Presbyopia: Exploring the final frontier

by Maxine Lipner **Contributing Editor**

The galaxy of presbyopia procedures continues to expand as ophthalmologists pursue lenticular, corneal, and scleral approaches to the stars.

While most of the refractive world has to this point been well explored, that's not the case for the final frontier of presbyopia. But practitioners are pioneering innovative approaches, from replacing the patient's lens with unique intraocular lenses to performing scleral relaxation and expansion procedures. Practitioners are shooting for the stars with multifocal and accommodating IOLs, small-diameter corneal inlays, excimer lasers, conductive keratoplasty machines, and more.

The presbyopic galaxy

Unlike other refractive difficulties, presbyopia affects everyone at some point. Understanding the cause of this universal phenomenon harks back to the underlying concept of accommodation, said Adrian Glasser, PhD, assistant professor at the College of Optometry, University of Houston.

"Accommodation is defined as an optical change in the power of the eye," Glasser said. This means that the crystalline lens must produce this optical change, making it pivotal to the accommodative process. Another very important feature is the ciliary muscle, which is the driving force in producing the accommodative change. "The ciliary muscle doesn't actually push directly on the lens, so all that is required is that the ciliary muscle undergo an accommodative movement inside the eye."

With accommodation, the legendary Hermann von Helmholtz postulated that when the ciliary muscle contracts, it releases the resting zonule tension, which otherwise pulls on the lens equator and keeps it in a relatively flattened, unaccommodated state. The release

CK rocket blasts off

of zonular tension enables the lens to “round up” to a more accommodative configuration due to the forces of the capsule on the lens, Glasser said. Researchers are not sure specifically what goes awry with the eye’s apparatus during the aging process. “One thing that has been identified is that some loss of accommodative movement of the ciliary muscle occurs,” Glasser said. There is, however, no accommodative decrease in the lens diameter in the presbyopic eye, as seen in the young accommodating eye.

“There are many contributing factors to the progression of presbyopia, but perhaps the weakest link in the chain is the failure of the crystalline lens to undergo accommodative optical changes in the presbyopic eye.”

A competing theory put forth by Ronald A. Schachar, MD, adjunct professor, University of Texas-Arlington, postulates that when the ciliary muscle contracts, it increases zonular tension at the lens equator. “He believes that with accommodation, the lens diameter actually increases slightly — that the edge of the lens is actually pulled out toward the sclera during accommodation,” Glasser said. “We tested the accommodative mechanism in rhesus monkeys and found no evidence to support this notion.”

Emanuel S. Rosen, MD, visiting professor of ophthalmology at University of Manchester Institute of Science and Technology, Manchester, England, said presbyopia is the result of the hardening lens. “There is a natural fact that the crystalline lens, like a tree, puts a new ring on it regularly,” Rosen said. “Every year or so it gets thicker, harder, and it doubles in weight, size, and thickness during a lifetime.” In the end, the rigidity of the lens keeps it from changing shape and accommodating. “The Schachar theory suggests that the lens is more flexible than we credit it for, but because of its expanding diameter, the … ciliary muscle tugs at the zonule are less effective. Hence, scleral stretching is supposed to apply a little more pressure to it. There may be a little mileage in that, but the underlying problem of a rigid lens is really fundamental.”

Lens options shine brightly

Today, many practitioners find themselves turning to lenticular wares, such as multifocal or accommodating IOLs, with the idea of replacing the patient’s presbyopic lens to provide near vision. R. Bruce Wallace III, MD, assistant clinical professor of ophthalmology at Tulane University School of Medicine, New Orleans, said various forms of refractive lensectomy can help many patients who do not want to depend on spectacles. Wallace calls this procedure, in which the lens is replaced with a multifocal or accommodative IOL, PRELEX (presbyopic lens exchange). “PRELEX is a word patients can remember, that they can tell their friends about.” The term helps to get the patient’s mind off a lens and onto a procedure, he said.

Currently, the multifocal AMO Array lens is the lens of choice for PRELEX. Use of the Array, however, does call for adaptation on the part of the patient. “The lens provides the retina with multiple imagery in all areas of focus at one time,” Wallace said. “The brain has to learn to tune out what it doesn’t need to see.” It can also take patients a while to adapt to the new near vision. “Many earlier studies suggested that the Array is a J3 lens — actually it’s a J1 lens in our experience, but it takes a while for the brain to learn how to use the near part of this lens.” Wallace said that hyperopes are better candidates for PRELEX than myopes, who often have fairly good near vision without glasses and tend to be difficult to satisfy.

Wallace has had excellent results with the technique due to careful patient selection. “We’ve not had any serious complications, but we do know that that could occur, because this is intraocular surgery,” he said. “There is the possibility of infection, of posterior segment pathology such as retinal detachments, particularly in myopes, particularly in people who have not had previous posterior vitreous detachments.”

Rosen agrees that lenticular surgery is best suited for hyperopes, particularly those with a high degree of error. “With the lens growing inside the eye, it tends to become crowded and they don’t seem to have the same retinal risks as short-sighted patients,” he said. “So, if you’re a good surgeon, removing the lens and replacing it, even with a monofocal lens in the long-sighted patient is, I think, a terrific process — they’re my happiest group of patients.”

I. Howard Fine, MD, clinical associate professor, Oregon Health Sciences University, Portland, in private practice at Oregon Eye Associates, Eugene, thinks lenticular modalities are going to dominate presbyopic approaches. “With lenticular modalities, we will be able to address the underlying refractive error, be it hyperopia, myopia, astigmatism, as well as presbyopia.” Fine has had good results already with the Array multifocal IOL. “We have done a lot of refractive lens exchanges and have great success with that. One hundred percent of our patients binocularly are at least 20/40 and J5 — so, they can drive and read a newspaper without correction.” However, the lens has been associated with halos around light sources at night in a minority of patients, he said.

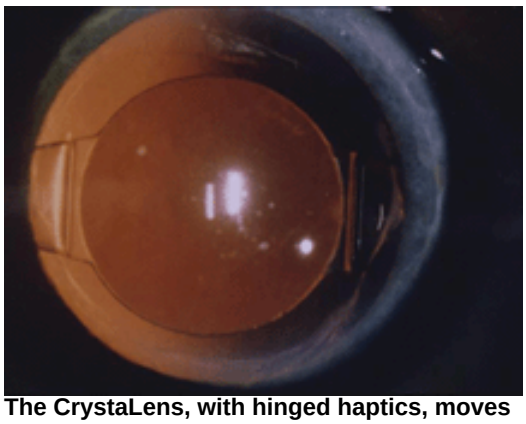
The only accommodative IOL under investigation in the United States is the CrystaLens (C&C Vision). Fine, who participated in the Food and Drug Administration study, found that patients got excellent results. “Virtually all the patients in whom we did bilateral implants ended up with at least 20/30 [distance] and J3 [near] — these are spectacular data,” he said. Fine also reported that 88% of binocular patients had 20/25 distance vision with J2 or better for near and 70.9% had 20/20 vision with J1 or better for near.

Stephen G. Slade, MD, assistant clinical professor, University of Texas-Houston, has also worked with the CrystaLens. The proprietary silicone IOL with hinged haptics moves forward during accommodation. The ciliary muscle bulks up as the patient squeezes it to accommodate, which displaces some of the vitreous body and pushes the lens forward, he said. His results have been good. “We’ve had results in the high 80 percentiles of people who can see J3 up close and still have excellent distance vision,” he said.

The corneal Milky Way

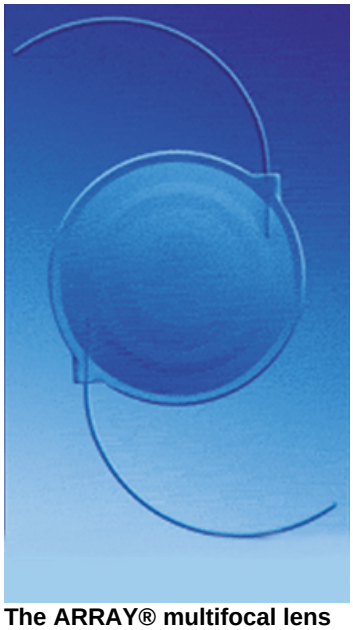
One of the gravity centers of the refractive presbyopic frontier is refractive monovision — a technique in which one eye is refracted for distance vision and the other for near. Most often, the technique has been paired with laser in-situ keratomileusis. Dimitri T. Azar, MD, director of cornea, contact lens, and refractive surgery services at Massachusetts Eye and Ear Infirmary and associate professor of ophthalmology at Harvard Medical School, Boston, has conducted several studies on refractive monovision. “We now know that about 80% of the patients who try this are successful,” he said. “It does not eliminate the need for glasses, but it clearly reduces the dependence on glasses,” although they may need both distance glasses and spectacles for reading.

The technique is not for everyone, however. Azar found in a study that patient opinions about the technique matter a great deal, regardless of the actual visual outcome. “If someone thinks that this won’t work, there is no point convincing them that it will. But if somebody thinks that this is a reasonable idea, then there is a high likelihood that it will work.”



The CrystaLens, with hinged haptics, moves forward during accommodation.

Of the current presbyopia approaches, monovision is the safest, Azar said. “It is the one that I would recommend to my patients because it’s the least aggressive. But it is, unfortunately, the most time-consuming in explaining things to the patient.” It is necessary to take the time to tell patients that they might not be happy with monovision and that it might be necessary to return to the operating room and correct the eye for distance.



The ARRAY® multifocal lens

LASIK isn’t the only refractive means to provide patients with monovision. With recent FDA approval of conductive keratoplasty (Refractec) for the temporary correction of hyperopia, many are looking to CK for off-label monovision correction as well. The device uses radio-frequency energy, delivered by a thin needle-like probe, to shrink corneal collagen in specific areas. Striae form between the points during the healing process, producing the constrictive band responsible for corneal steepening.

This monovision technique works well for patients older than 40, with up to 3 D of hyperopia, said Marguerite B. McDonald, MD, clinical professor of ophthalmology at Tulane University, director of the Southern Vision Institute, New Orleans. “With the first few patients, we tell everybody who is just starting out to pick somebody over 40 who is up to 2 D, if they really want to shine,” said McDonald, who

was the medical monitor for the FDA trial. The CK technique is a noninvasive way to induce myopia for monovision in a person who is plano or hyperopic.

"CK is an attractive alternative for patients who never thought they were candidates for LASIK."

— Marguerite B. McDonald, MD

Hyperopia results have been excellent (sidebar on page 19). McDonald has also had good results with monovision. "I did a 65-year-old man yesterday who was hyperopic and he walked in today J1 at near and 20/32 at distance," she said. CK is an attractive alternative for patients who never thought they were candidates for LASIK. "All those people who were afraid of cutting and flaps, they're all going to take to this like ducks to water." The technique is extremely safe. "We're not removing tissue — we're not cutting any tissue, we're not operating over the visual axis, we're not severing more than the occasional corneal nerve. There's no potential for huge disaster." In addition, the optical zone, as measured on topography, is bigger than with hyperopic LASIK by about 1 mm.

One additive technique being tried for "modified monovision" is the small-diameter corneal inlay (Bausch & Lomb). Richard L. Lindstrom, MD, clinical professor of ophthalmology at the University of Minnesota, Minneapolis, believes this technique holds promise. The practitioner implants a 1.5- to 2.2-mm diameter hydrogel lens with an effective power of +2.5 to +3 D in the nondominant eye. "This creates a bulls-eye center multifocal effect in the one cornea," Lindstrom said. "The patient sees near through the center and distance through the lens."

With this technique, the dominant eye is used for distance and the nondominant eye becomes multifocal. "The technique works quite well with contacts and intraocular lenses, and our results in about 10 patients … were quite promising." A typical patient ends up 20/25 and J2 in the implanted eye and 20/20 and J7 in the other eye with the technique. With both eyes together, the patient is usually at 20/20 distance, with J2 vision for near. "Halo and loss of contrast are limited to the nondominant eye, so complaints are minimal and stereopsis is retained," Lindstrom said. "For sustained fine work, reading glasses are necessary in some cases, but in our study patients, seven of eight [patients] examined at 5 years postop were independent of glasses for 90% of their activities and none complained of halos." The technique is reversible and requires minimally invasive surgery, he said.

Scleral orbits

Some practitioners are settling the foundation of their treatment on scleral ground. James C. Hays, MD, in private practice in Atlanta, believes that as the crystalline lens enlarges

with age, the ciliary muscle becomes less effective at tugging on the zonule. The best way to treat presbyopia is to expand the circumference of the ciliary muscle, putting more tension on the zonules, Hays believes. He uses anterior ciliary sclerotomy (ACS). Hays relaxes the sclera, decreasing the crowding effect on the ciliary body. Not very much expansion is needed — just a few hundredths of a millimeter in each spot. “This allows expansion of the ciliary muscle, a circular muscle, restoring the inner diameter and that allows the zonules to tighten up,” he said.

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Hays had promising initial results of approximately J3 at near; however, he found that the effect fades with time. “Our results with ACS have been such that early on if we do not put something into the incisions to keep them from healing … the effect fades out by 6 months to almost zero as the sclera heals,” he said. Hays recently began inserting titanium tissue barriers in the incisions. “It’s too early to know for sure, but the first guy took his patch off and he looked at his watch and he said, ‘Oh my God, I can see what time it is.’” The procedure is best suited to individuals who are within 1 D of emmetropia who are between the ages of 44 and 55. “I think the effect will make their vision like it was 10 years before.”

“SRP is the only procedure that gives a range of focus without affecting the distance vision at all.”

— Gene W. Zdenek, MD

Another technique is the use of scleral expansion bands (Presby Corp.), which are being used during the surgical reversal of presbyopia (SRP) procedure. Gene W. Zdenek, MD, medical director, Valley Multispecialty Surgery Center, in private practice in Reseda, Calif., said that increasing ciliary space by between 400 and 600 µm can do a lot to relieve the crowding of the ciliary muscle and enhance its effectiveness. Scleral expansion also changes the angle at which the ciliary muscle can pull on the zonules, making it more effective, he said. With the SRP technique, the bands are inserted posterior to the surgical limbus at the oblique axis 2.75 to 3 mm behind the surgical limbus, 400 µm deep into the sclera. For the past 5 years, Zdenek has performed the procedure on more than 100 patients. He finds that about 75% to 80% get enough accommodation to be relatively happy. In a group of 60 patients treated with the

technique, Zdenek found that patients got an average of 3.6 D of accommodation, with a range of 1 D up to 11.1 D. While there has been some regression, Zdenek also had some long-term success. “I have six patients who were done over 4 years ago; I just saw two of them in my office and they were accommodating between 4 and 6 D at over 60 years of age.”

This is the only procedure that restores true accommodation, Zdenek believes. “It’s the only procedure that gives a range of focus without affecting the distance vision at all,” he said. Multifocal lenses give a good range, but decrease contrast sensitivity, and the accommodating IOL offers a limited range, Zdenek points out. Clear lensectomy permanently changes the patient. SRP bands can be left in or removed if the procedure doesn’t work, offering an element of reversibility.

Looking beyond the frontier

Just as in the 1980s, the key progression in ophthalmology was based on the intraocular lens, and in the 1990s, it was LASIK, this is going to be the decade of presbyopia, Zdenek said. “Presbyopia is the last frontier of the refractive surgeon and maybe even ophthalmology, because we haven’t conquered it — but we will — it’s coming.” The answer will be connected to stopping the lens from growing, he said.

Implanted scleral expansion band (full circular band model)

Fine sees an innovative new lens as the answer. “Ultimately, there will be an injectable, flexible polymer.

Scleral expansion bands compared with a penny (band segment model)

We will remove the cataract through a 1-mm capsulorrhexis, inject that polymer to refill the capsular bag, then seal the capsulorrhexis. This lens will be flexible enough to allow for accommodation.” Such a lens would stabilize the vitreous base, making all patients, even high myopes, candidates. It could be available in as little as 5 years. He sees cataract and refractive surgery as soon coming together. “I think that this is really the last frontier. It is presbyopia that is going to result in the final total convergence of refractive cataract surgery and refractive surgery — they will become one field.”

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