

Refractive

Multifocal IOLs Expand Presbyopia Options

By Lori Baker Schena, Contributing Writer

Last November's approval of the first accommodating IOL in the United States has shifted the refractive spotlight to the potential of refractive lens exchange as a solution to presbyopia.¹ Understandably, this attention to accommodative lenses has prompted renewed interest in another solution for presbyopia—the multifocal IOL.

Indeed, the FDA approved the first multifocal IOL, the AMO Array, in 1997; to this day, it is the only one available in the United States. However, a new IOL, the AcrySof Restor diffractive IOL, is currently under clinical investigation.

Whichever lens—accommodative or multifocal—eventually dominates the marketplace, there is no doubt that refractive lens exchange for presbyopia is the fastest-growing refractive surgery procedure, said Richard L. Lindstrom, MD, founder of Minnesota Eye Consultants and adjunct professor emeritus of ophthalmology at the University of Minnesota.

However, it's important to note that use of the AMO Array and Crystalens IOLs for presbyopia is considered an off-label application. In contrast, in mid-March, conductive keratoplasty (CK) became the first corrective eye procedure approved by the FDA for treatment of presbyopia.

How Multifocal IOLs Work

"Multifocal optics work on the principal of simultaneously presenting different focal lengths to the retina," said Roger F. Steinert, MD, a corneal disease and refractive surgery specialist with Ophthalmic Consultants of Boston.

The Array multifocal IOL features a series of multiple concentric rings of varying optical power that mimic the eye's natural ability to provide near, intermediate and distance vision.

"It's amazing that the multifocal concept works, because one would think that the out-of-focus light would be distracting to patients," said Dr. Steinert. "The reason the lens is well-tolerated is that we have a very complex imaging processing system that allows a considerable amount of modification of the perception of optical information obtained. The net result is that patients have the ability to 'clean up' an image, ignoring the out-of-focus light focus and paying attention to the in-focus light focus, thus achieving both distance and near vision."

Dr. Lindstrom added that with the multifocal lenses, patients select either the far or the near vision focal plane, depending on what they are doing. If patients are reading, they selectively block out the distance. If they are looking at something that is far away, the near focus is still there, but the patient learns to more or less ignore it. The brain ultimately chooses which focus to emphasize.

Yet there is a price to pay for this, including a reduction in contrast sensitivity, which Dr. Steinert said is unavoidable, and the tendency to see halos around points of light at night. "The challenge in implementing multifocal lenses is to determine if there is some reliable way of differentiating the patients who have a good ability to image analyze and decode the multifocal image from those whose brains rebel against that and instead experience a high level of distraction," Dr. Steinert said.

Surprise Candidates

One thing that has surprised the industry is patient response to these lenses. In the

beginning, it was thought that the best candidates would be older people who would not be out at night and thus could adapt more easily to the multifocal lenses.

"However, we have found the reverse to be true, with a higher acceptance among middle-aged and even younger people, who are more motivated and have a more flexible nervous system in terms of learning or adaptation," Dr. Steinert said.

Clinical studies confirm the patient satisfaction among younger people. Dick et al. report six-month results with the AMO Array multifocal IOL for refractive lens exchange in 50 eyes of 25 patients with a mean age of 51 years (preoperative spherical equivalent refraction between -15.5 and +5.75 D and cylinder between 0 and 1.5 D).

All patients achieved UCVA of 20/30 and J4 or better. Moreover, patient satisfaction was extremely high: All patients were satisfied with their uncorrected distance visual acuity, and all patients except two (one eye each) were satisfied with their uncorrected near vision. Photoc phenomena occurred postoperatively in 16 of the 25 patients (most frequently starbursts and halos). But two-thirds of all patients were not bothered by it, and all patients said they would undergo the procedure again.²

New Lens on the Horizon

Patient satisfaction is, in fact, one of the main tickets to success for multifocal lenses.

Dr. Lindstrom discovered that this was the case during the early 1980s when he worked on two of the first multifocal IOLs—the two-zone, bull's-eye designed bifocal lens (Nuvue, IOLAB) and 3M's diffractive multifocal IOL.

"This is what we found out about patient satisfaction in the early studies of the multifocal IOLs," he said:

- For a "20/happy" patient, one needs to achieve 20/30 or better uncorrected distance vision.
- One needs to achieve J3 or better uncorrected near vision.
- The patient must have less than 1 D of residual ametropia or residual astigmatism.

Without patient satisfaction, the multifocal lenses could never have moved forward in their development, he said. During the 1980s, Dr. Lindstrom also served as medical director for 3M Vision Care, where he helped develop the 3M diffractive IOL.

This technology has since evolved and was eventually acquired by Alcon, which modified the posterior surface and made only the central 3.6 millimeters the diffractive portion of the lens. This diffractive multifocal AcrySof Restor lens reduces the halo symptoms, emphasizing distance vision under photopic conditions and near vision under mesopic conditions.

At the European Society of Cataract and Refractive Surgeons meeting in January, Francesco Carones, MD, of Milan, Italy, presented his preliminary results with the AcrySof Restor lens. In a study of seven patients (10 eyes) who underwent implantation of the lens for the treatment of cataracts or presbyopia, all eyes had 20/25 or better UCVA, 20/20 or better BCVA, and J2 or better UCVA at near (30 centimeters). At intermediate distance (60 cm), all eyes could read J4 or better. Patients were extremely pleased by the results and reported no complaints regarding night vision or intermediate distance vision.

Dr. Lindstrom predicted that the new hybrid diffractive/refractive multifocal lens should be available sometime in the near future, giving patients who are candidates for multifocal lenses another option.

Two Keys to Success

Patient selection. Ideal candidates for refractive lens exchange should have normal, healthy eyes with no macular degeneration or diabetic issues, Dr. Lindstrom said. These patients should also be highly motivated and seeking spectacle independence. Additionally, they should be fully informed about the potential loss of contrast sensitivity and increased halo symptoms at night.

Surgeon performance. Accurate biometry and excellent refractive cataract surgery skills are essential, said Dr. Lindstrom. "Surgeons must select the power properly when implanting these lenses and manage astigmatism; otherwise, we don't have happy patients," he said. "And some patients undergoing refractive cataract surgery may need an enhancement, using excimer laser or CK to adjust the power. Surgeons must now have all the skills necessary to manage these patients effectively."

Who's on First?

Whether accommodative or multifocal lenses become the dominant player in the refractive lens exchange market is still up in the air. "Without a doubt," said Dr. Lindstrom, "the recent FDA approval of the Crystalens has increased the level of interest in refractive lens exchange, compelling surgeons to take another look at the older Array multifocal lens technology along with the newer accommodative lenses."

Cost may drive the decision: The Crystalens IOL is more expensive than the multifocal Array lens by \$600. In addition, the accommodative amplitude is less in accommodative lenses than multifocal lenses. Yet the accommodative lenses do not appear to have the loss of contrast sensitivity and increase in halos and glare associated with the multifocal lens.

1 See "New Hope for Presbyopes," May, at www.eyenetmagazine.org/archives.

2 *J Refract Surg* 2002;18: 509-518.

Dr. Lindstrom has a financial interest in all of the products mentioned. Dr. Steinert is a consultant to Advanced Medical Optics but has no financial interest in this technology.

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