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Feature

Presbyopia Calls on a New Generation

By Lori Baker Schena, Contributing Writer

As more and more Baby Boomers enter their 50s and 60s, America will be wading into a pandemic of presbyopia. Is ophthalmology prepared?

Presbyopia is one of the great certainties of life. That reality is hitting home, and hitting hard, across the United States, with more than 110 million Americans now over age 45. It's a reality that Jay S. Pepose, MD, PhD, medical director of Pepose Vision Institute in St. Louis, Mo., lives with every day, both personally and in his practice.

"As a 51-year-old emmetrope, I can't see the speedometer or radio when I drive, and I need reading glasses around the office, a fact that always puzzles my refractive patients," Dr. Pepose said. "I don't yet need cataract surgery, and so I am in presbyopic 'no-man's-land,' along with millions of members of my generation."

New breed coming through. Ophthalmologists are finding that the cataract patients of today are a new breed of individual. Even after age 60, many are far from retirement, and one can find them in their spare time on the golf course, playing tennis or running marathons. This is the generation of early adopters, who embraced LASIK eight years ago only to find themselves coping with presbyopia. They know excellent vision without glasses and expect to experience the same after cataract surgery. They want vision that allows them to work on the computer as well as knit a sweater. "For all these reasons," said Dr. Pepose, "cataract surgery is now refractive surgery."

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A Cornucopia of Corrections

There is no shortage of treatment options for presbyopia. They range from spectacles to refractive techniques and intraocular lenses. Each has its supporters and skeptics.

Spectacles

Marguerite B. McDonald, MD, noted that even bifocal spectacles have become technologically advanced. At the Joint Meeting in Las Vegas in November, she cited proprietary wavefront technology that is used in some progressive glasses and helps eliminate certain vision distortions associated with conventional lenses. This technology is featured in the Varilux Physio and Varilux Physio 360 (Essilor), and the lenses cost about 30 percent more than traditional progressives.

Ophthonix of San Diego manufactures iZon lenses, which use wavefront measurements of the eye to customize a correction. The company notes that these progressives are fully customized spectacle lenses that correct for conventional, sphere, cylinder and axis as well as higher-order aberrations of the eye.

While these progressive spectacles theoretically offer improvement over their lower-tech counterparts (and don't forget contact lenses—many patients are perfectly happy with monovision contact lens wear or bifocal contacts), it is apparently not enough for the current generation of presbyopic patients weaned on refractive surgery. Spectacles are old news, and even the idea of wearing readers is not bearable for some patients, contributing to the growing popularity in treatment alternatives for presbyopia.

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SURGERY

Scleral expansion bands. Though aspects of presbyopia remain a mystery, most

ophthalmologists accept a theory advanced almost 200 years ago by Hermann von Helmholtz, who proposed that when the eye sees distance, the ciliary muscle relaxes, causing the lens zonule and suspensory ligaments to pull on the lens and flatten it. When the eye views a near object, the ciliary muscle contracts, causing the lens zonule to slacken and the lens to return to a more convex form.

About a decade ago, Ronald Schachar, MD, challenged Helmholtz' theory, arguing that the ciliary muscle actually pulls on the crystalline lens' equator in an outwardly radial manner. The changes in lens shape result in a flattening of the peripheral surface of the lens and an increase in the curvature of the central region, allowing accommodation. Presbyopia occurs because the lens grows in size as it ages, crowding the ciliary muscle so that the muscle no longer works properly, increasing the lens power. His scleral expansion band technique to surgically reverse presbyopia is based on this theory.

Dr. Pepose was involved in the multicenter clinical trial of scleral expansion bands, but results published in the *American Journal of Ophthalmology*[1] showed that they only modestly improved near vision in approximately half of the presbyopic patients studied.

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LASIK. In the United States, monovision LASIK is one of the main surgical options for presbyopic patients, explained Samuel Masket, MD, clinical professor of ophthalmology, University of California, Los Angeles. Most of the investigational activity with LASIK is occurring internationally, with investigators studying presbyopic LASIK, also known as presbyLASIK. This technique uses a multifocal ablation profile where the central zone is steepened for near and the peripheral zone is targeted for distance.

One supporter of presbyLASIK is Jorge L. Alió, MD, PhD, chairman of ophthalmology, Miguel Hernandez University, Alicante, Spain. His experience with presbyLASIK was published last May in the *Journal of Refractive Surgery*.[2] In an open-label, prospective, noncomparative pilot study, 25 patients with a mean age of 58 years, mean preoperative spherical equivalent refraction of +1.6 ± 0.63 D and mean spectacle near addition of +2.27 ± 0.37 D underwent presbyLASIK with proprietary software from Technovision using an H. Eye Tech excimer laser platform. After six months, 16 (64 percent) patients achieved a distance uncorrected visual acuity greater than or equal to 20/20 and 18 (72 percent) patients achieved a near UCVA greater than or equal to 20/40. Seven (28 percent) patients lost a maximum of 2 lines of best corrected visual acuity. Dr. Alió did note a significant change in corneal aberrations after surgery. The coefficients for coma increased and the coefficients for spherical aberrations decreased.

In the article, he concluded, "Central presbyLASIK may be used to provide improvement in functional near vision in patients with presbyopia associated with low and moderate hyperopia. However, factors involved in the loss of best corrected visual acuity in some cases and loss in vision quality should be further clarified prior to its general use." While this technique still needs refinement, Dr. Alió noted that presbyLASIK has great potential and "in five years could be the treatment of choice for hyperopes with early or intermediate presbyopia."

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Corneal inlays. Another investigational surgical alternative for presbyopia scheduled for clinical trials is the Acufocus ACI 7000 inlay. Dr. Pepose is one of the clinical investigators and at press time expected to start enrolling his patients at the beginning of the month. The Acufocus corneal inlay is an ultrathin 3.8 mm diameter inlay with a central opening of 1.6 mm, made of polyvinyldene fluoride, a material that has a long history of use in other medical devices, he explained. The inlay is placed in the midcornea under a flap. Tiny, porous holes throughout the Acufocus inlay are intended to facilitate nutrient flow in and to the cornea. The small artificial pupil in the inlay mimics the optical effects of looking through a pinhole, in an effort to restore intermediate and near vision in presbyopic patients without sacrificing distance vision.

"What attracted me to the inlay was the revolutionary idea of the pinhole technology," noted Dr. Pepose. "Here is something we have known about for decades but have never tried to apply clinically or surgically. Unlike some of the new premium lens technology,

pinhole technology is a mechanism people readily understand: an opaque disc with a small aperture in the center, where the peripheral unfocused rays are obscured while the central rays pass unaffected, thereby increasing depth of field. This is just like adjusting the F-stop on a camera to increase the range of focus. I look forward to seeing the results."

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Conductive keratoplasty. In 2004, conductive keratoplasty (CK) became the first procedure approved by the FDA for the treatment of presbyopia (it had already received approval for hyperopia in 2002). It is designed for patients who would benefit from a spherical treatment of between 1 D and 2.25 D to achieve a myopic endpoint of between –1 D and –2 D in their nondominant eye. CK is a thermal technique that works by using radio frequency to shrink peripheral corneal collagen, thereby steepening the central cornea.

While CK was not immediately embraced by ophthalmologists due in large part to its sporadic results, it has been gaining popularity among practitioners since the introduction of the "light touch" technique in 2004. Experts have noted that light touch requires fewer spots (eight vs. 16 or 24 spots) than traditional CK, greater predictability, more space for enhancement and more comfort for the patient. Perhaps most important, induction of cylinder is minimal, thus reducing the incidence of induced astigmatism.

Debra G. Tennen, MD, assistant clinical professor of ophthalmology at the University of California, Los Angeles, treats a predominantly young demographic with many patients in the 35 to 55 year range. In 2005, "I purchased a CK machine to treat this young and active community," noted Dr. Tennen, who was involved in the very early CK studies a decade ago and observed a lot of regression at the time. "It wasn't until light touch came out that the procedure was actually viable," Dr. Tennen noted. "It is a safe procedure, and so for mild presbyopia, it is much safer than doing a more invasive procedure."

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Intraocular Lenses

Dr. Masket describes the various surgical options for presbyopia as less than perfect, which is why "at the end of the day, you need to consider intraocular lenses." Indeed, one could write a book on the two "premium" multifocal IOLs, ReStor (Alcon) and ReZoom (Advanced Medical Optics), and the one accommodative IOL, Crystalens (Eyeonics), that have received FDA approval for the treatment of presbyopia. Each has its strengths, and some ophthalmologists are advocating "mixing and matching lenses."

ReStor. Dr. Masket's most extensive personal experience is with the ReStor, a multifocal diffractive IOL designed to provide near, intermediate and distance vision. He notes that the success of this IOL depends on a number of factors, including adhering to the "4 As": Astigmatism control, Accurate biometry, Appropriate formulae and Adjust the outcome (bioptics). It is also important to provide extensive counsel to the patient, to "under promise and over deliver," said Dr. Masket. "The patient needs to understand that there is a compromise in the quest for spectacle independence. They must accept the fact that there will be imperfections in vision." Dr. Masket is an advocate of implanting both eyes with ReStor and allowing for cortical summation.

Dr. Pepose has some concerns about uniformly implanting bilateral ReStor lenses, as there is a subgroup of patients who are not happy with the intermediate vision it provides. "ReStor patients read very well because the lens provides excellent near focal point," Dr. Pepose said. "However, their intermediate vision is not as good, which hinders some patients from working on a computer without needing to put on glasses." He noted that some ophthalmologists address this issue by implanting a Crystalens in the dominant eye for distance and intermediate vision, and ReStor in the nondominant eye for near vision.

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ReZoom. This is a second-generation multifocal lens that distributes light over five optical zones to provide near, intermediate and distance vision. Patients who opt for this

multifocal tend to have better intermediate vision than ReStor patients but near vision that is not as good. Again, many ophthalmologists are attempting to overcome these shortcomings by implanting a ReZoom in one eye and a ReStor lens in the other. The disadvantages of ReZoom can be halos and glare, which is why Dr. Pepose takes great care to determine if patients drive a lot when it is dark. “I have stopped asking whether patients drive at night, and instead ask if they drive in the dark,” Dr. Pepose said. “This simple clarification helps me navigate the decision tree in my office as I determine which lens is best.”

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Crystalens. More and more, Dr. Pepose is choosing the Crystalens, which is designed to provide good vision at all distances by moving forward and backward along the axis of the eye. It may also benefit from a phenomenon called accommodative arching, where the lens implant achieves a transient central power gradient with attempts at accommodation. It has a 4.5-mm, square-edge optic and a long-hinged plate design with polyimide loops at the end of the haptics. When the lens is placed in the capsular bag, the long, flexible haptics push the lens optic back against the posterior capsule and the vitreous. With accommodative stimuli, the ciliary muscle changes shape and enlarges within the vitreous cavity. The pressure in the vitreous rises relative to the pressure in the anterior chamber, pushing the vitreous forward and causing the lens to move forward as well. The company recently released the Crystalens Five-O, which features an enlarged 5-mm optic design that also increases the surface area contact between the plates and capsular bag by 17 percent. The company asserts that this design will reduce the potential for postoperative glare and halos.

Dr. Pepose explained that doctors might be initially reluctant to implant a Crystalens because of the unfamiliar mechanism of the lens and the less-than-stellar results from the European trials. He noted that the Crystalens fared better in the U.S. trials due to intense attention to biometry and surgical technique, as the lens requires a meticulous capsulorhexis with no tears. Doctors also shy away from the extra up-front chair time that is required when implanting an accommodative lens.

If ophthalmologists choose to implant these premium IOLs, “they must have an exit strategy in terms of bioptics,” stressed Dr. Pepose. “The average general ophthalmologist who is not familiar with laser vision correction, or doesn’t do it, and gets into these lenses in a big way without having the ability to adjust them later, is asking for trouble. Even if you don’t have good access to a laser, it is better to find and work with a colleague who does. Bioptics are imperative to fine-tuning these lenses.”

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Not so fast? While the refractive specialists involved in the leading edge of premium IOLs are enthusiastically embracing the new technology, others are not so quick to follow. Michael H. Cunningham, MD, a comprehensive ophthalmologist in Spokane, Wash., reflects this hesitation. For Dr. Cunningham’s practice, which caters to an older demographic, the issue is money. “All of these premium IOLs offer great advantages,” he noted. “Yet when I tell patients about the additional money to implant that lens, they reply ‘I have been in glasses for 40 years and don’t feel a need to spend more money. And you can’t guarantee that I won’t need glasses.’ And I can’t.”

Dr. Cunningham noted that the current generation of patients also has high expectations, and managing these expectations is a challenge. If patients do request premium IOLs, he makes sure they are well-coached and well-informed. “I have placed several ReZoom lenses in people who are good candidates from both an ocular and a personality standpoint. These patients are very happy, so I am confident that I will enjoy using this new technology. I am also excited about the prospects of presbyopic lenses continuing to improve.”

One alternative Dr. Cunningham offers is monovision, calculating the IOL power for distance in one eye and near in the other eye. “They are usually very happy with this alternative, and most adjust well.”

Dr. Tennen is more enthusiastic about multifocal lenses, which now make up almost 40 percent of her cataract cases. She notes that there is much more up-front extra work in

patient education to implant premium IOLs. She has doubts about the Crystalens, noting that she has heard stories of losing accommodative power over time. "I'm interested in the ReZoom lens, and the idea of mixing and matching lenses, but am waiting for the larger practices to flesh that out. I like to see what works in large groups of patients and how a new device or lens will behave. Then I can apply it to my own patients."

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How Much Is That Lens in the Window?

The multifocal and accommodative IOLs now on the market are relatively expensive. The ReStor, ReZoom and Crystalens, for example, each cost around $900 per lens.

Not surprisingly, Medicare initially declined to reimburse the cost of these lenses, given its policy of paying for the restoration of functional vision, and not the more expensive goal of eliminating spectacle dependence.

A concession in that policy, announced in May of 2005, allowed for Medicare patients to opt for these premium lenses and still receive coverage for basic cataract removal and standard lens replacement if they were willing to pay the overage.

Even with partial reimbursement, however, the total cost to the patient for pre- and postoperative counseling, measurements and examinations for a presbyopia-correcting lens implant may approach or exceed $2,000. Quite possibly, Baby Boomers may one day win more concessions in reimbursement.

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FUTURE VISION

Dr. Tennen believes that five years from now, clear lens exchange will be increasingly popular as newer lenses come on the market. Currently, many physicians are reluctant to do this procedure just so that a patient does not need reading glasses.

Dr. Alió predicts that corneal inlays will be the device of choice for myopes with early and intermediate presbyopia, and those with advanced presbyopia will be candidates for an advanced refractive lens exchange with a lens he is currently using, the Softec HD (Lenstec) aspheric lens. Five years from now, he projected, hyperopes with early or intermediate presbyopia will benefit from presbyLASIK, and the advanced presbyope will benefit from the accommodative lenses. "Emmetropes with early and intermediate presbyopia will benefit from the corneal inlays, while those with advanced presbyopia may not have many options, as multifocal lenses do not work in this population," he added.

For Dr. Pepose, who vividly remembers the transition from extracapsular cataract surgery to phacoemulsification, from the days of inpatient surgery to minimally invasive outpatient surgery, and from monofocal lenses to today's accommodative lenses, the future continues to look bright. "Without a doubt," he added, "it is increasingly apparent that lens surgery and refractive corneal surgery are becoming one and the same, as highlighted by the importance of bioptics in achieving good vision in patients with presbyopia."

Whatever its future holds, presbyopia researchers are heirs to an honorable tradition. It was, after all, Benjamin Franklin who, in 1784, invented the first bifocals.

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1 Qazi, M. A. et al. *Am J Ophthalmol* 2002;134:808–815.
2 *J Refract Surg* 2006;22:453–460.

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