



# Best Practices

in Integrated Care

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# Best Practices

in Integrated Care

This ongoing series, to be featured in each issue of *AOC* and its sister publication *CRST*, will clarify how eye care providers can best work together to provide patient-centered care of the highest quality possible.

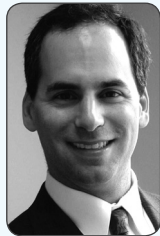
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# THE ROLE OF THE OPTOMETRIST IN COLLABORATIVE CARE FOR PRESBYOPIA

Communication is vital.

**BY J. CHRISTOPHER FREEMAN, OD, FAAO**



Like death and taxes, presbyopia is an inevitable part of life. When people reach their early 40s, they start to experience changes in vision that can be unsettling. The optometrist, who knows his or her patients' eyes better than anyone else, plays a key role in helping patients to adjust to presbyopia, to make the best choices regarding their vision correction, and to under-

stand the future changes in vision that they should expect as the aging of the human lens and visual system continues.

Anatomically speaking, presbyopia is caused by a hardening of the crystalline lens. From the patient's perspective, however, it is experienced as a change in vision—a refractive issue. Dealing with refractive issues is the bread and butter of optometric care, and therefore it naturally falls to the optometrist to see patients through this life change.

Part of the optometrist's role, especially in a collaborative care setting, is to prepare patients for the continued effects of their changing lenses, with the long view that their eventually inelastic, cloudy lenses will have to be replaced in a surgical procedure. In fact, our communication with patients about their presbyopia should always include surgical options, not just for eventual cataract surgery, but for potential options now, if they would prefer to try to minimize their dependence on glasses and contact lenses. Therefore, although the optometrist may play the dominant role in care for presbyopic patients, the surgeon should be only a step away as part of a collaborative care arrangement to tend to all the needs of these patients.

### COMMUNICATION IS KEY

A key word in the preceding paragraph was "communication." At its onset, presbyopia is a new experience for patients, and the primary eye care provider must help them understand their condition. This may involve a lot of conversation. Especially for patients who have never worn glasses, the increasing inability to read can be an upsetting change. We must acknowledge that we hear these patients' concerns and reassure them that what is happening to them is normal and can be easily addressed.

Patients' changes in vision caused by presbyopia can be upsetting for two reasons. First, patients are losing a function that they have always had. This is true even for patients who have worn glasses or contacts since childhood; they have always been able to read due to their natural accommodative ability, but now that is diminishing. Second, and perhaps more important, the onset of presbyopia is a sign of the aging process—in fact, often one of the earliest recognized signs—and patients may not be ready psychologically to accept the fact of their aging.

Although this change can be upsetting for anyone, it may be especially hard for the lifelong emmetrope. For a myope who has worn glasses since age 7, for example, the sudden need for a reading segment or a progressive addition lens may be no more of a life event than any other past prescription change. Then again, it may be. It is important for the primary eye care provider to try to get into the patient's mindset, empathize, and set the expectation that this is a progressive condition, and that every 1 to 2 years a stronger reading add will probably be needed.

### WHAT THE PATIENT WANTS

When the conversation about presbyopia occurs, the primary eye care provider must lay out options for the patient regarding how to deal with it. One should make it clear that presbyopia is a universal condition, and there are a number of good ways to address it, including glasses, contact lenses, and surgery.

I believe we optometrists should present the option of vision correction surgery to patients who wear glasses or contacts for any type of refractive correction, and presbyopia is no exception. We should make clear that presbyopic refractive surgery is an alternative, just as progressive spectacle lenses or monovision contacts are. The choice will depend on what the patient wants to do.

It may be a good idea at this point to ask budding presbyopes to fill out a patient information sheet or survey to help gauge their interest in different correction options and get an idea of their daily activities and lifestyle needs and wants. The questionnaire should probe, for example, whether near or intermediate vision is especially important due to some hobby or professional activity, or whether independence from glasses is highly valued because of an active outdoor lifestyle. All of these factors will help to point toward certain modes of correction and away from others. Of course the ultimate choice must be mutually agreed upon, with the patient's full consent and commitment.

The options for correction are many. Spectacle wearers may easily move to a bifocal or a progressive addition lens with a low add; many highly advanced progressive options are now available. Contact lens wearers may want to try a multifocal contact or a monovision approach, with one eye corrected for near vision. Contacts may also be attractive to emmetropes who have never worn glasses. For many emmetropes, simple over the counter reading glasses may suffice, at least in the early years.

### SURGICAL OPTIONS

Some patients may not want to deal with any artificial appendages for reading, and thus they may express interest in a surgical approach. Surgery is a big step and an important commitment for patients; after all, other than an inconvenient refractive status, in most cases their eyes are healthy. It is important for the optometrist to assess the patient's level of motivation and to set expectations for what can be delivered. What are the patient's goals? Does he want to be able to play golf and see the score card without glasses? Does she want to be able to continue using a computer terminal for hours every day in her job?

Once you understand the patient's goals, you must be honest about the degree to which they can be met. If the goal can be partially but not completely met, maybe that will be good enough to satisfy a highly motivated patient. If the patient's goals can be adjusted to fit reality, there is a greater chance he or she will be happy with the results of surgery. When realistic expectations are not communicated properly and goals are not met, the result is an unhappy postoperative patient,

whether for presbyopic or any other type of refractive surgical correction.

With all of this in mind, the optometrist's next step is to lay out the options that will work for this particular patient. Here, the age of the patient, the nature of the existing refractive error (myopic, hyperopic, or emmetropic), and the anatomic status of the eye (corneal thickness, lens clarity, etc.) will likely point toward one approach or another. In a relatively young patient, a corneal approach with monovision LASIK or a corneal inlay may be the best route. In an older patient who is beginning to show some changes in the lens, or, to use the term of the moment, signs of *dysfunctional lens syndrome*, a refractive lens exchange with a pseudoaccommodating or multifocal IOL may be the better way to go. Again, the choice will depend on the patient's goals, his or her level of motivation, and the anatomic landscape.

The next step is to refer the patient for surgery, and at this point communication is again key, this time with the surgeon. The optometrist must clearly communicate what he or she thinks the patient needs and wants. The optometrist must clearly convey the plan mutually agreed upon with the patient, so that the surgeon does not have to start from scratch and reinvent the wheel.

A crucial factor in integrated or collaborative care is the assumption that the referring optometrist really knows this patient's eyes—plus his or her needs and desires—and can speak as a sort of surrogate for the patient. The surgeon can then take this information, ask more questions, confirm or modify what the optometrist has conveyed, and proceed with surgical planning. This provides a smooth transition and allows the patient to feel that he or she is being collaboratively cared for, and it may help to relieve some of the anxiety that can surround surgery.

### EARLIER RATHER THAN LATER

In dealing with presbyopia, certain options are best introduced earlier, when the accommodative deficit is relatively small, rather than later.

This is the case with monovision. A modified version of monovision, or blended vision, can be an excellent choice for many early presbyopes. At this stage, they do not need a big difference in correction between the eyes, so the new strategy and corresponding small amount of anisometropia is easily adjusted to. They can learn to suppress the vision from eye that is not being used and see comfortably at both near and far. Then as presbyopia progresses and they need a greater difference in prescriptions, between the eyes they are used to the arrangement and can handle the incremental adjustments. If, on the other hand, a patient tries to adapt to mono-

vision after 10 to 15 years of presbyopia, when he or she needs a 2.00 D or 2.50 D add, the difference may be too great to achieve suppression, and the strategy is more likely to fail.

The same can be said about progressive addition spectacle lenses. I like to try to get presbyopic patients into progressive lenses as early as possible, as opposed to lined bifocal lenses. This is because the weaker the add strength, the less peripheral distortion there is. The patient can more readily adjust to the small amount of distortion, and then it is easier to adjust to the progressively greater distortion with incremental increases in add power over the years.

Progressive lenses become especially important as the patient reaches the need for a 2.25 D or 2.50 D add. At that point, with a bifocal lens, they will have too big a jump from the distance to the reading segment, and they will miss the intermediate range. With the common use of computers, tablets, and mobile phones in the modern age, the intermediate distance is increasingly vital.

One strategy that may be attractive to people who use a computer all day in their jobs is a vocational bifocal or progressive lens. This is a pair of glasses to be used mostly at the work desk, with intermediate correction in the top and reading in the bottom. Because the power difference between the top and the bottom is less of a change, a straight bifocal lens may be acceptable to patients for this application, rather than a progressive. They should leave this pair at the desk, however, and wear their regular glasses for the drive home.

### CONCLUSION

Vision care for the presbyope is not a one-time thing. Presbyopia is a progressive condition, and the eyes are continually changing. Listening to patient complaints is important, as is communicating proper expectations. It may be that strategies must be adjusted if the first solution is not working. There are many alternatives, and the collaborative care optometrist may have to present multiple options to find the one that works best for a particular patient. Remember, no one knows that patient's eyes better. ■

#### J. Christopher Freeman, OD, FAAO

- staff optometrist, Landstuhl Regional Medical Center, Department of Ophthalmology, Warfighter Refractive Eye Surgery Program, Landstuhl, Germany
- past president of the Optometric Council on Refractive Technology.
- [jcfreeopt@yahoo.com](mailto:jcfreeopt@yahoo.com); +49-6371-9464-6361

# AN INTERVIEW WITH GREGORY D. PARKHURST, MD; AND ARTHUR A. MEDINA JR, OD



Parkhurst NuVision, in San Antonio, Texas, is a leading center for vision correction surgery in the region. It is also a model for collaborative care between optometry and ophthalmology. Gregory D. Parkhurst, MD, physician-CEO of the center, performs

a comprehensive range of refractive surgery techniques, and Arthur A. Medina Jr, OD, serves as chairman for refractive surgery clinical care at the center. The duo work with a network of referring primary eye care providers in a collaborative model to provide refractive surgery services to a large swath of south Texas and beyond.

Their philosophy includes paying attention to what Dr. Parkhurst calls the three “lifetime vision events”—ocular maturity, the onset of presbyopia, and the development of cataract. It also includes a primary emphasis on refractive surgery that Dr. Medina has developed during his more than 30 years participating in collaborative refractive surgery care.

The busy duo sat down for a joint interview with AOC regarding how they manage presbyopic patients and how they are helping to educate the next generation of optometrists about collaborative eye care.

## REFRACTIVE SURGERY FIRST

**AOC:** Please describe how you present presbyopia-correcting options to your patients.

**Arthur A. Medina Jr, OD:** My philosophy with patients, regardless of their refractive error, is equal opportunity for all treatment options. That is, I always present all treatment options: refractive surgery, glasses, and contact lenses. And I purposely communicate them to the patient in that order, with refractive surgery first.

If they hear glasses or contacts first, they’ve already tuned me out by the time I get to refractive surgery. But when I mention refractive surgery first, you know, they’re expecting glasses and contacts because that’s what they’ve become accustomed to thinking that’s

all an optometrist does. But you can tell that it knocks them back on their heels a little bit emotionally. You’ll hear objections like, “No, I can’t have laser surgery, because I’ve been told I’m not a candidate” for one nonfactual reason or another. So it creates an opportunity to start giving them factual information about their options.

Obviously, in the presbyopic community specifically, we’re developing so many more options. I wish more of my colleagues would adopt the same refractive surgery-first approach, which I have been professing and attempting to teach over many years.

**Gregory D. Parkhurst, MD:** Dr. Medina has done a great job of spreading the word for that philosophy locally. We have a team of committed optometric primary care doctors in this market who do the things that he just mentioned. With the pressures on the optometric profession and the marketplace, we expect to see the integrated medical model become the standard.

One of the ways that we’re changing so that refractive surgery is becoming the norm for people’s vision treatment, is that we’re now training the next generation of optometrists who see refractive surgery as a legitimate first-line vision care solution for their patients. The way we’re participating in that effort here is that we have a full-time in-house rotation, in which four fourth-year optometry students rotate for a month through our refractive surgery center. During their rotation they get a real taste, touch, and feel for the way refractive surgery patients can be managed and the outcomes that they can achieve when the right procedure is selected for the right patient. They are doing the pre- and postoperative care, and they receive a good understanding of what refractive surgery can offer, not only for their patients, but for themselves as practitioners.

**Dr. Medina:** This is a unique program, where fourth-year interns from the Rosenberg School of Optometry in San Antonio get to see how our philosophy works in practice. In a typical, conventional optometric practice, the majority of practice growth comes from glasses, contacts, and routine eye examinations. So, to see refractive surgery treated as an equal opportunity treatment modality, and then get to see first hand the preoperative, intraoperative, and post-



operative care, and the long-term outcomes that have been achieved with that unique working relationship, it gives them a brand new perspective and elevates practice potential through new revenue streams in the medical model.

**Dr. Parkhurst:** Once these students rotate through our refractive surgery center, they have a new and different appreciation for the value of refractive surgery. Many of them come out saying, “I’m going to recommend this to all of my patients who qualify, and I’m going to have it myself.” Just last week, one of the students decided, after seeing the kinds of results we get, “I don’t know why I’m struggling with these contacts. I’m going to have LASIK.” So we did LASIK on her. There’s a different mindset when the optometrist integrates refractive surgery as a completely mainstream core business of the practice.

**Dr. Medina:** Let me give you another example of how we put refractive surgery first. When a prospective patient calls my office to make an appointment, the staff collects the normal demographics on the patient. When the patient is asked the purpose of the visit, the staff has been instructed to ask, “Is this examination for refractive surgery, glasses, or contact lenses?”

So the first introduction of refractive surgery as an option is done by the staff before the patient has even set foot in the facility. Once in the facility, patients see informational materials throughout the office about various refractive procedures. At the completion of the eye examination, the primary care provider tells the patient, “Miss Smith, you have mild nearsighted astigmatism, and your treatment options are a refractive surgical procedure, spectacles, or contact lenses. If you’re contemplating the refractive surgical procedure, we can set you up with our assistant, and we’ll bring you over to our laser center and offer you a complimentary consultative evaluation, and that will be at no expense to you.”



**AOC:** Do you have any data on how patients’ adoption of refractive surgery in your practice with this approach compares with that of other practices across the country?

**Dr. Medina:** Data that I have seen indicate that, for Americans who need vision correction, about 63% wear glasses, 16% wear contacts, and only 0.25% per year have corrective refractive surgery. In my practice, the rate of refractive surgery is at least eight to 10 times higher than that.

### THE SECOND LIFETIME VISION EVENT

**Dr. Parkhurst:** What we’re finding is that refractive surgery in 2015 is really becoming a mainstream, normal way of treating vision, compared to what it has been in the past. There are a lot of reasons why that’s the case. Not the least of which is the coming of the millennial generation, who have been born into and grown up with technology. They trust technology. They’ve seen their parents go through LASIK, and there’s a much higher adoption of refractive surgery in that demographic.

The other big thing that’s opening up refractive surgery procedures to many more patients is the option now of being able to treat the second of what we call the three lifetime vision events, which of course is presbyopia. We have patient education pieces that we leave in our primary care doctors’ offices that describe the three major lifetime vision events. The first is reaching ocular maturity. We know that about 90% of kids become full grown adults, as far as their eyes go, by the age of 18. That’s their first lifetime vision event. The second lifetime vision event is in their 40s when they hit presbyopia. And the third lifetime vision event is when they have cataracts, typically in their 60s.

For a long time, we’ve had great solutions for the first and the third life vision event, but not the second. A lot of people out there think they’re not candidates for refractive surgery, either because presbyopia has already occurred or because it is impending in their near future. But now we have surgical solutions for almost any vision disorder, including some great options for presbyopia with both corneal and lenticular approaches: the new corneal inlays, and better IOL technologies for refractive lens exchange. So we now have good solutions for all three of the lifetime vision events, and that message is being communicated to all of our patients starting at a young age.

**Dr. Medina:** What makes this particularly important is that, since 2010, the number of baby boomers over the age of 50 are increasing at a remarkable rate. So that patient population is immense and continuing to grow.

**AOC:** When the patient is reaching or approaching the presbyopic age, what sorts of discussions do you have?

**Dr. Parkhurst:** We've been using a couple of important diagnostic devices to help guide that conversation with the patient. We have quite a bit of experience using the HD Analyzer (Visiometrics), which provides an objective scatter index that gives us an idea of the crystalline lens status. We also use the iTrace (Tracey Technologies), which provides information on aberrations in the lens. Both of these diagnostic tools supply objective data about the clarity of the crystalline lens.

For presbyopic patients, the level of higher-order aberrations, or lack thereof, in their crystalline lens, and the overall health of the crystalline lens, helps us to know whether to guide them toward a lenticular versus a corneal approach.

So, when we do consultations for patients in their 40s, 50s, and 60s who are thinking about having refractive surgery, we of course collect critical clinical information like refractive error, and we look at anatomic information with topography, such as corneal health and thickness, but we also look at the lenticular quality. For example, the iTrace has what's called the dysfunctional lens index module that allows us to scan the patient with aberrometry and get an idea of how clear the crystalline lens is optically. It's been surprising to me how many patients who are pretty young, even in their 50s, already have lenticular changes that may not be visible at the slit lamp, but that show up on the dysfunctional lens index.

When we see that, that guides us away from a corneal approach and toward a lenticular one. For patients who have perfectly clear aberrometry scans of their crystalline lens, our approach is to talk about treating the cornea. There are many options for blended vision. We can do a mini-monovision offset with LASIK to target the dominant eye for distance and leave the nondominant eye slightly myopic.

For patients who don't adapt well to a simulation of blended vision or monovision, we talk to them about approaches that will accomplish distance and near vision in the same eye, because most patients who fail a monovision trial fail it because they don't like the distance vision in their near vision eye. Their close vision is fine with monovision, but they don't like the tradeoff that they give up in distance to accomplish that. So then the conversation goes toward procedures that will accomplish the same quality of near vision but still maintain their distance.

Now we have the ability to accomplish that with corneal inlays: Kamra (AcuFocus) has US regulatory clearance, and we expect the Raindrop (ReVision Optics) to be cleared likely next year. With these devices the patient can regain near vision without giving up distance. In our own data on the Raindrop, we've seen an average gain of 5 lines of near acuity with negligible or no loss in distance vision. We can consistently get patients with the Raindrop seeing J1 unaided and still maintain 20/20 binocular acuity. It's a strong corneal approach for presbyopia.

**Dr. Medina:** We address presbyopia as very much a treatable condition, with variable options depending upon what the patient's visual demands are. We concentrate on the needs of that patient instead of a sort of one-size-fits-all mentality. We have a command of multiple technologies, we apply real sensitivity to what the patient's needs and wants are, and then we select the procedure that will work best for that patient, custom designing the treatment for that patient's visual demands and expectations.

In my practice, we have a much higher acceptance of blended vision because of how cautious and careful we are in explaining to the patient what to expect and clinically illustrating, as closely as we can before surgery, what their expectations should be.

We also try to build expectations toward presbyopia in our younger patients. For example, for LASIK patients in their late 30s who have not reached presbyopia yet, we place in that patient's mindset that in the future we will have treatments for their presbyopia that can go under their corneal flap, and we might actually perform their flap at a different thickness, anticipating their future need for an inlay.

It's a real mindset, and an investment in educating patients not just to what their current needs are, but also to what their future needs will be. Because of this, we've developed a reputation. As you know, LASIK begets LASIK, as patients talk about their successful outcomes and refer other patients.

**Dr. Parkhurst:** I completely agree with that, Art. And although this conversation is focused on presbyopia, you really can't separate presbyopia refractive surgery from the overall concept of an integrated optometric practice where refractive surgery is a main component. Presbyopia is one topic, but the overall story is that you offer refractive surgery in your optometric practice, regardless of the patient's age.

## PATIENT EDUCATION

**AOC:** You are mentioning a lot of discussions with the patient. Where do they take place?

**Dr. Medina:** Well, first of all, there is a real overlapping of the education efforts. Typically it starts in the primary care optometric office. The patient has been seen in that facility for a number of years and has trust and confidence in that facility and the information that is disseminated there. But the information is also being coordinated between the primary care facility and the surgeon's facility. The information, the terminology, the explanations that the patient will hear in both locations are very similar, if not identical. So the patient feels that there's a seamless continuity of care, as opposed to an abrupt referral.

That requires ongoing education from the surgeon's facility to the primary care providers. We undertake a coordinated effort to

inform, educate, and expose our network of primary care providers to what and how things are being said in the surgeon's office. So the two components complement one another.

**Dr. Parkhurst:** It is important that the first conversation is taking place in the primary optometry family eye care office, so that patients are always told the same things every visit every year, these are the procedures for which you are a candidate. For example, "It looks like you're doing great with contacts, but don't forget you should not be wearing them 24 hours a day, so you need a backup pair of glasses. And if you ever have interest in refractive surgery, you look like you'd be a good candidate. Be sure to let me know when you have interest."

So the seed is planted over a period of years, so that when the patient finally is struggling with contacts, or some event occurs and they're finally ready to rid themselves of corrective eyewear, they know where to go. And they go and ask their primary eye care doctor about it.

## SELECTING THE PROCEDURE

**AOC:** As providers of refractive surgery, are any of the presbyopia surgical options more satisfactory to you than others? Do you lean in a certain directions?

**Dr. Parkhurst:** One of the things that we do as an organization is to take a comprehensive look at every available technology for every patient. We think about each one critically: Would this be a good procedure for this patient? We custom fit the right procedure to the right patient. In a facility that specializes in all refractive surgery, we have a complete toolbox. It's not like all we have is a hammer, so everything looks like a nail. There are many clinical scenarios where a corneal procedure might be better than a lenticular procedure in this patient, or vice versa.

It depends on the desires and needs of the patient, the visual demands of the patient, but also the ocular anatomy and health. What's the thickness of the cornea? What's the refractive error? Are we talking about high hyperopia or low myopia? How much astigmatism is there? What's the health of the crystalline lens? We take a look at all of that to make sure that we're finding the right procedure for the individual.

So we offer plenty of patients inlays, and we offer just as many patients refractive lens exchange. I can tell you that, recently, we've been pleased with the quality of the inlays that we have access to, and also the improved qualities of the IOLs. Both corneal and lenticular approaches seem to be getting better and better.

**Dr. Medina:** I can't agree more. Again, along with the assessment of the technologies available and the ocular anatomy, we pay attention to what the patient's visual demands are. A patient may have

similar anatomic components to another, but one is an accountant and the other is a truck driver. We may select a different technology depending upon their career and what their day-to-day visual demands are. We give them options and help guide them through what tool would best work for their visual demands.

That kind of attention to detail is what gives our patients the good outcomes that they share with their neighbors. These patients are exuberant about sharing their experiences with other patients. So that's another critical component to the success of how we treat patients.

**Dr. Parkhurst:** That also highlights the value of the integrated system where the OD and the MD work so closely together. The primary optometric physicians have the advantage often of having had a relationship with these patients over months or years. They have a better understanding of what a patient's visual demands are than a refractive surgeon can develop during a brief consultation. So there's value for the patient in having this two-provider team to care for their eyes. They have the clinical and professional advantage of access to the latest and best technology and a surgeon who focuses only on doing surgery rather than primary eye care, in combination with a primary eye provider who specializes in understanding the demands and needs of each patient. The patient benefits maximally with the integrated system of two providers, as do the providers. Everybody wins in this integrated model.

**Dr. Medina:** I cannot emphasize enough how hard we work at making it a cooperative arrangement, and that's what makes it so successful: Neither the primary care physician nor the surgeon is intimidated from having open, candid discussions and exchange of information about a particular patient's anatomy or visual demands or any factor that could best enhance that patient's experience and outcomes. I liken it to how the cardiologist and the cardiovascular surgeon work closely together. That close working relationship does nothing but benefit the patient and the patient's outcome. ■

### Gregory D. Parkhurst, MD

- physician-CEO, Parkhurst NuVision, San Antonio, Texas
- [gregory.parkhurst@gmail.com](mailto:gregory.parkhurst@gmail.com)
- financial disclosure: consultant to ReVision Optics

### Arthur A. Medina Jr, OD

- chairman of refractive surgery clinical care, Parkhurst NuVision, San Antonio, Texas
- [art.medina@ymail.com](mailto:art.medina@ymail.com)
- financial interest: none acknowledged



# IS DYSFUNCTIONAL LENS REPLACEMENT LASIK FOR THE BABY BOOMERS?

The terms *very early cataract* or *precataract* are dismissive and imply that the patient's only option is to wait for surgery.

BY GEORGE O. WARING IV, MD



Patients in their mid-50s to 60s often present for a LASIK evaluation because they no longer want to use glasses for both distance and reading. These baby boomer patients have difficulty seeing at distance, due to congenital ametropia, and at near, due to their progressive presbyopia. They do not come in stating that they cannot drive at night due to glare;

instead, they are seeking an elective procedure to provide spectacle independence. For many years, we performed LASIK on these types of patients. However, they would frequently come back complaining that their LASIK had “worn off.”

In my practice, we began paying attention to the source of the issue for these patients: the aging of the crystalline lens. Using an advanced ocular analysis and including a digital “lens-centric” examination, we often find that baby boomer patients presenting for LASIK do not have clear lenses; instead, they have *dysfunctional lens syndrome* (DLS), a clinical entity that has been overlooked and inadequately characterized for years. DLS describes a constellation of ways that the crystalline lens progressively becomes dysfunctional due to aging, including opacification and loss of accommodation. Additionally, higher-order aberrations increase in the aging lens, and exacerbation of narrow angles may also occur.

The term *dysfunctional lens syndrome* characterizes the dysfunctionality of the lens as a spectrum of changes that occur ubiquitously with age. Part of the rationale behind the terminology is to avoid the use of the terms *very early cataract* or *precataract*. These terms are dismissive and imply that the patient's only option is to wait for that very early cataract to

“Dysfunctional lens replacement for DLS is becoming increasingly popular in our practice, and patients respond well to this treatment because we educate them appropriately.”

ripen or for that precataract to become a cataract, delaying surgery by 5 to 10 years or longer.

Dysfunctional lens replacement for DLS is becoming increasingly popular in our practice, and patients respond well to this treatment option because we educate them appropriately. Combining the use of dilated Scheimpflug imaging and associated densitometry with the AcuTarget HD (AcuFocus) double-pass wavefront diagnostic device, we take patients on a digital tour of their eyes, showing them their dysfunctional lens and the resulting light scatter. The AcuTarget HD generates an ocular scatter index, which gives patients a score for their quality of vision. A patient may have 20/20 visual acuity but have clinically relevant light scatter (Figure). Showing patients the light scatter (point spread function) and

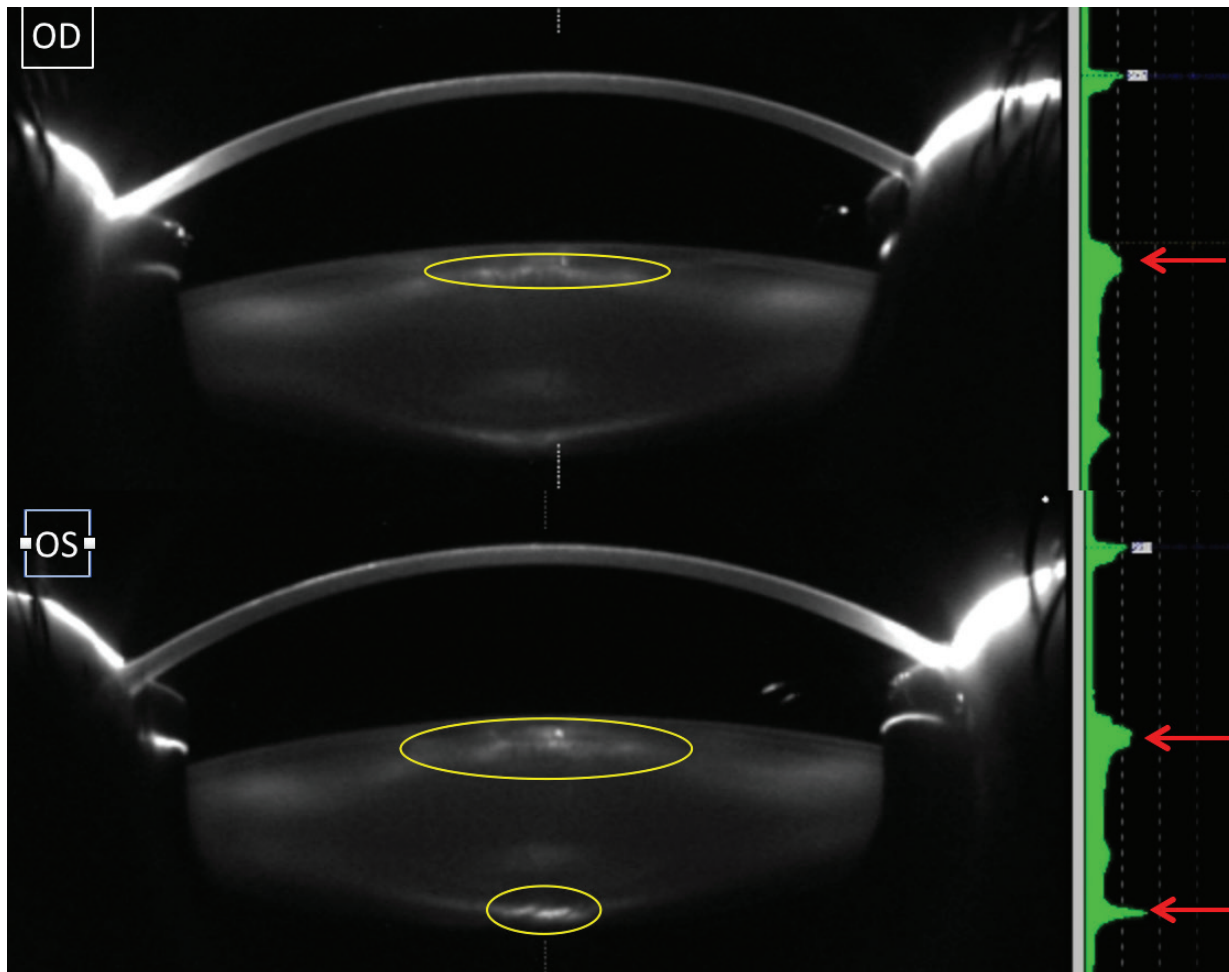


Figure. A patient may have 20/20 visual acuity but have clinically relevant light scatter.

increased ocular scatter index helps them to understand the value of addressing the source of the problem, the aging crystalline lens, and addressing it with a single procedure while preventing future formation of cataracts.

During the refractive consultation, we emphasize to all patients that DLS is a normal part of the aging process and that no action is required. For patients who wish to pursue surgery to treat presbyopia, dysfunctional lens replacement is presented as an option. As with all surgical procedures, we outline the relative risks and benefits of each technique. We are careful to point out that lens surgery is more invasive than LASIK, as the former is an intraocular procedure and thus carries increased surgical risks.

## CONCLUSION

In my community, patients are hearing about this treatment and seeking it out. Of course, when patients present with

a clear lens, unless they are high hyperopes, I advise them that they may be better candidates for a corneabased procedure. The paradigm is certainly changing. Dysfunctional lens replacement is an all-in-one solution, and this procedure may end up being considered LASIK for the baby boomers. ■

### George O. Waring IV, MD

- director of refractive surgery and an assistant professor of ophthalmology at the Storm Eye Institute, Medical University of South Carolina
- medical director of the Magill Vision Center in Mt. Pleasant, South Carolina.
- waringg@musc.edu; Twitter @georgewaring
- financial disclosure: consultant to Acufocus

# CORNEAL INLAYS ON THE HORIZON

The FDA approval of the first of these implants could mean more devices in this category will soon become available in the United States.

BY JOHN A. HOVANESIAN, MD



Emmetropic presbyopes are typically accustomed to perfect vision for most of their lives, making them challenging refractive surgery patients. Corneal inlays offer this patient population—once presbyopic—a more tolerable alternative to monovision by improving their near and intermediate visual acuity, typically in their nondominant eye.

This past April, the Kamra inlay (AcuFocus) received FDA approval, the first US approval for a technology of this kind. Two other inlays, the Raindrop Near Vision Inlay (ReVision Optics) and the Flexivue Microlens (Presbia), have received CE Mark approval in Europe and are progressing toward FDA approval in the United States.

## INLAY TECHNOLOGIES

### The Raindrop Near Vision Inlay

The Raindrop inlay is 2 mm wide and 30  $\mu$ m thick. Placed under a LASIK flap or in a 150- $\mu$ m corneal pocket, this hydrogel implant creates a dedicated near vision zone in the central cornea. Hydrogel, which is used in soft contacts, is biocompatible with the cornea and performs well from a refractive standpoint. Unlike the Kamra, which is dark in color and visible from the side in eyes with light-colored irides, the Raindrop inlay is transparent. As such, the device does not obstruct the surgeons' view of internal structures of the eye in the event later surgery is needed.

Patients' satisfaction (> 90%), visual acuity, and other measures of success are remarkably similar with the Kamra, Raindrop, and Flexivue Microlens.<sup>1</sup> Based on 1-year results, patients implanted with the Raindrop achieve a visual acuity of 20/40 as early as 1 week postoperatively and report a high level of satisfaction.<sup>2</sup>

ReVision Optics completed enrollment of its US phase 3 clinical trial in 2013. Six-month follow-up data from 75 of 100 sub-

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jects enrolled in the first portion of the trial are promising.<sup>1,3</sup> All subjects had a near UCVA of 20/25 (J1) or better in the treated eye and achieved 20/25 (J1) or better when tested bilaterally. Almost all of the subjects (97%) achieved an intermediate UCVA of 20/32 or better in the treated eye, and 99% achieved 20/32 or better when tested bilaterally. In terms of distance UCVA, 96% of subjects achieved 20/40 or better in the treated eye, and all subjects achieved 20/20 or better when tested bilaterally. Ninety-one percent of subjects gained 4 or more lines of near UCVA in the treated eye, as measured on a standard eye chart. None of the subjects experienced a loss of 2 or more lines of distance BCVA compared to their preoperative measurements. Almost all subjects (94%) were satisfied with the correction they received after implantation of the Raindrop inlay.<sup>1,3</sup> More recent data on a subset of patients who were tested with defocus found a functional range of vision of 3.50 D and no loss of contrast sensitivity in either photopic or mesopic conditions, with and without glare, with the Raindrop inlay.<sup>4</sup>

## THE FLEXIVUE MICROLENS

The Flexivue Microlens is a hydrophobic acrylic implant that measures 3.2 mm in diameter, with a 0.5-mm central hole and 15- $\mu$ m edge thickness. The lens, which is clear, provides a refractive add power of between +1.50 and +3.50 D, depending on an individual patient's needs. It is placed in a corneal pocket. Whereas the Kamra uses a pinhole effect to increase depth of focus, both the Raindrop and the Flexivue Microlens do not, making more light available in dim light settings with the latter two implants.

Earlier this year, Presbia received approval from the FDA to commence the second stage of its US pivotal trial. Published case studies suggest improvements in near visual acuity from J6 to J1 or 20/50 to 20/20.<sup>5,6</sup> Limnopoulou et al evaluated 47 emmetropic presbyopes. At 12 months, near UCVA was 20/32 or better in 75% of operated eyes, whereas mean distance UCVA was statistically significantly decreased from  $0.06 \pm 0.09$  logMAR (20/20; range, -0.08 to 0.26) preoperatively to  $0.38 \pm 0.15$  logMAR (20/50; range, 0.12 to 0.8;  $P < .001$ ), and mean binocular distance UCVA did not change significantly ( $P = .516$ ).<sup>7</sup>

## LOOKING FORWARD

The Kamra's availability in the United States suggests that it will not be long before the other inlays are also approved, giving surgeons more technologies to choose from to best suit their patients' needs. Although the three inlays are available outside the United States, their use has been limited. Based on my expe-

rience, the FDA's approval will represent a level of safety and trustworthiness for inlay technology that will likely increase the use of all three implants around the world. ■

1. Hovanesian JA. Update on corneal inlays for the correction of presbyopia. Paper presented at: Hawaiian Eye 2014; January 18, 2014; Koloa, Kauai, HI.
2. Garza EB, Gomez S, Chayet A, Dishler J. One-year safety and efficacy results of a hydrogel inlay to improve near vision in patients with emmetropic presbyopia. *J Refract Surg.* 2013;29(3):166-172.
3. Business Wire. ReVision Optics receives FDA approval to complete enrollment in its phase III clinical trial with the Raindrop Near Vision Inlay for improving near vision in patients with presbyopia. <http://bit.ly/1SCGjcn>.
4. Hovanesian JA. Creating a range of uninterrupted vision using a non-refractive hydrogel corneal inlay. Paper presented at: The ASCRS/ASOA Annual Symposium & Congress; April 18, 2015; San Diego, CA.
5. Stojanovic NR, Panagopoulou SI, Pallikaris IG. Refractive corneal inlay for near vision improvement after cataract surgery. *J Cataract Refract Surg.* 2014;40(7):1232-1235.
6. Bouzoukis DI, Kymionis GD, Limnopoulou AN, et al. Femtosecond laser-assisted corneal pocket creation using a mask for inlay implantation. *J Refract Surg.* 2011;27(11):818-820.
7. Limnopoulou AN, Bouzoukis DI, Kymionis GD, et al. Visual outcomes and safety of a refractive corneal inlay for presbyopia using femtosecond laser. *J Refract Surg.* 2013;29(1):12-18.

### John A. Hovanesian, MD

- private practice, Harvard Eye Associates, Laguna Beach, California
- clinical instructor, Jules Stein Eye Institute, University of California, Los Angeles
- (949) 951-2020; drhovanesian@harvardeye.com; Twitter @DrHovanesian
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