

**UNDERSTANDING THE
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LOGIC PRESBYOPIA TREATMENTS**

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Presbyopia

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Chasing the Holy Grail

By Elizabeth Yeu, MD
and Jacob Lang, OD



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THERE IS TREMENDOUS excitement as presbyopia treatments expand to include an array of pharmacologic options—truly a holy grail of eye care. But there's no pretending this is the miracle cure we all wish it would be. Some of the compounds and formulations will work better in some eyes, and there will be patients that these options won't help. There are always side effects, but some (hopefully most) patients will tolerate these so they don't have to wear glasses in public. Listening to our patients and determining what's important to them will be critically important in helping us guide their treatment. It will be up to us as physicians to determine which formulations are most appropriate for each patient, and how to use these medications in conjunction with other methods of treatment.

Not only will we be able to help our existing patients that are already affected, but it is quite possible that our younger patient population may never need to experience untreated presbyopia. With the blitz of direct-to-consumer marketing that is sure to occur from our industry partners, patients who have never seen an eye doctor and are simply ordering reading glasses from Amazon will be interested in using the drops instead, and will come see us. This will give us the opportunity to diagnose and treat this new patient population for any number of other problems that can happen to the aging eye, including dry eye disease and glaucoma.

As we continue to chase the holy grail and with so much focus on the pharmacologic treatments, some would argue that advances in contact lenses and IOLs could easily be pushed to the background. Rather, all ships

will likely rise with this greater attention and public awareness of presbyopia management. All technologies will advance, become more nuanced, and our patients' overall satisfaction sans reading glasses may actually result

from a combination of pharmacologic treatment plus contact lens, laser, or intraocular surgical intervention.

"Listening to our patients and determining what's important to them will be critically important in helping us guide their treatment."

In this issue, we will take a deeper dive into some of these topics, with an update on pharmacologic treatments, a discussion of the opportunities they

present, and a look at how patients will be learning about them. We also explore how to talk to your patients about presbyopia, protocols for initial management, using IOLs and contact lenses with presbyopia patients, how an integrated OD/MD practice works, and how presbyopia can affect the quality of life of certain sports enthusiasts. ■

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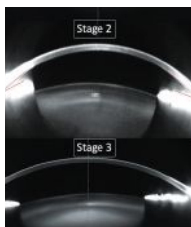
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PRESBYOPIA NEWS & NOTES

Compiled by Steve Lenier, Managing Editor

VUITY Receives FDA Approval as First Drop to Treat Presbyopia

- At press time, Allergan announced the FDA approval of VUITY (pilocarpine HCl ophthalmic solution) 1.25% for the treatment of presbyopia, commonly known as age-related blurry near vision, in adults. VUITY is the first and only FDA-approved eye drop to treat this common and progressive eye condition that affects 128 million Americans.

The daily prescription eye drop works in as early as 15 minutes and lasts up to 6 hours, as measured on day 30, to improve near and intermediate vision without impacting distance vision, according to Allergan. Specifically designed for presbyopia, VUITY is

evaluated the efficacy, safety and tolerability of VUITY for the treatment of presbyopia. In both studies, VUITY met the primary endpoint, reaching statistical significance in improvement in near vision in low light (mesopic) conditions without a loss of distance vision, versus the vehicle (placebo) on day 30 at hour 3. No serious adverse events were observed in either study.

In other news, Allergan launched BlurryNearVision.com, an interactive website offering presbyopia information.

B+L Announces Positive Outcomes for Premium LuxSmart IOLs

- Bausch + Lomb has announced positive outcomes following the one-year

by 200 surgeons across 18 countries. It is not yet available in the United States. More than 5,000 cataract patients have now been treated worldwide, including more than 4,000 across Europe. B+L says LuxSmart is suitable for use in patients with some co-morbidities and could be used to achieve near vision through micromonovision (with the difference between the two eyes being less than 0.75D). It is a hydrophobic lens, designed with Pure Refractive Optics (PRO) technology.

Evaluation in bilateral cataract patients indicates that LuxSmart performs extremely well at distance (BCDVA, -0.03 logMAR) and intermediate (DCIVA at 80 and 66 cm, mean 0.07 and 0.14 logMAR, respectively). DCNVA at 40 cm reached 0.38 logMAR, when treating bilateral cataract.

VUITY met the primary endpoint, reaching statistical significance in improvement in near vision in low light conditions without a loss of distance vision.

an optimized formulation of pilocarpine, delivered with pHast technology.

The approval of VUITY is based on data from two pivotal phase 3 clinical studies, GEMINI 1 and GEMINI 2, which

real-world evaluation of its premium LuxSmart lens, since its European launch in 2020. LuxSmart is designed to provide continuous vision from distance to intermediate, and has been adopted

M&S Technologies Introduces DVA-5000 for Clinical Trial ETDRS and Contrast Sensitivity Function Testing

- M&S Technologies has introduced the DVA-5000 for Clinical Trial ETDRS and contrast sensitivity function testing, part of the company's Clinical Trial Suite (CTS). The company says the automated-testing protocols used in the DVA-5000 are significantly more efficient and

accurate than traditional testing methods. CTS test results are automatically calculated and ready for review as letter score, logMAR, decimal score, and Snellen equivalent. Secure and trusted reports are immediately available in XML or CSV format for export to any EDC, Reading Center, or other location of choice.

M&S says it's important to note that the FDA recognizes CTS testing modules as an acceptable method of testing in all phases of clinical trials, including PMA trials. Over the past several years, CTS has been used in more than 140 clinical trials, including 40 active trials. All CTS modules, including the DVA-5000, provide accurate, consistent, and repeatable paperless test results from site-to-site and visit-to-visit.

Orasis Appoints Julie Speed as Senior VP, Head of Strategy and Marketing

• **Orasis Pharmaceuticals** has appointed Julie Speed as senior vice president (SVP), head of strategy and marketing. Ms. Speed has two decades of leadership experience in eye care and will be responsible for developing brand strategy and building the marketing organization as Orasis prepares for Phase 3 readout and FDA submission for the

company's lead candidate for the treatment of presbyopia, CSF-1.

Ms. Speed's experience covers both pharmaceuticals and medical devices. Her expertise spans from commercial

for the treatment of presbyopia. The executives and experts discussed therapeutic utility and commercial potential for BRIMOCHOL, as well as results of a recent market research survey.

The main drivers for market uptake and adoption for presbyopia-correcting eye drops **will be efficacy and treatment duration...**

leadership positions at Alcon and Johnson & Johnson Surgical Vision, advancing commercial strategy and brands, to start-up organizations EyeVance and TearLab, building marketing strategy and teams from the ground up. She also has broad marketing and launch experience with U.S. and global brands.

Visus Therapeutics Hosts Inaugural Capital Markets Day in New York City

• **Visus Therapeutics** recently welcomed investors, analysts, and media to its inaugural Capital Markets Day in New York City. Visus' management team and leading eye care experts presented new information on the company's lead asset, BRIMOCHOL, an investigational eye drop

The company also discussed its ophthalmic drug candidates and introduced a novel drug delivery platform licensed from DeSiTech that has the potential to help optimize the clinical benefit of ophthalmic therapies.

Research results that were presented include: an estimate that the addressable population for presbyopia-correcting drops in the U.S. is between 70-90 million; the main drivers for market uptake and adoption for presbyopia-correcting eye drops will be efficacy and treatment duration, with most ECPs preferring a drop that lasts at least eight hours; and that approximately half of the ECPs highlighted the value of a preservative-free eye drop option for patients with dry eye disease. ■

Understanding the Opportunity of Pharmacologic Presbyopia Treatments

By Richard L. Lindstrom, MD



Dr. Lindstrom is founder and attending surgeon emeritus at Minnesota Eye Consultants, senior lecturer and a trustee of the University Foundation at the University of Minnesota, and visiting professor at the UC Irvine Gavin Herbert Eye Institute. He is a board-certified ophthalmologist and internationally recognized leader in corneal, cataract, refractive and laser surgery, as a researcher, teacher, inventor, writer, lecturer and highly acclaimed physician and surgeon.



APPROVAL FROM THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) of the first eye drop to enhance near vision and reduce the handicap of presbyopia is anticipated in late 2021 or 2022. These miotic eye drops constrict the pupil to increase depth of focus.

An easy way for the clinician to think of this is to consider the drops equal to a +1.00 to +1.50 diopter reader. This analogy can help eye care providers select patients who are most likely to benefit, and to demonstrate to patients the near vision improvement they might achieve with these eye drops.

The number of presbyopia patients in

America is truly staggering, estimated at 120 million and growing. Many of these patients are emmetropic and have never seen an eye doctor. The launch of drops to treat presbyopia and reduce the dysfunction and quality of life burden presbyopia represents will encourage many of these patients to contact our offices and seek consultations. We must

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be thoughtful about how we will manage this new influx of patients seeking our care.

Evolving Practice Models

Both optometrists and ophthalmologists will be able to see and treat these patients—but not every eyecare provider (ECP) will find the mild-to-moderate presbyope ideal

“The number of presbyopia patients in America is truly staggering, estimated at 120 million and growing.”

for their practice. I see at least three practice models evolving.

The first and largest group will include ECPs who provide comprehensive eye care, prescribing and dispensing eyeglasses as well as contact lenses. For these ECPs, capturing presbyopic patients will be of great value, generating complete eye examination fees and the potential purchase of eyeglasses and/or contact lenses. Plus, these patients likely have other treatable, undiagnosed eye problems—such as ocular surface disease, cataract, glaucoma, and retinal pathology—that will generate meaningful work for the comprehensive ECP. If satisfied with their care, these new, middle-aged patients will refer their family and friends to the practice.

New patients are the lifeblood of every practice, and very satisfied 40- to 60-year-olds—especially females—can generate many word of mouth referrals. In turn, these patients will age in the practice and eventually require surgical care, including cataract surgery and perhaps even refractive lens exchange, as their presbyopia progresses.

The second eye care model will be the integrated eyecare practice with ophthalmologists managing the more severe eye disease and surgical patients, and optometrists providing adjunct medical eyecare and vision services. These practices should also seek to capture the middle-aged presbyope, who can initially be managed by an optometrist, and

will develop a need for more advanced care provided by an ophthalmologist.

The third practice model is represented by the secondary and tertiary care ophthalmologists who see cases primarily on referral from other ECPs. These physicians will not want the mild-to-moderate presbyope in their practice to displace a new patient slot that could be filled with someone who requires consultative eyecare or surgery. I believe these practices will do best by referring the presbyope to a colleague in their referral network. The practice's front office team can manage the referral process.

Complete Examinations for Overall Eye Health

Every new presbyopic patient, most of whom will have never been treated by an ECP, deserves a careful and comprehensive eye examination. I believe a meaningful secondary benefit of the approval of presbyopia-treating eye drops will be the earlier detection and timely treatment of much undiagnosed eye disease.

“If satisfied with their care, these new, middle-aged patients will refer their family and friends to the practice.”

Prepare Now

Eye drops to reduce the handicap and burden of presbyopia will be a significant new opportunity for every eye care practice. It is incumbent upon each of us to decide in advance of FDA approval how we will manage the presbyope seeking treatment, so we are prepared to properly manage this new influx of patients. ■

Disclosures

Dr. Lindstrom's disclosures include relationships with Allergan, J&J Vision, Orasis, Minnesota Eye Consultants/Unifeye Vision Partners and Visionary Ventures.

How to Start the Conversation: Early Presbyopes

By Gina M. Wesley, OD, MS

IN THE WORLD OF PATIENT education and practitioners, we each have our own style and method that works for us in our clinics. For success with that education, and to ensure that it resonates, repetition of my message from visit to visit is critical. I find that my patients value consistent information presented in a “what to expect” style of messaging. In the western medicine framework of “treat/prescribe,” once an issue is found, the approach of “here’s what could be coming/prevention/options” is refreshing for many patients.

Talking to Patients

An ongoing dialogue with each patient helps to lay the groundwork for follow-through on vision care recommendations. When a patient understands how vision changes as we age, I find they are more likely to be open to a wider variety of visual correction options. This specifically applies to presbyopia, a condition that affects millions of patients every

year—more patients than glaucoma, dry eye and macular degeneration combined.

Here are some examples of the messaging that I use with patients at various ages to prep them and set expectations for vision, and for presbyopia specifically:

Under Age 18: My primary goal is to ensure your vision is clear, comfortable and performing well for school, learning and extracurricular activities. Let’s talk about how we can achieve that in addition to the protection you need for

lifelong ocular health and optimal vision.

Age 18-29: You are in your prime post-graduate and early working years. I want to ensure your vision is not only clear and comfortable for what you do each day, but consistent from day-to-day as well. I will continue to recommend protective strategies and educate you on possible changes in your vision you may notice, such as fatigue at the end of a screen-heavy day.

Age 30-39: In this stage of your life, you may appreciate new options that will keep your vision clear and comfortable. This may include focus-boosting contact lenses or anti-fatigue spectacle lenses. You may notice that your vision suffers when you are tired or have poor lighting, especially when trying to read or work on your digital device. These near vision changes will continue as you approach your 40s, but I will keep you up to date on all of your options for visual enhancement. There

“When a patient understands how vision changes as we age, I find they are more likely to be open to a wider variety of visual correction options.”

are new pharmaceuticals, like eye drops, that are being developed to work with our natural vision as well as enhance vision with glasses or contact lenses.

Age 40+: You may notice that your near vision is changing, and perhaps becoming more difficult to manage. I understand this can be frustrating, but I’m going to give you an update on your current vision and what options you have to manage it, as every patient is unique and has varying demands and

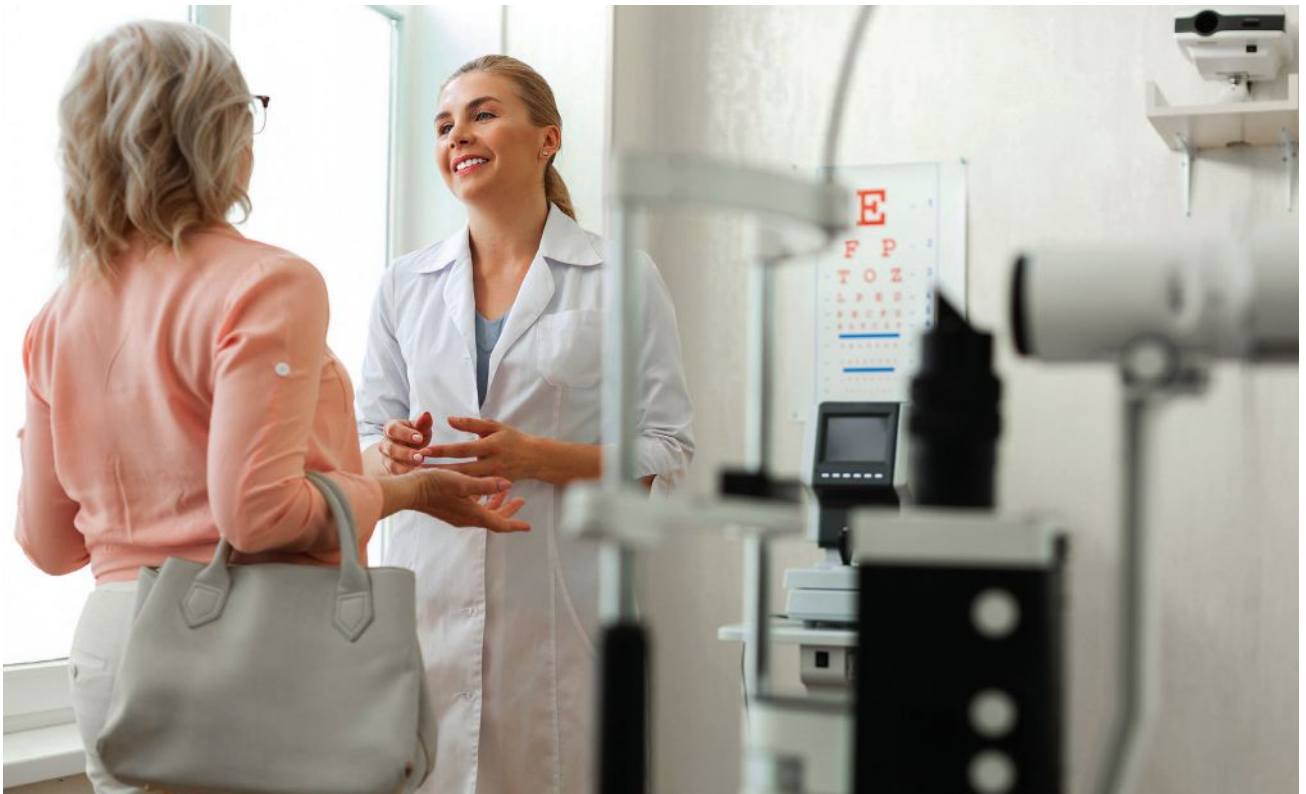


Dr. Wesley practices at Complete Eye Care in Medina, MN, which she opened in 2008. She is a member of the Minnesota and American Optometric Associations, and lectures, advises, conducts research and publishes on many aspects of the optometric industry.

expectations. The great news is that options beyond glasses, contact lenses and even surgeries continue to develop, and I expect new pharmaceutical eye drops to soon be available as yet another option to enhance your vision. When available, it will be important for us to have a conversation about whether or not this is an option for you, how it would work, and the importance of regular care to ensure eye health, safety and visual performance.

1. What frustrates you the most about your near vision? Are there certain times you notice these frustrations more than others?
2. What kind of work do you do? What about daily tasks or other activities?
3. Do your visual needs change or stay consistent, especially for near vision?

Once you have gathered initial answers and goals, correctly coaching your patient



Discussing the Options

Currently, there are several pharmaceutical products under development for presbyopia.¹ These drops are expected to enhance near vision, both with and without other corrective options, via once or twice daily dosing. Depending on the product, its formulation and efficacy, clinicians will choose what is safest and best for their patients. Considerations will include a patient's current ocular health and visual status. An example of some questions to prepare for your patients would include the following:

on expectations once treatment commences will be critical. Much like talking to patients regarding multifocal contact lenses or multifocal IOLs, laying the foundation as to what to expect and probable outcomes will put them on the path to success. This will also help you weed out patients who are not good candidates for these therapeutics, such as those with visually demanding jobs that require very precise visual acuities and sustained visual performance. These conversations may include the following points:

- Using this drop will allow you greater

flexibility with your vision. However, each patient's experience is unique based on his or her current visual status, visual tasks, and corrective therapies.

- The goal is to use the prescribed drop as necessary and as indicated for maximum success with minimal safety concerns.
- Understand that the varying formulations of these therapeutics—including the concentration of active ingredient(s) and other supporting ingredients—will feel and act differently for each patient. Finding the correct option for you will include assessing effectiveness while maintaining safety regarding your ocular health.
- Lastly, this drop should be comfortable for you to use as regularly as you need to meet your vision goals.

The more prepared you are to have these conversations, the greater your likelihood of success. This not only applies to your cur-

set is high, those doctors who can diagnose, treat and manage this condition will be set for even greater clinical revenue and success. Add in the possible glaucoma and macular degeneration patients, and the potential becomes even greater. If only a fraction of these OTC readers consumers trickles into our offices, we will be reaching a greater subset of Americans and achieving public health outreach on a scale not yet realized.

An additional benefit is that these new therapeutic products will not be met as stand-alone solutions. Many patients will use them to enhance or supplement their current mode of vision correction, or combine them with other vision-correcting options. Consider the potential multifocal contact lens wearer who could achieve great visual success at computer and near work if their pupil size was modulated, as these therapeutics are set to do. Or, the patient desires to use

a progressive addition lens more fully for a variety of activities, but needs greater flexibility with near and distance vision. These are only a few of the examples

of possibilities of combination treatments your patients could benefit from.

“Once you have gathered initial answers and goals, correctly coaching your patient on expectations once treatment commences will be critical.”

rent presbyopic patients, but also to the new patients you'll likely gain access to as word of this technology spreads. More than 50 million over the counter reading glasses are purchased yearly by Americans.² Ask yourself how many of those patients are seeking out any sort of regular eye care? And how can they even be aware of all the options for vision enhancement?

Assessing Future Potential

When a product or therapeutic becomes available that can address patient needs in a new way, these patients will be steered to our offices, seeking prescriptions and advice. To their own benefit, consider how many disease states will be detected in these patients who would otherwise have not sought out care. With an estimated 30 million Americans suffering from dry eye³, and the probability that the crossover amongst this same patient

Start Now

Dialing in your educational groundwork to prepare patients for what's to come, what to expect, and what options they have—and continuing that dialogue—is likely the top “to-do” item for practice and patient success when it comes to novel presbyopic therapies. Start those conversations now. You will set yourself apart from your peers, positioning yourself for both patient and clinic success. ■

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By Steve Lenier,
Managing Editor

Managing the Presbyopic Patient



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George O. Waring IV, MD, is founder and medical director of the Waring Vision Institute in Mt. Pleasant, SC, director of refractive surgery at Medical University of South Carolina, Storm Eye Institute, and medical director at Magill Vision Center.



Gregory Parkhurst, MD, is the founder of Parkhurst NuVision, a San Antonio LASIK and vision correction practice, specializing in all forms of modern refractive surgery.

THE ART OF MEDICINE ALLOWS for differences in how physicians manage their patients, and advancing technologies allow adaptation for greater success. Taking a look at how some of the experts do it can be fascinating.

Capturing Patients

Presbyopia patients often don't understand the cause of their loss of near vision.

Gregory Parkhurst, MD, has a practice that is focused on vision correction, primarily refractive surgery. Patients coming to see him want to be able to see without glasses or contact lenses. Dr. Parkhurst says, "They usually associate the new problem with something going wrong with their eyes and think they need to get checked. But the general public doesn't know about presbyopia."

He explained that these patients just know something is changing with their eyes, and they're concerned about it, and come in specifically asking about what they're noticing.

"So they find us either through referral—since we work with a lot of doctors in the community—or by an online search," he says. "They're coming because they're symptomatic, and they want a solution."

The Waring Vision Institute is a surgical vision correction practice that employs a concept called "surgical vision for a lifetime." George Waring IV, MD, explains this means they offer vision correction procedures for each stage of ocular maturity.

He says as patients begin to lose reading vision in their mid-to-late 40s and early 50s, they can be categorized into stages of

dysfunctional lens syndrome, with stage 1 being mild presbyopia, stage 2 being moderate presbyopia with early opacity and higher order aberrations, and stage 3 being advanced presbyopia with opacities significant enough to adversely affect a patient's daily activities, which is a cataract and in the United States, qualifies for submitting to insurance or Medicare. (Waring GO, Rocha KM. Characterization of the Dysfunctional Lens Syndrome and a Review of the Literature. *Curr Ophthalmol Rep* 6, 249–255, 2018).

Dr. Waring says the Waring Vision Institute has developed a standard work-up track for each stage of the dysfunctional lens, or each stage of ocular maturity for each patient, and said, "Because of this, we are also known as a surgical practice with one of our core competencies being the surgical correction of presbyopia."

Cathleen McCabe, MD, focuses on cataract surgery and refractive surgery, so the majority of early presbyopia patients coming to her practice are seen by the practice's optometrists, who are usually the primary care doctors.

"The place I encounter them for the first time," she said, "is if they come in for either a LASIK evaluation, or a clear lens replacement evaluation. There will be a significant number of patients who have never needed glasses before, and once they realize they need help to see up close, the first thing they think of is a surgical intervention. Most commonly that would be LASIK, but they don't realize that LASIK doesn't solve that for them in a way that they're anticipating."

She said for those at an age where they're

presbyopic, the discussion will often include at least the option of a more permanent solution like a clear lens replacement. The patient will ask whether they should have it done now, versus waiting, and what the pros and cons of waiting are. But she said before making the decision, the patient needs to understand what's happening.

Diagnosis

Dr. Waring helps patients understand what is happening with their eyes by using digital visual imaging of the patients eyes. "In our advanced vision analysis center," he said, "everybody gets high resolution tomography (Pentacam) which includes a Scheimpflug image of their lens, with lens densitometry, and then a high resolution macular OCT as well. We take patients on a tour of their eyes, and not only does it help us make better deci-

"They usually associate the new problem with something going wrong with their eyes and think they need to get checked." —Dr. Gregory Parkhurst

sions in terms of helping them understand what they're going to be a good candidate for, if anything, but it also helps us educate them."

Dr. Parkhurst considers several factors in determining what is going on. He looks at a patient's vision prescription, and the overall health of the front of the eye. His practice does corneal topography and tomography (Pentacam), wavefront aberrometry (iTrace), and scans of the crystalline lens, as well as looking at the anterior chamber depth, and the health of the endothelium. They use an HD analyzer to look at the internal aberrations or optical light scatter, and measure not only distance vision but near vision, and then determine the total refractive error problem. "It's usually not just presbyopia alone," Dr. Parkhurst said. "It's more often presbyopia along with some other refractive error, so then we talk through the difference. Depending on the patient's age, stage, refraction, and their anatomy, we embark on a discussion about

the different procedures we can do to help."

"These types of diagnostics are important," Dr. McCabe said, "because we want to make sure the reason they're not seeing well at near is not that they also can't see well at distance. They may have some other pathology going on. Sometimes they come in and we think that they're presbyopic, but when we really check they're not seeing well at distance either, and they have some other disease process or a need for glasses that include both distance and near."

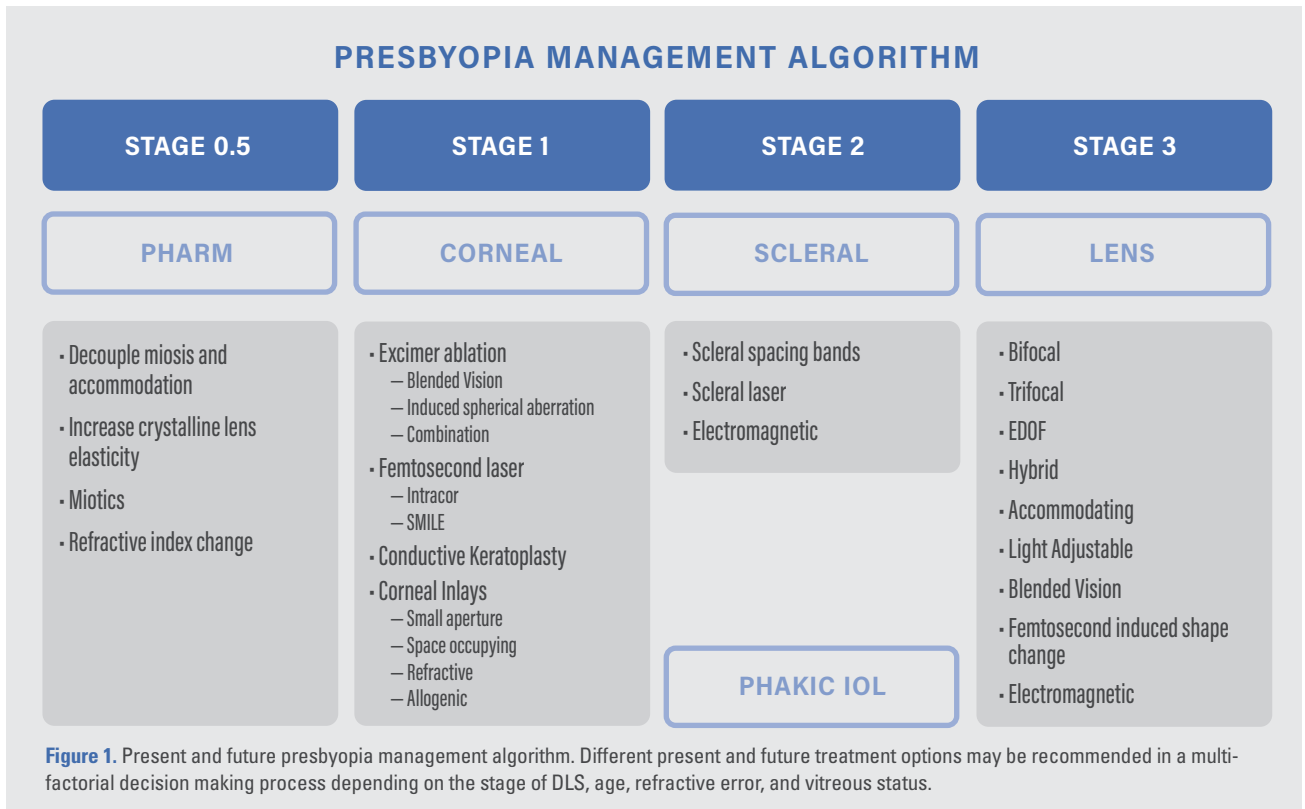
She said what can happen is the natural aging changes that cause presbyopia may reveal that the patient needs to start wearing distance glasses as well. This is especially true for latent hyperopes, who, because their natural lens was still able to change shape effectively, could overcome their need for glasses. But now with a stiffer lens that can no longer happen.

Dr. Parkhurst also commented on latent hyperopes, saying, "When people are young they can accommodate through farsightedness, and see distance clearly and see intermediate and even see near clearly. But then over time as their presbyopia sets in and they lose the ability to accommodate, they first tend to notice their near vision going out. Then over time, as they age and presbyopia worsens, even their distance vision can deteriorate further on in the progression."

Determining the Best Solution

When he talks with his patients, Dr. Parkhurst lets them know their presbyopia is totally normal. "I say things like 'Welcome to the club, this happens to all of us, this is no surprise, no cause for alarm, don't worry, this is just part of the normal aging process,'" he said. "I assure them they're not going blind, and say 'By the way we can absolutely fix this. There are a few different ways and we can work together to figure out which of those ways is best for you.'"

After looking at the patient's prescription, anatomy, age and where they are in progression, Dr. Parkhurst puts the patients into categories, separated by refractive error, and by age.



“Based on all that,” he said, “we determine which of the treatment options fits their eyes best from an anatomical perspective. And we usually give a specific recommendation, such as ‘In your case we recommend blended vision LASIK, with some drops as a boost, because you’re myopic, and you’re young.’ We don’t generally recommend doing a lens exchange for a young myope, who is potentially at risk of peripheral retinal tears. But if we have a 60-year-old hyperope with similar complaints we’re going to say ‘With your anatomy you’re an awesome candidate for a trifocal IOL.’ But the nice thing is that we have so many different options to custom fit and prescribe to our patients, the right surgery, and possibly soon in combination with a pharmaceutical.”

Dr. McCabe sees the upcoming pharmacologic treatments as a way to let patients delay a lens-based procedure. Especially when patients come in with healthy eyes, not needing help with distance vision, her conversations often focus around how important it is for them to be glasses free now.

“With a clear lens replacement,” she said, “or in a permanent change to the ocular surface like hyperopic LASIK, you’re committing them for life rather than giving them something that’s easily reversible.” She said an advantage of waiting is that new technology is always coming out, so unless the patient has a cataract, the benefit may outweigh the negatives of waiting for newer technology, and she sees the drops as a way to bridge the gap until they need to commit to a permanent solution.

Dr. Waring says the drops will be “a gateway drug for those with first experiencing presbyopia, or stage 1 dysfunctional lens,” providing an opportunity to help patients earlier.

Treatment

The Waring Institute has developed an algorithm for present and future presbyopia management (Figure 1).

“Very soon, we will be utilizing pharmacological options in the earliest stages of presbyopia when these are available,” Dr. Waring said. “We look at not only the stage of the

“There will be a significant number of patients who have never needed glasses before, and once they realize they need help to see up close, the first thing they think of is a surgical intervention.”

—Dr. Cathleen McCabe

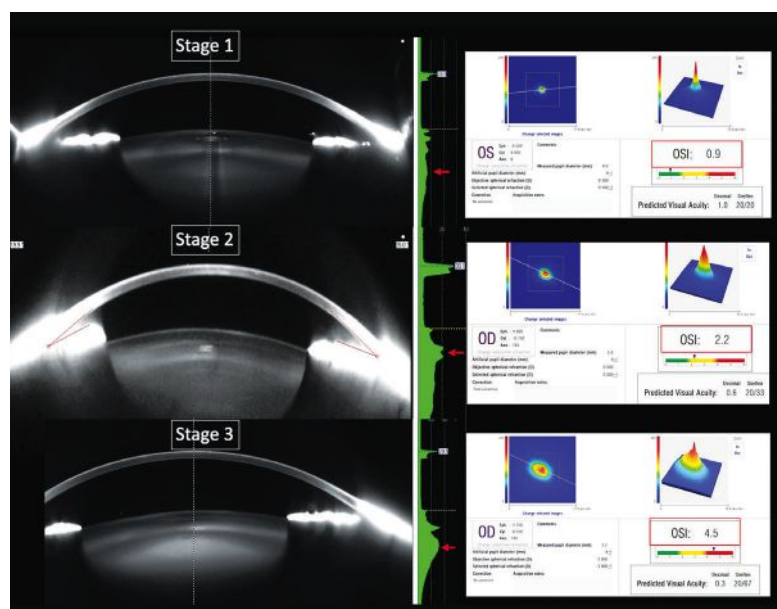


Figure 2. The three stages of dysfunctional lens syndrome. From: Waring GO, Rocha KM. Characterization of the Dysfunctional Lens Syndrome and a Review of the Literature. *Curr Ophthalmol Rep.* 6, 249–255, 2018

dysfunctional lens, which typically correlates with age, but also the other important factor—refractive error. And those are the three key elements of our decision making for the correction of presbyopia.”

He said in the context of refractive error, the more myopic somebody is, the later they may recommend a lens-based intervention. But with more hyperopic or farsighted patients, they intervene with a lens-based procedure earlier. Lens clarity, vitreous status and patient input are also taken into account.

Dr. Waring said, “Overall, we are moving more and more toward lens-based procedures, thereby treating the source of the dysfunction. Historically, however, for stage 1, if the patient has other congenital ametropia, we may do a corneal-based procedure like LASIK, particularly if they are nearsighted. However if they’re stage 1 and farsighted, we will typically do a lens-based procedure. For stage 2 we usually do a lens-based procedure, because now we’re also trying to fix early opacity at the lens level. The rare exceptions to this are people with high myopia, because of the risk of retinal detachment. For these patients we may recommend a corneal-based procedure or an implantable contact lens as a bridge with blended vision until the vitreous separates. For stage 3, which is cataract, we

do lens-based procedures.”

Dr. Waring said this has evolved over the years and they now do lens-based procedures earlier than in the past. “The reasons are multifold,” he said. “The patients are usually coming for LASIK, and now we can offer a lens-based procedure with femtosecond laser. It has similar benefits to LASIK—it’s a laser-based procedure, it’s quick and takes about the same amount of time as LASIK, and usually they’re seeing well the next day like LASIK. But it has a number of additional benefits above and beyond LASIK for presbyopia or lens dysfunction. It goes to the source of the problem, it maintains depth perception and stereo acuity by allowing use of presbyopia-correcting implants, which improves patient satisfaction, and it prevents cataracts.”

Dr. Parkhurst said, “What we’re dealing with here is dysfunctional lens syndrome, manifesting itself as trouble seeing, so we’re trying to place the patient onto the continuum of the different stages. Is it strictly presbyopia with an otherwise perfectly clear lens, or are they starting to have some loss of clarity or aberrations developing within the crystalline lens, or are they showing some early signs of cataract? We want to separate out what is the health, clarity, and function of the crystalline lens, and what is their age, because that’s

often going to direct us between offering a lens based treatment or a corneal treatment.”

For someone who is relatively young, their lens is perfectly clear and all they’re having trouble with is accommodation—especially if they’re emmetropic or myopic—Dr. Parkhurst usually will consider laser vision correction, which they most commonly do with the technique of blended vision. He explained that with blended vision, there is overlap in terms of the two eyes’ accommodative zones. So the brain adapts and fuses that with good stereopsis into one seamless range of vision. “Especially with younger patients,” he said, “we can usually accomplish a blend where they’re still using both eyes together, and we have a lot of patients these days that we’re using this strategy on. And we’re letting them know as their presbyopia advances over the next few years we’re going to augment their laser vision correction with eye drops that are in the pipeline.”

Dr. Parkhurst says another group of patients presents with presbyopia as the first vision problem they’ve ever had, and ask about getting LASIK or a refractive lens exchange. He’s looking forward to presbyopia-correcting drops as a way to give those patients some time, so they can be kept happy until they’re older, at which time a refractive lens exchange may be most appropriate. “And then there are the ones that show up when they’re 75,” he said, “and say their presbyopia is driving them crazy. We look in and say ‘Well yes, and you have a cataract, so let’s fix that.’”

Educating Patients

A large part of educating patients comes during the in-person visits. Dr. Waring said, “Our whole team is educated on being educators.” He said for his practice it starts with community outreach, letting people know it’s a normal part of aging for our near vision and reading vision to deteriorate, and we have options to fix this. “We invite people in for an advanced vision analysis, and run educational

symposia for the public, where we teach them about the different stages of the aging lens and lens dysfunction, as well as some of the options,” he explains. “We can show them why they lost their ability to focus for reading, in layman’s terms. We don’t even use the term presbyopia. We also reassure them that there’s nothing scary or dangerous going on, but left unmanaged it will get worse. And we explain how we can help them.”

Dr. Parkhurst uses an electronic messaging platform called Ocular Innovations to reach patients before and after consultations. He describes it as an educational engagement arc, using text messaging as the primary communication medium. Patients are entered into the channel via a QR code, often at the time of referral. Scanning the QR code captures the patient’s cell phone, and when they opt

“We take patients on a tour of their eyes, and not only does it help us make better decisions in terms of helping them understand what they’re going to be a good candidate for, if anything, but it also helps us educate them.” —Dr. George Waring IV

in you can drip educational content over time.

“For example,” Dr. Parkhurst said, “we can send a little video that says ‘Hey I know you’re having surgery tomorrow, make sure you get a good night’s sleep, we’ll see you in the morning.’ And then same thing in the post-op engagement arc, you can continue to send educational content.” He also recorded custom videos for each of his co-managing doctors, to be distributed to the patients of those doctors.

Dr. McCabe has focused her educational efforts on in-person conversation so far, but she says presbyopia-correcting drops may change that. “Because we have something that will be easily accessible, and accepted by patients,” she said, “the need and the advantage of a greater effort and outreach has come to light. So certainly we, along with ophthalmology in general, will be looking for ways of educating the population, now that we have a good solution to present to them.” ■

The Drops: What We Know So Far

By David Kading, OD,
Megan Schmauder, OD, and
Selena Huang, OD



Dr. Kading owns three practices in the Seattle area (Specialty Eye), focusing on dry eye disease, specialty lenses and front of the eye conditions. He performs research as part of the post-graduate residency that he hosts in Seattle, and lectures internationally.



Dr. Schmauder is the current binocular vision and contact lens fellow at Specialty Eye in Seattle. She graduated from Pacific University College of Optometry in 2021 and enjoys exploring the lovely Pacific Northwest.



Dr. Huang is the current ocular surface and cornea & contact lens resident at Specialty Eye, emphasizing front of the eye disease, dry eye treatment and fitting specialty contact lenses for complex eye diseases.



PRESBYOPIA IS A PHYSIOLOGICAL accommodative insufficiency associated with aging of the eye that progressively worsens the ability of the crystalline lens to focus on near objects. Like death, taxes and cataracts, it is one of the few near certainties of life. Presbyopia classically presents around the age of 40, and currently affects an estimated 1.8 billion people globally (128 million in the U.S. alone). As the eye ages, the natural lens becomes progressively less flexible, eventually compromising near vision. Common symptoms include eyestrain and headaches that are worsened by near tasks, difficulty reading small print and a need

for more light when reading. But you already knew all that.

More importantly, with the ubiquity of presbyopia, it is no surprise that discovering a novel way to correct it has been likened to finding the holy grail of the eye care world. Presbyopia can be currently managed with contact lenses, eyeglasses and surgery. Wouldn't it be nice to have an age reversing eye drop? We can, and we will. Broadly, these drops can be classified into two categories: miotic agents intended to increase depth of focus by decreasing pupil size to an ideal 1.5 to 2.5 mm PD, and compounds intended to soften the crystalline lens. Of these two options, miotics are far closer to coming to market.

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Miotics

• Abbvie/Allergan AGN-190584

One of the newest preservative-free miotic drops is AGN-190584 from Abbvie/Allergan. It consists of low concentration pilocarpine (1.25%), and includes a proprietary multi-faceted vehicle with the goal of creating exceptional near visual acuity without a reduction of distance acuity or night vision. While its primary mechanism of action is through pupil constriction, AGN-190584 also aims to maintain pupillary response to different lighting conditions—an effect known as dynamic pupil modulation. Currently, the drop has completed a phase 3 clinical trial (GEMINI I), and has been submitted to the FDA for approval after meeting both its primary and secondary efficacy endpoints.

In the phase 3 trial, 323 participants were randomized in a one-to-one ratio to AGN-190584 vs. vehicle (placebo). With a once-daily dosing system, a statistically significant proportion of patients was able to gain three lines or more of mesopic, high contrast, binocular Distance Corrected Near Visual Acuity (DCNVA) at day 30, hour 3 and hour 6. It showed a rapid onset of 15 minutes and a duration of up to 6 hours without loss of distance vision. In addition, 75% of patients in the treatment group achieved >2 line improvement in mesopic DCNVA, 93% achieved >20/40 vision in photopic DCNVA, and improvements were observed in intermediate acuity for up to 10 hours. Constricted pupil sizes over time are expected to return to baseline within 24 hours with minimal to no side effects, and no tachyphylaxis was found. Side effects of the drop include headaches, conjunctival hyperemia, visual blur, and eye pain. Overall, patients who had received AGN-190584 had a reduction in the use of presbyopia-related coping behaviors such as squinting or changing the size of electronic screens, compared with those who received vehicle. In addition, it is preservative free and would be a good option for patients with concurrent ocular surface disease.

• Eyenovia MicroLine

Eyenovia MicroLine is another presbyopia drop in a phase 3 clinical trial. The VISION-1 study evaluated the safety and efficacy of the company's 1 and 2% pilocarpine Micro-Array Print formulations vs. placebo, administered by a proprietary dispenser, the Optejet. The results showed statistically significant improvements in DCNVA in low light conditions at 2 hours post-treatment. MicroLine was well tolerated with no serious adverse events. The dispenser delivers the solution in a well-distributed mist, offering convenience, cleanliness and a reduced chance of systemic absorption.

• Orasis CSF-1

This drop has been dosed twice a day in testing, and no negative impact on distance or night vision has been reported. The major benefit of Orasis CSF-1 is that it is titratable; which means patients are not trapped into an extended duration of effect should they choose to revert back to their reading glasses or stop the drop due to side effects. In addition, it is also preservative free and may be a better option for patients with presbyopia and dry eye disease. The primary endpoint is a 3 line improvement in near visual acuity with minimal loss of best corrected distance vision. The secondary endpoint is a 2 line improvement in near with slight impact on night vision along with various safety and tolerability measurements. It has recently demonstrated good safety, efficacy and comfort in its phase 2b study, and is currently enrolling participants in its phase 3 clinical trials, NEAR-1 and NEAR-2.

• Ocuphire Pharma Nyxol + Low-Dose Pilocarpine

Ocuphire recently completed its phase 2 proof of concept trial (VEGA-1) to evaluate a combination of Nyxol (PF phentolamine 0.75%) and low-dose pilocarpine in the treatment of presbyopia. It is one of the only drops to combine a cholinergic agonist with an alpha adrenergic antagonist, and thus acts on both the iris sphincter and iris dilator

muscles. Its primary and secondary endpoint compares the amount of letter gain in photopic distance and corrected vision along with its duration of action and side effects. It met its primary and secondary efficacy endpoints, and is expected to be moving on to phase 3 soon.

• **OSRX Pharmaceuticals Eyefocus**

This is a compounded miotic eye drop—available in EyeFocus and EyeFocus+ strengths—

“Presbyopia-correcting drops are on the horizon, and have the potential to become a potent tool in the treatment of one of the most common conditions optometrists face.”

which contains low concentrations of pilocarpine, phenylephrine, pheniramine and ketorolac. The company recently completed a proof-of-concept study in nine patients aged 44-64, and early results appear promising.

• **Lenz Therapeutics (formerly Presbyopia Therapies) PRX-100/Liquid Vision**

Liquid Vision uses aceclidine, a novel chemical entity in the U.S., to cause pupillary constriction without induced myopia (improving near vision without impairing distance). Its phase 2b study showed a rapid onset at 30 minutes as well as a duration of at least 7 hours, and a phase 3 trial is expected soon.

• **Visus Therapeutics Brimochol**

Brimochol is a proprietary combination of carbachol and brimonidine that is currently enrolling 40 patients in its phase 2 trial, with results expected towards the end of the year. It appears that carbachol may have a longer duration of action than pilocarpine, leading to treatments that may last up to 8 hours. Also, the addition of brimonidine has reportedly mitigated some of the adverse effects seen with miotics (headaches, hyperemia and brow aches). Two phase 3 studies enrolling up to 500 patients are expected in the near future.

Lens Softening

There are currently two companies attempting to tackle the root cause of presbyopia by developing products designed to soften the crystalline lens.

• **Novartis Dioptin**

Novartis is currently planning a phase 2b dose-finding trial for Dioptin, an ester of naturally occurring R-lipoic acid and choline that penetrates through the cornea and acts to reduce disulfide bonds between lens proteins, ideally restoring lens elasticity that has been lost with age. A phase 2 study of 78 subjects did not meet primary efficacy endpoints, but research is ongoing.

• **Viewpoint Therapeutics VP1-001**

Viewpoint Therapeutics is in preclinical investigations evaluating the molecule VP1-001 as a way to stabilize the protein alpha-crystallin, ideally working to treat both presbyopia and cataracts. Alpha-crystallin is a crucial component of the natural lens, with an important role in maintaining transparency and flexibility. It tends to destabilize with age, leading to light scatter and lens rigidity.

Meeting the Need

Presbyopia-correcting drops are on the horizon, and have the potential to become a potent tool in the treatment of one of the most common conditions optometrists face.

There is an unmet need for a topical drop to improve near vision from early presbyopes to pseudophakes. Contraindications include high myopes and a history of retinal tears, due to the pharmacological action of pilocarpine. As clinicians, we are excited and anxious to see how we will be able to utilize these tools to improve the lives of our patients. Overall, studies have shown significant improvement in near vision with presbyopia drops. ■

The authors would like to thank each of the companies for their contribution to our understanding of their forthcoming presbyopia medications.



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Getting the Drop on **Presbyopia**

By Darrell White, MD

PATIENT: Doc, I used to be able to count the freckles on a flea at a thousand meters and now I can barely count the peas on my plate. What's going on?

DOC: Sadly you have a case of over 40-itis! You can use "cheaters" or get bifocals. It's only going to get worse over the next 20 or more years!

PATIENT: Wait...how come I never see anyone on TV or Facebook wearing cheaters? There has to be something else I can do.



Dr. White is a cataract and refractive surgeon practicing in Cleveland, OH. Among the first LASIK surgeons in the U.S., he is eagerly awaiting the arrival of presbyopia-correcting eyedrops.

AS WE HAVE READ IN *PRESBY-opia Physician* and elsewhere, 2022 is the year we will see the introduction of eyedrops to eliminate the need to wear reading glasses. There are three products from three drug companies, all expected to arrive on the market within the next two years. What makes this so interesting is that all three of the treatments will likely have an almost identical mechanism of action. Even more interesting—and from a business standpoint, and a possibly unprecedented

situation—it is highly likely that all three of the products will have nearly identical business models.

Because of this we will be gearing up for a fascinating case study opportunity over the next year. How can three medications, all eyedrops and with mechanisms of action so similar that they could reasonably be considered identical, differentiate themselves in the marketplace? Not only that, but these three medications are in a product category that heretofore did not even exist. Blowing the launch of even one of these products could tank the whole game.

This puts additional pressure on the executive teams at Allergan, Visus and Orasis, not to mention their respective marketing agencies. How do you introduce an entirely new category of treatment?

Over the past many years I have had the great privilege to participate in the creation of brand new products in almost all sectors of eye care. One thing I learned from sitting at the table and listening to the sales and marketing executives is that a deep and very intense knowledge of who will use the product is an essential part of bringing a product to market. This is a unique aspect of the presbyopia market: we really do not need to do much research to find potential candidates, do we? Pretty much every adult over the age

“Blowing the launch of even one of these products could tank the whole game.”

of 45 in the developed world is a potential candidate for a presbyopia-correcting eyedrop. The key, then, is to determine what smaller segments of this demographic will be more likely to use these medications, and then design programs to reach them.

Patient Populations

“Everybody” is an exaggeration, but some segmentation of this demographic is obvious. Anybody who has great distance vision without glasses or contacts will rebel against any glasses whatsoever. It will be even easier to convince those in this segment who have already misplaced or lost their first 20 pairs of cheaters. Ditto contact lens wearers. About 10 years ago I would have stopped right here and called it a day. Now, however, we must also include everyone over the age of 45 who spends the majority of their day looking at a computer. Those whose primary job involves staring at a screen all day long often find both reading glasses and progressive bifocals to be as much a source of frustration as they are a solution. A fair estimate is that this particular demographic probably

adds another 15 or 20 million candidates for presbyopia-correcting eyedrops as soon as their everyday glasses no longer do the job at work.

Still, at the end of the day, one of the hardest parts of bringing a new product to market is nearly a nonfactor when it comes to presbyopia-correcting eyedrops. The patient population is largely self-identifying, and they are desperate for a solution that does not include wearing glasses. All of the heavy lifting of identifying the market has been done by the customers themselves.

Direct-to-Consumer Marketing

Let’s assume—very reasonably—that the majority of marketing will be direct-to-consumer (DTC). The easiest way to reach candidates is where they live: on their devices! All three of the expected products will be targeting early and mid-stage presbyopia candidates. These groups spend an inordinate amount of time online. While they are just old enough to not be considered “digital natives,” we can definitely think of them as first-generation immigrants to the digital world. As such, they are quite comfortable seeking solutions to their problems using Google or another search engine. I imagine a “digital first” marketing strategy from each company in this space, most likely using an online advertising platform as a way to reach potential candidates.

Social Media

Those on the younger end of this population, say 40 to 50 years of age, are almost all on at least one social media platform. Indeed, the vast majority of this age group will more than likely be utilizing all of the “big three” platforms: Facebook, Twitter and Instagram.

In my office I tell my patients that presbyopia is inevitable. With a big smile on my face and a chuckle in my voice I tell them that the only way to avoid presbyopia is by “checking out”—a very bad life management strategy! Naturally, the same is true for every

celebrity, and it is no less true for those individuals known as social media “influencers.” For me the unifying characteristic of this group is that no amount of personal vanity is so great that it prevents them from capitalizing on their fame and making money.

Think about it. George Clooney is 60 years old. Have you ever seen him wearing reading glasses? Jennifer Aniston has been a part of everyone’s digital world for about 20 years. She’s 52 years old! I envision a “last person standing” race to get Jennifer Aniston to wear reading glasses for 30 seconds, use an eyedrop, and smile her way to freedom on Instagram. Can’t you see that too? Jay-Z is 51 years old, and Kanye West is 44.

“While they are just old enough to not be considered ‘digital natives,’ we can definitely think of them as first-generation immigrants to the digital world.”

For goodness’ sake, Beyoncé just turned 40! Talk about an all-star lineup of presbyopia-stricken jetsetters. We may certainly see some of them, or their peers, in traditional media like television and newspaper ads. But my bet is that they will be inescapable on social media.

Medical treatment of presbyopia is a brand new space in the marketplace. It’s a new way to address a very old problem. I predict we will see some very old, very traditional marketing, especially when it is geared toward the 55 and older part of the presbyopia population. However, in this very new world, I think we can all expect to see an increasingly digital approach to marketing all three of the expected pharmacologic options. Facebook, Twitter and Instagram will be ground zero for this digital approach.


After all, if it works for George, Jennifer and Beyoncé, it’s gotta work for everybody, right? ■

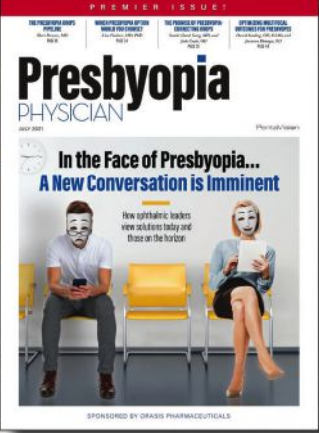
NEW!

Stop by the *Ophthalmology Management* booth (#2911) at the AAO meeting in New Orleans to pick up the November issue of

Presbyopia

PHYSICIAN





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EYENOVIA IS MAKING IT POSSIBLE

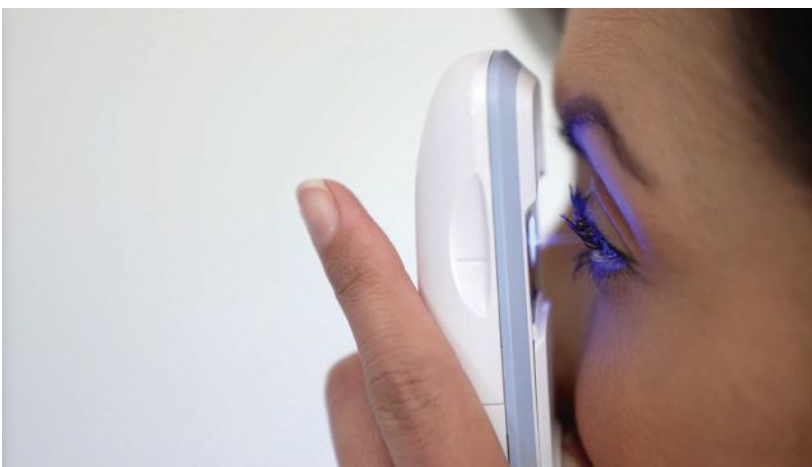
We create transformative therapies for use in progressive myopia, presbyopia, and mydriasis. Our innovation in ophthalmic delivery has potential to change the way eyecare professionals and patients view eye care modalities. Eyenovia strives to create drug therapies that are more effective, safer, and smarter than traditional eyedroppers. Our Optejet® dispenser is designed to deliver minimal amounts of medication to the eye, horizontally, while maintaining similar efficacy to traditional eyedropper treatment. The Optejet® also comes equipped with Bluetooth capability, to help track patient compliance and adherence more easily.

We envision the Optejet®'s technology being utilized for additional applications and drug therapies. Reduction in systemic exposure and toxicity with the Optejet®'s microdosing, compared to a traditional eyedropper, could mean the dispenser may have a better tolerability and safety profile than existing topical treatments. For therapies where adherence is vital to treatment success, the Optejet® can assist with patient compliance.



INTRODUCING THE OPTEJET®

Designed to be the easiest way to dispense eye drop medications to the eye. What once involved steady hand-eye coordination and tilting your head back has now become as simple as the push of a button. Benefit from your eye medication taken as a mist that coats the eye faster than you can blink without the frustration associated with traditional eye drops.



MICROLINE (PRESBYOPIA) UPDATE | VISION-2 STUDY

In April 2021, VISION-1, Eyenovia's first Phase 3 study for presbyopia, met its primary efficacy endpoint of the proportion of subjects gaining 15 letters in mesopic binocular DCNVA at 120 minutes. Both dose levels of pilocarpine were well tolerated.

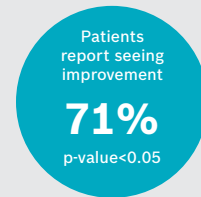
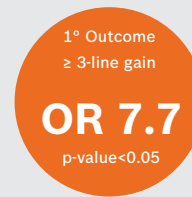
Eyenovia continues to prepare for VISION-2, its second Phase 3 presbyopia study, targeting first patient enrollment in November 2021.

If approved, MicroLine will be the only product that uses a novel dispenser to deliver pilocarpine formulations as a topical ophthalmic. This could improve upon the safety, efficacy, comfort and convenience to the patient relative to traditional eye drops.

MicroLine has been licensed to Arctic Vision for China and Korea; additional licensing opportunities exist in other geographies.

VISION-1 MET PRIMARY ENDPOINT

FORMULATION IS WELL-TOLERATED AND COMFORTABLE



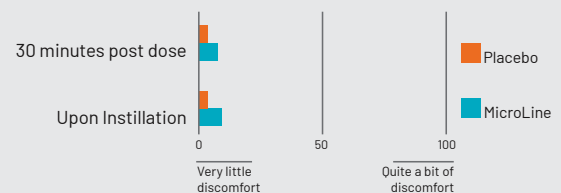
KEY SAFETY OUTCOMES

All AEs were Transient in Nature

	MicroLine	Placebo
Moderate Hyperemia ¹	2%	0%
Instillation Discomfort	2%	0%
Brow Ache	2%	0%

¹Resolved by 3 hours post-dose

PATIENT COMFORT ASSESSMENT



RESEARCH GROUP FOCUS



Eyenovia recently conducted focus groups with presbyopic participants, aged 40-55YO (N=18), to evaluate the impact of presbyopia on patients and interest in future treatment options for presbyopia. Participants were introduced and asked to compare two product concepts, one representing pilocarpine eye dropper treatment, and the other representing microdosed pilocarpine treatment – the participants significantly favored the microdosed pilocarpine option.

PRESBYOPIA FOCUS GROUPS DESCRIBE A BETTER OPTION

The ideal product profile would include:

No risk of headaches

"I'm much more willing to try [microdosing] because of my fear of headaches"

Lower risk of red eye/other side effects

"None of those side effects, that's huge"

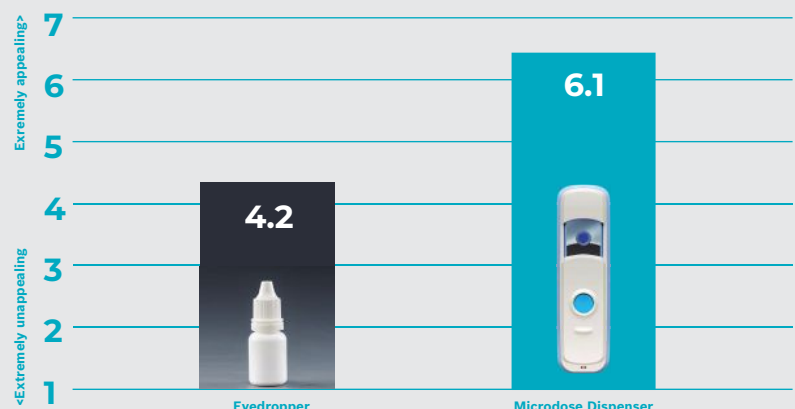
It's futuristic and "cool"

"That spray is neat, I'd have no problem using that in front of coworkers"

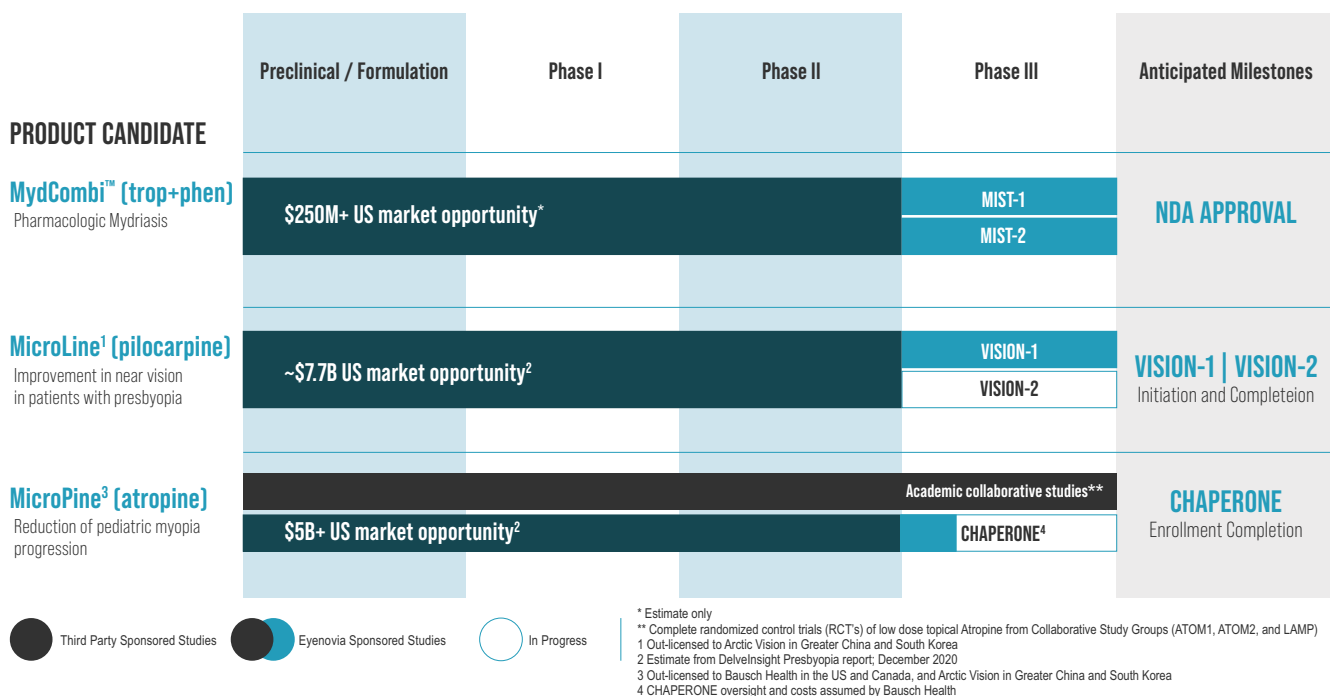
Convenience (ability to administer without head tilt/needing a mirror

"I prefer the mist, don't have to use the dropper"

HOW APPEALING ARE THE EYEDROPPER AND MICRODOSE TREATMENTS TO YOU?



Multiple Late Stage Clinical Assets



REMOTE THERAPEUTIC MONITORING OPPORTUNITY

Exciting news about our Optejet® digital health system and our ongoing efforts to enable a remote therapeutic monitoring platform for all of our smart microarray print pharmacologic projects.

Earlier this year, we shared exciting compliance data from one of our Phase 3 trials showing that the first 28 subjects were on average 90% compliant using the Optejet® dispenser. This compares favorably to the 50% compliance rate typically recorded for eyedropper bottles¹. The technology in the Optejet® has the potential to become the first smart delivery system for pharmacologic eye treatments. With fully embedded digital health functions, we will be able to track therapeutic compliance and adherence.

The Optejet® digital health system could be the first to enable smart pharmacological eye therapy and digital health for chronic eye diseases. This would open a new pathway for more personalized eyecare and may enable a new reimbursable paradigm for remote therapeutic monitoring. The American Medical Association manages the procedure code set that physicians and other health professionals use to identify the services for which they bill.

During a recent meeting of its editorial panel, new CPT codes for remote therapeutic monitoring were approved with five new codes that will become effective in January, 2022. Some will cover acquisition and review of compliance and adherence data for pharmacotherapy. And this may provide a pathway for providers and clinics to get reimbursed for such care. We are closely monitoring the CMS and payer adoptions of remote therapy monitoring and other Telehealth initiatives, as we work to create and enable the first pipeline of smart eye therapeutics with our Optejet® remote therapeutic monitoring platform. We look forward to a time in the near future when doctors will be able to deliver better, smarter care that is covered under a potential remote therapeutic monitoring CPT code.

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Increasing Collaboration with an Integrated Practice

This practice model can fluidly serve patients and leverage the advent of presbyopia-correcting drops

By Louis Pilla,
Contributing Writer



Mark Buboltz, OD, serves as the Optometric Residency Coordinator at Minnesota Eye Consultants and is adjunct clinical faculty at the Illinois College of Optometry. He has special interests in dry eye management and specialty contact lenses as well as ocular disease, urgent care, surgical management, and primary care.



Mark Hansen, MD, performs cataract and intraocular lens implant surgery, corneal transplants and other surgeries for patients with corneal diseases, along with a variety of glaucoma procedures. He also performs refractive surgery, including laser vision correction procedures such as LASIK and PRK as well as refractive lens implant surgery.

PROVIDING YOUR PATIENTS with a seamless eye care experience can be challenging, particularly when collaboration between ophthalmologists and optometrists is less than smooth.

As presbyopia-correcting drops hit the market, that collaboration will become even more critical. With robust communication between ophthalmologists and optometrists, clinicians can provide patients access to this new pharmacologic option and other eye care services that may surface during eye exams.

In this article, we'll explore how an integrated practice model benefits both doctors and patients, specifically looking at a large practice based in Minnesota. And we'll take a closer look at how that practice will handle the advent of presbyopia-correcting drops.

Synergistic Environment

With five locations in the Minneapolis/St. Paul region, Minnesota Eye Consultants boasts a staff of roughly 300 employees. That includes 13 fellowship-trained ophthalmologists, 11 optometrists, two ophthalmology fellows (cornea and glaucoma), two optometry residents, and two physician assistants. The practice was founded in 1989 by Dr. Richard Lindstrom, "one of the first to create a synergistic environment for optometry and ophthalmology to work together," says Mark R. Buboltz, OD, optometrist and optometric residency coordinator at Minnesota Eye Consultants.

Minnesota Eye Consultants uses the integrated practice model, where ophthalmologists and optometrists work in the same

practice. This contrasts with the community model, where ophthalmologists and optometrists work in separate locations but arrange to work together.

Team Approach

The integrated model essentially uses a team approach to care for each patient, explains Mark S. Hansen, MD, Minnesota Eye Consultants, anterior segment and refractive surgeon. In an integrated model, patients will receive a "full, comprehensive experience," says Dr. Buboltz.

"It is quite easy to get second opinions and learn from each other when we're working alongside each other..."

"In the integrated practice, the optometrists are able to, for the most part, spend more time with the patients, really addressing their concerns. Before the patients get to the ophthalmologist, usually our optometry team is able to more comprehensively take care of them."

When patients have been followed in the clinic for some of their more primary eye care needs, "we're able to really understand exactly their vision goals and guide them in the right direction," notes Dr. Buboltz.

"I see our optometry team as the primary eye care provider for our patients," says Dr. Hansen. "Just like the primary healthcare provider, they know and understand the patient and his or her visual needs."

"Since we work together in clinic, the optometry team can make recommendations for refractive outcomes and provide a deeper

understanding of the patient's desires because of the years of history that they have together. They are better able to provide insights that we might not catch in the 20- to 30-minute consultation before surgery is scheduled."

In the integrated model, says Dr. Hansen, the optometry and surgical teams work in the same physical area. "The clinic space was designed this way to encourage collaboration and teamwork."

"It is quite easy to get second opinions and learn from each other when we're working alongside each other," notes Dr. Buboltz. "From an optometry standpoint, I find that the more I understand about different surgeries and their mechanism of action, the more

"Due to the large number of patients that will need or want treatment, utilizing an integrated model will be important."

I understand about the disease." In addition, the practice supports meetings and journal clubs so clinicians can stay updated on new surgical and treatment techniques.

Serving a Demanding Patient

As an example of how an integrated practice delivers high-quality, patient-focused care, consider the case of a patient who had "very high demands for her vision," as Dr. Buboltz puts it. A wearer of multifocal contact lenses, the patient was developing cataracts that were impacting her vision.

Dr. Buboltz referred her to one of the cataract surgeons at Minnesota Eye Consultants. Based on his years of fitting this patient with contact lenses, Dr. Buboltz observed that this patient was likely not a good candidate for a premium IOL, such as a multifocal lens, because of her high demands.

With this knowledge, the patient received a standard lens and is doing well after being refitted with multifocal contact lenses. She often requires multiple vision adjustments to her contact lenses; thus, a multifocal IOL would have been significantly more challenging to adjust with refractive surgery.

Drops Make Collaboration Even More Critical

With the upcoming arrival of presbyopia-correcting drops, Dr. Hansen expects many patient calls and clinic visits once patients hear of this new near-vision option. "This will begin in both the optometry clinic with routine exams and also surgeon clinics when discussing refractive options for patients," he notes.

"Presbyopia is a condition that will affect every patient at some point," he points out. "Due to the large number of patients that will need or want treatment, utilizing an integrated model will be important."

"We are a refractive surgery practice and have many patients that are trying hard to avoid glasses and contact lenses as much as possible," says Dr. Buboltz. "I think

there will be significant excitement once we are able to start advertising these drops."

The practice sees many patients in their mid 40s who may have had LASIK and now are frustrated with the loss of near vision, says Dr. Buboltz. Presbyopia-correcting drops will offer "another option for these types of patients, whether they see our optometry team or our ophthalmology team."

For early presbyopes, these drops may help keep them in a single-focus contact lens for longer before having to shift to readers, or monovision or multifocal lenses, Dr. Buboltz notes. He also is intrigued by the off-label potential to decrease pupil size and thus reduce aberrations, especially for patients bothered by night-time glare after LASIK or multifocal cataract implants.

Today, all the options for treating presbyopia, especially in contact lenses, involve degrading visual quality in one way or another, explains Dr. Buboltz. "If you can just increase the depth of focus with these drops, I think there are going to be patients that are going to be a lot happier than with their multifocal or monovision lenses."

While the presbyopia-correcting drops may

not be a “saving grace” for older patients with more severe presbyopia, cautions Dr. Buboltz, for “the early presbyopes that are struggling, I think it’s going to be a very useful drop before they have to get into next options.”

Dr. Buboltz says advertising and word of mouth about presbyopia-correcting eye drops will cause more people to think about their eyes and schedule an appointment to see if these drops are right for them, and will give eye physicians an opportunity to comprehensively evaluate patients and catch other eye issues, such as dry eye, glaucoma, and corneal ectasia earlier on in the disease path.

Trust and Humility

For clinicians working in an integrated practice model, “It’s a relationship of trust and humility on both sides,” says Dr. Buboltz. He says in a true integrated practice model, where the surgeon is primarily in surgery, and the optometrist handles the bulk of the

“With the upcoming arrival of presbyopia-correcting drops, Dr. Hansen expects many patient calls and clinic visits once patients hear of this new near-vision option.”

clinical work, the surgeon must trust the optometrist that his or her surgical patients are being well taken care of on the front and back ends, in order for the surgeon to see success and for patients to receive the best overall care.

An important part of starting an integrated practice, points out Dr. Hansen, is finding partners that have the same patient care goals and practice ideas, and understanding that both parts are critical.

The integrated practice model, says Dr. Buboltz, “lets both the optometrist and ophthalmologist practice to the highest scope of their training, including more surgery time for the ophthalmologist.” ■

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Targeting for the Presbyope

By Derek Cunningham,
OD



YOU ARE LIKELY STARTING TO SEE MORE AND MORE PATIENTS that participate in some type of recreational activity that involves targeting or aiming. As the Baby Boomers and members of Generation X accumulate more disposable income and free time, many of them take up shooting as a hobby. Presbyopia will pose some challenges and limitations that can be extremely frustrating to these patients. Let's take a closer look at the unique challenges that a presbyopic patient will encounter and how eye doctors can help.

There are endless aspects of the visual system that can be enhanced to help a patient acquire (meaning visually detect), target and track an object. For the most part, it was thought that many of these principles would not change after presbyopia, but

this really depends on how deeply you want to assess visual changes in the aging eye. A recent article in the *Journal of Sport and Performance Vision* cites studies that show there are reduced visual metrics that drop off beyond near focus. These include but are not



Dr. Cunningham practices at Dell Laser Consultants in Austin, Texas, and is a co-founder and partner at Sports Vision Pros. He currently trains civilian competition and tactical military and law enforcement shooters in vision performance.

KVDKZ/STOCK.ADOBE.COM

limited to contrast sensitivity, glare recovery, saccades, tracking and reaction times¹. These presbyopia-related metrics are poorly understood in performance vision and will apply to many dynamic vision tasks in the aging eye. In many ways, these variables will affect a photographer or even a daily driver as much as they affect a shooter. Most of these metrics are far more subtle and less devastating than the loss of near focus, so let's concentrate on what the loss of near defocus does to a shooter.

To understand the effects of near defocus on a shooter, consider the type of shooting that most of your patients will be involved in. Keep in mind that shooting does not refer only to guns; it can include a variety of sports such as archery or even spear fishing. Most types of shooting fall into two categories—static and dynamic. There are also significant differences between rifle and pistol shooting that you should consider.

Static Shooting with a Rifle

A common type of shooting used in a situation like hunting will involve static shooting through a scope. Of all types of shooting, this one is least affected by presbyopia. The optics of the scope should be set at infinity, and the reticles—crosshairs, for example—that overlay the target should also be at that distance. As long as the shooter's vision is fully corrected, a good sight picture should

be as useful as for any pre-presbyope. The only real concern I have in this situation is dry eye. Dry eye prevalence increases in the presbyopic demographic, and dryness will degrade the image quality. This could hold true for any static target shooter, since they greatly reduce their blink rate while concentrating on a target. Reduced blink rate

“Keep in mind that shooting does not refer only to guns; it can include a variety of sports such as archery or even spear fishing.”

will lead to a break-up of the tear film and reduced vision quality. Dry eye can be an issue at elite levels in all categories of static shooting.

If the shooter is not using a scope, but open sights that are fixed to the rifle, then presbyopia can have a significant effect. As the butt of the rifle is typically pressed against the shoulder of the shooter, the near sight is often as close to the eye as 4 to 6 inches (10 to 15 cm), and the far sight anywhere between 17 to 20 inches (43 to 50 cm) from the eye. These are accommodative dioptric values of 7 and 2 diopters! In most cases, the near sight does not require the resolution that the far sight does, but it is used for alignment during aiming. As a patient's presbyopia progresses, the process of aligning the front and rear sights becomes increasingly difficult. Stressful shooting tasks (timed competition shooting, for example)

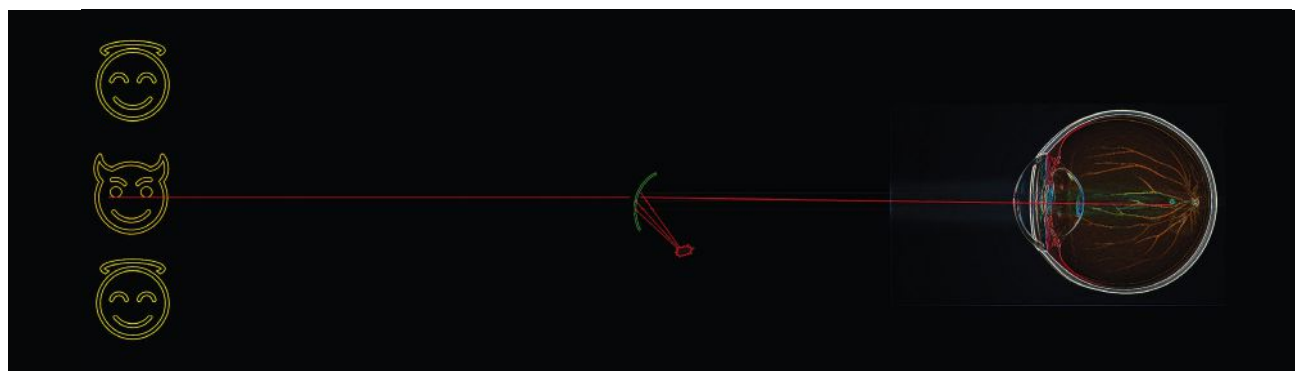


Figure 1. The image shows how a red dot sight uses an LED light to project onto a silvered spherical mirror. The result is a collimated light beam that gives the appearance of a red dot projected towards the target for the shooter. Image is courtesy of Sportsvisionpros.com.

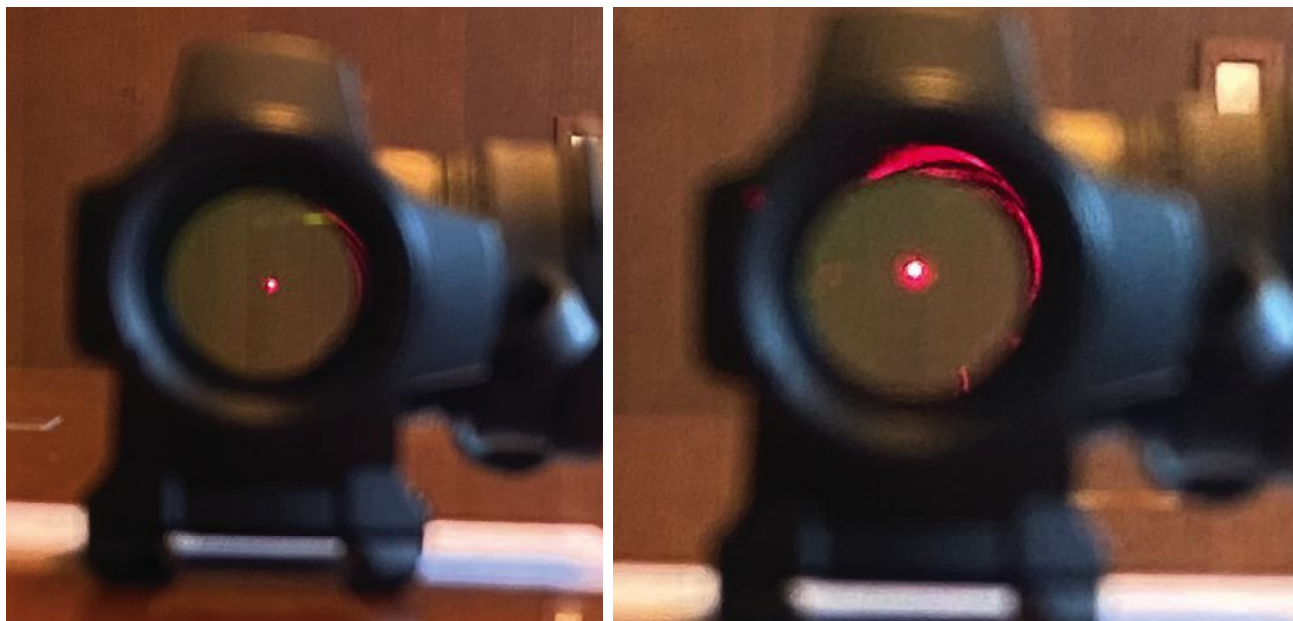


Figure 2. A shooter's view of the red dot when in focus (left) and defocused by one diopter to approximate a presbyopic image (right).

will amplify this difficulty, as will dynamic shooting tasks like trap or skeet.

Static Shooting with a Handgun

In general, handguns are far more difficult to shoot accurately than a rifle. Because the device is not braced against the body, aligning the front and rear sights is much more challenging. In addition, the distance between the front and rear sight is much shorter, making the subtlest misalignment more significant to the aim. The target distances will be much shorter for this type of shooting, but

“Most presbyopes use progressive lenses, but these lenses are problematic for shooters for multiple reasons.”

the technique of aiming is quite different than a rifle. Because alignment of the front and rear sights is more difficult, the shooter will focus on the front sight of the pistol as opposed to focusing on the target as in rifle shooting. This places more accommodative importance on the clarity of the front pistol sight located at the end of arms' length.

Early presbyopes tend to manage this very well, but advanced presbyopes can struggle significantly trying to clear the sight.

Static handgun shooting will also become problematic for the shooter because they must transfer their focus from the handgun sights to the target and back. This, in essence, is accommodative rock, and can greatly slow a presbyopic shooter's target acquisition time.

There are some devices that can help the presbyopic handgun shooter tremendously. Red dot sights are aiming devices that have become popular for their accuracy and speed of acquisition. For presbyopes, they provide significant aid due to their ability to project an aiming dot onto the target. This allows the shooter to maintain their focus on the target and avoid almost all of the presbyopia-related limitations of handgun shooting.

Red dot and holograph sights—the same concept as red dot but using a projected holograph reticle—can also be fitted to tactical rifles, giving a forward-projected sight that benefits presbyopes in the same way that red dots do.

Dynamic Shooting (for both rifle and handgun)

The visual demands of dynamic shooting—when either the target, the shooter, or both are moving—are exponentially more complex than static shooting. Now, we are also concerned with factors like peripheral awareness, saccades, multiple object tracking and depth perception.

Vision correction for these patients is not straightforward. Most presbyopes use progressive lenses, but these lenses are problematic for shooters for multiple reasons. First, the design of the lens will require head movement in order to gain accommodation, destabilizing the aiming axis. Second, the peripheral distortion of the lens will affect the target as an object is tracked. And third, most of these lenses are not fit in appropriate shooting safety frames. That leaves the majority of shooters having to wear another pair of safety glasses over their progressives. The more refractive planes, the more image distortion occurs.

I prefer to have my shooters wear contacts for correction as opposed to spectacles. Beyond the advantage of easily accommodating proper safety eyewear, contact lenses have the benefit of reducing peripheral distortion. Presbyopes have their own challenges with this form of correction. Many patients in this age group are not eager to try contact lenses if they have not worn them before. This group of patients is also very detail oriented and sensitive to image quality. Although the new multifocal contact lenses are much better than they used to be, most shooters will feel that the static image quality was better with their glasses. Note that this is a separation that is almost negligible between monofocal contact lenses and spectacles. The trade off with image quality is often worth it for more dynamic vision and better safety.

If a patient desires surgical correction for presbyopia, we have had good success with new generation presbyopia-correcting IOLs.

I have now had several competitive shooters win national competitions after refractive lens exchange. The barriers here are the risks of surgery, and cost.

One of the most significant developments for presbyopic shooters may be available to us in a year or two. Currently, several companies are developing eye drops indicated to treat presbyopia. The drops will work by constricting the pupil for several hours, providing a pinhole effect at near. I would not expect these drops to help an emmetrope read a pill bottle at 10 inches, but it certainly should give a big boost to clarity at the intermediate distance. For some, the constricted pupil may even provide increased clarity at distance. For shooters, this should allow the presbyopic eye

“Beyond the advantage of easily accommodating proper safety eyewear, contact lenses have the benefit of reducing peripheral distortion.”

to function as close to the pre-presbyopic performance level as possible.

I foresee almost every presbyopic shooter benefiting from presbyopia-correcting drops. The Emmetropes are the easiest and most obvious group, but it will go beyond that. In tandem with these drops, spectacle wearers could benefit from optically superior single vision glasses in appropriate safety frames. The contact lens-wearing presbyope can also benefit from the clarity of single vision lenses. Even the presbyopia-corrected IOL patient should see an added benefit from using these drops.

It is important to understand the visual demands of your patients that shoot, both professionally and recreationally. Presbyopia will require adjustments for these patients, but every eye doctor has the tools to keep these patients on target. ■

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Ensure a Successful Contact Lens Fit For Your Presbyopic Patients

By Micaela Crowley, OD

APPROXIMATELY 1.8 BILLION people worldwide are currently affected by presbyopia.¹ According to the 2020 report on International Contact Lens Prescribing, only 14% of all soft contact lens fits are for multifocal designs. When considering presbyopic contact lens wearers alone, 52% wear multifocal contact lenses, 10% wear monovision contact lenses and the remaining wear distance-only correction contact lenses with glasses for intermediate and near tasks.²

Some contact lens fitters may avoid multifocal and monovision contact lens fits due to their challenging nature and potential for requiring more chair time. However modern technologies, fitting techniques and appropriate candidacy selection can make all the difference in ensuring success for both the patient and doctor.

Patient Selection

The ideal multifocal contact lens candidate is a longstanding contact lens wearer with early symptoms of presbyopia, who lives an active lifestyle and exhibits motivation to reduce dependency on glasses. While this exact person rarely presents to clinic, it does not mean the remainder of our patients should not be fit in multifocal contact lenses, or at least given the option to adapt.

Although not required, contact lens familiarity is ideal for first-time multifocal contact lens patients because it omits the frustration of learning how to handle contact lenses. Keep in mind these patients'

visual needs are for close vision and they may not have the near visual acuity necessary for insertion and removal. This is particularly the case for patients with both hyperopia and presbyopia.

A younger presbyopic age is preferred over a long-time progressive or reading single vision wearer. The younger the patient, the more of their own accommodative system exists to help get them through their day. They require less of a reading add in the multifocal contact lens itself. Another reason is that many older patients with presbyopia

"The ideal multifocal contact lens candidate is a longstanding contact lens wearer with early symptoms of presbyopia, who lives an active lifestyle and exhibits motivation to reduce dependency on glasses."

have become accustomed to progressive or reading glasses which accommodate a higher add and provide superior optics compared to a multifocal contact lens.

Last but certainly not least, an excellent candidate for multifocal contact lenses is a person who lives an active lifestyle compared to one who spends hours or entire days on the computer or reading. An active person will require less magnification in their contact lenses compared to one who works at a desk all day long. They would be much more accepting of the functional vision provided by multifocal contact lenses, as many presbyopia patients who pursue contact lens wear are doing it because they do not want to be burdened with glasses any longer.



Dr. Crowley provides comprehensive eye care at Lexington Eye Associates, a tertiary care group in Massachusetts. In addition to optometric care, she is director of dry eye and professional practice liaison.

Establish Realistic Expectations

This cannot be emphasized enough. Although, admittedly, many patients do not understand the limitations of vision correction with contact lenses at the presbyopic age until they go through the process themselves. However, it is crucial to outline a realistic visual expectation prior to starting the refit to a multifocal contact lens.

Preferably, identify the patient's needs and reason for wanting a multifocal contact lens. Be honest if they tell you that they want to be completely glasses free. Make sure you emphasize that vision will be clearer with glasses than it is with contact lenses. If you are honest from the start, the patient will not be surprised when this is the reality they experience during the multifocal fit process. Many

“Many patients are forgiving and willing to accept the limitations as long as they are prepared for what to expect.”

patients are forgiving and willing to accept the limitations as long as they are prepared for what to expect. Most patients are thrilled with the vision they do achieve with multifocal contact lenses and the fact that they do not need to reach for reading glasses to look at a price tag at the store, or juggle multiple pairs of glasses throughout their day.

Know Your Product

Various soft and custom multifocal contact lens options exist on the market to best suit you and your patients' needs. Contact lens manufacturers have really stepped up and offered more options and expanded parameters for our presbyopic patients than ever before. This stands true for astigmatic presbyopes and those in our older patient population who develop dry eye and require a daily disposable option.

Monthly Disposable Options

Biofinity multifocal contact lenses use Balanced Progressive Technology with two

different center-distance and center-near designs, and four add powers up to +2.50.³ The Biofinity multifocal is available in a toric design with cylinder power up to -5.75 in 5 degree increments around the clock.

Bausch + Lomb's Ultra multifocal contact lens uses a center-near three zone progressive aspheric design. The fitting is streamlined with only two add selections of either low, for up to +1.50 add powers, and high, for +1.75 to +2.50. The Ultra multifocal lens is now available for astigmatic patients with cylinder power up to -1.75 D around the clock in 10 degree increments.

Air Optix multifocal functions with its proprietary Precision Profile Design, utilizing center-near bi-aspheric optics to allow transition between distance, intermediate and reading. It is available in three add powers, including low, medium and high.

Biweekly Disposable Options

The newest multifocal contact lens released to the market is the Acuvue Oasys multifocal with Pupil Optimized Design. It is a center-near three zone multifocal lens with a proprietary pupil optimized design which accommodates for pupil size by both age and refractive error. It also exhibits a hybrid back surface with center aspheric and spherical periphery.

Daily Disposable Options

The Clariti multifocal contact lens utilizes a center near with progressive intermediate and peripheral distance design. This means it transitions from reading, to intermediate near, then intermediate distance, and finally, distance from the center to the periphery. This allows patients an easy transition at all ranges.

Three daily disposable options use the same multifocal design as their manufacturer's monthly disposable multifocal option. These are Alcon's Dailies Total 1 (same as Air Optix), Johnson and Johnson's Acuvue Moist (same as Acuvue Oasys Multifocal), and Bausch + Lomb's BioTrue (same as Ultra).

The MyDay Multifocal by CooperVision

is soon to be released to the market. While the specific design has not been revealed, it is confirmed to be different than any other daily disposable multifocals on the market. More to come with this lens!

Rigid Gas Permeable (RGP) Options

Various custom hard contact lens options exist for presbyopic patients, including multifocal, simultaneous and translating designs.

Bausch + Lomb's Boston multivision lens offers a back surface aspheric design for distance and intermediate vision with an additional +1.50 add for reading.

SOFT CONTACT LENS OPTIONS	RGP OPTIONS
MONTHLY Biofinity MF Ultra MF Air Optix MF	MULTIFOCAL Boston Multivision (B&L) Reclaim HD (Blanchard) Essential (Blanchard)
BIWEEKLY Acuvue Oasys MF	Golden Eye AFM (Valley Contax)
DAILY DISPOSABLE Clariti MF Dailies Total 1 MF AV Moist MF BioTrue MF Soon to be released: MyDay MF	Platinum Eye (Valley Contax) VFL 3 (Conforma)
TORIC MF Biofinity Toric MF Proclear Toric MF Ultra Toric MF Astera Toric MF (Alden)	TRANSLATING Buckley Bifocal (Valley Contax)

Blanchard Lab manufactures two multifocal RGP options, including the Reclaim HD and Essential lenses. The Reclaim HD is a bi-aspheric lens with various custom options to optimize vision at all distances while reducing aberration. The Essential multifocal utilizes both translating and simultaneous technology with a center distance in primary gaze and aspheric periphery with a series of add power options.

Valley Contax also offers three RGP options for presbyopic patients. First, the Golden Eye Aspheric Front Multifocal (AFM) uses a center distance design with front surface aspheric optics and back surface spherical fitting characteristics. This means the provider can change each independently without influencing or having to change the other. Their second option is the Platinum Eye which uses a bi-aspheric simultaneous multifocal design with an aspheric back surface and aspheric front surface for additional add power. Lastly, Valley Contax offers the Buckley Translating lens, or back surface spherical executive bifocal, for those patients who cannot tolerate aspheric optics. Just be sure the person's lid apposition is tight enough to hold the lens in place.

Use Your Resources

Last and certainly not least, use the resources provided to you by each manufacturer to ensure success with multifocal contact lens fits. There are various apps, websites and fitting guides available to streamline the multifocal fit. In the case of RGP lenses, utilize the consultants to help with any questions or troubleshooting that may arise.

Finally, enjoy providing this to your patients! It can sometimes be challenging but the reward and joy it brings to your patients will be worth every effort. ■

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What IOL Should I Recommend?

By Mitch Ibach, OD, and
John Berdahl, MD



Dr. Ibach is a residency-trained optometrist at Vance Thompson Vision in Sioux Falls, SD. He focuses on advanced anterior segment care including cornea, cataracts, glaucoma and refractive surgery.



Dr. Berdahl is a board-certified ophthalmologist practicing at Vance Thompson Vision in Sioux Falls, SD. His published work has primarily focused on the fundamental causes of glaucoma, MIGS and astigmatism management during and after cataract surgery.

MORE THAN FOUR MILLION Americans will undergo cataract surgery to restore vision clarity this year.¹ Added clear lens replacement surgeries (refractive lens exchanges) will be performed in patients with a clear but dysfunctional, partially accommodating lens who desire surgical correction. With the high safety standards and elegance of modern-day cataract surgery, one of the biggest decisions for patients is how they want to use their eyes after surgery with respect to glasses and contact lenses. Cataract surgery for many patients is an opportunity to correct distance or distance/near vision allowing levels of independence from glasses. As clinicians we need to be armed to confidently answer the question, “What IOL do you recommend?” Two cases will be reviewed to lay out a methodical plan to answer the aforementioned question.

CASE 1

Kenneth is a 76-year-old Caucasian male who presented for a cataract evaluation. Ken’s chief concern is “blurred vision” for over 1 year with additional concerns of glare and halos during night driving. Ken has no major systemic conditions or systemic medications that should affect his surgical outcome. He uses artificial tears on an “as needed” basis.

Entering manifest refraction (MRx) is OD: +0.50-0.75x100 & OS: +0.75-1.25x068

Slit lamp exam: Anterior segment was remarkable for *Demodex* blepharitis and meibomian gland dysfunction (MGD) in both eyes with mild-moderate nuclear sclerotic cataracts. The posterior segment was unremarkable with a vertical cup/disc ratio of 0.3v OU and a flat and clear macula OU (see Figure 1 - ONH/Mac OCT).

Step 1: Understand the demographics, habitual refraction, ocular health and biometry.

It is unfair to recommend against, or rather leave out, premium IOLs based on age, but age is important to consider. This especially is the case in younger patients (<60) having cataract surgery. This patient demographic has not experienced total presbyopia with minimal functional accommodation, and carefully educating on this point will lead to happier patients.

Second, a patient’s habitual refraction should be considered when making IOL recommendations. A near emmetropic patient commonly will have much different refractive goals than a mixed hyperopic astigmat who has worn glasses most of their life. Another habitual refraction to pay close attention to is the low myope who chooses to counteract their presbyopia by removing their glasses to read or apply make-up. This can be a terribly disappointed patient if a monofocal IOL is recommended, chosen and targeted for plano. In a

study on satisfaction after multi-focal IOLs, hyperopic patients had a higher satisfaction than myopes, with the lowest satisfaction level being in patients with habitual low myopia.²

Examining ocular health with a concentration on pathology that may limit best corrected visual quantity and quality is a must before making any IOL recommendation. In many cases, treating corneal comorbidities like ocular surface disease (OSD), epithelial basement membrane dystrophy (EBMD), or mild irregular astigmatism (IA) before surgery, then reassessing biometry, will lead to improved outcomes. Finally, zeroing in on biometry can help lead physicians in the IOL discussion. Patients with greater than 0.7D of corneal astigmatism will likely benefit from astigmatism correction whether delivered with optical correction or in their IOL. Consistent biometry measurements across multiple devices also leads to confidence and better refractive outcomes.

Step 2: Listen before you recommend.

In our practice, during the counseling process before cataract surgery, all patients in some variety will be asked, “Do you prefer to wear glasses for most activities after cataract surgery, or do you prefer to gain independence from glasses?” There are many ways to ask this question, but a patient’s reply will provide a guide for our IOL recommendation.

Next, we move into daily visual tasks and goals including their occupation and hobbies. Regardless of age, our world has gone small-screen with digital devices and reading tasks, and scrutinizing near vision is important.

In Ken’s case, he’s retired and cherishes his snow-bird lifestyle in his RV. He spends his winter months fishing and golfing in Florida before driving cross-country to be grandpa the book-reader and backyard T-ball coach.

Step 3: Match the technology to the patient.

In 2021, we are spoiled with multiple IOL options that are enticing for a patient. As physicians, our job is to recommend an IOL that can meet and exceed our patient’s visual

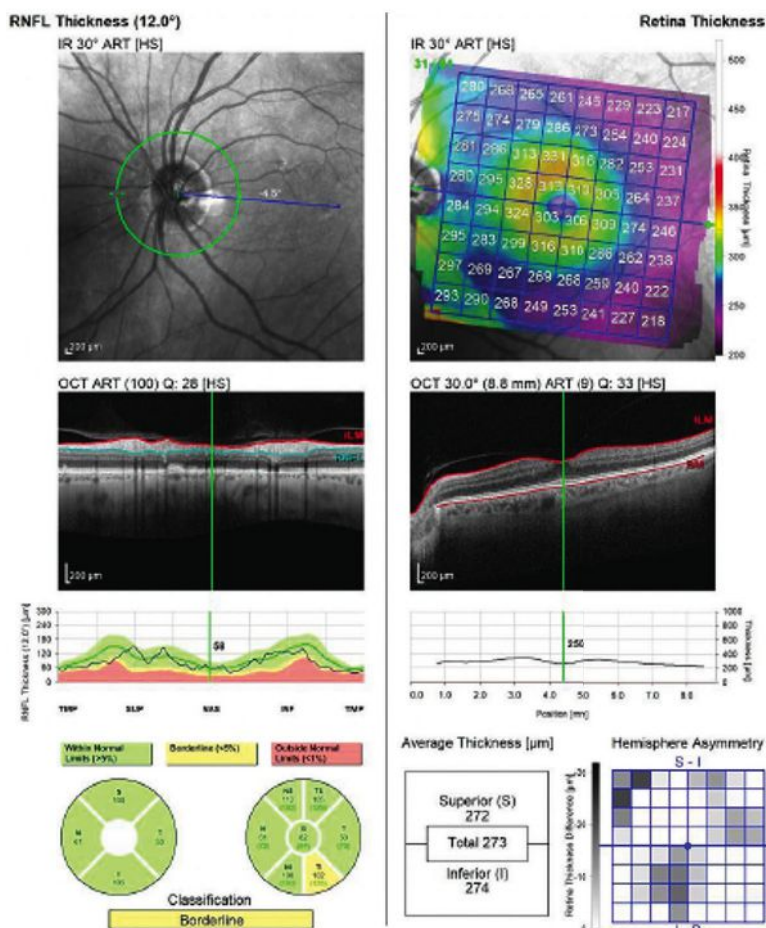


Figure 1. Optic nerve (RNFL) and macula optical coherence tomography (OCT) OS. Biometry is shown in figures 2 and 3.

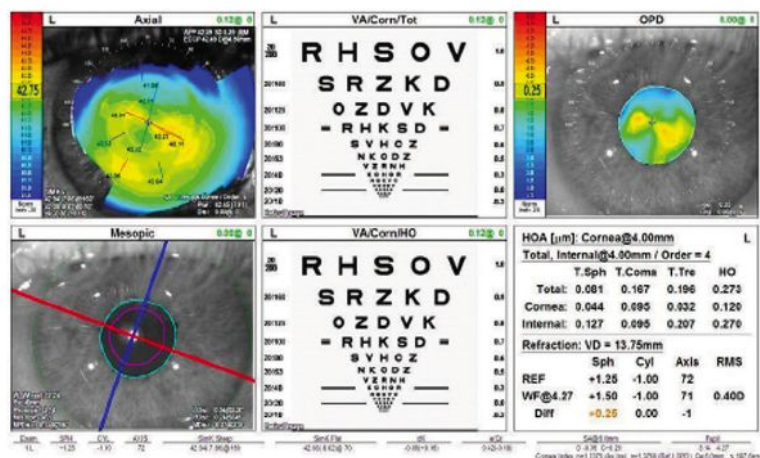


Figure 2: OPD scan (Nidek). Shows anterior corneal elevation (topography) top left with correlated keratometry values. Also quantifies cornea and internal higher order aberrations (HOAs). Finally, adds value for pupil size and comparison of the visual axis to pupillary axis (Angle K).

Figure 3.
Lenstar
Biometry for
OS. Gives a
predicted
lens power
for OS.

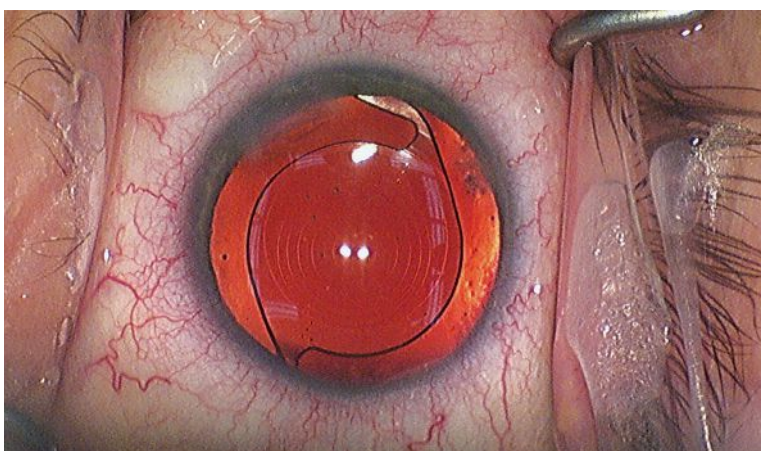
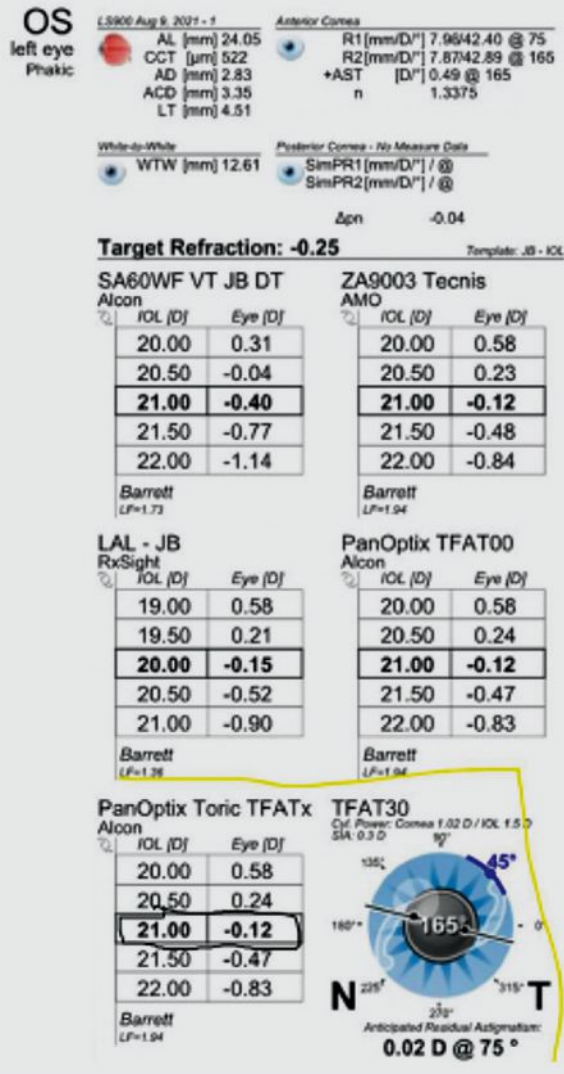


Figure 4. Dilated view of an implanted trifocal IOL (PanOptix, Alcon).

goals. There is no IOL that checks every box that our natural accommodating clear crystalline lens once did; so leveraging each IOL's positive characteristics is key.

Ken desired as much independence from glasses at distance and near that current technologies could provide. With this in mind, our recommendation was PanOptix (Alcon) (Figure 4), a trifocal presbyopia-correcting IOL (PC-IOL).

The goal for trifocality is a more continuous range of vision from distance to intermediate to near. A 2021 study published in *Ophthalmology* concluded that over 80% of patients with PanOptix responded “never” to requiring glasses correction, for all activities.³ Another strong option considered for this patient was Synergy (Johnson & Johnson), a diffractive IOL with a design focused on a “continuous range of vision,” according to the company.

With any lens recommendation, but heightened in the premium IOL space, setting pre-operative realistic expectations is paramount. These IOL technologies are powerful, but a pearl to keep in mind is to under-promise pre-operatively, and let the surgical outcome over-produce. With diffractive PC-IOLs, discussing post-operative glare and halos is recommended. Over time, in our experience, almost all patients will undergo neuro-adaptation, which lessens the awareness of positive dysphotopsias.

CASE 2

Heidi is a 49-year-old Caucasian female who traveled eight hours to see us for a cataract evaluation. Heidi had 8 cut radial keratotomy (RK) OD and 16 cut RK OS about 30 years ago. She later had a LASIK enhancement over her RK OD. Importantly she reports she had “very good” vision after the LASIK enhancement, and her refraction has stayed mostly stable over time.

Heidi previously showed her desire to lessen optical correction with RK, and she confirms this preference, if possible, with cataract surgery. Presently, she utilizes soft contact lenses with a monovision set-up OS for near.

Entering MRx in both eyes is a low level of hyperopia with astigmatism in both eyes. Anterior segment exam is remarkable for 8 cut RK OD and 16 cut RK OS (Figures 5 and 6). Heidi has visually significant anterior cortical cataracts in both eyes. Posterior segment exam is unremarkable in both eyes.

Step 1: Understand the demographics, habitual refraction, ocular health and biometry.

Heidi is a very active, young patient, who needs to undergo cataract surgery for her best vision. Heidi hasn't aged into complete presbyopia yet, and for patients similar in age to Heidi, this is an important education point. Her previous RK and the amount of irregular astigmatism on the cornea/topography will help to drive the implant conversation.

Step 2: Listen before you recommend.

Heidi's preference was to pursue premium implant options with a focus on predictability. Before her cataracts worsened, she was mostly happy with a monovision set-up in contact lenses.

Step 3: Match the technology to the patient.

The variability in corneal curvature measurements coupled with an unstable cornea post-RK makes this recommendation a more challenging one. Thankfully, her topographic shape demonstrates a centered flattening after corneal refractive surgery with repeatable keratometry values on multiple biometry devices. Despite good quality measurements, hitting the refractive target is more challenging in patients with previous corneal surgery, and this challenge is multiplied with previous RK. Our recommendation for Heidi was to focus on good quality distance vision (dashboard, computer), and use near optical correction as needed. Prioritizing predictability, we chose to do an optic adjustable IOL with the light adjustable lens (LAL, RxSight). We planned for a monovision initial target of plano OD and -1.00 residual myopia OS. With three

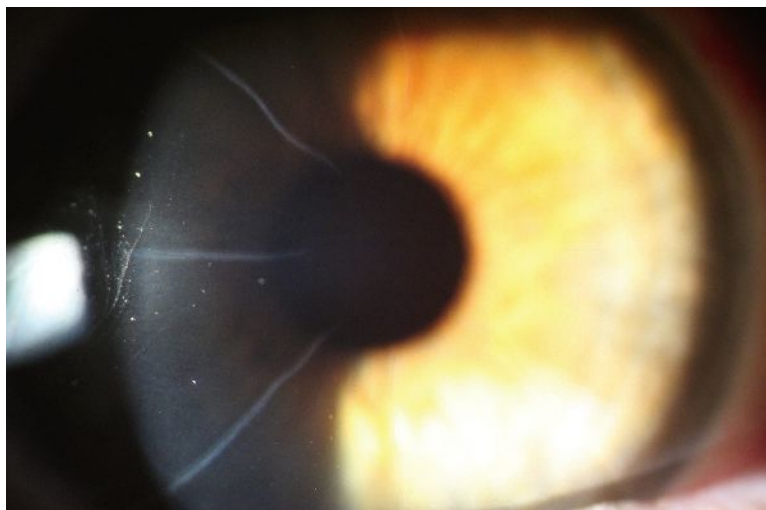


Figure 5. Slit lamp view of RK incisions OD.

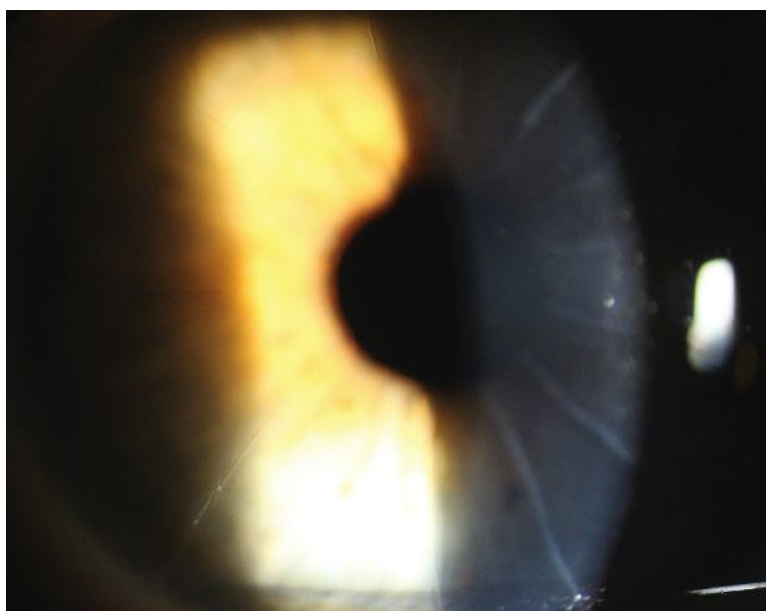


Figure 6. Slit lamp view of RK incisions OS. Figures 7 and 8 show biometry.

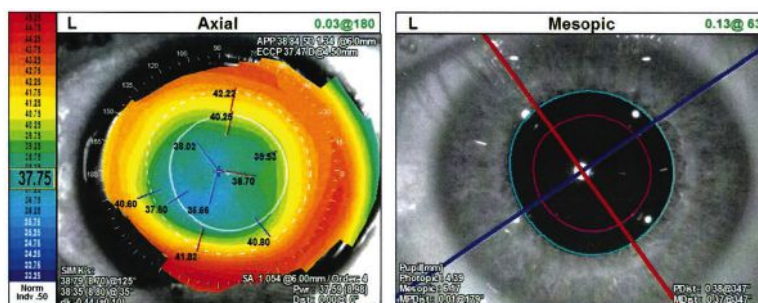


Figure 7. OPD scan (Nidek) of OS.

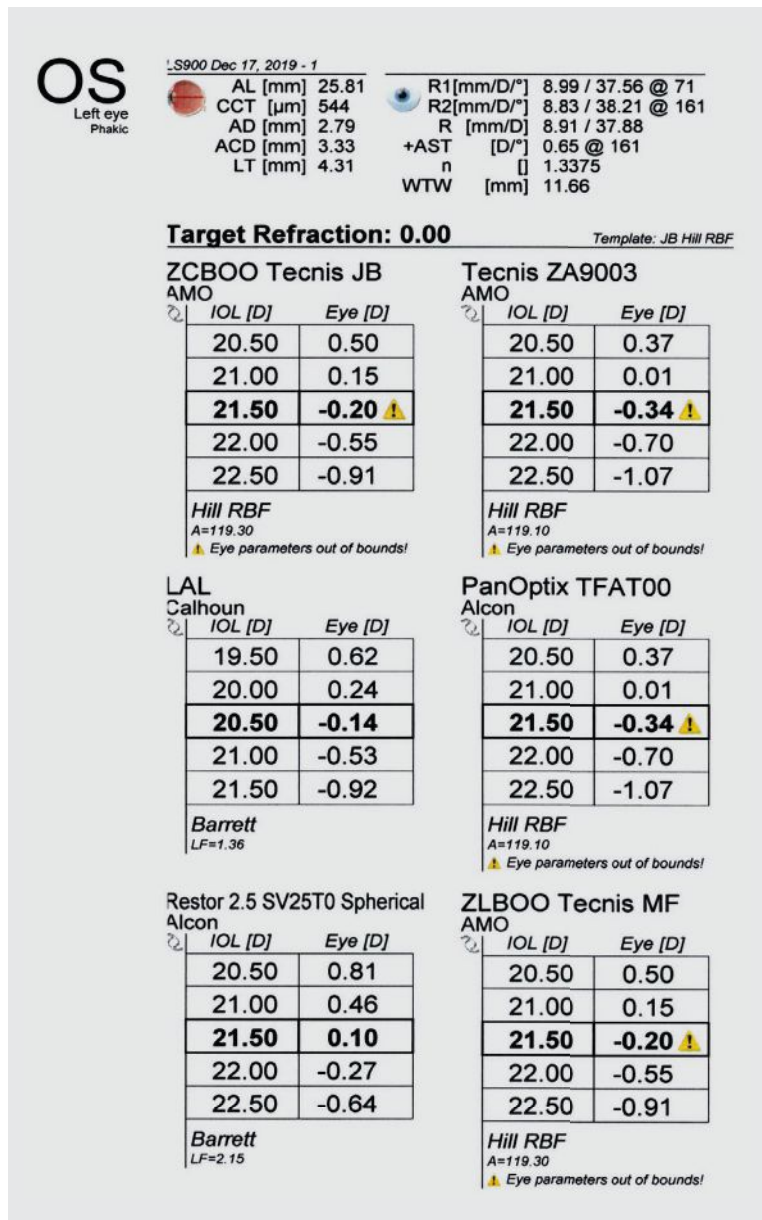


Figure 8. Lenstar biometry OS.

adjustments available, these “test drives” allow Heidi to have a real-life trial of the visual set-up and we can adjust as needed.

SUMMARY

As physicians, our patients rely on us in their moment of vulnerability before surgery to make a strong recommendation and execute the plan. With a surfeit of robust IOL technologies, the IOL recommendation serves as a precursor to our patients’ lifelong vision decision.

Over 70% of U.S. surgeons offer PC-IOLs in their practice, but patient adoption has a recent slight decrease to under 7%, according to Market Scope data.⁴ Despite this statistic, the appetite for near vision is unchallenged. A recent Asurion survey found Americans check their cellphone nearly 100 times per day, about once every ten minutes.⁵

As MDs and ODs, to achieve happy patients, the first step is understanding the PC-IOL technologies, the second step is gaining experience with PC-IOLs and the final step is confidently recommending the PC-IOL when appropriate. Whether the practice utilizes corneal enhancements (laser vision correction), optic adjustable IOLs (LAL) or a combination of both, this is essential in refractive precision and patient satisfaction. All patients after cataract surgery will demand some sort of near-vision correction, and when steps 1, 2 and 3 all match, physicians should confidently make an IOL recommendation. ■

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Upcoming Accommodating IOLs

By Mitchell A. Jackson, MD



TREATMENTS FOR PRESBYOPIA HAVE EVOLVED SIGNIFICANTLY, from over-the-counter reading glasses, to multifocal or monovision contact lenses, to monovision laser vision correction, to modern day premium intraocular lenses (IOLs). With presbyopia-correcting eye drops and their formula manipulations of topical pilocarpine or equivalent on the horizon, and laser scleral microporation in the not-so-distant future as well, the modern presbyope—in many cases—will be able to achieve visual freedom for the rest of their lives.

Over the last few years, we have enhanced our premium IOL armamentarium significantly with FDA approvals of the Vivity non-diffractive EDOF and PanOptix trifocal IOLs (Alcon) and Eyhance monofocal with “benefits” and Synergy combination trifocal-EDOF IOL (Johnson & Johnson). Other companies, such as Carl Zeiss Meditec and Bausch + Lomb, also have trifocal IOLs in clinical research stages.

However, limitations still exist with these current approved technologies, including complaints of glare and halo, reduced contrast sensitivity, positive and negative dysphotopsias, waxy vision, and neuroadaptation failure. The good news is that accommodating IOL technologies are on the horizon that should eliminate and/or address the drawbacks of current presbyopia-correcting IOL options. I will discuss four of these (PowerVision, Atia



Dr. Jackson is Founder and CEO of Jackson-eye, in Lake Villa, IL. He serves on the editorial advisory boards of several publications, is a board member and VP of the American College of Eye Surgeons, a founding member of the American College of Ophthalmic Surgeons, and founding member and past 2018 President of the Cataract External Disease and Refractive Surgery Society.

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“The good news is that accommodating IOL technologies are on the horizon that should eliminate and/or address the drawbacks of current presbyopia-correcting IOL options.”

Vision, Opira, and Juvene), but this is not an exhaustive list.

PowerVision (recently acquired by Alcon)

This is a fluid-based intraocular lens that enables near vision by squeezing a tiny amount of fluid (less than a drop) from the haptics at the periphery of the IOL into the center. When the eye attempts to move to its disaccommodated state, the capsular bag squeezes fluid the opposite way, deflating the lens and enabling distance vision.

Atia Vision (Shifamed)

This modular dual lens design includes a shape-changing accommodating engine and exchangeable front optic. The former is a hydraulic multiplier design, mimicking the natural dynamic accommodation mechanism of the eye. It maintains direct contact with the open capsular bag for efficient energy transfer from the ciliary muscle to the optic. The exchangeable front optic is a fixed lens that addresses each patient's individual prescription needs. The lens is available in multiple powers and degrees of toricity, and even offers an opportunity for future upgrades as optic technology advances and evolves.

Opira (ForSight Labs)

This sulcus-based, dynamic, shape-changing IOL features direct ciliary body engagement without zonular or capsular bag intermediaries. This IOL is haptic-fixated within the capsulorhexis and has a dynamic anterior surface and static posterior lens available for toric

correction and postoperative adjustment.

Juvene (LensGen)

This fluid-filled, modular, dual-design, accommodating IOL is designed to change curvature, mimicking the natural lens. Published data in the Grail Study (IDE)—with data up to one year on 58 implants—demonstrates excellent range of vision, effective lens position, and rotational stability. Study data reflects that 100% of patients achieved 20/25 at distance and intermediate corrected vision (CDVA, DCIVA), and 86% of patients achieved J2 at corrected near vision at 40 cm

“But initial data and designs appear to be promising, with the minimal risk of adverse events we are seeing with our current armamentarium.”

(DCNVA). In a recent JCRS publication no patients exhibited development of posterior capsular opacification.¹

All of these accommodating IOLs are still in investigational stages and not yet available in the U.S. for implantation. But initial data and designs appear to be promising, with the minimal risk of adverse events we are seeing with our current armamentarium. ■

Disclosures

Dr. Jackson is a consultant for Alcon, Johnson & Johnson, Bausch + Lomb, and Carl Zeiss Meditec.

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VIVITY IS EXPANDING THE UTILIZATION OF PC-IOLs

By Steve Lenier,
Managing Editor

SHAMIK BAFNA, MD, CALLS THE Alcon Vivity a game changer in the world of presbyopia-correcting intraocular lenses (PC-IOLs).

"Prior to this lens," Dr. Bafna said, "all of the lenses that had extended depth of field (EDOF) were diffractive technology lenses. And even though that's a fantastic technology, the downside is that because it splits light, it tends to cause visual dysphotopsias such as glare and halos."

He explained that Vivity is the first non-diffractive EDOF lens, which for the first time offers patients a range of vision, but with the visual disturbance profile of a monofocal IOL. This means patients experience less of the blur and dysphotopsias that occur with most diffractive lenses.

"The previous lenses on the market, the ones we're most familiar with, have diffractive rings, and are plagued by bothersome symptoms for a lot of patients, including decreased contrast, halos and glare," Dagny Zhu, MD, added. "The fact that the Vivity is non-diffractive—it doesn't have rings that split light—really mitigates a lot of the bothersome symptoms traditionally associated with diffractive presbyopia-correcting IOLs." She noted that in her experience, visual disturbances with Vivity are very comparable to those encountered

when using a monofocal lens.

"You're basically offering the best of both worlds," Dr. Zhu said. "The minimal visual disturbance profile and excellent quality of vision of a monofocal, plus the extended depth of focus that you would get similar to a low-add multifocal."

She says her clinical experience matches or

in some ways even exceeds the outcomes of the FDA trials, and that even though the near is not going to be as strong as a traditional multifocal, she's obtained good outcomes with Vivity. She notes intermediate vision around 20/25 or 20/20, and often pretty good functional near vision as well, around 20/30, or even 20/25 or 20/20 in a handful of cases.



Dagny Zhu, MD, is a board-certified ophthalmologist specializing in cornea, cataract, and

refractive surgery. She is Medical Director and Partner at NVISION Eye Centers in Rowland Heights, CA.



Shamik Bafna, MD, is a board-certified refractive and cataract specialist at the

Cleveland Eye Clinic and Clear Choice Laser Eye Center. He has been in practice for nearly 25 years and specializes in laser-assisted cataract surgery with a focus on reducing a patient's dependence on glasses.

Real Life Experience

Drs. Zhu and Bafna both began implanting Vivity shortly after it became available, and each has implanted a few hundred of the lenses.

Dr. Zhu said she's been "pleasantly surprised" at the great quality and range of vision that Vivity provides.

"I always tell my patients they may still need to use their readers for fine print," she said, "but overall, for

things like looking at their phone or their computer, they'll be very happy with the Vivity. And sometimes I'm surprised to see that patients get even better near than I had promised them!"

Dr. Zhu has encountered problems with

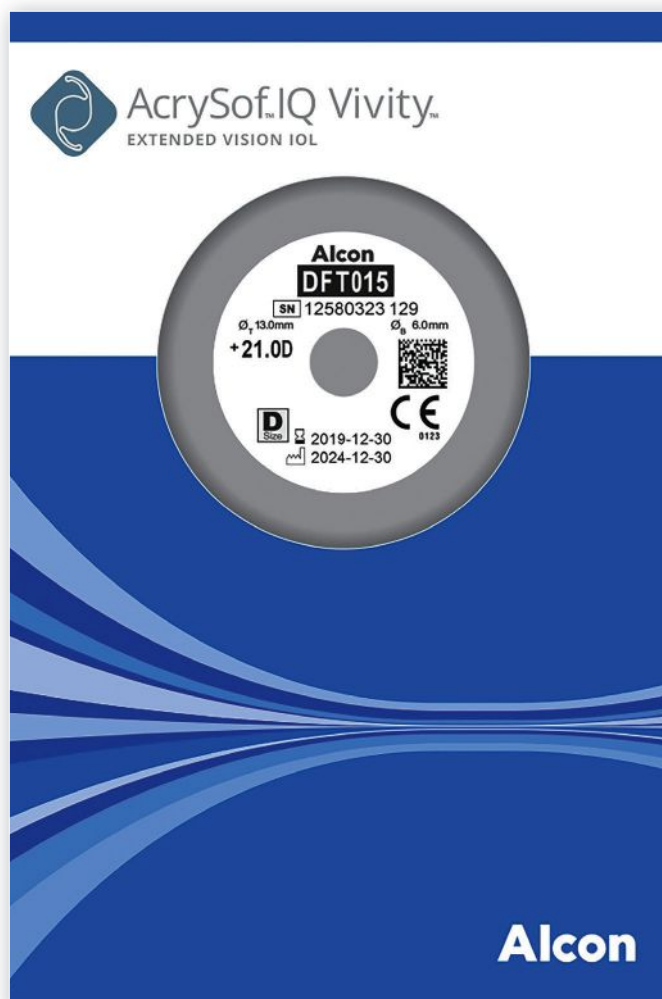
Vivity similar to those experienced with monofocal lenses. “There will always be a small handful of patients that still experience some halos and glare, some nighttime dysphotopsias, but you get that with monofocal lenses and even virgin eyes,” she said. “I haven’t had to explain any of these lenses for that reason. It’s just not as bothersome as it would be with a traditional diffractive lens.”

She noted that it’s important to keep in mind the Vivity is different than a monofocal lens, so care should be taken if considering it for use in eyes that are very irregular.

Dr. Bafna has found that his patients are very happy with their distance and intermediate vision, and they’ve got functional near vision. He pointed out one exception: “I think the only patients that may sometimes have concerns are my low myope patients where I employ Vivity,” he said. “They’re used to having very good near vision, and even though you may have a pre-operative discussion with them and explain that their near vision may not be as good as what they’re used to, patients tend to forget those conversations after surgery.”

Patient Populations

With any emerging medical technology, clinical experience allows doctors to explore different uses, and to identify what patients are



the best candidates. Both doctors say the addition of Vivity has not reduced the number of patients they treat with other IOLs.

Dr. Zhu pointed out the downside of Vivity is it doesn’t give as strong of near vision as a traditional diffractive multifocal lens. “So I’m actually using it concurrently with the trifocal,” she said. “And I decide between one or the other based on the patient’s exam, lifestyle, and personality.”

She explained that in terms of the patient exam, the Vivity is more forgiving. “If there is some ocular surface disease or a little irregularity of the ocular surface, I might be traditionally afraid to put in a diffractive lens,” she said. “But I feel pretty comfortable putting a Vivity lens in, again because it’s so similar to a monofocal in terms of the quality of vision.”

Regarding patient lifestyle, she said that for a patient who is Type A, or OCD, or the type that pays a lot of attention to the detail and quality of vision, or who does a lot of nighttime activities like driving, she feels the Vivity lens is superior to the traditional diffractive lens because of the reduction of dysphotopsias and increased overall quality of vision.

Dr. Bafna said when Vivity was launched he wasn’t sure where it would fall into his spectrum, especially because he loves using the PanOptix trifocal. “I found that Vivity allows me to take care of patients that I would not have been able to take care of with PanOptix. By employing this lens, I’ve almost

“Vivity is the first non-diffractive EDOF lens, which for the first time offers patients a range of vision, but with the visual disturbance profile of a monofocal IOL.”

doubled my utilization of presbyopic lenses,” he explained. “I still use the PanOptix with the patients I normally would, but now there’s a new subset of patients that I can offer Vivity to, whereas in the past I would have deferred to more of a monofocal lens.”

He also believes patients with a Type A personality, or with very high expectations, are potentially good candidates for this lens.

Dr. Bafna has identified several patient groups that may benefit from Vivity.

1. Patients expressing a desire to have a greater range of vision—some distance, some intermediate, and some functional near vision—who cannot tolerate any night vision

disturbances. This may be someone like a truck driver or an airline pilot. In the past, this group would have faced the tradeoff of tolerating some degree of dysphotopsias. Now, Vivity is a choice that won’t result in quite as much range of vision as a diffractive technology, but has a dysphotopsia profile very similar to that of a monofocal lens.

2. Prior refractive surgery patients. Dr. Bafna points out the biometry in a prior LASIK patient is not predictable, and therefore you may not want to employ diffractive technology in those patients. He said the Vivity is very forgiving since the defocus curve is fairly flat around emmetropia, so even if the biometry is a bit off, the procedure can still be a success.

3. Patients who don’t have a pristine eye. If diffractive technology is used in these patients, the optics will be off from that perspective. So for an eye with a mild epiretinal membrane, or a little bit of dry eye disease, or that has some drusen that isn’t yet AMD but has the potential of eventually developing further pathology, Dr. Bafna will employ Vivity. “Even if the patient with drusen has further degradation toward

macular degeneration, because I do not split light, all I’m doing is stretching it and shifting it through the X-Wave technology within this lens,” he said. “I’m able to get all of the light energy to the retina, so I’m not worried if there’s some loss of vision or similar.”

4. Dry eye patients. Even after optimizing the ocular surface prior to cataract surgery, some patients just have an inherent degree of dryness. Dr. Bafna says in the past, with diffractive technology, you end up where you feel their vision quality is not as good as you’d like it to be. But with Vivity, again because it’s not splitting light, he is confident he can provide that extended range of vision. →

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"I think that the **Vivity lens is a great gateway lens to presbyopia correction**, because the upside is so high with very little downside, as long as you set appropriate expectations from the start..."

Individualized Use

Because the compromise with Vivity is with near vision, Dr. Zhu believes the upcoming pharmaceutical presbyopia treatments may be a useful adjunct to Vivity.

"The great thing about these presbyopia-correcting drops," she said, "is when they come to market—depending on the label and study data—we may be able to adapt them to different situations. Not necessarily just the early presbyopic virgin eyes, but potentially for patients who have had surgery already: LASIK patients or pseudophakic patients with multifocal or EDOF lenses who just want a little more near."

Dr. Bafna uses Vivity for blended vision, which he says is very different from monovision. He said many patients are averse to monovision because they feel like their near eye doesn't see distance and their distance eye doesn't see near. But when you have a very small defocus of -0.50 to -0.75 , patients still feel like they've got very good distance vision, along with near vision and good stereopsis.

"With Vivity," he said, "I feel it's the closest thing to your natural phakic monovision because you do have that range of vision. So all you're doing is moving that range of vision down a little bit from where it normally would be."

Increased Access

Dr. Zhu ended by saying that no one wants to over promise and under deliver, which was the situation eye care professionals could find themselves in with some existing IOLs. "I think that the Vivity lens is a great gateway lens to presbyopia correction, because the upside is so high with very little downside, as long as you set appropriate expectations from



the start," she explained. "So I think it really increases the market, in terms of the percentage of surgeons who can start using presbyopia-correcting lenses and also the number of patients to whom we can offer presbyopia-correcting technology. I think the Vivity lens has really increased the number of surgeons and patients who can access that market." ■

Disclosures: Dr. Zhu is a consultant for, and recipient of, a research grant from Alcon. Dr. Bafna is a consultant to Alcon.



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