topography exhibits a "kissing dove" pattern typical of pellucid marginal degeneration.

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A Cultural Divide

Many ODs prefer empiric MK treatment to culturing, but this approach could be risky.

Microbial keratitis (MK) is arguably the most acutely sight-threatening pathology in the optometric scope of practice. Reduced vision, need for surgery and loss of the eye are all possible outcomes, which can make MK management unsettling.

Once you suspect MK and have deduced which organisms you're likely dealing with, you must decide whether to refer the case elsewhere or continue management based on your comfort level working with corneal ulcers and what will provide patients the best chance at a good outcome. If you choose to manage instead of refer, the first critical step in determining treatment is deciding whether you should culture the ulcer or not.

THE STRATEGIES

There are three basic approaches to culturing:

1. Culture (or refer for culturing of) all likely MK.
2. Culture (or refer for culturing of) likely MK on a case-by-case basis based on the size, depth and unusual historic risk factors of the ulcer.
3. Always treat likely MK empirically, culturing (or referring) only if empiric treatment fails.

While the first approach may prove time consuming and a bit foreign to many optometrists, the last approach can get you and your patient into trouble both clinically and medical legally. The second option is probably the best practice pattern, representing a compromise between risk and benefit. For case-by-case culturing, mnemonics and algorithms can help indicate when culturing is

appropriate. These have to do with some combination of the size and depth of the ulcer, its proximity to the visual axis, extent of the anterior chamber reaction and any unusual features (which may include history).

A reticule on your slit lamp makes size measurement easy, but not all slit lamps have one. Holding a ruler close to the lesion can be difficult and inaccurate, and if you struggle with this, try to use the overall size of the cornea (usually 12mm) or the size of the patient's pupil as a reference to compare with the ulcer.

Lesions greater than 3mm in diameter in any meridian (or $\frac{1}{4}$ of the corneal diameter) should be cultured or referred for culturing. Any ulcer that immediately threatens vision—either through direct involvement and opacification of the visual axis or from creation of irregular astigmatism when a post-infectious scar develops—bears culturing as well. Also, any ulcer with features (e.g., feathery margins, satellite infiltrates, pigmented infiltrates) or history (e.g., vegetative trauma) suggestive of a fungal etiology should be cultured, as fungal infections have a greater likelihood of leading to the need for surgery.¹ If you opt to refer a case for culturing, hold off on antimicrobial treatment if the referral center can see the patient within 24 hours.

If you decide to culture the patient yourself, be aware of differences among various culture protocols. Pre-packaged culture swabs are the backbone of optometric culturing. However, while they are well suited for conjunctival culturing, they more accurately represent “culture-lite” rather than full culturing when assessing corneal infections.

Pre-packaged culture swabs can be effective with larger ulcers, but it can be nearly impossible to retrieve enough material to inoculate swabs when dealing with small or dry ulcers. Also, the transport soy broth sponge does not support all ophthalmic pathogens, and you cannot use these swabs to apply material to a microscope slide for gram staining purposes. The swabs are far too large for retrieving material from smaller ulcers, and the swab head, which is approximately 5mm, can often obscure your view of the ulcer, making it difficult to see what you are doing.

Better for full culturing services and plating media directly would be the platinum spatula, which allows for quick sterilization between gathering specimens, a sterile foreign body spud, a #15 Bard Parker blade (with a lid speculum placed) or moderate-gauge needle (with a lid speculum placed), though the last two increase potential handling concerns since they are sharp objects.

THE PROCEDURE

When gathering material, first instill a drop of anesthetic. Some argue against this approach because proparacaine can reduce your culture yield. This may be true, but a patient not allowing you to touch their cornea will reduce your culture yield even more. In an already painful eye, the chance of a patient allowing you to gather a corneal specimen without an anesthetic is close to zero, so help the patient help you by anesthetizing the eye.

Once you have gathered the specimen, apply it to a liquid medium such as thyoglycolate broth—which is often best inoculated with a swab



Some standard culturing tools include blood (red), chocolate (brown) and Sabouraud dextrose (clear/yellow) agars as well as thioglycolate broth (in test tube), a Kimura spatula and a gram staining slide.

that can be broken off and left suspended in the media—or a solid agar-based media where the specimen is inoculated onto the surface in a series of concentric Cs. For full culturing services, multiple media will be inoculated; blood, chocolate and Sabouraud dextrose agar or inhibitory mold agar for fungus are the standard three.

When inoculating multiple media, make sure to either sterilize your specimen-gathering tool or use a new one between sample collections to avoid re-inoculating material back into the cornea at a different level.

Next, you can inoculate a light microscope slide with material for gram staining. Though gram staining has an even lower yield than culturing, it can provide faster information regarding the general features of your causative pathogen. Usually, these are ready to read within an hour when stat interpretation is requested.

Because culture media has a short shelf life, it's not practical to keep a full complement stocked in your practice. Luckily, requesting media

from a lab is usually quick since most outpatient microbiology labs have courier services available to deliver and pickup media. If you choose to culture yourself rather than refer out, establish a relationship with a lab prior to a corneal ulcer walking into your office so you can avoid potential administrative hurdles.

Once you've completed your culture, you will receive reports back from the lab at time intervals dependent on the media and what

(if anything) is growing. Early culture results will usually be reported in one to two days, and again a week later. Fungal cultures will be read after a week and then again at a month. If growth exists, you can request sensitivity testing, which reports efficacy of various antibiotics to the isolates and is helpful in titrating the most effective antibiotic strategy.

With a sensitivity test, the antibiotics listed aren't generally ones we use in eye care because sensitivity testing is derived from a systemic test. Microbiology labs run a standard minimally inhibitory concentration (MIC) test regardless of the origin of the infection. This is important for two reasons.

First, as a systemic test, the MIC test is concerned primarily with the safe systemic administration of antibiotics so it will not test for concentrations high enough that they could cause significant morbidity when dosed systemically. However, because we can safely achieve much higher corneal concentrations than are tested for and because effectiveness of all

antibiotics is concentration dependent, we may occasionally achieve *in vivo* efficacy with an antibiotic that a given isolate *in vitro* has been determined to be resistant to. Said plainly, because of our ability to achieve high tissue concentration in the eye, sometimes we can have success treating with an antibiotic that MIC testing suggests won't work.

The second reason the systemic origin of MIC testing is important is that one of our front-line antibiotics, besifloxacin, has no systemic equivalent and is not tested. This makes it difficult to have full confidence that besifloxacin will be effective if an isolate shows resistance to moxifloxacin on sensitivity testing, regardless of what 2009's ARMOR study showed (that besifloxiacin was only slightly less effective than vancomycin when dealing with MRSA isolates).²

Due to both real and perceived barriers involved in culturing, empiric therapy is the primary treatment strategy used by most optometrists when managing corneal ulcers. For the majority of cases, this will be effective. However, when this approach is ineffective, it has potential to dramatically increase the chances of an ulcer requiring surgical intervention. To help avoid this outcome, perhaps a shift towards a more culture-forward strategy would be wise. I've never regretted the choice to culture, but I have managed ulcers that made me wish I gathered a culture prior to initiating therapy. **CCCL**

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