

TOOLS IN THE TOOLKIT: A SURGICAL PERSPECTIVE



Presbyopia-correcting eye drops will give doctors and patients more options.

JOHN P. BERDAHL, MD

The treatment of presbyopia and emerging presbyopes without cataracts hasn't changed much since Ben Franklin invented bifocals. Obviously, we can do better than that, as correcting presbyopia during cataract surgery has been one of the greatest areas of advancement over the last 15 years.

Attempts at corneal inlays to correct presbyopia haven't produced the outcomes we'd hoped for. From there, however, we did learn that aperture optics can help with close-up vision by increasing depth of focus. This knowledge has led to the development of innovative pharmacologic solutions, including a presbyopia-correcting eye drop by Orasis (OR-uh-sis) Pharmaceuticals, which is now in phase 3 clinical trials.

SURGICAL OPTIONS BUT WITH TRADEOFFS

Our recommendations for presbyopia correction are tempered by considerations of a patient's age and our assessment of risks versus benefits. Typically, we don't perform lens-based surgeries on emerging presbyopes unless they have additional refractive error, such as high hyperopia or moderate to high myopia.

Instead, we advise patients to use readers or bifocals, or we prescribe monovision or bifocal contact lenses. For some, we may consider monovision LASIK. While these are the most frequently discussed options for presbyopes in their 40s to mid-50s, there are some meaningful trade-offs with all of them.

Patients who use optical devices—eyeglasses and contact lenses—have to put them on, take them off, and care for them, and they can be broken or lost. Patients with monovision LASIK give up some distance vision in one eye in exchange for near vision in that eye, and both eyes aren't working together at all distances.

The lenses that are available for refractive lens exchange, which some people might consider, are not as good as our natural lenses were when we were 20 years old. There's a chance for positive dysphotopsias, patients don't get a smooth range of vision, and people in their 40s to 50s still have accommodative capabilities.

An eye drop that increases depth of focus, can be used on an as-needed basis, and takes advantage of the accommodation we still have in our 40s and 50s can be a great solution for many people.

LOOK FIRST TO YOUR PLANO PRESBYOPES

Within the emerging presbyope category are two subcategories: people who have refractive error and are moving to bifocals; and people who don't wear eyeglasses or contact lenses but are starting to need some help with their near vision. I think this eye drop becomes almost a no-brainer—and I don't use that term lightly—for the latter group.

In my opinion, presbyopia-correcting eye drops likely will be the treatment of choice for plano presbyopes who have never had to use an optical device. Their reasoning? "Why not just carry eye drops in my pocket and add a drop when I need to see up close?"

Don't discount patients who are already wearing eyeglasses or contact lenses and are now becoming presbyopic. Some may look at this as an

CURRENT STATUS OF ORASIS CSF-1

The Orasis (OR-uh-sis) presbyopia-correcting eye drop induces miosis to create a pinhole effect and increase depth of focus for improved near vision. The company reports clinical trial results to date have demonstrated significant improvements in near vision and a superior safety profile. The drop is currently in NEAR-1 and NEAR-2 phase 3 trials in the United States.

opportunity to finally be free of their devices, thinking, “I can get LASIK for distance and then just put drops in my eyes as needed for my up-close vision.” I also believe pseudophakes who have monofocal lenses will be able to benefit from these drops.

To me, however, presbyopia-correcting eye drops should definitely be our first choice for plano presbyopes.

BALANCING EFFICACY, SAFETY, AND COMFORT

Safety and efficacy are paramount for any pharmaceutical agent, and eye drops must be easy to use and comfortable. Side effects such as stinging and burning on instillation must be

minimal and short-lived, and preservative-free drops are preferred to avoid a negative impact on the ocular surface. Presbyopia-correcting eye drops must meet additional criteria.

From my point of view, first, we need to remember that we do have options for presbyopia that are essentially risk-free—bifocals, for example. Therefore, a presbyopia-correcting eye drop has to be close to risk-free. Second, it must be comfortable, and third, it must be tolerable. In other words, it shouldn’t make my eyes red or cause any other unwanted side effects. Does it last too long or not long enough? Those are the things that I care about the most.

With the appropriate balance of efficacy, safety, and comfort, I believe we can tilt the risk-benefit ratio in favor of the Orasis product so that patients want to use it. My impression from the publicly available data is that the Orasis drop is quite comfortable. I would have no reservations at all about putting it in my own eye. I think Orasis is going to have a compelling comfort and duration story.

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PRESBYOPIA CORRECTION THROUGH THE EYES OF A SURGEON



With limited surgical options, patients will appreciate the safety and convenience of an eye drop.

ELIZABETH YEU, MD

The decade between age 40 and age 50 is a dynamic time for near vision loss from presbyopia. People who never wore eyeglasses find they need readers, often before their friends need them, and myopes who wear eyeglasses or contact lenses suddenly discover they see better up close without correction. While it’s a confusing time visually for patients, it’s particularly

troubling for people who are close to emmetropia, as they worry that something is significantly wrong with their vision. I reassure them and then discuss their options.

LIMITED SURGICAL OPTIONS

When emerging and early presbyopes come in to see me as a surgeon for an evaluation, I can offer two options, although neither is ideal. I may suggest

monovision LASIK to give them as much freedom as possible. This takes some time preoperatively, however, as we do a monovision contact lens trial for those who are naïve to it. I also must stress to patients that this surgery will help them see at certain distances, but we cannot provide both near and distance vision in each eye of patients who are presbyopic, and their near vision will continue to degrade as they get older.

Refractive lens exchange (RLE) can be a viable option for some patients, mainly hyperopes, and I may consider it for emmetropes, depending on the patient’s age and motivation. I generally don’t offer RLE for high myopes, and even presbyopic patients with moderate myopia (–5.00 D or less) are not good candidates for RLE, because of their inherently higher risk of a retinal tear or detachment as myopes, and what they see and appreciate up close without correction may subjectively far outweigh the quality of vision they would have with our current presbyopia-correcting lenses.

As surgery candidates, presbyopic patients have limited options, particularly those who are younger and need only an extra diopter of near vision. They still have some accommodative amplitude. They just need a little extra “oomph.”

WHAT WE NEED FROM A DROP

It's so important for us to optimize vision and patient satisfaction from a symptomatic standpoint and from a visual stability standpoint, particularly when prescribing a topical therapy. Presbyopia-correcting drops should be ocular surface friendly with a low side effect profile. We don't want to induce accommodative stress, headache, browache, or any of the issues associated with miotics. The ideal solution will have the lowest strength of active ingredient to provide the desired effect and, preferably, will be preservative-free.

NOT JUST FOR PHAKIC PATIENTS

Now in phase 3 clinical trials, a pharmacologic solution developed by Orasis (OR-uh-sis) Pharmaceuticals to treat presbyopia is designed to provide that extra "oomph" as patients traverse that decade of presbyopia onset and beyond.

A presbyopia-correcting eye drop will open up more options for our phakic patients, allowing for a greater range of vision and greater independence from spectacles. A drop that can be instilled up to four times a day will enable patients to use it when they need it most.

I'm also excited to have the opportunity to prescribe this drop for my pseudophakic patients, particularly those who are somewhat myopic in the nondominant eye. By using this drop in the nondominant eye, these patients will have more freedom and avoid the frustration of searching for their reading glasses and repeatedly putting them on and taking them off.

NEW STRATEGY FOR CATARACT SURGERY PLANNING

Just as interesting as the utility of these presbyopia-correcting drops for a wide range of patients is the idea that we can plan ahead for our current cataract patients. Not all patients

are candidates for, or thrilled about the side effect profile of, diffractive multifocal IOLs. I'm most excited about prescribing these drops for patients who have mini- or modified monovision and/or extended depth of field or monofocal "plus" lenses. We recognize that the small aperture IOL (AcuFocus IC-8), diffractive and non-diffractive IOL options (Tecnis Symphony, Johnson & Johnson Vision; Acrysof Vivity, Alcon), and a boosted monofocal IOL such as the EyHance lens (Johnson & Johnson Vision) will provide an extended range of vision but will generally not exceed more than 1.00 D to 1.50 D of pseudo-accommodative amplitude. Now, we can tell patients that in the future, they can use this presbyopia-correcting drop if they feel they need a boost for reading more microprint size, such as a book, a newspaper, or a journal.

When planning a monovision procedure, we want to keep visual acuity for the two eyes as close together as possible but give as much freedom from spectacles as possible. Again, we could plan modified monovision with the near eye no more than 1.50 D to give good vision at the intermediate or computer distance and then prescribe presbyopia-correcting drops for patients to use for reading or close work.

As patients get older, traditional monovision becomes more difficult. Either the near eye doesn't have enough myopic error to support microprint (-1.50 D to -1.75 D) or the near eye may be too strong (-2.00 D or more) for intermediate vision, requiring patients to wear over-the-counter reading glasses or lean in to look at a computer screen. They're losing stereopsis and missing curbs and encountering other difficulties with night-time driving. A presbyopia-correcting drop gives us a strategic option as we're planning their surgery to target a weaker, more manageable myopia goal and potentially supplement with further pharmacologic correction. This will be particularly helpful for patients who don't qualify for multifocal lenses or are turned off by the potential for positive dysphotopsias that are associated with our presbyopia-correcting diffractive technologies.

EMBRACE THIS ADVANCED SOLUTION

As surgeons, we want to embrace all of the technologies available to us, and I believe a presbyopia-correcting eye drop fits this category. Not everyone will choose surgery, particularly when their options involve some level of compromise. I believe the Orasis drop will be a worthwhile alternative to spectacles for many of our patients.

What's more, by prescribing an advanced pharmacologic solution for presbyopia, not only are we giving patients the means to maintain their independence from spectacles, we're also demonstrating that we're on the cutting edge of all technology, whether it's surgical or not surgical. Knowing this, patients will be encouraged to move toward the advanced surgical options as they become more presbyopic.

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PRESBYOPIA & THE PATIENT'S PERSPECTIVE



We're all looking forward to trading readers for eye drops.

NICOLE FRAM, MD

For years, I've had patients who are in their mid-40s come in describing an acute visual decline that they fear is caused by something very serious like a brain tumor.

After confirming that they're experiencing the early effects of presbyopia, I explain that as we grow older our natural lens doesn't move the way it used to—just like the rest of our body doesn't move the way it used to—and we need help with reading glasses. Often, patients look at me and say, "You can reconstruct the front of the eye with lasers and rehabilitate people's vision, and this is all you've got? Reading glasses?" It's a humbling experience.

Until I reached my 40s. I didn't know what it was like to not be able to read my text messages or see my food. Now, I understand how presbyopia affects people's lives. We can't just overlook it.

WHERE ARE MY READERS?

In many ways, presbyopia is your first sign of aging. Psychologically, it's difficult to deal with the fact that you now have to think about certain things you were able to do without a thought—like what you'll do in a restaurant if you can't see the menu, or in my case, how I'll see the small numbers for my lens calculations. The idea that I always

have to have reading glasses with me is a whole paradigm shift.

Many patients don't want to constantly be putting reading glasses on and taking them off. Presbyopia-correcting contact lenses or even a single contact lens to mimic mini monovision are options, but with dry eye so prevalent in this patient population, contact lenses may be contraindicated. In the end, most people just have to accept the fact that they'll be dependent on readers.

Being able to prescribe a presbyopia-correcting eye drop that can bridge patients through the period from their mid-40s well into their 50s, before they need cataract surgery in their 60s, is exciting. This means we can actually help people with their day-to-day activities and with so much of what we do in the intermediate world. This seems like an unmet need that we've ignored for years.

KEY FEATURES OF A DROP

The beauty of having an eye drop that corrects presbyopia is that it's titratable. It puts control in the hands of the users. Patients can instill a drop when they need it, and if the effect starts to wear off, they can instill another drop, up to four times a day. On a day when they don't need to

be spectacle-free, they don't have to use the drop. I feel good about finally being able to give patients an alternative to readers. In fact, I have an Excel spreadsheet listing the patients that I have to call once the Orasis (OR-uh-sis) Pharmaceuticals drop is approved.

I'm excited about the Orasis eye drop, which is currently in phase 3 clinical trials, as the company reports it has a low side effect profile, is well tolerated, and is preservative free. The side effect profile is extremely important, particularly for a drop that causes miosis to increase depth of focus to correct presbyopia. A drop will be beneficial only if it mimics—or takes patients back to—their pre-presbyopic state without degrading distance vision and night-time vision. We don't want to take away one problem and cause another problem. In addition, we don't want to cause new symptoms like headaches and browaches, which may be associated with miotics. Potentially, the lower the concentration, the lower the side effect profile will be. I'll be looking closely at the clinical trial data, but potentially there are huge benefits to the Orasis product.

MEETING AN UNMET NEED

Pharmacologic drops to help with presbyopia management is an unmet need that will bridge a huge gap from the mid-40s to mid-50s and help our patients in incredible ways. It's something that has been neglected because we didn't have solutions. Now, we can offer patients an option that will enhance their quality of life. ■

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