# Presbyopia PHYSICIAN

MARCH 2023

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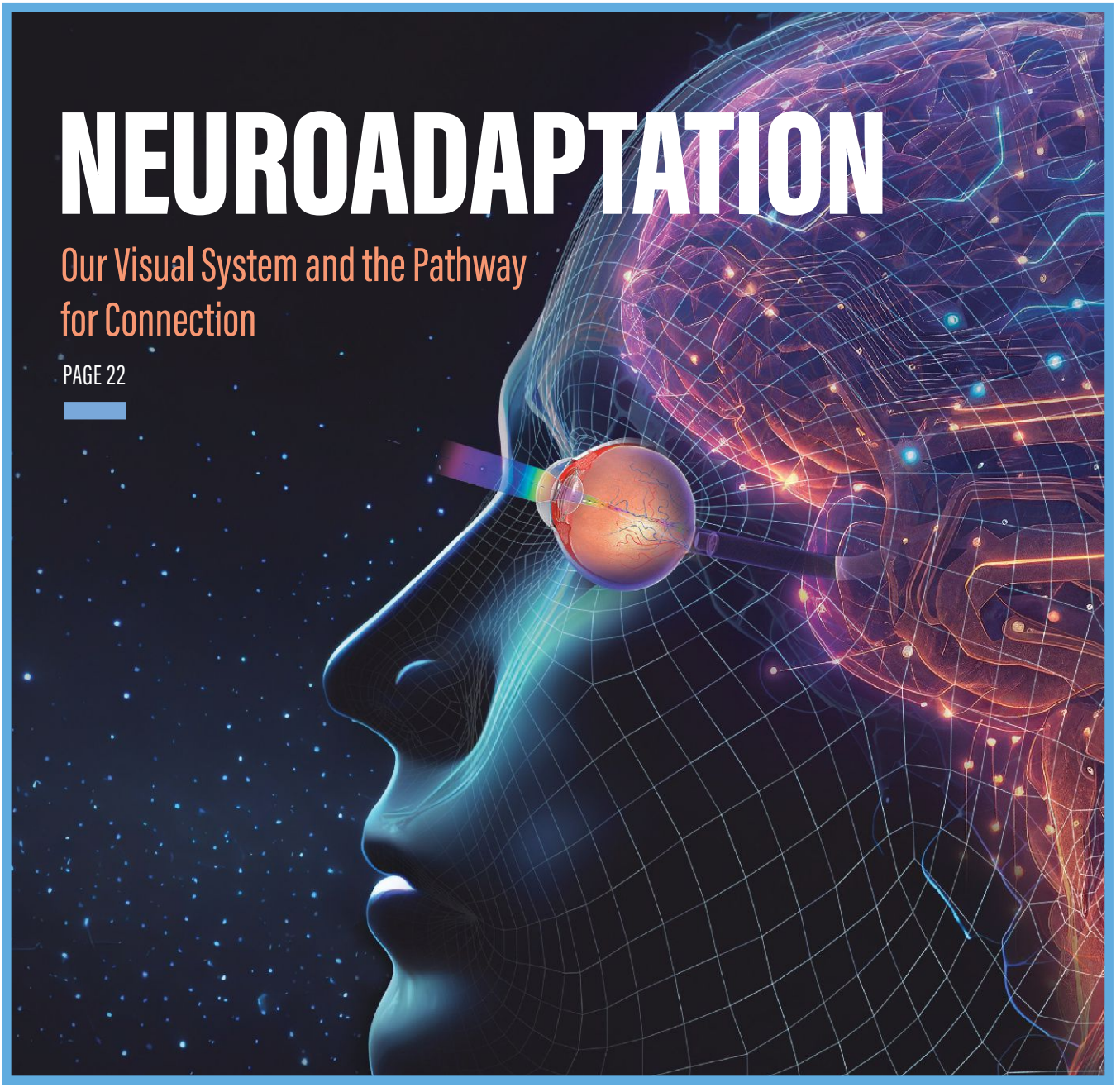

## NEUROADAPTATION

### Our Visual System and the Pathway for Connection

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# RESHAPING **VISION POSSIBILITIES**

ORASIS PHARMACEUTICALS®

# Presbyopia PHYSICIAN

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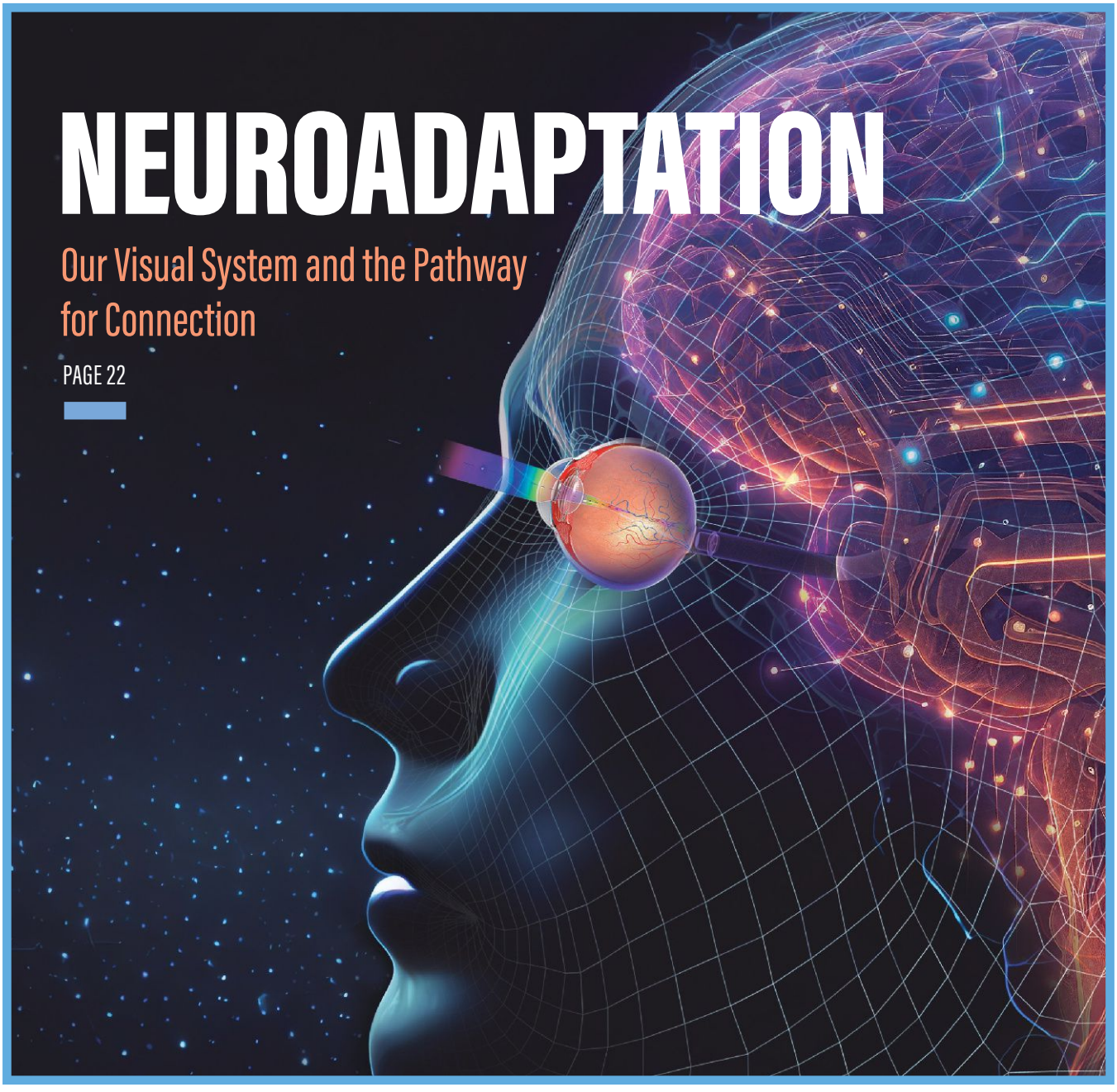

## NEUROADAPTATION

### Our Visual System and the Pathway for Connection

PAGE 22

# Vuity®

(pilocarpine HCl ophthalmic solution) 1.25%

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Presbyopia PHYSICIAN

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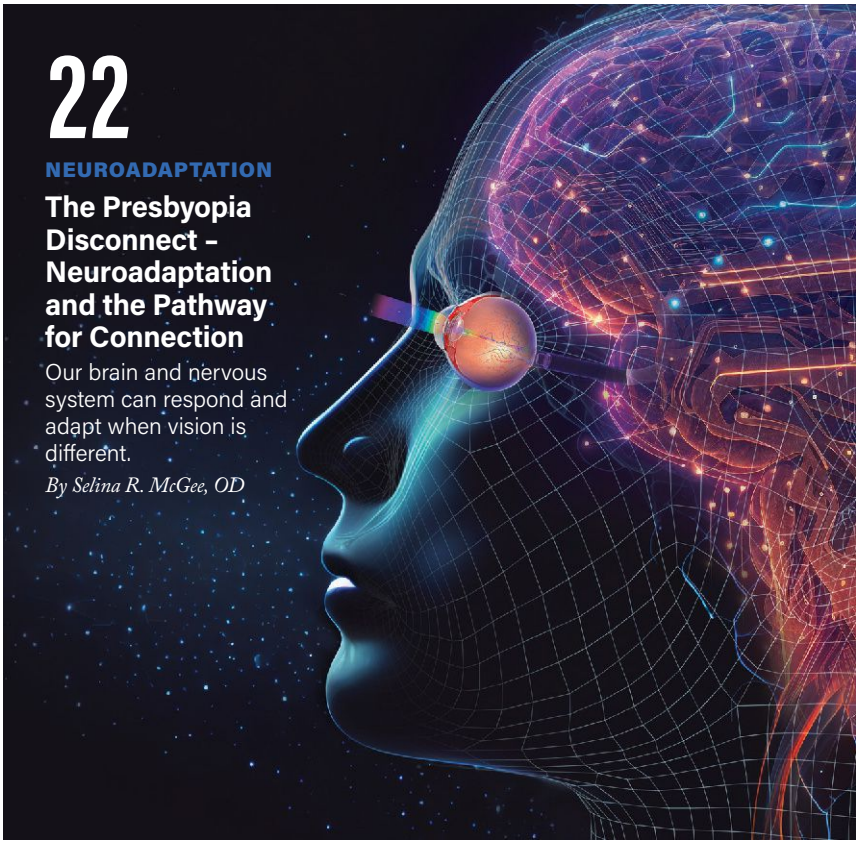



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# See the Future

## DIGITAL EYECARE TECHNOLOGY

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# The Dynamics of Eye Care, and the Growing Presbyopia Treatment Options

*By Elizabeth Yeu, MD, and Jacob Lang, OD*

**Dr. Yeu** joined Virginia Eye Consultants in 2013, has been a partner since 2014, and continues her commitment to residency training in ophthalmology as an assistant professor of ophthalmology at the Eastern Virginia Medical School. She is medical director of the CVP Mid-Atlantic Surgery Center and sits on the board of directors for the Virginia Eye Foundation.

**Dr. Lang** is the lead optometrist at Associated Eye Care in Minnesota and is the director of the practice's ocular disease residency program. He specializes in cornea and ocular surface diseases, as well as therapeutic contact lenses and surgical comanagement. He is also adjunct clinical faculty at the Illinois College of Optometry, The Ohio State University, and Salus University.

IF THERE IS ONE WORD THAT DESCRIBES THE EYE CARE profession so well, it is *dynamic*. It is so applicable in our evolving understanding of the aging of the eye. Now, this succinct adjective is so relevant as it describes the progress that frames the journey of our pharmacologic management options for presbyopia, as Dr. Milton Hom further explores. There are nuances to mechanisms of actions (MOA) differences in formulation strengths, preservative-free formulations, shorter and longer half-lives, different potential implications on the ciliary body, and others. And these are just the beginning of what has been learned so far! There is so much of how we will be able to work bi-directionally with MD/OD counterparts, and how we will be able to incorporate pharmacology with fewer spectacles, contact lenses, pseudophakes, and lasers!

**"If there is one word that describes the eye care profession so well, it is *dynamic*."**

Continuing on dynamism, I (EY) am often reminded when I evaluate patients who read Snellen lines well beyond what I would expect based on the maturity of the cataract, that it truly is *the brain that sees*, thus Dr. Selina McGee dives into how dynamic neuroadaptation helps the brain understand the visual images it receives. Neuroadaptation can help elevate quality of perception of vision with light-splitting IOLs, such as multifocal IOLs as explained by Dr. Vance Thompson. Also, check out the articles on laser blended vision (Presbyond) and refractive lens exchange/clear lens extraction as options for our presbyopia patients, and an explanation of biomechanics and kinematics as they relate to dynamic range of focus of the eye. We also get input from Drs. Ralph Chu and Jessica Heckman on experience with the first-in-class FDA-approved bifocal IOL.

Please enjoy this very comprehensive issue that continues to expand our understanding of presbyopia, and the management thereof. Thanks again, and see you soon.

***Chief Co-Editors***

*Elizabeth Yeu, MD and Jacob Lang, OD*


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# PRESBYOPIA NEWS & NOTES

*Compiled by Andrew E. Mathis, PhD, Contributing Writer*

## FDA Accepts NDA for Orasis' CSF-1

▪ **Orasis Pharmaceuticals** has announced that the U.S. Food and Drug Administration (FDA) accepted for review its New Drug Application (NDA) for investigational CSF-1 (low dose pilocarpine hydrochloride 0.4%), and assigned a Prescription Drug User Fee Act (PDUFA) goal date of October 22, 2023. The NDA is based on data from two Phase 3 clinical trials (NEAR-1 and NEAR-2), which involved more than 600 patients and evaluated the efficacy and safety of CSF-1.

In a press release Orasis said both trials met their primary and key secondary endpoints on Day 8, achieving statistically significant 3-line or more gain in distance-corrected near visual acuity (DCNVA), and no loss of 1-line or more in distance visual acuity. The most common treatment-related adverse events were headache and instillation site pain, and these occurred in only 6.8% and 5.8% of participants, respectively. Only 2.6% of all CSF-1 participants in the trial reported moderate treatment-related adverse events. All other adverse events were mild.

## Ocuphire Starts Enrollment in VEGA-2 Presbyopia Trial, Announces PDUFA Date for Reversal of Mydriasis Indication

▪ **Ocuphire Pharma** has begun enrolling its phase 3 study of Nyxol 0.75% phentolamine eye drop, the company announced in January. The trial, called VEGA-2, is a randomized, double-masked, placebo-controlled study to be conducted at 30 centers in 2 stages. In the first stage, Nyxol will be compared with placebo in 320 subjects; in the second stage, another 320 subjects will be randomized to receive Nyxol plus low-dose pilocarpine (LDP), Nyxol plus LDP vehicle, placebo plus LDP, and placebo plus LDP vehicle.

"In our previous phase 2 VEGA-1 trial, Nyxol alone demonstrated compelling results with rapid onset and sustained 18-hour duration of efficacy and a favorable safety profile," said Ocuphire's chief medical advisor Jay Pepose, MD, PhD, in a press release. "Then the LDP combination option also offers the potential for tunability of treatment based on the patient's lifestyle and response to Nyxol alone."

The primary endpoint of VEGA-2 will be the proportion of subjects with ≥15 letters of improvement in photopic binocular distance-corrected near visual acuity and with <5 letters of loss in photopic binocular BCDVA in Nyxol-treated subjects. Ocuphire will also launch another phase 3 presbyopia trial and a 1-year safety study later this year.

In other news, Ocuphire has announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for Nyxol for the treatment of pharmacologically-induced mydriasis. The FDA assigned a Prescription Drug User Fee Act (PDUFA) date of September 28, 2023.

**The primary endpoint of VEGA-2 will be the proportion of subjects with ≥15 letters of improvement in photopic binocular distance-corrected near visual acuity and with <5 letters of loss in photopic binocular BCDVA in Nyxol-treated subjects.**

## Eyenovia Announces Development Collaboration with Formosa Pharmaceuticals

▪ **Eyenovia** has entered into a development collaboration agreement with Taiwan-based Formosa Pharmaceuticals. A press release says the agreement "seeks to combine Eyenovia's Optejet dispensing technology with Formosa's unique APNT nanoparticle formulation platform for the potential development of new topical ophthalmic therapeutics that employ the Optejet dispenser."

The release further explains that Formosa's proprietary APNT platform reduces an active pharmaceutical ingredient's particle size with high uniformity and purity, allowing penetration to the eye, and enhancing bioavailability.

The companies intend to collaborate on testing formulations and engaging in discussions with the Food and Drug Administration (FDA), with the goal of executing a Development and Commercialization Agreement under which the companies would work to develop new drugs leveraging APNT formulations in the Optejet dispenser.

## New C-Suite Faces at Ace Vision Group

▪ **Ace Vision Group (AVG)** announced in January its appointment of new leadership for its business development and commercial teams. John Frantzis, the new chief business development officer, comes to Ace from Heru, a company spun off from the Bascom Palmer Eye Institute that makes a wearable visual fields testing device, and he has experience on the management teams of Summit Technology and Avedro. The new chief commercial officer Alex Lopez was most recently CCO at Legrande Health, in addition to experience in ophthalmic therapeutics at Alcon.

The two new hires are expected to play key roles in the rollout of Ace's VisioLite Ophthalmic Laser System, which helps treat presbyopia by laser scleral microporation (LSM) – a laser process that overcomes ocular rigidity to allow for recovery of dynamic range of focus (DRoF). "Building an impeccable executive leadership of C-level talent will contribute immeasurably to AVG's continual growth toward commercialization of our flagship technology, the VisioLite Ophthalmic Laser System and the LSM procedure," said Ace founder and CEO AnnMarie Hipsley, DPT, PhD, in a press release.

More recently, AVG announced the appointment of Cristos Ifantides, MD, MBA, as director, clinical applications development, who will lead education and clinical adoption efforts of AVG's presbyopia technology platform.

## B+L and AcuFocus Merge Following First Apthera Implantations

▪ **Bausch + Lomb** announced January 17 that it has acquired AcuFocus, a privately held company, via one of its subsidiaries in preparation for an eventual merger with AcuFocus' parent company. "We believe that the IC-8 Apthera enhanced depth of focus (EDOF) IOL will bolster our surgical portfolio by enhancing our IOL offerings, which is a strategic area of focus for Bausch + Lomb," said Joseph C. Papa, CEO of Bausch + Lomb, in a press release.

This merger news comes less than 2 weeks after AcuFocus announced the first implantations of its Apthera IOL, which is the only small-aperture nontoric EDOF IOL for cataract patients with corneal astigmatism as much as 1.5D and who also want their presbyopia treated.

The implantations were performed by Vance Thompson, MD, at his private practice in Sioux Falls, SD, who said, "This unique lens mitigates presbyopia's effects in an elegantly simple way—by filtering out peripheral defocused and aberrated light that degrades image quality to allow only central focused light to be delivered to the retina." ■

# Another Year Older and Wiser...

## Presbyopia Progress in Pharmaceuticals - An Update!

*By Jade Coats, OD*

**Dr. Coats** works in a large OD/MD practice in Arkansas. The majority of her clinical practice is dedicated to ocular disease, comprehensive eye care, perioperative care, and contact lenses, with a special interest in the ocular surface and dry eye disease.

**WOW! WHAT A YEAR IN THE PRESBYOPIA PIPELINE.** The prospects of topical presbyopia options are growing, the marketing dynamics are shifting, and the landscape of treatment options is evolving.

### VUITY (Allergan/AbbVie)

Serving 120,000 patients with 190,000 prescriptions filled, and counting, Vuity (pilocarpine hydrochloride ophthalmic solution 1.25%) made a splash in 2022 as the first available topical eye drop treatment for presbyopia.[1,2] As primary eye care providers responsible for managing the majority of refractive errors with spectacle and contact lens correction, it is no surprise that nearly 75% of Vuity prescriptions have been written by optometrists.[1,2]

By increasing the depth of focus via pupil constriction, Vuity demonstrates improvement with near and intermediate vision in as little as 15 minutes, lasting up to 6 hours with once-daily dosing.[2] FDA approval of Vuity was based on two phase 3 studies (GEMINI-1 and GEMINI-2), in which the primary endpoints included a statistically significant proportion of participants gaining 3 lines of improvement at near, without losing more than 1 line of corrected distance visual acuity (CDVA) at day 30, hour 3, versus placebo.[2]

Allergan has announced positive topline results of an additional P3 trial (VIRGO) evaluating the efficacy and safety of twice-daily administration of Vuity, improving near vision without compromising distance vision at hour 9 (3 hours after the second drop) on day 14.[2] The final results have not yet been published.

### CSF-1 (Orasis)

Orasis is on track to be next to market, with recent FDA acceptance of its NDA. CSF-1 (0.4% pilocarpine ophthalmic solution) is a preservative-free topical presbyopia treatment that will be available with a dosing schedule that provides the patient flexibility to add a second dose after 3 or 4 hours to extend the effect out to 8 hours, if desired.[3] Two P3 studies (NEAR-1 and NEAR-2) have wrapped up with results showing CSF-1 to be well tolerated among patients, with a safety profile that does not compromise distance or night vision.[3]

The P3 trials confirmed the primary and key secondary endpoint goals of a 3-line or more improvement in distance-corrected near vision acuity (DCNVA) without loss of best-corrected distance visual acuity (BCDVA).[3] Participants were dosed twice daily on both eyes at an interval of 2 hours between doses on days 1-8 and an interval of 3 hours on days 8-15.[3] On day 15, participants achieved statistically significant 3-line improvement in as early as 20 minutes and lasting up to 8 hours after the first dose.[3]

Notably, these results were achieved with a minimal effective dose of pilocarpine, which is less than one-third the concentration of the only commercially available treatment.[3] More new data on CSF-1 will be presented at SECO. Orasis anticipates an approval in quarter 4 of 2023 and plans to launch in early 2024.

### MicroLine (Eyenovia)

Eyenovia offers a unique presbyopia treatment option that includes a proprietary spray dispenser (Optejet) with Microdose Array Print (MAP) technology. Allowing for less

waste, decreased exposure to preservatives, and a convenient spray (no need to tilt the head back), this option provides an alternative administration of pilocarpine.[4,5]

The third P3 study (VISION-1) evaluated the safety and efficacy of the 2 formulations, pilocarpine 1% and 2%.[4] In October 2022, Eyenovia announced positive results of the fourth P3 trial (VISION-2) confirming the safety and efficacy of MAP with a primary endpoint of improved high-contrast binocular distance corrected visual acuity (DCVA) in low light conditions 2 hours after treatment using MicroLine 2%.[5]

Notably, proprietary market research by Eyenovia has also revealed that nearly 80% of patients 40-55 year old who otherwise would not have worn glasses would prefer the Optejet device over traditional drops.[5]

### Brimochol (Visus Therapeutics)

Utilizing a synergistic effect, Brimochol brings together a combination of carbachol (a cholinergic agent) and brimonidine tartrate (an alpha-2 agonist).[6,7] The 2 active ingredients constrict the iris sphincter and inhibit iris dilator contraction, helping to create a pinhole effect.[6,7]

After positive results of the P2 studies (VIVID), Visus announced P3 trials (BRIO-I and BRIO-II) to evaluate the safety and efficacy of Brimochol PF.[6,7] Measuring data in emmetropic phakic and pseudophakic presbyopia patients, the primary efficacy endpoint is the percentage of patients who gain 3 lines of improvement in binocular near visual acuity without losing 1 line of distance vision.[6,7]

P3 studies are still ongoing. Visus is hopeful for a launch in 2025.

**"The prospects of topical presbyopia options are growing, the marketing dynamics are shifting, and the landscape of treatment options is evolving."**

### Nyxol, and Nyxol + Low-dose Pilocarpine (Ocuphire Pharma)

Ocuphire has studied combinations of Nyxol 0.75% phentolamine (or 1% phen-

| PHARMACOLOGIC | COMPANY | DEVELOPMENT STAGE |
|---|---|---|
| VUITY | Allergan/AbbVie | FDA approved (QD dosing). Trials for investigational BID dosing ongoing. |
| CSF-1 | Orasis | P3 complete, NDA accepted by the FDA. |
| MicroLine | Eyenovia | P3 complete, awaiting NDA submission. |
| Brimochol | Visus | P3 ongoing. |
| Nyxol, and Nyxol + low-dose pilocarpine | Ocuphire Pharma | P3 planned, accepting enrollment. 1-year safety study planned. |
| LNZ100<br>LNZ101 | Lenz Therapeutics | P2 complete, P3 planned. |
| ~~Dioptin (UNR844-CHLORIDE)~~ | ~~Novartis~~ | ~~On hold.~~ |

tolamine mesylate) and 0.4% low-dose pilocarpine (LDP), in addition to Nyxol alone. Nyxol ophthalmic solution is a nonselective alpha adrenergic antagonist offered in a preservative-free formulation that acts on the iris dilator muscle, decreasing pupil diameter and inhibiting the contraction of the smooth muscle of the iris.[8,9] Creating a "pinhole effect," the smaller pupil leads to increased depth of focus with rapid onset of action and sustained duration of effect.[8]

**"Serving 120,000 patients with 190,000 prescriptions filled, and counting, Vuity (pilocarpine hy-drochloride ophthalmic solution 1.25%) made a splash in 2022 as the first available topical eye drop treatment for presbyopia."**

In the VEGA-1 P2 trial, Ocuphire validated the effects of Nyxol dosed before bedtime and LDP (which activates the iris sphincter muscle) dosed during the daytime.[8,9] With 61% of subjects gaining 3 lines of near vision at 1 hour, Ocuphire achieved primary endpoints of P2 and showed a favorable safety profile.[8,9] Positive results were also reported with Nyxol alone and more studies have been planned.[8,9]

As of January 2023, Ocuphire had reported enrollment of the first patients for the VEGA-2 P3 trials.[9] Following VEGA-2, Ocuphire plans to initiate a second P3 trial (VEGA-3) and a 1-year safety study (LYRA-1).[8,9]

## LNZ100 and LNZ101 (Lenz Therapeutics)

Headquartered in California, Lenz Therapeutics is undertaking testing for 2 investigational preservative-free formulations of aceclidine: LNZ100 (1.75% aceclidine) and LNZ101 (1.75% aceclidine + brimonidine).[10]

Aceclidine (a muscarinic acetylcholine receptor agonist) is a parasympathomimetic miotic that alters pupil size by targeting the iris sphincter.[10] The formulation by Lenz Therapeutics demonstrates the ability to influence the pupil size with minimal effect on the ciliary muscle (compared to pilocarpine and carbachol).[10]

The topline results of the P2 trials (INSIGHT) included participants ranging in ages from 46 to 73, consisting of some patients with prior vision correction and pseudophakia.[10] Both LNZ100 and LNZ101 achieved the primary endpoint of 3-line or greater improvement in near visual acuity, without losing 1 line or more in distance visual acuity at 1 hour.[10] The primary endpoint was met in 71% and 56% of treated subjects, respectively, compared to 6% of vehicle-treated subjects.[10] ■

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## PRESCRIBING PRESBYOPIA-CORRECTING SOLUTIONS:

# Getting Into the Groove

As with all of our services, prescribing Vuity is about understanding patients' needs and setting expectations.

*By Rachael Wruble, OD*

**Dr. Wruble** is an optometrist and the owner of Belmont Eye, Belmont, NC, and Northlake Eye, Charlotte, NC. She is a private and corporate practice consultant for revamping practices.

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So much of what we talk about as optometrists is understanding patients' needs and setting appropriate expectations. We do those things by listening and educating. I know it sounds simple, but those things truly are the foundation of virtually all of our patient encounters. Prescribing solutions for presbyopia, including our newest tool, Vuity (pilocarpine HCl ophthalmic solution 1.25%; Allergan/AbbVie), is no different.

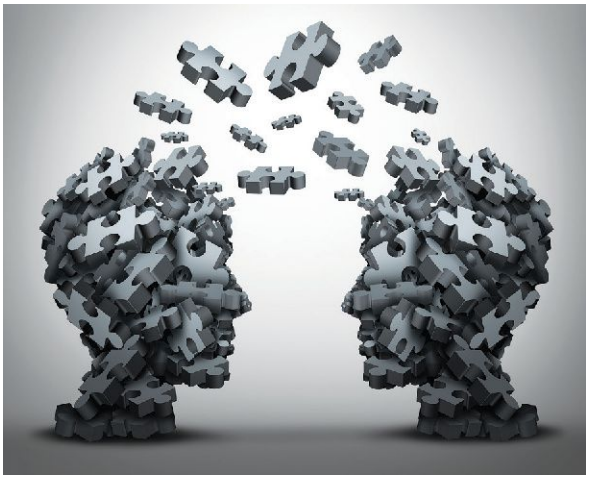
### Comprehensive Exam

First and foremost, to assess a patient's candidacy for the pharmaceutical, we must perform a thorough comprehensive dilated examination, which includes examining the retina. I want to know the patient's history, and if he or she has had LASIK. It's important to have a discussion of risks, and the patient should be educated on signs and symptoms of retinal detachment. If the patient is at greater risk for retinal complications, I let them know the drop is not a good option.

Second, we need to discuss exactly what patients can expect. This is important because patients are already frustrated about losing near vision and needing to wear glasses or contacts to see up close. Ensuring that they understand that this pharmaceutical option will not eliminate the need for those things is key. In other words, the drop is not a cure. It is another tool in the toolbox that will be advantageous in many situations, but patients will require traditional correction part of the time.

Third, I recommend that patients use the drop for 30 days to evaluate its full benefit. I compare it to when one is sick and taking an antibiotic. I say that, although one might feel better in 3 days, if the medication is stopped too soon, it is not going to work as completely as it was intended.

I like to use my husband as an example when I discuss the side effects, such as dimming of distance vision. He is also an optometrist and happens to be a presbyope who is on the drop. I explain that the dimming lasts approximately 1 to 3 days and it improves every day. In his experience, there was a little bit of dimming for the first 30 minutes or so on the third day, after which it completely resolved. This is another reason why I tell patients to use the drop for a month to really get that full effect.



### Lessons Learned

In the past, I would send all of my prescriptions directly to the pharmacy. The pharmacy

may or may not have substituted generic medications and sometimes charged astronomical fees. Our experience would be all over the map, with no consistencies. Some pharmacies would not even have the drug. Now, I use UpScript, which works directly with patients. The service sets patients up on a program with which they can earn points toward a free bottle each time they fill a prescription. The cost is consistent, and UpScript sends the medication directly to the patient.

I have learned to consider many different types of patients as candidates, not just 40- to 50-year-old early presbyopes. For example, one of my patients is a 75-year-old avid golfer. He is a friend of my dad, which is how he heard about the drop. This gentleman's goal was to see the scorecard better. When he walked in, I thought, "Well, he is not an ideal candidate." After the comprehensive eye exam, I told him that the drop was not going to eliminate his need for reading glasses. He understood and emphasized that he just wanted to see the scorecard on the golf course. He was thrilled—he loves it! He can't see a menu in a dimly lit restaurant, of course, but outside in the sunshine, it worked exactly how he wanted it to. This opened my eyes to our need to understand patients' daily activities and goals and not have preconceived ideas about the "typical" patient.

I also love Vuity for my scleral lens patients, especially those with irregular corneas. I find it has the greatest impact on keratoconic patients. I have not had much success with multifocal sclerals in this group; therefore, I set them up for great distance vision. Although they see better at distance than they would with glasses, they cannot see well up close. The drop helps them with near vision, and the small aperture effect also decreases problems with glare and halo that these types of patients experience.

Some of my patients will take a second dose of the drop, off label. I let them know that it is not FDA approved for BID dosing, although there is a current study examining this dosage. My heavy computer users, for example, often use it twice per day. I make sure to recheck their retinas after a couple of months.

## Other Pearls For Use

Ensure that your staff is aware of this drop. The biggest way we can lose patients is if they call the office or come in and ask questions, and the staff is not informed about the product. Educate your staff, especially the presbyopes among the staff members. Invite them to try the drop—after confirming their retinal health with a comprehensive exam—and get their thoughts. In the exam room, we have a limited amount of time, and if the patient is there for other reasons, presbyopia solutions might not always be on our radar. If the whole office is invested—from the front desk to the technicians—when a patient mentions having trouble with near vision, the staff can encourage him or her to discuss the situation with the doctor.

Do not limit your options. This technology will not take away from your optical; rather, it is another aid—a piece of technology that can help your patients see up close. They're still going to need their other tools, their prescription reading glasses, computer glasses, everyday glasses, etc. You want to be able to say that there is something new we can offer and that you want to make sure the patient has all the technology available to correct his or her vision.

## Conclusion

Having settled into a routine with prescribing Vuity, I recognize that the drop can be useful for a wide range of patients. Understanding patients' goals and setting the proper expectations are integral to having success, once a comprehensive exam confirms that the patient is a good candidate. Being a full-service optometry practice means offering patients a range of options to meet their vision needs. This technology is complementary to our other presbyopia-correcting tools. ■

***Disclosure***

*Dr. Wruble is a consultant to Allergan.*

## PRESBYOPIA DROPS:

# Patient Selection and the X Factor

*By Milton M. Hom, OD*

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**Dr. Hom** practices in Azusa, CA. He is an internationally recognized expert and researcher in therapeutics, dry eye, presbyopia, contact lenses, and allergy. He is also co-medical director for the multisite Neurosensory Abnormalities in SymptomAtic Ocular Surface Patients (NASA) study. He has written 4 books and published more than 200 papers and peer-reviewed abstracts.

I REMEMBER YEARS AGO FIRST hearing about presbyopia drops. I was very impressed with the mechanism of action and early proof of concept studies. Shortly after, I was invited to be part of the clinical studies. Then, I read the inclusion and exclusion criteria. In retrospect, they were among the narrowest criteria I have ever seen. I was thinking, "How in the world am I going to find patients that fit the criteria?"

Well, somehow we did meet full enrollment for this and subsequent studies. Why do I bring this up? First, the earlier studies were designed to take advantage of the best aspects of the drops. This means choosing the patients whom they feel will experience the greatest success—or in other words, patient selection. I think more than anything else, patient selection is extremely important with presbyopia drops.

Let's start off with the slam dunk patients—

the patients who were in the early clinical studies. They were emmetropes with a low to moderate add. Zero refractive error at distance works the best with a miotic drop. I remember a conversation years ago with the presbyopia contact lens guru Dr. Pete Kollbaum from Indiana University. He helped design presbyopia contact lenses for a major manufacturer. I asked him why the lens system that he designed only had about +1.50D difference between the eyes (one distance biased, the other near bias). Essentially, there was a total of +1.50D add power in his system. What about the +2.50D add presbyope? Pete went on to explain that the pupil size gets smaller and makes up the difference. In other words, for a +2.50D add, the contact lens picks up +1.00D to +1.50D, and miosis picks up another +1.00D to +1.50D. There is variability in the contact lens add because the lens is aspheric. That was my introduction to how a small pupil can be used to optimize a presbyopic treatment—because smart Pete said so.

**"I really think that pupil size makes a huge difference between success and failure in the real world."**

So what was the lesson I learned? Miosis is worth about +1.50D add. Therefore, going back to patient selection, I use the +1.50D add as a rule of thumb. This drop will give the right patient about a +1.50D add. This translated into the original narrow inclusion/exclusion criteria I talked about earlier. The early clinical studies had an age requirement, something like 40-50 years old. Why? Because you don't want a +2.50D add patient.

As noted, emmetropes are at the top of the list for these drops. Other refractive errors would work too, but keep in mind that the patient must be distance corrected. Would I put a -2.00D in the drop? No way: the quality of near vision with the drop usually will not be as good as no correction at all for these types of patients. How about a -9.00D? Not a chance: unless the patient wants to wear his or her distance lenses or contacts, the drop is not going to work. Of course, there will always be exceptions.

Now, I have found, outside of the clinical studies, that I can place patients beyond 50 years old successfully in the drops. It really depends on visual demand or, in clinical parlance, working distance. Therefore, if the "older" presbyopic patient looks at an 18- to 20-inch distance from the screen, simple math says all you need is about a +1.50D add. Or how many times have you seen patients hold their phone at about 20 inches anyway? It's something to consider.

One aspect of the early clinical studies was establishing how long the drop lasts. In those early studies, we had to keep the patients in our office for 10-12 hours, and they were not supposed to leave. My study staff referred to it as patient imprisonment. We had to test the patient minutes after instillation of the drops and at hourly intervals for 10 visits. One of the investigators at another site told me that they brought in Barcalounger chairs for the patients. I wasn't smart enough to think of that. Luckily, the later studies did not require that much contact time. The current rule of thumb is about 4 hours of efficacy. The newer drops might establish longer times or go to twice-a-day dosing.

**"High motivation can push everything into the success category."**

Then, the studies had a pupil size guardrail. Large pupils were not allowed in the studies. The studies showed high success rates with the drops. I really think that pupil size makes a huge difference between success and failure in the real world. I heard somewhere that the optimum pupil size

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*By Vance Thompson, MD*

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## OPTIMIZATION:

# The Key to Multifocal IOL Success

### Introduction

MULTIFOCAL OPTICS ARE PART OF OUR NATURAL OPTICAL system and can be a beautiful part of our postoperative cataract surgery visual life, if we doctors do our best to close the loop on a comprehensive multifocal implant surgery experience. Having worked with multiple modern day multifocal implants, and witnessed high rates of patient satisfaction with them all, has taught me there is a common denominator to achieving success with them. That common denominator can be summarized in one word, optimization.

I have found it interesting that doctors will do their very best to refract a patient to plano and prescribe the best glasses prescription for patient satisfaction after traditional monofocal implant cataract vision but leave low levels of untreated, visually significant, refractive error in patients with multifocal implants seeking quality vision without glasses. The path to visual joy is simply not that different with a multifocal patient compared to a monofocal patient. Both types of patients can be quite happy if their eye health is great from front to back, and their tear film, implant centration, posterior capsule, and refractive error are treated to the best of our ability. In this article, I review how to optimize the patient's optical system, along with how to set proper expectations (for the doctor and the patient) regarding the multifocal implant journey.

## The 2 Major Optimization Phases of the Multifocal Implant 1-year Journey

Quality patient selection and education include setting up the operating surgeon and his or her team's expectations, along with the patient's expectations. Industry has blessed us with amazing implant technologies, and we must continue to progress in our understanding of how to optimally deliver them to our patients. Multifocal implants are delivering some of the highest implant vision patient satisfaction ever, and wow, can it be a boost to the enjoyment of practicing vision correction surgery when you are practicing on the cutting edge, and you, your team, and your community are enjoying the benefits of doing so.

**"In general, multifocal implants will dedicate a majority of the visual light energy to distance and the minority to near and intermediate."**

I like patients to understand there are 2 basic time periods in the multifocal implant journey: the period of optimization of their vision and the time during which their brain optimizes their new optical system. The time of vision optimization includes any preoperative preparation (such as tear film treatment), the lens replacement surgery itself, and the 4 to 6 months after surgery of working to achieve a plano or near plano refraction, along with uncorrected crisp 20/20 vision in each eye alone. The second 4 to 6 months is the brain optimizing our visual adaptation to simultaneous vision (seeing distance, computers, and cell phones all at the same time), or what we call neuroadaptation.

Therefore, I like patients to understand that we are embarking on a 1-year journey, and if they remain patient during that 1-year journey, at the end they will have some of the world's most advanced optics in their eyes and be able to enjoy the reading range of people in their 30s for the rest of their lives. This is a powerful value proposition to patients who value spectacle independence.

Even though it is not talked about as much, I also believe this is a powerful value proposition for patients who do not mind wearing glasses but who do not want to have the distortions and increased chance of falling risk that accompanies them.[1] Lord and colleagues concluded that multifocal glasses impair depth perception and edge-contrast sensitivity at critical distances for detecting obstacles in the environment.[1] As a result, wearers were more than twice as likely to fall compared to elderly people not wearing bifocals, trifocals, or progressives. The fact that older people may benefit from wearing single-vision glasses or no glasses when negotiating stairs and in unfamiliar settings outside the home is an important consideration in our patient education. There are patients who do not mind wearing glasses and love the idea of single-vision glasses after cataract surgery.

## Don't Worry: The Reading Halo Is for Sure

In general, multifocal implants will dedicate a majority of the visual light energy to distance and the minority to near and intermediate. The exact amount varies with different

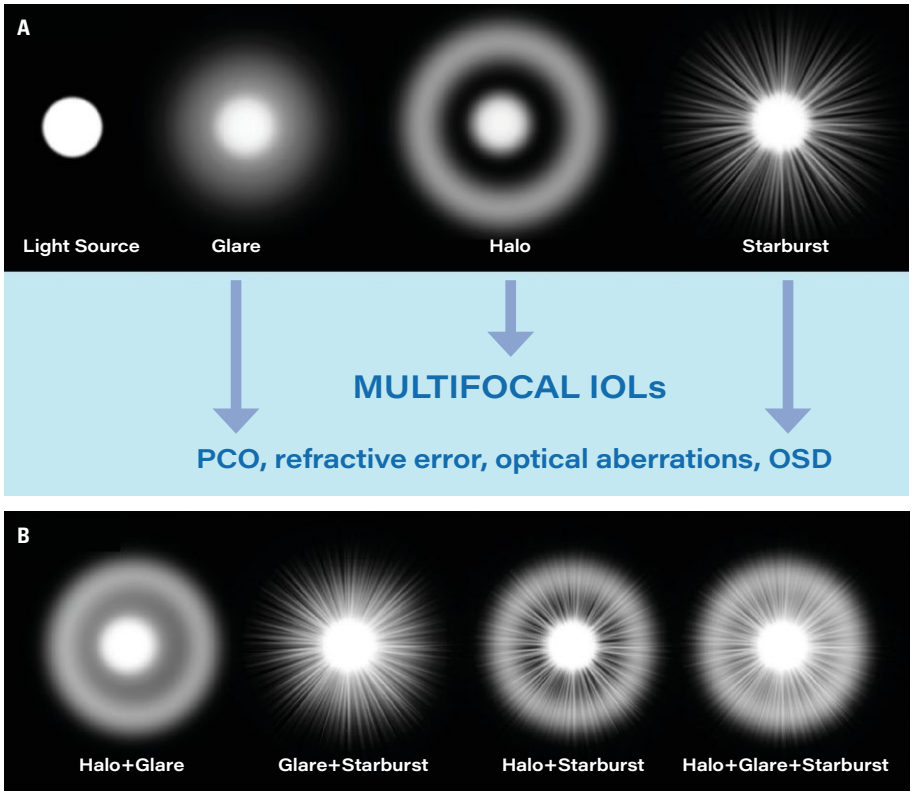


**Figure 1.** (A) Sources of positive dysphotopsias. (B) Combination of sources of positive dysphotopsias.

implants, but in general, you can think of most of the light energy being dedicated to distance and the minority dedicated to computer and cell phone distance. I tell patients, "The part of the implant that gives you the reading range of someone in their 30s is the same part of the implant that causes halos at a distance around lights at night. Don't worry when you see them; expect them. They get better with time, and my work is to fine tune your vision. One of the reasons these implants were FDA approved is because they get better with time and are typically not bothersome at 1 year." I like to say 1 year because it takes time to optimize the vision to a crisp 20/20 in each eye alone in the first 6 months whether it is tear film, refractive error, or yttrium aluminum garnet (YAG) laser capsulotomy that is needed, and then neural adaptation occurs for the next 3-6 months.

Dysphotopsias result from light that is off axis. A positive dysphotopsia after cataract surgery is an artifact or the presence of extra light, often described as glare, starbursts, or halos. This contrasts with negative dysphotopsias, manifesting as the absence of light on a portion of the retina and described as a dark, temporal, arcing shadow.

The pattern and amount of light energy that is off axis creates a characteristic and unique shape and intensity of the dysphotopsia. In general, there are 3 distinct types of dysphotopsias or distortions of a point source of light: glare, halo, and starburst (Figure 1A). Glare and starbursts generally result from posterior capsular opacification (PCO), refractive error (eg, astigmatism), optical aberrations, and/or problems with the tear film or ocular surface. Halos are the characteristic dysphotopsia caused by multifocal intraocular lenses (IOLs).

While companies have optimized trifocal optics beautifully, we need to keep up with our job and understand how to minimize aberrations by understanding and treating our patients, as well as coaching them on what to expect. Understanding that, when patients are describing glare, halo, and/or starburst, they are giving you a clue as to the source or sources. The combination of dysphotopsias can be very disconcerting to the patient and doctor, and understanding that we can treat the halo and starburst sources to optimize the neural adaptation to the multifocal halo is very important (Figure 1B). It is our job to treat what we can treat and educate on what is normal (for instance, implant-related halo) and how it typically greatly improves with time through the process of neuroadaptation.

## Doctors Optimize the Patient's Eyes So Their Brain Neuroadaptation Can Optimize Their Vision

Neuroadaptation is a very important time during which our brain adapts to and optimizes the patient's new optical system.[2] For it to occur optimally, the surgeon must follow a methodical process to completion for every multifocal patient.

For the uninformed patient, positive dysphotopsias (glare, halo, and starburst) can be a common cause of dissatisfaction after multifocal implant cataract surgery.[3,4] They are also considered a leading cause of IOL explantation.[5] It is important for surgeons who are implanting multifocal implants to continually remember that patient satisfaction can be very high if we play our role in the process. If patients are educated well to expect glare and halo with healing and other issues we minimize (such as refractive error, tear film, PCO) and to expect halo from the reading part of the implant that gets better with time, their satisfaction can be very high. For most patients, dysphotopsias improve over time, and it is felt that neuroadaptation plays a central role in this improvement. Although the phenomenon of neuroadaptation is not perfectly understood, its contribution to improving image quality over time is well recognized and respected. It is key that we optimize the patient's image through quality surgery and postoperative care for optimal neuroadaptation to occur.

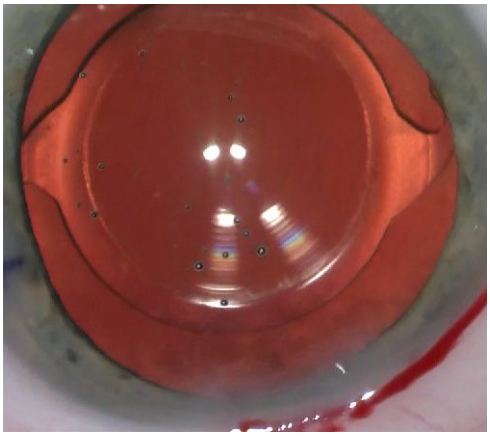

**Figure 2.** Quality centration of the optic and the capsulotomy minimizes long-term tilt or decentration problems with capsular contraction.

## Optimizing Image Quality

Surgical steps to optimize image quality are to center the implant on the subject-fixated coaxially sighted corneal light reflex.[6] This is basically the first Purkinje image with the patient fixation. I like to also center the capsu-

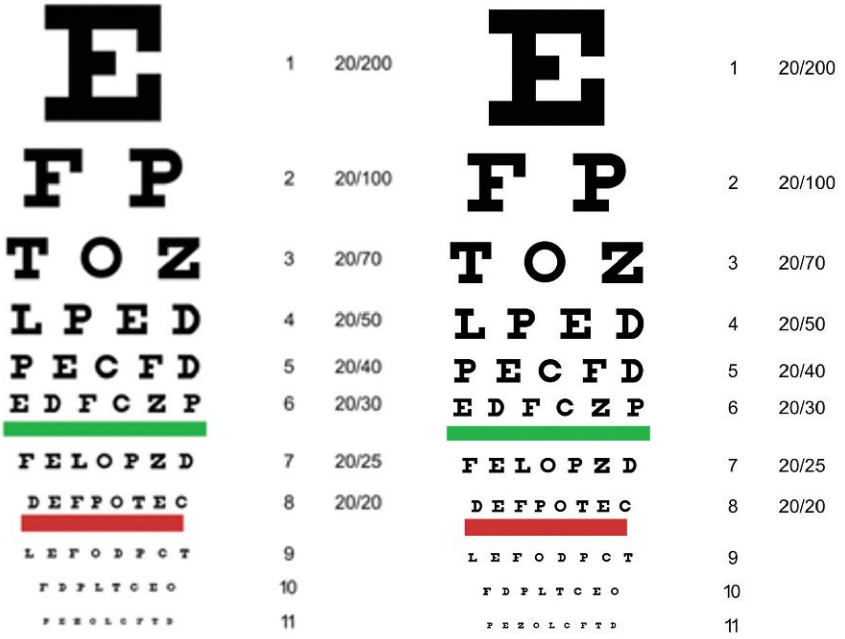


**Figure 3.** We need to ask the patient how sharp the 20/20 line is and work hard to achieve the crispness of the Snellen chart on the right for the happiest patients.

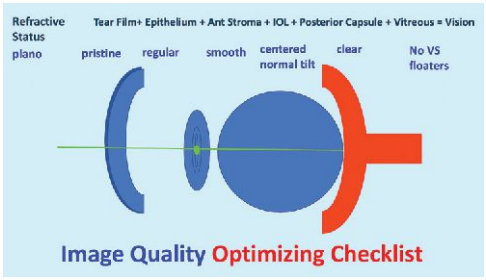


**Figure 4.** Optimizing the refractive error and eye from front to back is what makes for the most complete neuroadaptation and the happiest patients.

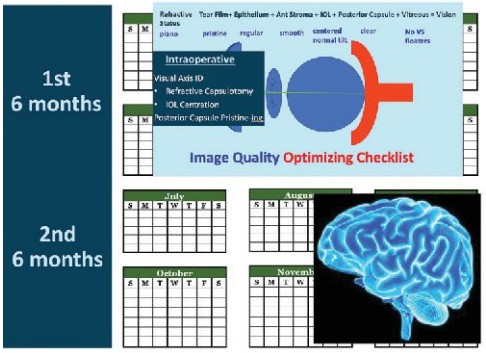


**Figure 5.** Setting your and your team's, along with the patient's, expectations for what happens during the first and second 6 months of the 1-year journey makes for the happiest multifocal patients.

lotomy on the same image and make it 5.0mm to 5.2mm in diameter, so it overlaps the optic, and then with capsular contraction, any potential tilt or decentration of the implant is minimized (Figure 2).[7,8] I also consider it very important to polish the posterior capsule through which light is traveling so that I don't have a hazy capsule confusing things in the early postoperative period. Therefore, I like to protect the posterior capsule using a polymer tip on the irrigation/aspiration handpiece and not a metal tip to polish. I like to call this process "posterior-capsule pristining."

The first step in optimizing image quality postoperatively is understanding how to assess it. History is very important. If a patient says his or her image is blurred, even if he or she reads your 20/20 line, we must listen to the patient and help him or her to achieve the image being sought. If your technician writes that the vision is 20/20, he or she must also document that it is "not clear" if that is how the patient feels (Figure 3).

If the patient's best corrected image quality, what I like to call BCIQ, is reduced, a very helpful test is a gas permeable contact lens over refraction. If the manifest refraction is not crisp and the gas permeable contact lens over refraction is crisp, we know that the patient's issue is corneal surface related, such as tear film or epithelial issue that needs to be treated. I think about the eye from front to back to make sure all sources of blur are accounted for as we journey toward best image quality so that optimal neuroadaptation can occur (Figures 4 and 5). Before an implant exchange is considered, it is helpful to have addressed all of these potential image quality–reducing issues.

## Conclusion

If you follow these steps to optimize the image quality in the first 4 to 6 months to allow for optimal neuroadaptation in the second 4 to 6 months, your patients who desire multifocality will have a high rate of patient satisfaction. Setting your and your patient's expectations through quality preoperative education and postoperative care will take your satisfaction with delivering multifocality to another level in your practice. ■

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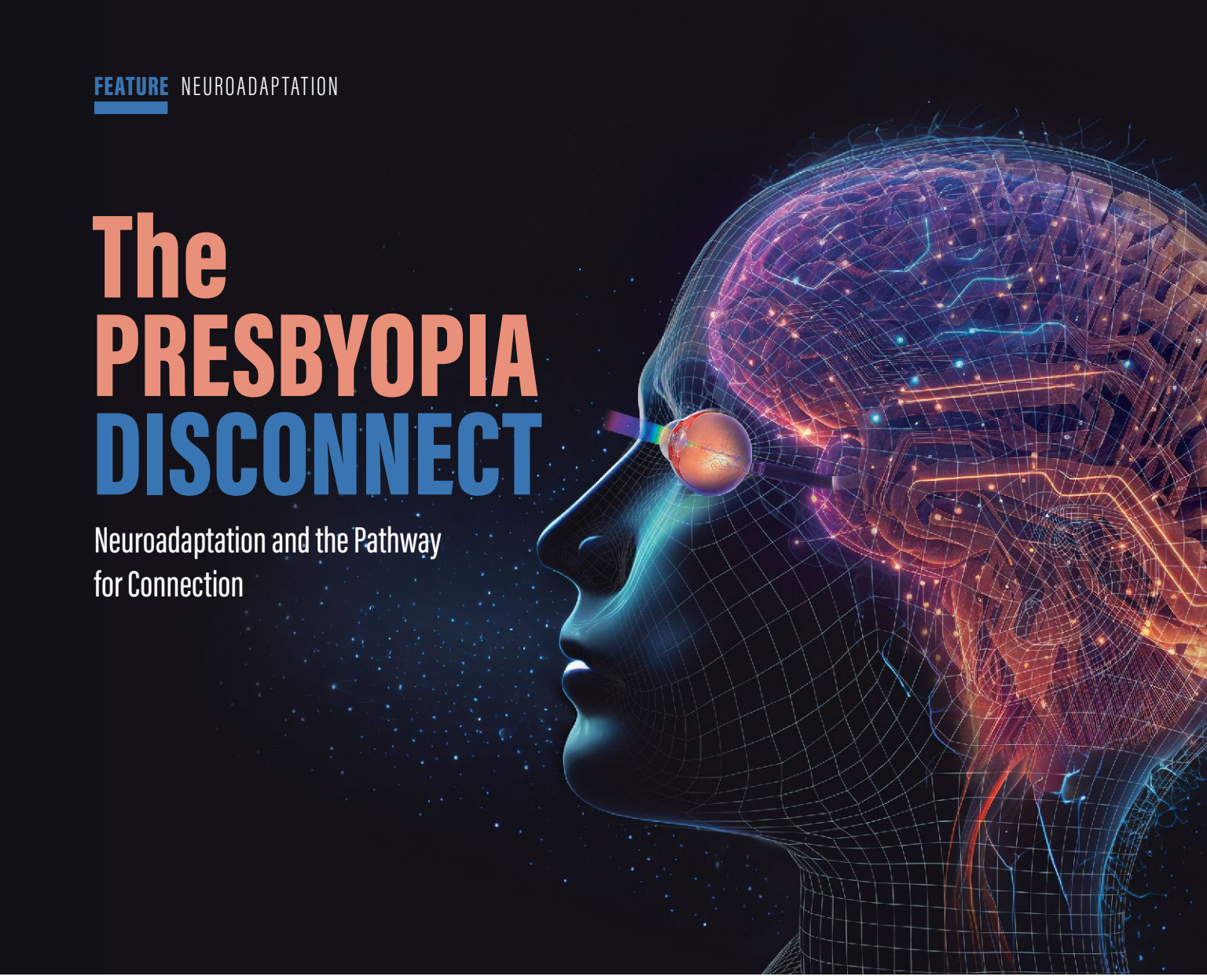
# The PRESBYOPIA DISCONNECT

## Neuroadaptation and the Pathway for Connection



*By Selina R. McGee, OD*

**Dr. McGee** is the founder and owner of BeSpoke Vision. She is an adjunct assistant professor at the Northeastern State University College of Optometry and sees Sjögren's patients at the Oklahoma Medical Research Foundation.

HAVE YOU EVER HAD PATIENTS who were really frustrated with their progressive add lenses? Have you wondered why your multifocal contact lens wearers won't wear their lenses, even when their vision measures 20/20? Have you had a patient try a presbyopia therapeutic drop and fail to ever use it again? What about premium intraocular lens (IOL) patients who are incredibly unhappy with the investment they made because their expectations just weren't met?

You are not alone. These have all happened to every eyecare provider, including myself. What's really going on in these scenarios and what can we do to set our patients and ourselves up for success?

The human visual system is incredibly complex and extremely adaptive. The brain has the ability to respond to input from the outside world and rapidly filter out "noise." This process of reacting when something disturbs vision is called neuroadaptation. Neuroplasticity is the process by which the brain can reorganize its structures, functions, or connections through changing how the nervous system responds to stimuli and "neuroadapts"[1]—in simple terms: new image, same brain. Neuroplasticity does decrease through the aging process[2] and should be considered when matching patient desires with current technology, along with setting patient expectations.

### HOAs

How do we know what to discuss, and when, with patients? Let's talk about higher-order aberrations (HOAs) for a moment as these can play a role in patients' visual quality.

Lower-order aberrations, such as myopia, hyperopia, and astigmatism, are what we traditionally correct with current technology. HOAs include coma, trefoil, and spherical aberrations. Normally the retinal image quality due to HOAs goes unnoticed.[3]

However, when they change or go beyond the normal 7% due to surgery or a disease process, they can be quite bothersome to patients.[4] Many factors affect HOAs, including anatomical factors, such as tear film and keratoconus.[5] Pupil sizes between 2mm and 5mm give the best visual acuity. Pupils smaller than 2mm can degrade vision due to diffraction, and pupils larger than 5mm can reduce vision due to spherical aberrations.[4]

The relationship between the cornea and lens can change HOAs, as can aging lenticular changes.[4] Refractive error amounts can also contribute to HOAs and are now thought to be due more to the axial length of the eye.[4] This matter is currently undergoing intense research regarding how to slow axial length changes, in the case of myopia, by correcting a peripheral hyperopic defocus on the retina to slow growth.[4] I've greatly simplified this conversation for our purposes regarding neuroadaptation.

## Neuroadaptation

Knowing this information, how do we apply it clinically? Patients have no understanding of neuroadaptation. They truly expect to "just see." Intentional conversations and assessment of the patient are paramount for successful outcomes. First, ensure that all patients are screened and treated for dry eye disease.[5] Doing so establishes best visual outcomes regardless of whether the patient is a candidate for spectacles, contact lenses, therapeutic drops, or surgery,

**"This process of reacting when something disturbs vision is called *neuroadaptation*."**

for their presbyopia. If the ocular surface is not maximized, any type of correction will have limited successful outcomes.

Next, teach patients that their visual system will need to undergo neuroadaptation and that the timeline varies from patient to patient, and depends on the type of correction. I have found it incredibly helpful to discuss with patients that there will be a period during which their brain adjusts to seeing a new image.

Third, establish what success looks like for you and your patient. I have one very smart colleague who defines success in an unconventional way. He cut off his near point cards at 20/40. This is what you and I consider success and completely functional vision. By doing this, he doesn't entice patients to wonder why their correction can't make them see 20/30 or 20/20. Instead, he defines success for the patient.

I've listed below best practices about neuroadaptation and setting proper expectations.

### SPECTACLES:

- Spectacles are easier with smaller powers; therefore, I encourage patients to fill prescriptions for progressive addition lenses when the add power is small.
- Ten to 14 days is the typical time to neuroadapt.
- Patients should try to wear every new prescription every day to help build pathways.
- Limit switching back and forth from habitual prescriptions and new prescriptions.

### CONTACT LENSES:

- Let the patient wear the prescription, and limit in-office changes to fewer than 2.
- Center near designs take longer.
- The larger the anisometropia, the longer it takes.
- Neuroadaptation might take only a week, but it may take a few months, depending on the contact lens design, due to the brain seeing simultaneously focused and defocused images.

### THERAPEUTIC DROPS:

- Remind patients that this is depth of focus vision, meaning clarification not magnification.
- Have patients use the drops every day for 2 weeks based on findings that depth of focus gradually increased over 14 days, possibly suggesting a neuroadaptation response similar to what has been observed with enhanced depth of focus IOLs.[6,7] The findings showed a peak at 2 weeks.

### SURGICAL PATIENTS:[8]

**Careful history**

- Rule out significant ocular pathology.
- Screen out patients with high expectations.
- Avoid young patients with great preop visual acuities.
- Avoid eyes with large pupil size.
- Avoid patients with type A personalities.

**Pre-op considerations**

- Comprehensive medical/ocular history examination
- Contrast sensitivity
- Refraction
- Optical coherence tomography of the macula
- Topography
- Pupillometry/angle kappa

**Patients can experience any of the following postop, which can last up**

**to 6-12 months. Rarely, in some patients, the brain will never adapt.**

- Halos/glare
- Reduced contrast sensitivity
- Positive/negative dysphotopsias
- Shadows
- Waxy vision
- Residual ametropia
- Posterior capsular opacification

Armed with all this information, we as prescribers can be completely transparent about expectations. We must remember that patients don't know what they don't know. The more time spent up front with the patient asking the right questions, the less chair time later with the patient trying to backpedal and establish what success should look like. Remember: any discussion before a problem arises is an explanation; any discussion after is an excuse. Utilize a lifestyle questionnaire to help you choose patients wisely, establish what the patients want to accomplish with and without spectacles, or make them less spectacle dependent.

## The Presbyopia Opportunity

Presbyopia is a journey, both for us as eyecare providers and for our patients who spend half their lives presbyopic. When you look at the rates of our patients utilizing multifocal contact lenses, therapeutic drops, and premium IOLs, there is more opportunity. The current technology accessible today gives patients a truly customized approach that is unprecedented. Remember, there isn't just one solution for presbyopia, leverage all the technology to empower patients with presbyopia to utilize different modalities for their situations. Set up your presbyopia conversations for successful outcomes with these pearls. Connect patients with the right technology, help patients understand the connections that their brains need to make that technology work, and stop the presbyopia disconnect! ■

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was 2-3mm for near vision. Here is where the guardrail worked in the clinical trials. If the patient had a large, say 9mm, pupil, the drops would probably not be able to bring the size into the optimal range. The patient would probably be left with a pupil that was too large, and you wouldn't get much, if any, near effect. I heard stories about the drops not working very well. I really don't think people look at the pupil size prior to using the drops. Now, don't get me wrong—there are other reasons for failure (like I covered before). But I think pupil size needs to be considered when selecting patients. Conversely, how about a small pupil to begin with? Well, it could be another factor for "failure." Getting the pupil to less than 2mm in size can take away near and also distance efficacy.

Regarding pupil size, I was really concerned about the effect on night distance vision. With smaller pupils and lower light levels, it sounded like a recipe for disaster. I was absolutely shocked to see that some of the patients' night vision improved over their normal vision. Some were clocking down to 20/10 vision. Go figure.

Then there is the elephant in the room—vitreoretinal problems. Avoiding many potential retinal problems just takes common sense—things we learned back in school, such as high myopia, a history of retinal conditions, etc. I hear some of my colleagues not only require a retinal exam but also optical coherence tomography. They want to see if there are any pre-existing vitreous conditions prior to prescribing the drops.

Back to patient selection: as I said before, for myself, the most highly successful patient is the low to moderate emmetrope. The inventors of the drops knew this and designed the earlier studies to reflect it. Now, I could go outside of the perfect patient, but in doing so, the rate of success decreases. Nonetheless, one could still have a successful patient. Greater refractive errors, larger or smaller pupils, the working distance of the patient, how many hours the patient needs near vision, etc., are all factors that influence the success rate.

Now, you may have patients that have all of these factors going against them, they are well outside the profile of the perfect patent, but yet they succeed. Taking a cue from contact lenses, patient motivation is the X factor. High motivation can push everything into the success category. An example is a patient not wanting to wear reading glasses on a date. I have had patients, despite all the factors stated before going against them, succeed because they were extremely motivated. The X factor was at work. ■

# Dynamic Range of Focus of the Eye: Understanding Biomechanics and Kinematics: Part I

*By AnnMarie Hipsley, DPT, PhD, Zoltan I. Bocskai, PhD, and Edwin Price, PhD*

**Dr. Hipsley** is founder and CEO of Ace Vision Group. She has been an entrepreneur for more than 30 years, founding her first private practice in 1991. She is the inventor of the revolutionary LaserACE and the newly developed Laser Scleral Microporation (LSM) procedure, both aimed at restoring physiological dynamic accommodation. Over the past 20+ years, she has trained more than 100 ophthalmic surgeons worldwide in the use of near infrared lasers for biological tissue microporation.

**Dr. Bocskai** received his PhD in biomechanics of the human eye and an MSc in structural engineering from Budapest University of Technology and Economics. He has over a decade of experience as a commercial software developer in numerical methods and computational mechanics. Dr. Bocskai joined AVG's digital engineering team to support the development of the first physics-based biomechanical model of dynamic range of focus (DRoF) of the human eye.

**Dr. Price** received his PhD in biology from the University of Western Ontario and a BA in biology from Kalamazoo College. He has spent more than a decade conducting university research in comparative physiology, physiological ecology, and toxicology. At Ace Vision Group, he applies this expertise to the company's ophthalmology research endeavors.

## Introduction

A PRIMARY FOCUS IN OPHthalmic health care has been on providing solutions to help our patients "see" more clearly and curtail the effects of uncurable age-related eye diseases, such as presbyopia, cataracts, glaucoma, and age-related macular degeneration (AMD). The eye contains more than 2 million working parts and is considered the second most complex organ in the body next only to the brain.[1] Considering that the muscles of the eye are the fastest and strongest in the body with a resilient capability to adjust to rapidly changing conditions, it is surprising that more in-depth neuromuscular and biomechanical constructs have not been a fundamental cornerstone of ophthalmic education.[2] Nonetheless, a more extensive understanding of the physiological and biomechanical mechanisms is essential to developing more anatomically congruous innovations for treatment solutions, as well as disease prevention.

We do not often think of the eye in biomechanical terms, instead relegating it to a mere light-transducing optical organ. However, the eye is an intricate biomechanical machine: it is a pressurized sensing device capable of whole organ and precise intraorgan movements, as well as complex biotransport and elegant hydrodynamic drainage systems, all driven by extraocular and intraocular neuromuscular engines.[3,4] When discussing the dynamic functions of the eye, it is of critical importance to understand the structure and function of its elaborate design and, most specifically, the biomechanical mechanisms that are cardinal for the efficient function of the eye organ, both visually and physiologically.

Outlined in Figure 1 below are the key anatomical components that all have unique structures and functions that contribute to the efficient Dynamic Range of Focus (DRoF) capability of the eye for a given visual task, which is both a necessary and a precise biomechanical function that allows the eye to process visual information with the best focus possible given a particular visual system.

Given this complexity, biomechanics can be the key to understanding the normal functions involved in dynamic accommodation—dynamic focusing between phases of near-to-far and far-to-near—as well as other intricate physiological processes of the eye, such as the regulation of intraocular pressure, aqueous outflow dynamics, and circulation of ocular blood flow. In addition, understanding the pathogenesis of common disorders, such as presbyopia, glaucoma, AMD, and myopia, is enabled when we take a biomechanical view, rather

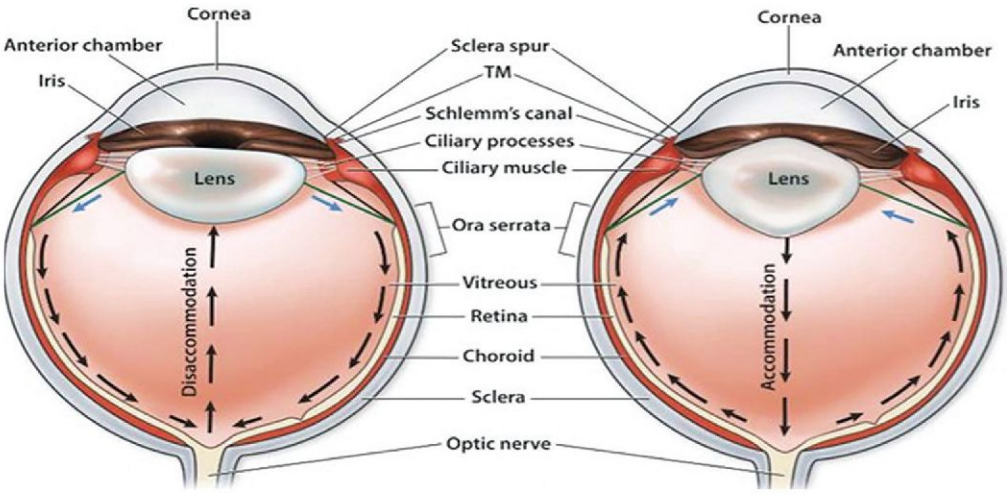
than viewing the eye as simply an "optic."[14-21] In this review, we give an overview of ocular biomechanics and the critical importance of the dynamic internal movements of the eye, namely the eye's ability to perform DRoF with concentration on the impact of biomechanics and kinematics. We further emphasize the understanding of the dynamic mechanical events occurring inside of the eye organ necessary to perform highly complex and efficient tasks as a response to numerous neuromuscular commands.

## Ocular Biomechanics

Biomechanics is the study of human movement, by which all moving structures can be analyzed. Biomechanical principles must be considered in the examination of the internal and external forces that produce or control movement and to understand structure and function of muscle movements and the impact of forces on connective tissues, muscles, capsules, and other related anatomic structures.[22] Biomechanics can be broken down into 2 broad areas: statics

**Figure 1.** Key anatomy of the DRoF biomechanical functions of the eye.[5–12] Figure from [13].

### KEY ANATOMY




| Anatomical Structure | Description/Function |
|---|---|
| **Cornea** | **"Static Lens":** provides the majority of the eye's dioptric focusing power. Does not provide dynamic adjustment of focus.[12] Bends light to focus it through the pupil and onto the retina.[5] |
| **Sclera** | **"Outer Tunic":** White, opaque, fibrous outer layer of the human eye, containing collagen and elastic fibers. Shapes the Globe and protects delicate inner eye structures. |
| **Iris Muscle** | **"Controller of Light":** sphincter pupillae(circular muscle) & pupillary dilator(radial muscle) control the size of the pupil and the amount of light on the retina. |
| **Ciliary Muscle** | **"Neuromuscular Engine"** :Ciliaris Musculi: 3 fiber directions-longitudinal, meridional and circular fibers serve to dynamically change the shape of the lens, enabling the eye's DRoF function to focus upon near or distant objects.[6] |
| **Lens** | **"Dynamic Lens":** transparent ellipsoid optic behind that changes its shape to dynamically focus light on the retina, allowing you to see details from varying distances. |
| **Zonules** | **"Pulley System":** Zonnuli: fibrous suspensory ligaments that connect the ciliary body to the lens,[7] and act as pulleys to change the curvature of the lens through various vectors.[8] |
| **Bruch's Membrane Choroid Complex (BMCC)** | **"Potential Energy Generator":** Bruch's membrane is a highly elastic structure capable of stretch-recoil during the phases of DRoF from far to near and vice versa. Bruch's membrane and Choroid (BMCC) may be considered together mechanically as a complex.[9] **"Biological Spring":** The choroid is a biological spring, and it passively stretches the ciliary muscle in all phases of accommodation pressed by the hyaloid membrane of the vitreous chamber[10] |
| **Retina** | **"Transistor":** Tissue lining the back wall of the eye that translates visual information into an image that is sent to the brain.[11] |

and dynamics. Statics include geometry and stress, which fall under the mechanical laws of physics, while dynamics is broken down into kinetics and kinematics. Kinetics is the study of forces acting on "rigid bodies," and kinematics describes the mechanics of body movements without considering the forces that cause them to move (Figure 2).[23]

Ocular biomechanics is not a new field. In fact, it is a primary point of interest in the posterior globe due to its effects on the pathophysiology of age-related diseases, such as glaucoma and AMD.[24-26] By contrast, the study of ocular biomechanics in the anterior globe as it relates to the effects on pathophysiology of age-related diseases affecting the anterior segment, such as presbyopia and open angle glaucoma, has been sparse. Nonetheless, the development of ocular biomechanics and kinematics constructs in the anterior globe for translation into clinical utility is a promising area of study.[15,17,20,21,27] The process of DRoF, accommodation and disaccommodation belongs squarely in the fields of biomechanics and kinematics because it involves movement and related forces.

It is of critical importance to understand the kinematics, or the behavior of the accommodative/disaccommodative movements or the geometry of motion; related displacement, velocity, acceleration, and time, without reference to the cause of the motion during dynamic focusing. Moreover, we must also understand the kinetics of dynamic focusing in order to have a way to explicate the forces occurring during accommodation/disaccommodation as well as other movement-related variables involved in the function of DRoF (Figure 3).

Accommodative/disaccommodative movements involve complex interactions of muscle function and joint lever systems under the control of the nervous system: the ciliary ganglion and ultimately the master and commander—the brain. When studying dynamic neuromuscular movements like those of the musculi ciliaris (ciliary muscles) of the eye, it is important to fully comprehend the mechanical and physical laws that govern these movements, as well as the biomechanical interactions between the anatomical structures in the eye. Although it is almost impossible to

**"The process of DRoF, accommodation and disaccommodation belongs squarely in the fields of biomechanics and kinematics because it involves movement and related forces."**

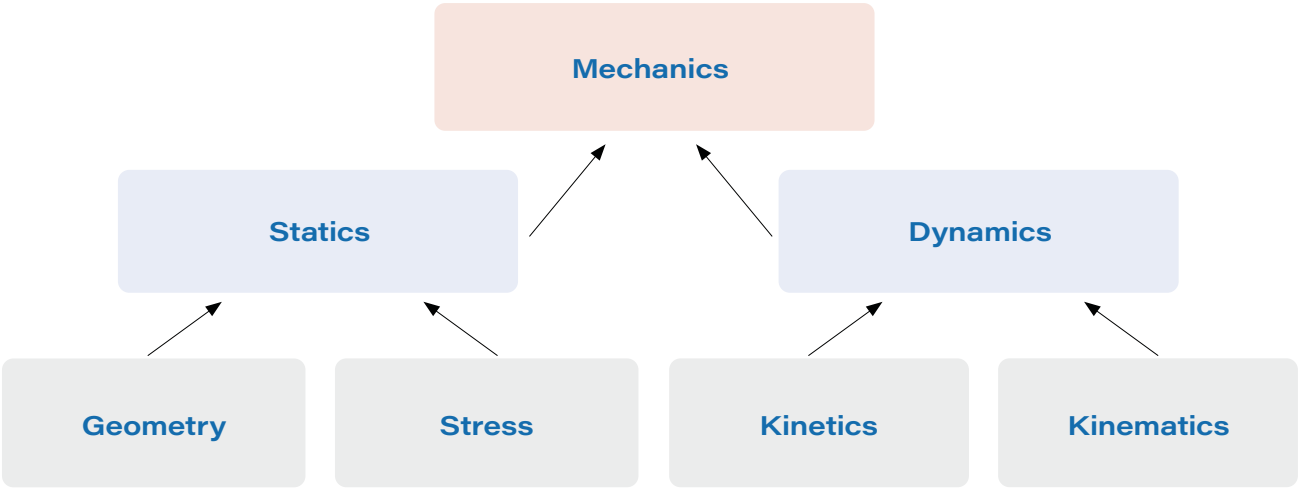



**Figure 2.** Mechanics (including statics) are categorized schematically. Designed after ref [23].

capture all of the biomechanical aspects that contribute to DRoF function, we provide here an overview of major components of this complex biomechanical apparatus.

## Conclusion

Ocular biomechanics are fundamental to the basic functioning of the eye and its ability to adjust focus dynamically. Since this capability is inherent to how the eye "works" naturally, there must be an effort to push forward the knowledge of biomechanics in the anterior segment. This would further develop the opportunities for treatment solutions and interventions that are recovery based and not simply vision correction based. Rehabilitation is currently proven to be an effective intervention for recovery of function in other areas of the body where biomechanical issues involving muscles, ligaments, and capsules exist. Likewise, rehabilitation for vision recovery given the proper identification and solutions for a specific biomechanical dysfunction in the eye organ is possible.[29] The eye organ, by design, is inherently built to perform enormously complex and intelligent biomechanical movements based on neural commands from our

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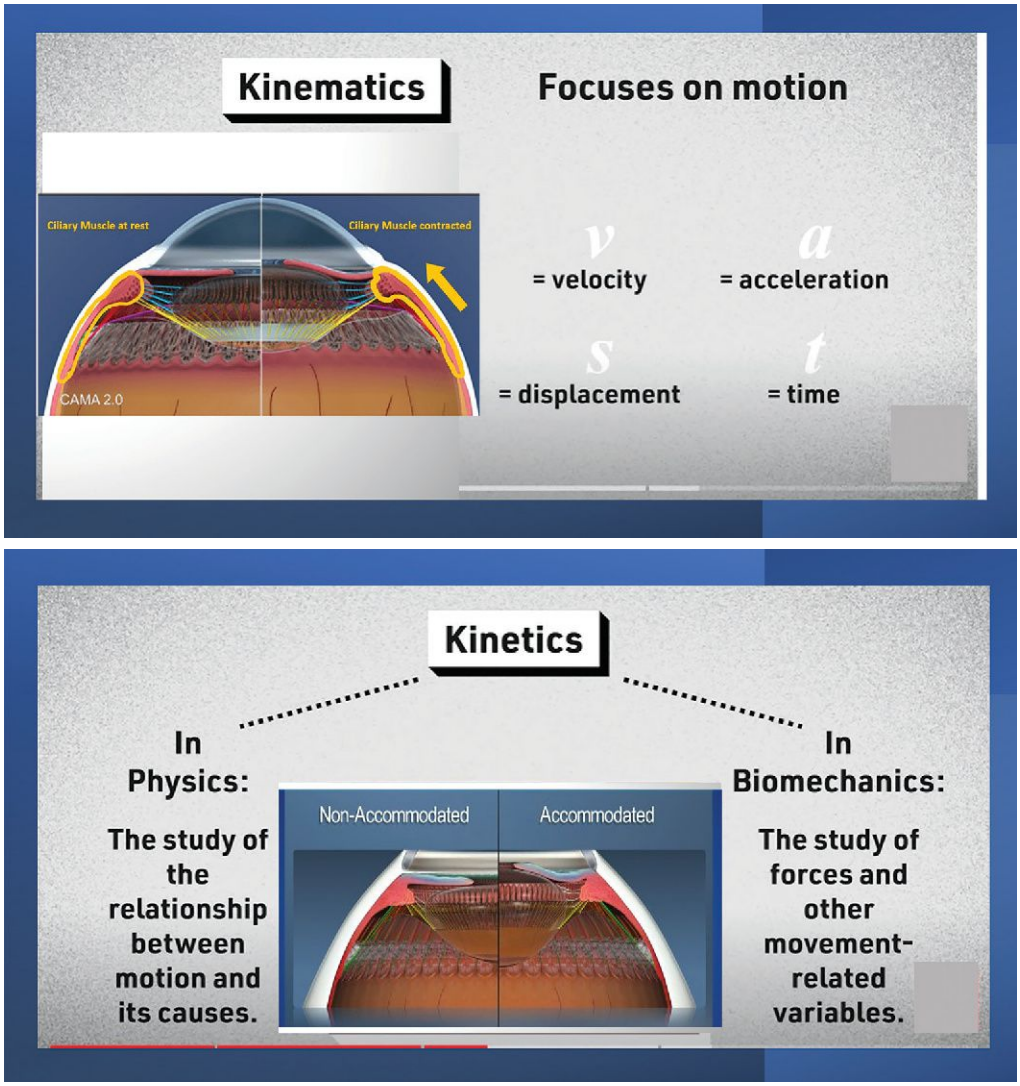
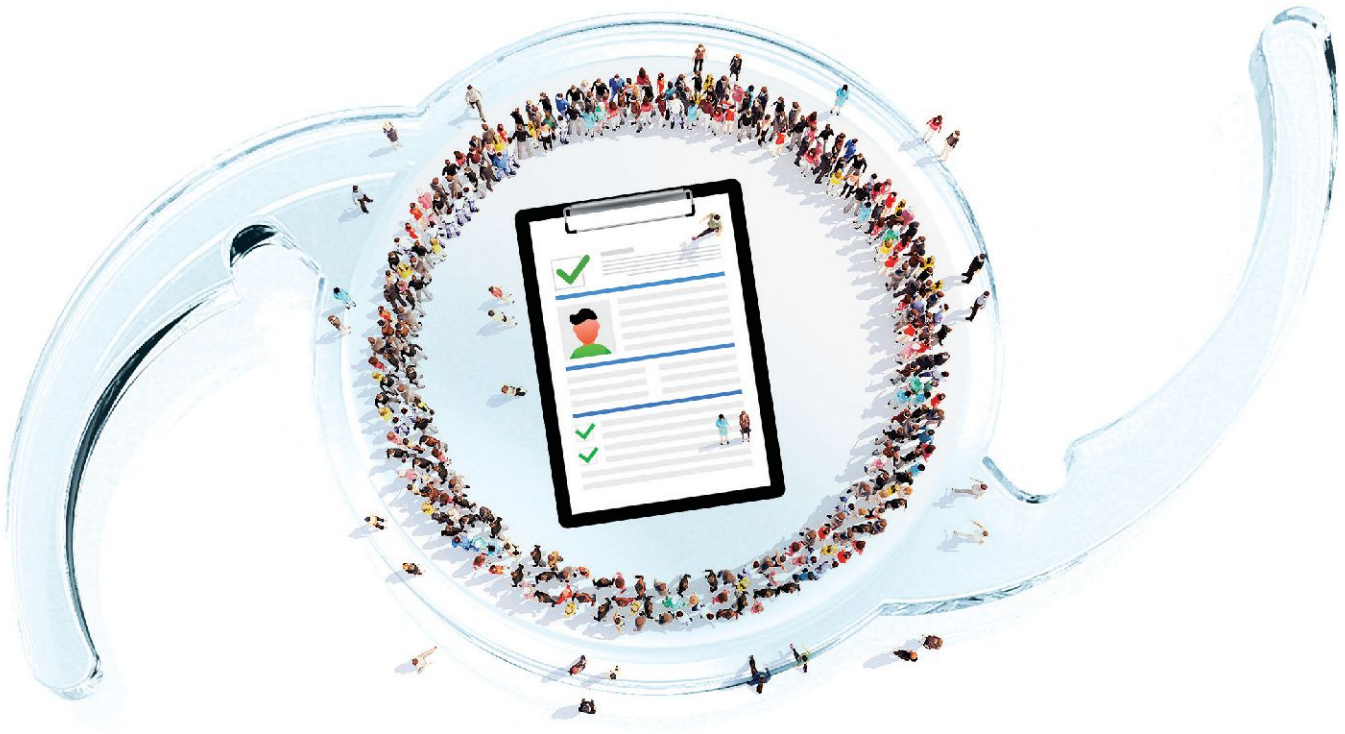



**Figure 3.** Kinematics and kinetics in accommodation. Diagrams are from [28].



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*By Tim Earley, OD*

## CLEAR LENS EXTRACTION:

# Compelling Cases in Presbyopia Management

**Dr. Earley** is a 1998 graduate of the Pennsylvania College of Optometry. He currently practices at NorthEast Ohio Eye Surgeons, an OD/MD group practice in Medina, OH, where he specializes in dry eye, specialty contact lenses, and diseases of the retina. He is a national lecturer, educator, consultant, and presenter on numerous optometric topics.

I WAS TOLD BY MY BUSINESS partner many years ago that my approach and perspective in the management of my presbyopic patients would change dramatically once it became an issue for me. I can't tell you how true those words were!

### Some Background

As I enter my sixth decade (I hit the big 5-0 this past October), I continue to find new and novel ways to navigate the journey that is presbyopia. As a 24-year post-LASIK (essentially emmetropic) presbyope, I simply don't want to rely on eyeglasses or contact lenses. I admit, I became very spoiled by my life, which was essentially independent of eyewear (except for a great pair of sunglasses!). I had an amazing 20-year ride! Like many of my patients who have had refractive surgery or have never required a significant prescription, the reality of our loss of accommodation is making our lives a bit more difficult than we'd like.

In my experience, many emmetropic and post-refractive surgery patients are not as easy to please with more conventional eyewear options. Most of us are bothered by progressive addition lenses (PALs), which are more easily tolerated by folks who always needed a distance correction. We find the designs to be difficult to use with our monitors, and we find ourselves removing our spectacles to drive and view distance objects. We then discover that we can't see our dashboard, GPS, or phones when we glance at a more near viewing distance. To address the many and

varied viewing distances, I fit many patients successfully in soft multifocal contact lenses. My soft multifocal contact lens fit success rate in new, modern designs and materials is more than 90%. However, my success rate for emmetropes and post-LASIK/photorefractive keratectomy (PRK) patients is less than 60%. The change from a prolate to an oblate corneal surface after the "flattening" of the central cornea in refractive surgery impacts quality of vision in the post-refractive surgery patient population. Induced higher-order aberrations may also play a role. Regardless, this patient population is more difficult to fit in soft multifocal contact lenses.

**"I begin all conversations about the expectations of a clear lens extraction surgery by stating clearly that there is no surgical option that will ever guarantee patients that they will not need eyeglasses after surgery."**

Whatever the cause, many of these patients are frustrated. And many of my patients fall into this category because we had an on-site refractive surgery center in our practice for many years. I have dabbled in presbyopia eyedrops in this patient population, and we have fit every type of contact lens, from monovision soft to multifocal gas permeables, hybrids, and sclerals. Many patients feel that these options leave them dissatisfied with one area of vision or another. Some of these possible solutions are not effective for a long workday, or they leave patients needing multiple pairs of eyeglasses to meet their needs (eg, computer glasses, reading glasses, and/or an occupational prescription).

## Patient Selection

Over the past couple of years, after some conversation with our surgical team, we have begun to suggest clear lens extraction as an option for patients for whom most traditional eyewear has fallen short. Clear lens extraction is exactly what it sounds like: our cataract surgeons remove the crystalline lens of a patient that has no visually significant cataracts. To be clear, we broach this option not as a first choice but as an option for those who are good candidates, who understand the risks of an invasive lens replacement surgery, and who are failing to achieve the vision they need with conventional eyewear. These patients must also be comfortable with the cost of such a surgery and must be properly informed of the potential shortcomings of some of the intraocular lens (IOL) technologies.

We have probably all had a patient in our exam chair state the following: "Doc, I really do not want to wear glasses!" I have heard this many times, and it will not be a surprise to hear that it is almost always from a post-refractive surgery patient who has loved life without eyewear. There are other cases as well. I have had patients who found contact lenses and eyeglasses did not work for them due to their profession. These are typically firefighters, police officers, EMTs, or other first responders. We have had patients for whom conventional contact lenses or eyeglasses were not an option due to their incredibly high prescription. The distortion/weight/limitations of these high-power lenses were making them unable to perform work duties or normal activities of daily living. In any of these cases, a clear lens extraction surgery may be a great option.

## Setting Expectations

It goes without saying that the advances in IOL technology have been a major factor in my decision to recommend a clear lens extraction in recent years. With patient expectations raised to an all-time high by the success of refractive surgery, many patients believe that achieving the same quality of vision at all viewing ranges should be just as straightforward as maximizing distance with LASIK/PRK. Of course, this is not always the case.

I begin all conversations about the expectations of a clear lens extraction surgery by stat-

ing clearly that there is no surgical option that will ever guarantee patients that they will not need eyeglasses after surgery. The semantics here are very important! I say that our goal is to make patients as spectacle independent as possible, and this could mean different things to different patients. Taking a very thorough history and documenting exactly which levels of vision (distance, midrange, near) are most important not only plants the seed that we may not make all levels perfect, but it also helps with IOL selection. I also find it very important to inform my patients that an IOL will only do its job as well as we can expect if the other ocular tissues are also healthy. We discuss proactive and preventive therapies for dry eye disease, floaters, and any retinal conditions. If I am confident that all ocular tissues are healthy, I can be confident in my refraction and the choice of IOL(s). Lastly, I verify that all systemic diseases, primarily diabetes and other cardiovascular conditions, are under good control. Once this discussion is complete and the conversation properly documented, we move on to the fun part: IOL selection!

## Lens Selection

For patients with no prior corneal surgery, the IOL options are virtually unlimited. We discuss monovision as an option if (and only if) the patient has had a long history of successful monovision in contact lenses (or refractive surgery). We present the numerous multifocal IOL options that are on the market and explain the pros and cons of each. Many true multifocal IOLs are a simultaneous vision design with alternating rings of power. While patients who have been successful with multifocal soft contact lenses often do well with a simultaneous design IOL, the optics are not the same. I try not to overpromise with any multifocal as each patient's experience is unique. However, I have found that many patients who adapt well to a multifocal contact lens design tend to adapt well to a multifocal IOL as well. In addition to multifocal designs, manufacturers have also brought trifocal design IOLs to market in recent years. Theoretically, a trifocal lens design will introduce fewer aberrations and 3 more discrete areas of clear vision vs. a multifocal design.

We have some great options in our arsenal for patients that may be more concerned about some of the possible limitations of simultaneous design IOLs (such as haloing or glare). More recently, we have begun offering increased depth of field IOLs. One such lens is Vivity (Alcon). While not a true multifocal, the Vivity lens is essentially a monofocal lens with a small "aperture" in the center that works on the pinhole effect. The small central aperture creates a zone of near correction that allows for excellent midrange vision for most patients. We recommend increased depth of field IOLs for patients who admit to hours of screen time each day for work or pleasure. They typically need a light near correction in glasses for small print.

One of the greatest and most impressive IOL options with which I've had the pleasure of working is the Light-Adjustable Lens (LAL, RxSight). An LAL is an implant that can be modified in vivo, which means that its power can be adjusted by changing the IOL shape using ultraviolet light. Our surgeons implant the LAL in many of our patients who are post-refractive surgery and have unique corneas. Having the ability to adjust the power of the IOL after it has stabilized in the eye allows for very precise outcomes. The IOL can be "touched up" a couple of times before the power is "set" by a final ultraviolet (UV) treatment. We have found that our post-refractive surgery patients who did well with monovision appreciate the option of having the lens "tweaked" to achieve the

**"We have some great options in our arsenal for patients that may be more concerned about some of the possible limitations of simultaneous design IOLs (such as haloing or glare)."**

vision they desire at the working distance(s) that they require. One consideration that we communicate to patients who opt for an LAL is that they will have to wear UV-blocking eyewear while awake for several weeks after surgery. This is necessary to prevent unwanted IOL power changes. Once the IOL is stable and the refractive goal is met, the final lock-in UV treatment is performed, and the patient can remove UV blocking eyewear and return to wear as needed.

## A Successful Clear Lens Extraction Case

One of the early cases of clear lens extraction that I comanaged with our surgical team involved a veterinary surgeon. Dr. Jones (not his real name) presented to my practice as a frustrated new patient. His frustration was largely with his inability to comfortably perform surgical cases on his canine patients due to a lack of clear vision. He presented wearing a gas permeable multifocal design (aspheric) with his dominant eye set for distance/intermediate and his nondominant eye set for intermediate/near. He reported that he had tried other combinations of powers, fit philosophies, and materials and chosen his current lenses because they were the best he could find. He described how his reduced depth perception was making it nearly impossible to tie sutures and how he had resorted to using loupes, magnifiers, and glasses over his contacts in some cases. Generally speaking, he was not happy with his vision or his visual performance in his contact lenses.

After I explained his other options and carefully examined his ocular health, it became clear that his corneas were no longer tolerating his rigid gas permeable (RGP) contact lenses. He had signs of hypoxia and some peripheral corneal opacification and scarring from decades of RGP use. He asked if there were any options that would allow him to be spectacle and/or contact lens independent. Dr. Jones was 54 years old at the time and did not have visually significant lens changes. I let him know that I would speak to our surgical team and inquire as to whether they would consider him as a clear lens extraction candidate. Fortunately, our surgical team does presurgical assessments for our cataract patients in our office. I was able to sit in while our surgeon explained the pros and potential cons of a clear lens extraction. In the end, Dr. Jones was excited about the prospect of being essentially free of contact lenses and eyeglasses, and he decided to proceed with the clear lens extraction surgery.

Dr. Jones was given multiple IOL options and settled on a true multifocal design given his needs at near. A simultaneous vision design lens was implanted in each eye 2 weeks apart. When I saw Dr. Jones for his 1-day postop on the second eye, it was perhaps the first time I had ever seen a grown man cry tears of joy in my exam chair! He was ecstatic. What was most surprising to him was the improvement in color/contrast and his improved depth perception. Over the following weeks and months, he would report back on how the clear lens extraction surgeries had improved his love of his work. He described how it would likely keep him performing surgery for many years (he was contemplating retirement prior to his surgeries).

This is just one case of many in which clear lens extraction made a significant difference in the lives of one of my patients frustrated by conventional eyewear. While I realize this option is not right for everyone, I feel much more comfortable recommending clear lens extraction for patients given the expertise and advanced intraoperative surgical equipment used by our team. It doesn't hurt that there are constant advancements in IOL technology as well. I would make the following recommendation to any colleague: have a discussion with your surgeon. Find out what his/her comfort level is with performing a clear lens extraction, and then consider this option for our struggling presbyopes. As a 50-year-old, it is definitely on my radar! ■

***Disclosure***

*Dr. Earley is a consultant and KOL for Alcon's Vision Care franchise.*

## PRESBYOND Laser Blended Vision:

# A Treatment Option for Presbyopic Patients Without Cataract

*By Dan Z. Reinstein, MD*


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**Dr. Reinstein** founded the London Vision Clinic in 2002, and holds professorships at Columbia, Ulster, and Sorbonne Universities. He is a consultant for Carl Zeiss Meditec and CSO Italia, and has a financial interest in ArcScan Inc.

PRESBYOPIA COMBINED WITH any refractive error has been a significant treatment challenge for refractive surgeons. Traditionally, the principles used for monovision contact lenses have been applied to corneal refractive surgery.[1] However, this practice retains many of the limitations found with such contact lenses, including loss of fusion and stereoacuity.[2]

Multifocal corneal ablation profiles have also been suggested; however, although an overall improvement in visual acuity has been recorded for both near and distance vision, the efficacy has remained relatively low,[3] and safety and quality of vision can be compromised.[4] A better solution that offers improved visual results and greater tolerance is still required.

### PRESBYOND Laser Blended Vision

It is helpful to consider presbyopia as the inability to accommodate, rather than a decrease in

depth of field of the eye. This decrease can be overcome, at least in part, using an optimized ablation profile that controls postop spherical aberration, thus increasing the depth of field of each eye without significantly compromising visual quality, contrast sensitivity, or night vision. The optimization used for PRESBYOND is based on the patient's age, refraction, preoperative spherical aberration, tolerance for anisometropia, and treatment centered on the corneal vertex.

We learned in the 1990s that spherical aberration increases in myopic ablations, leading to a decrease in visual quality and contrast sensitivity.[5] My early work in wavefront-guided repair of night vision disturbances, using what was at the time the highest-resolution aberrometer (210µm) coupled with Gaussian small-spot (0.7mm) high-repetition rate excimer laser ablation, taught me that even a modest decrease (27%) in harmful levels of spherical aberration restored contrast sensitivity and night vision quality to normal.[6]

**"In emmetropic patients, you cannot rely on the ablation inducing spherical aberration, so the spherical aberration component of the calculation is increased."**

This led me to consider up to approximately 0.6µm of spherical aberration (Optical Society of America, 6mm) as tolerable—this level can be filtered by the brain. This led to the concept of using spherical aberration to increase the depth of field of the eye.[6]

Within a few years, several researchers were able to experimentally duplicate this concept using adaptive optics systems, and to demonstrate that extended depth of field increased linearly with the increase in spherical aberration, but only up to a certain point.[5] Most important to note here is that adaptive optics studies proved that the depth of field increased with both positive and negative spherical aberration, showing that the effect was due to the spherical aberration itself, rather than a zonal change in refractive sphere power (eg, in positive spherical aberration, the larger the pupil, the more myopic the sphere of the refraction).

These laboratory experiments confirmed our surgical clinical research findings that a "therapeutic" range for spherical aberration producing extended depth of field existed, beyond which there were "toxic" effects of halos and reduced contrast sensitivity.

During my early work developing an algorithm for presbyopic correction, the initial aim was to be able to adjust depth of field enough to provide clear vision from distance through intermediate to near, creating an eye that could see 20/20 at distance and also see a computer screen and read J1. We discovered that, with photopic pupil diameters, the depth of field could be safely increased to 1.50D for any starting refractive error. Given a 1.50D depth of field, it would not be possible to obtain full distance and full near vision monocularly; therefore, based on the time-tested concept of introducing a degree of anisometropia between the eyes, the nondominant eye was set up to be slightly myopic so that the predominantly distance (dominant) eye was able to see at distance to intermediate, while the predominantly near (non-dominant) eye was able to see in the near range and up to intermediate.

Both eyes had similar acuity in the intermediate region, an optimal situation for stereopsis. Microanisometropia in this case draws on the inherent cortical processes of neuronal gating and blur suppression by "interocular rivalry" (the ability for conscious attention to be directed to the specific area with the best image quality within the entire visual field of both eyes). This contrasts with other attempts to treat presbyopia by inducing a cornea with 2 distinct focal points within the same eye: "intraocular rivalry."

A further component contributing to the increase in depth of field, which persists even in eyes that have lost the ability to change crystalline lens power during the accom-

modative effort, is the increase in depth of field afforded by pupil constriction during accommodation. The combination of controlled induced corneal aberrations and pupil constriction significantly increases the depth of field on the retinal image. Intraretinal and cortical processing and edge detection are the final components of laser blended vision: the pure retinal image, which is modified by spherical aberration, is further enhanced by central processing to yield the perception of clear, well-defined edges.

In principle, as described above, the depth of field can be enhanced through the introduction of either positive corneal spherical aberration, in which case corneal power increases with zonal diameter, or negative aberration, in which power decreases with distance from the corneal vertex.[5,7]

Most patients have some nascent positive spherical aberration before treatment, which is added to by the positive spherical aberration induced by standard myopic ablation. The important thing is to control the induction of spherical aberration to avoid increasing it above the tolerance threshold, which can cause loss of contrast sensitivity, and night vision disturbances, and can result in a topographic central island. To account for this possibility, the ablation profile includes a precompensation factor.

A standard large zone (7.00mm) hyperopic ablation induces negative spherical aberration that, in the case of hyperopic correction, is unlikely to increase above the tolerance threshold, even with up to +7.00D of correction, because most patients start with some positive spherical aberration, and the range of hyperopic treatments is smaller than the range of myopic treatments.[8]

In emmetropic patients, you cannot rely on the ablation inducing spherical aberration, so the spherical aberration component of the calculation is increased. This has an impact on the refractive accuracy. As emmetropic patients have high expectations and low tolerance to refractive inaccuracy, the best option is to increase the depth of field somewhat and ensure that the microanisometropia component is as accurate as possible.

The ablation profiles, taking age and preop spherical aberration into account, are referred to as nonlinear aspheric ablation profiles because the spherical aberration component is governed by a nonlinear function.

## Results

The outcomes using PRESBYOND Laser Blended Vision with the MEL 80 excimer laser (Carl Zeiss Meditec) have been published for myopia up to -8.50D,[9] hyperopia up to +5.75D,[10] and emmetropia.[11] All treatments were performed as bilateral simultaneous LASIK. For inclusion, patients had to be medically suitable for LASIK, presbyopic with corrected distance visual acuity no worse than 20/25 in either eye, and have a tolerance of at least -0.75D of anisometropia. The standard microanisometropia protocol corrected the dominant eye to plano and the nondominant eye to -1.50D irrespective of age.

At 1-year follow up, binocular uncorrected distance visual acuity was 20/20 or better, and binocular uncorrected near visual acuity was J2 or better in 95% of myopes, 77% of hyperopes, and 95% of emmetropes. Retreatment rates were 19%, 22%, and 12%, respectively, although they would have been 5%, 6%, and 4% had the criterion for retreatment been 20/32. The safety in terms of corrected distance visual acuity and contrast sensitivity was the same as for standard LASIK, with no eyes losing more than 1 line.

Mean mesopic contrast sensitivity either remained the same or improved slightly at 3, 6, 12, and 18 cycles per degree for all 3 populations. Stereoacuity, although slightly reduced,

**"A previously pseudophakic patient can be treated by laser blended vision protocols to set a total final spherical aberration of the eye that provides extraordinary range of vision."**

has been shown to be maintained at a functional level of 100-400 seconds.[12] Similar results have been reported by other groups, also reporting very high patient satisfaction and no reduction in quality of vision.[12-16]

The results of PRESBYOND in commercial airline pilots have also recently been published.[17] The results demonstrated that this technique can achieve good binocular vision in the very challenging cockpit environment, which requires clear vision at a range of distances and viewing positions, including optimal distance vision for taxiing and approach, clear intermediate vision to accurately view radio and autopilot systems, and sharp focus at near to operate navigation systems and overhead panels. All pilots achieved the visual criteria for aeromedical recertification by 1 month after treatment and reported that their newly gained spectacle independence improved cockpit functionality when compared with their previous refractive correction method.

The principle of correcting refractive error while modulating spherical aberration to benefit the depth of field can be equally applied to cataract surgery with intraocular lens (IOL) placement. A previously pseudophakic patient can be treated by laser blended vision protocols to set a total final spherical aberration of the eye that provides extraordinary range of vision.

Performing cataract surgery on a patient with prior laser blended vision in the cornea enables the choice of a monofocal IOL of appropriate asphericity to leave the eyes with optimized spherical aberration, without resorting to diffractive optics and all of the quality of vision and adaptation issues that are introduced by intraocular rivalry, as well as reduced contrast and the selective quantization of the reading distance.

## Conclusion

The combination of microanisometropia with increased depth of field through appropriate nonlinear aspheric ablation profiles improves visual outcomes substantially in comparison with the conventional monovision approach.

This goal can be achieved in the cornea and in conjunction with cataract surgery. Trials have shown that PRESBYOND Laser Blended Vision is effective in presbyopic patients with refractive errors between +5.75D and -9.00D, including emmetropic presbyopes. With the safety advantages of modern femtosecond LASIK, the rapid bilateral surgical procedure, and a recovery time of a few hours, patient satisfaction is extremely high. ■

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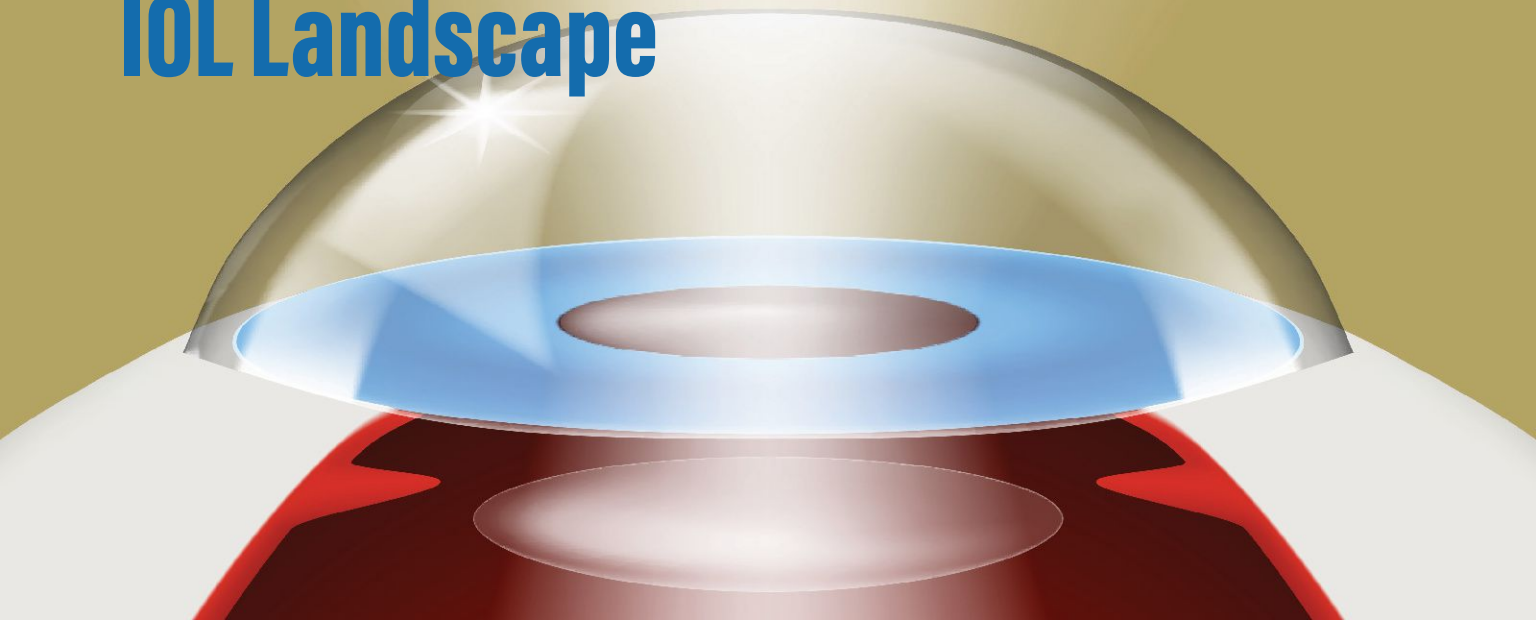
THE LIGHT ADJUSTABLE LENS:

# Reshaping the Premium IOL Landscape



*By Nicholas J. Bruns, OD*

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The introduction of the Light Adjustable Lens (LAL) has led to a paradigm shift in cataract surgery. With traditional surgery, postoperative refractive precision is dependent on preoperative biometry. Modern formulas consider a number of variables in an attempt to predict the intraocular lens (IOL) power needed to achieve a desired refractive outcome; unfortunately, even the most advanced formulas are unable to account for individual healing processes and resultant effective lens position (ELP). The expectations of the average cataract patient have evolved as much as the procedure itself in the last few decades, in part due to the proven success of corneal refractive procedures. Gone are the days of thick glasses after surgery—full, uncompromised spectacle independence is now the premium outcome our patients want.

## Setting the Stage: 20/Happy

Patient perception is as important as surgical outcome in reality. The buffet of IOL options can be overwhelming for patients. The discussion about which option is best revolves around a hypothetical world, ie, a world without a cataract impacting visual quality. The LAL allows much of this discussion to happen well after surgery, giving the patient a comforting feeling of control. After the cataract is removed, patients are able to better understand how a certain refractive condition will impact their lifestyle. They can then "test drive" and adjust their target on the fly to match their lifestyle needs. It has been suggested that eye dominance changes in roughly 20% of patients following cataract surgery.[1] Determining eye dominance is important for refractive targeting. Understanding that this may change in a patient postoperatively, it's easy to see why having refractive discussions after surgery would be advantageous.

The LAL isn't for the impatient patient. There is a substantial logistical burden that must be outlined. After the lenses are implanted in the typical fashion, at least 2

weeks must pass to allow for refractive stability before the first light adjustment can take place. Patients may need up to 3 adjustments, followed by 2 mandatory lock-in visits, with each of these encounters separated by 3 days. Additionally, because ultraviolet light (UV) is used to induce refractive change during the light adjustment procedures, patients are required to wear the provided UV protective glasses while outdoors or in high UV exposure settings prior to final lock-in. On average, patients can expect the process from surgery to final lock to take about 4-6 weeks.

I view the light adjustments as similar to a contact lens fit. I use trial frames and loose lenses to simulate an outcome, taking feedback from the patient to set a target. Patients then test drive their vision for at least 3 days before returning for their next adjustment. ActivShield (RxSight), an added UV protective coating to the anterior surface of the LAL, was introduced in 2021. Since its introduction, we have seen a higher degree of accuracy in our practice while no longer requiring patients to wear their UV glasses indoors.

### The Monofocal IOL With a Twist

A misconception about the LAL is that it's a simple monofocal lens aimed at precision distance vision. While this is partly true, it's also highly oversimplified. It is indeed a monofocal lens; however, given its aspheric design, it does allow for an element of extended depth of focus (EDOF). This aids in extending visual range even in a plano targeted eye. Additionally, patients can elect to add negative spherical aberration to their nondominant eye during the light treatments. This adds an additional 0.50D-0.75D of EDOF, providing a solution for presbyopia and reducing the need for reading glasses postoperatively. In our practice, we have strayed away from the term "monovision" as it implies full ocular independence and loss of binocular balance. Instead, we use the term "blended vision" because there is substantial overlap between the eyes, allowing for binocular summation for maintained depth perception. About 80% of our patients choose some form of blended vision, with the nondominant target being -1.00D to 1.25D on average. The beauty of the LAL is that we can customize the near target based on lifestyle. The added EDOF of the nondominant eye still preserves usable distance visual acuity. Even with a -1.25D target, a healthy patient can often maintain 20/30 or better unaided distance visual acuity without glare or halos.

**"The beauty of the LAL is that we can customize the near target based on lifestyle."**

The LAL has a spherical range of +/- 2.00D sphere and up to -3.00D cylinder.[2] Because of its cylindrical range, postoperative stability, and customization potential, we use the LAL far more often than monofocal toric IOLs in astigmatic patients.

### The Perfect Patient

As all refractive surgeons know, refractive precision is more elusive in a post-LASIK patient. The alteration of corneal architecture results in a miscalculated ELP, which in turn can lead to a refractive surprise. Post-LASIK patients commonly have lower tolerance for refractive error because of their years of spectacle independence. The LAL is a perfect solution for these patients, delivering LASIK-type results consistently. The LAL provides outcomes within 0.50D 92.1% of the time at 6 months postop according to the 2017 FDA trial, which is similar to modern corneal refractive procedures.[3] Compare this with a roughly 72% success rate with monofocal IOLs.[4] We have seen similar, if not better, results in our practice with the second-generation LAL with ActivShield.

While the post-LASIK patient seems like a slam dunk, we have repeated success with patients of all types, including those with active corneal or retinal pathology and even severe glaucoma. While other multifocal or EDOF IOLs require pristine cor-

neal and retinal health due to their optical nature, the LAL is a monofocal lens that is not influenced by subtle corneal or retinal irregularities. Unlike multifocal IOLs, it is reasonable to offer the LAL to patients with age-related macular degeneration, an epiretinal membrane, or glaucoma. While the optional added negative spherical aberration to induce EDOF may not always be in the patient's best interest, the ability for monofocal refractive precision is something from which all patients can benefit. We have experienced overwhelming success with post-radial keratotomy patients as well as with younger pre-presbyopic patients.

## Pearls for Success

It's no secret that the LAL comes with its share of challenges.

• **Detailed discussion is essential prior to surgery.** I often speak in analogies to help the patient understand the process. They must understand that this is a marathon, not a sprint. Similar to tailoring a fine tuxedo, it takes time, but the results will be custom and precise. As another analogy, I liken traditional cataract surgery to a par 3 on a golf course but only allowing a single swing—getting the ball on the green is a decent shot, and usually we're satisfied with that. With the LAL, we now get the chance to putt it 3 times, and are expecting to get it in the hole.

• **The surgical target should be set for plano with both eyes** regardless of the final refractive target. This allows for re-establishment of eye dominance postoperatively and allows room for the added negative spherical aberration to enhance depth of focus in the nondominant eye.

• **Tear film maintenance prior to surgery is key** with the LAL, as it is for all refractive surgeries. The tear film will drive the refraction, which is the dependent variable that we're trying to control. All of our patients are on a regimen of preservative-free artificial tears and lid hygiene beginning at the very least 2 weeks before surgery and continuing throughout the entire adjustment process. The light adjustments will often disrupt the tear film further, so starting prophylactic maintenance therapy is always advisable. Along the same lines, having the same clinician perform the subjective refractions is important to ensure reliability and repeatability.

**"The light adjustments will often disrupt the tear film further, so starting prophylactic maintenance therapy is always advisable."**

• **Staff education is arguably as important as patient education.** There will be multiple visits for these patients—needless to say, our staff will get to know them quite well during their light adjustment process. We ask our staff to engage with each patient and celebrate steps of improvement along the way. The day of the final lock-in is graduation, signifying the end of a long journey. We make sure to celebrate that with our patients, and they truly appreciate the team approach.

## Conclusion

The LAL is arguably the largest technological advancement in cataract surgery in recent decades. As a monofocal lens, it has applications in patients with significant ocular disease. The ability to customize range of vision further distances patients from spectacle dependence without inducing glare or halos as with multifocal IOLs—a giant leap toward the elusive cataract surgery holy grail. ■

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# A New Presbyopia IOL Option–the Lenstec ClearView 3

*By Jessica Heckman, OD, and Y. Ralph Chu, MD*

SURGICAL PRESBYOPIA CORRECTION options continue to evolve and expand. There is a new presbyopia-correcting intraocular lens (IOL) choice now available in the United States for patients and surgeons. The FDA approved in July 2022 the ClearView 3 from Lenstec, Inc., which is the first refractive, rotationally asymmetric, multifocal IOL to become commercially available in the United States.

The ClearView 3 posterior-chamber IOL is an aspheric, single piece IOL (Figure 1). The optic and haptics are both acrylic (hydroxyethylmethacrylate—26% water). The IOL has a 5.75mm optic with closed loop/modified-plate haptics. This haptic design provides good stability and helps to avoid any IOL tilt, which can negatively impact the performance of this type of design.[1] Different from symmetric multifocal IOL designs, which feature concentric rings providing different focal points, the ClearView 3 optic has 2 distinct zones—a distinct distance zone and a distinct near zone with a smooth transition area between them. The near zone has a +3.00D on the IOL plane, equating to an approximately 2.4D add on the spectacle plane. The index of refraction of the IOL is 1.456, and the recommended A constant is 118.0. The lens is available in dioptric range from 15.0D to 30.0D. It is manufactured in 0.25D steps in IOL powers from 15.0D to 25.0D to allow for greater ability to achieve the surgical refractive target.

## Study Results

The FDA study of the ClearView 3 lens, as well as others, showed good patient satisfaction and visual outcomes after implantation.[2-4] The FDA Investigational Device Exemption study of the ClearView 3 lens was a prospective, subject-masked, randomized, 2-arm, parallel group study. It included 340 subjects bilaterally implanted with the ClearView 3 multifocal IOL and 170 bilaterally implanted with a monofocal control IOL across 18 clinical sites.[5] The patients were followed up at 1 day, 1 to 2 weeks, 1 to 2 months, 4 to 6 months, and 1 year. The ClearView 3 provided significantly better uncorrected near visual acuity and distance corrected near visual acuity than the control lens in the clinical trial. At 1 year postoperatively, 99% of ClearView 3 patients had better than 20/40 uncorrected distance visual acuity (UCDVA), 96.2% had better than 20/32 UCDVA, and 83.4% had better than 20/25 UCDVA or

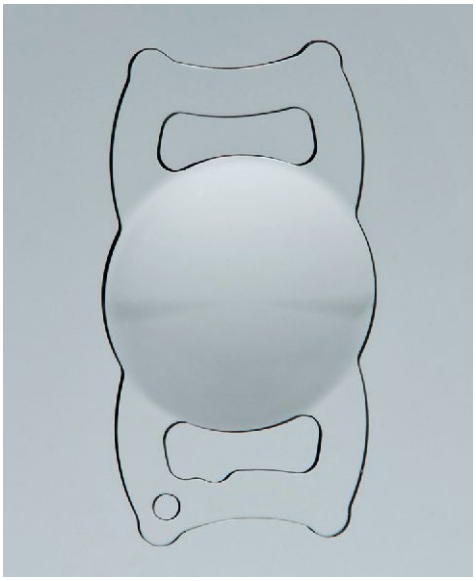

**Figure 1.** ClearView 3 from Lenstec, Inc., is a refractive, rotationally asymmetric, multifocal intraocular lens.

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better, compared to only 26.7%, 5.6%, and 2.5% of patients, respectively, with the control lens.[5] The study also demonstrated that the ClearView 3 multifocal IOL had comparable UCDVA and best corrected distance visual acuity (BCDVA) to that of the control IOL, with 100% of patients with the study lens and control lens with BCDVA of 20/32 or better and 97.9% of study patients with BCDVA of 20/25 or better, compared to 100% of control patients.[5]

Although the lens has distinct distance and near segments, multiple studies have shown good uncorrected intermediate visual acuity (UCIVA).[2-4] In the FDA clinical trial, the ClearView 3 IOL demonstrated improved UCIVA and distance corrected intermediate visual acuity compared to the control IOL. At 1 year postoperatively, 97.1% of patients with bilateral ClearView 3 IOL had UCIVA of 20/32 or better compared to 64.6% of control patients; 83.4% of the ClearView 3 patients had 20/25 or better UCIVA compared to 27.3% of control patients.[5] This intermediate visual acuity is considered to come either from the gradual transition zone between the 2 refractive areas of the IOL or from some induction of aberration from the IOL design providing a larger depth of focus.[2]

## Patient Satisfaction

At the final FDA study postoperative examination, the patients in the study were asked to rate on a scale of 1 to 5 how often they needed spectacle correction at distance, intermediate, and near, with a grade of 1 equaling never. Patients rated the need for distance correction at 1.26, intermediate correction at 1.27, and near correction at 1.33, showing very good patient satisfaction with the vision provided by the lens in the clinical trial.[5] The patient satisfaction reported in this study was very consistent with the satisfaction reported in multiple other studies of the ClearView 3 IOL.[2-4]

## Lens Placement and Patient Selection

The manufacturer's recommendation is to implant the lens with the near segment oriented inferonasally in both eyes. The bifocal design of the lens does allow the surgeon to orient the lens in an alternative rotational position. There have been several studies demonstrating that different placements of the lens are well tolerated.[6,7] This unique feature of the lens may expand the number of multifocal IOL candidates. A patient with a large angle kappa may be excluded from using some multifocal IOLs due to concerns about poor effects or reduced visual quality of vision from an implant not centered on the visual axis. With the ClearView 3 IOL, a surgeon has the ability to evaluate the placement, and he or she can adjust the orientation of the distance segment during surgery, utilizing the first Purkinje image as a reference. An early study showed potentially improved vision at an intermediate distance with a customized implantation approach vs standardized inferonasal placement as well.[6] Additionally, rotation of the IOL to move the distance segment into a more optimal position for an individual patient, could provide a surgical solution for a patient with visual concerns from the multifocal nature of the IOL, prior to considering explant to a monofocal IOL.

**"The ClearView 3 provided significantly better uncorrected near visual acuity and distance corrected near visual acuity than the control lens in the clinical trial."**

In our experience, good candidates for the ClearView 3 IOL include patients with generally healthy corneal and retinal health and, as with all multifocal IOL patients, a reasonable level of visual expectations from the technology. The IOL is not manufactured in toric powers, so patients requiring a toric lens are not ideal candidates for this technology, nor are patients needing IOL power outside of the manufactured range.

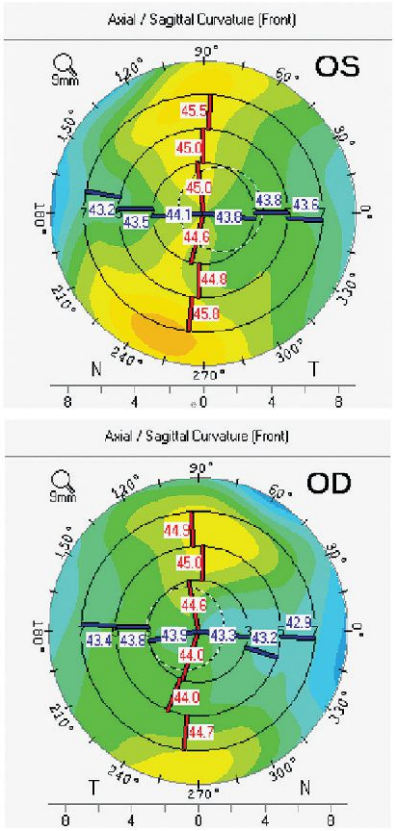


**Figure 2.** Topography of a patient considering ClearView 3 IOL shows regular astigmatism of less than 1.0D in both eyes.

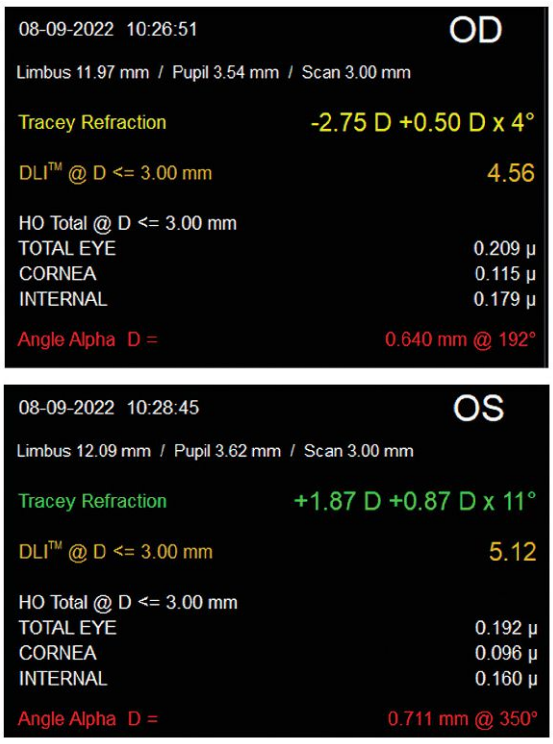


**Figure 3.** iTrace imaging measures a large angle alpha on a patient considering multifocal implantation.

## Case Study

The ClearView 3 lens was the lens of choice for a recent patient at our clinic. A 77-year-old woman with visually significant cataracts presented to us desiring reduced dependence on glasses at all distances. She had normal corneal and retinal health on dilated examination. Her corneal topography was normal and measured 0.53D OD and 0.11D of corneal cylinder (Figure 2). During preoperative testing her angle alpha measured 0.711 OD and 0.640 OS with iTrace imaging (Tracey Technologies; Figure 3). Given this finding, a multifocal implant with a concentric ring design may have resulted in a greater likelihood of visual challenges postoperatively. Prior to the ClearView 3 approval, this patient may have been encouraged to consider a monofocal or extended depth of focus type of lens vs a multifocal IOL. The ability to control the placement of the distance vision segment of the ClearView 3 IOL provided confidence to still offer a multifocal option.

The patient chose to proceed with cataract surgery with the ClearView 3 IOL. A 23.5D implant was successfully implanted in both eyes with the distance vision segment oriented over the first Purkinje image in both eyes. At 1 month postoperatively, the patient was very happy with her vision and using minimal glasses. Her uncorrected distance acuity measured 20/20 OD, 20/20 OS, and 20/20 OU. Her UCIVA measured 20/12.5 OD, 20/16 OS, and 20/16 OU, and her UCNVA measured J1 OD, J1+ OS, and J1+ OU.

## Happier Patients

The FDA approval of the ClearView 3 IOL provides another tool for surgeons to use to help patients improve their visual function and lifestyle after cataract surgery. More options for surgical presbyopia correction are enabling a customized approach to refractive cataract surgery. This ability to match technology to the appropriate patient continues to help surgeons and patients achieve great visual results. ■

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### *Disclosures*

*Neither author has any relevant disclosures to report.*

continued from page 28

consciousness that enable our communication with the visual experiences that we enjoy from the moment we open our eyes. This makes vision the most precious and miraculous experience we take for granted every day. Our fundamental understanding of the intricate movements that produce function in the eye organ is void of comprehension regarding the impact of biomechanics and kinematics. At best, we posess an incomplete understanding of the application of mechanical laws of physics to DRoF functionality and the biomchanical behavior of accommodative structures in both phakic and pseudophakic eyes. This gap in our knowledge has retarded our ability to create viable and sustainable technology intervention in the anterior segment specifically to address presbyopia and glaucoma.

This is Part I in a series of articles that will serve as a deeper dive into ocular biomechanics in the hope of bringing a new awareness to dynamic mechanisms occurring in the eye as a response to all of the visual commands which require dynamic focusing mchanisms. A much needed paradigm shift of adding biomechanical applications to solving dynamic problems in the eye organ is essential in finding more sustainable treatment solutions for age-related eye diseases that impact our visual dynamic functions. Since the presbyopia market of 2.1 billion people globally reemains a significant unmet and growing market, it is vital that we gain further knowledge in this area.[30]

We will continue to explore the kinematics of DRoF by illuminating the executive mechanisms involved as well as outlining the "phases of DRoF" specific to the biomechanical interrelationships in the next issue! Stay tuned... ■

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