

STATUS
UPDATE

IOLs for Presbyopia *Move Ahead*

Can refractive technology ever duplicate the functional elegance of the eye's natural lens? Several IOL makers are attempting to do exactly that, with incremental success.

Premium intraocular lenses are no longer a novelty. And though they cannot mimic the precision of the human crystalline lens, these IOLs continue to evolve, as manufacturers enhance them to offer patients the potential of largely spectacle-free lives.

The newest versions of premium IOLs have improved over their predecessors, according to Bonnie A. Henderson, MD. "The changes for the new generation of the IOLs are based on patient outcomes and feedback the companies receive from surgeons. The companies have been responsive to early concerns and have made significant attempts at improving their products. As long as patients are given accurate information regarding the advantages and disadvantages of these lenses, most patients are thrilled with the postoperative results." Dr. Henderson is an assistant clinical professor of ophthalmology at Harvard University.

Yet while most ophthalmologists acknowledge that the newer versions of these lenses are better, the industry has yet to reach the ultimate goal: a

lens that delivers essentially perfect distance, medium and near vision. "The large number of choices in premium IOLs illustrates that nobody quite has it right," said Jay A. Pepose, MD, professor of clinical ophthalmology at Washington University in St. Louis. "We are still several years off from the ideal multifocal or accommodative lens."

IMPROVING LENS TECHNOLOGY

There are currently four presbyopia-correcting IOLs approved by the FDA: the AcrySof IQ ReStor (Alcon), the ReZoom (Abbott Medical Optics), the Tecnis (Abbott Medical Optics) and the Crystalens (Bausch & Lomb).

The ReStor and Crystalens, in particular, have been modified in recent years to improve visual outcomes, said Dr. Henderson. Specifically, the ReStor platform is now available with an aspheric lens as well as a decreased add power to extend the near focal point. The Crystalens has increased add power to improve near vision. "And the AMO Tecnis Multifocal IOL has been introduced, with the unique aspect of having the diffractive portion on the entire optic rather than on the central portion," she said. The ReZoom lens is essentially unchanged, but following are some perspectives on current developments for the other three lenses.

BY LORI BAKER SCHENA, CONTRIBUTING WRITER

A CLOSER LOOK AT RESTOR AND TECNIS

In December 2008, the FDA approved Alcon's ReStor. AMO received FDA approval for its Tecnis Multifocal IOL in January of 2009.

The Tecnis is a pupil-independent, nonapodized fully diffractive aspheric lens designed to correct spherical and chromatic aberrations.

"When the ReStor +3 was first introduced, a lot of people, both patients and ophthalmologists,

were blown away by the depth of field, which is a lot more comfortable than the previous version. With this lens, the quality of vision is better and the near point is closer," said Dr. Pepose. "These have improved the lens, but the warning label still issues a caution for night driving and low lighting conditions. And the contrast sensitivity may be less than the monofocal lens."

Night driving not advised? Dr. Pepose said the night driving issue remains a concern for the Tecnis and ReStor. Patients should be made aware of possible

night vision problems, and they may be trading contrast sensitivity for better depth of field. For some patients, this is a good trade, but for truck drivers or x-ray technicians who work in a dark environment, this may not be a good trade, he said.

A trend toward acceptance. Roger F. Steinert, MD, said that in spite of contrast problems, the newer iterations of the Tecnis and ReStor IOLs are receiving strong marks among surgeons. "They seem to be performing reliably, giving patients a high quality of vision without glasses." Dr. Steinert is professor of ophthalmology and biomedical engineering and chairman of ophthalmology at the University of California, Irvine.

The Tecnis is a +4 in theory, but the multifocal rings, located on the back side of the lens, enhance the optical properties, he said, explaining that strong reading vision is preserved but without the drop-off of intermediate vision. The other advantage of the Tecnis multifocal is that patients can read under dim illumination, such as menus in restaurants, which has led to a significant growth in

surgeon comfort level and patient satisfaction with multifocal technology, Dr. Steinert said.

Eric D. Donnenfeld, MD, clinical professor of ophthalmology at New York University, said his favorite IOLs are the ReStor +3 and Tecnis multifocal. "ReStor +3 gives great intermediate and good reading vision, and the aspheric optics give good distance. The Tecnis lens is a better reading lens,

with good intermediate and good distance." He added that both lenses have quality aspheric optics, but the ReStor is pupil-size dependent, so the Tecnis is better for reading and distance vision.

In March, AMO announced that it secured FDA approval for a single-piece incarnation of its Tecnis multifocal lens. This lens has also received presbyopia-correcting CMS status, so Medicare beneficiaries can choose it for an additional fee.

Dr. Donnenfeld said that the new generation of lenses is making an enormous impact on his patients. "When you get a patient with refractive error and with these lenses you can achieve good vision at all distances, this is a life-changing event. There is no doubt that the availability of quality premium lenses is the biggest practice builder, as these excited patients talk to their friends and there is a great deal of word of mouth."

A CLOSER LOOK AT CRYSTALENS

In June 2008, Bausch & Lomb received FDA approval for its Crystalens HD, representing the fourth generation for this accommodating IOL, which was first approved in 2003. Dr. Pepose explained that the difference with the HD version is that the optic has been modified to increase the depth of field, thus improving near vision without compromising intermediate or distance vision. "This bispheric modification of the optic is a nice improvement. Plus the patient doesn't experience halos or glare. This accommodative lens combines some of the features of the aspheric lens with the accommodative lens."

The most recent addition to the Crystalens portfolio is the Crystalens AO. Approved in January, this lens combines the zero-aberration aspheric optics present on the Bausch & Lomb Akreos and SofPort lenses with the Crystalens platform. "The Crystalens AO is the first aspheric accommodating lens," said Dr. Pepose. "It is immune to the effects of decentration and has high image quality due to its aspheric design. Initial results have been quite favorable." Dr. Donnenfeld pointed out that aspheric optics have been demonstrated to improve the quality of distance vision. "The new Crystalens AO should provide better distance vision, particularly at night, and the zero-aberration lens should make small decentrations less of a problem."

For that irregular eye. Dr. Pepose said the Crystalens is preferred when the patient has an irregular cornea or has undergone hyperopic LASIK. Dr. Donnenfeld added, "The Crystalens is good for patients who have a mild irregular astigmatism, but the lens doesn't necessarily give good reading vision. So it is important to warn patients that they may be wearing reading glasses."



TECNIS



RESTOR

UV protection, and controversy. In addition to being the only FDA-approved accommodative lens, the Crystalens is unique for another reason: It is the only premium IOL not to offer UV protection. Whether this is a concern is up for debate.

According to Dr. Henderson, the early IOLs allowed all visible and UV light to pass through into the eye. Because of reports of photic retinopathy and cystoid macular edema associated with UV exposure, most IOLs manufactured after the mid-1980s incorporated a UV filter. "Although the exact relationship of quantity of exposure to UV light and damage to the retina is debated," Dr. Henderson said, "it is widely accepted that filtration of UV light is a desirable characteristic of IOLs."

Dr. Steinert added that the UV issue has been a concern dating back more than 20 years when Alcon and other companies created lens material that offered the retina protection from UV light similar to that of protection found in the natural lens. "Crystalens does not offer this UV protection," Dr. Steinert said. "And while it is interesting that some surgeons act like this is a highly desired product feature, I am not aware of many surgeons avoiding the Crystalens simply because of this issue. But it does remain a controversial subject."

Dr. Donnenfeld noted that with the Crystalens, he counsels his patients to wear sunglasses.

CAUTION: UNHAPPY PATIENT AHEAD

While the latest advances in premium IOLs represent real improvements in lens technology, the specter of an unhappy patient is a concern for cataract surgeons. "It is a myth that presbyopic IOL patients will tolerate small refractive errors," Dr. Donnenfeld said. "The reality is that presbyopic IOL patients are incredibly sensitive to small refractive errors, and refractive cataract surgeons must be willing and able to treat postoperative refractive errors."

The concern is exacerbated when patients paid a premium price for their lenses and are unhappy with the results, said Dr. Donnenfeld. He said the challenge extends far beyond the lens itself. "When premium lenses were first introduced, we used to focus on selecting the lens that was right for the patient: Do they want the best-quality distance and a little bit of reading vision, or do they need optimal medium distance? However, as the manufacturers continue to improve these premium lenses, the focus has shifted from which lens to choose to surgical technique—honing your skills to obtain the best refractive outcome."

Physician, mind thy Cs. The causes of glare, halos and loss of contrast sensitivity are not necessarily related to the lens but rather to what Dr. Don-

nenfeld refers to as the "Cs": cylinder and residual refractive error, cornea and ocular surface disease, CME, capsular opacities and centration of the IOL. He said that surgeons need to spend time managing the ocular surface, as disruption of the surface can induce distortion, which can be magnified by a multifocal IOL. "Nonsteroidals are key to managing the surface and can improve contrast sensitivity with these multifocals," he said.

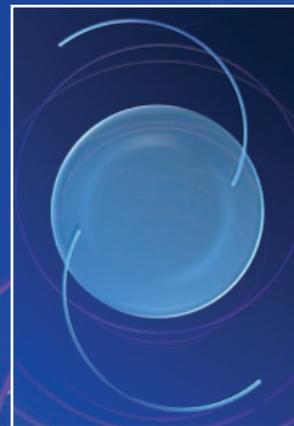
Dr. Donnenfeld also suggested that spending more chair time with the patient prior to surgery allows the surgeon to manage expectations. "Have the staff alert the physician if a patient is unhappy and have answers for the patient," including the possibility of limbal relaxing incisions or laser enhancements.

GROWING DEMAND FOR PREMIUM LENSES

Dr. Henderson said that more and more patients are asking about premium lenses and they tend to be well-informed, with a significant percentage arriving at the appointment armed with pages of information printed off the Internet. "They often have friends or neighbors who have had cataract surgery with a premium IOL and are happy with the outcome," Dr. Henderson added. "Many patients have heard the brand names of the lenses and even know the common problems associated with each of the types."

Rosa Braga-Mele, MD, director of the cataract unit at Mount Sinai Hospital in Toronto and associate professor of ophthalmology at the University of Toronto, said she has seen a growing demand for premium IOLs in her practice. She estimates that 40 percent of her patients choose a presbyopia-correcting IOL, with 85 to 90 percent of those selecting the ReStor +3 and the rest going with the accommodative Crystalens. "In respect to accommodative IOLs, I am not as impressed with these lenses as some of my colleagues," she said. "I think they are OK and give good distance vision and good functional intermediate, but they lack in near vision. Instead, I like the ReStor +3, which gives most of my patients spectacle independence, with a minimization of refraction or glare."

Patients are willing to pay (more money). Of course, the inevitable question arises as to how the Canadian health care system approaches cataract surgery reimbursement, especially given the health care debate raging in the United States. Dr. Braga-Mele explained that much like Medicare, the



REZOOM



CRYSTALENS

Canadian government pays for basic cataract surgery; premium IOLs and fees for the ancillary procedures cost the patient extra, ranging from \$2,500 to \$4,000. She stressed that every patient deserves to know about the availability of premium IOLs. “You can never assume who can afford a premium lens or not based simply on appearance,” she said. “I have had the stereotypical little old person who looks like they are without a cent and, when told of premium IOLs, says, “Of course I want this lens and can pay for it.”

ON, AND BEYOND, THE HORIZON

As for what advances in IOLs surgeons can expect in the near future, Dr. Steinert noted that the buzz at the Academy meeting in San Francisco was Abbott Medical Optics’ announcement of an agreement to acquire Visiogen and its accommodating

IOL, the Synchrony. Synchrony’s dual optic accommodating IOL is a three-dimensional, single-piece, foldable lens that has an anterior convex optic and posterior concave optic connected by a spring system. The posterior element of the lens has more surface area than the anterior element, which provides stabilization and centration for the device within the capsular bag. “The company has been quite vocal about the excellent results of this lens in terms of attaining a great degree of accommodation and patient satisfaction,” Dr. Steinert said.

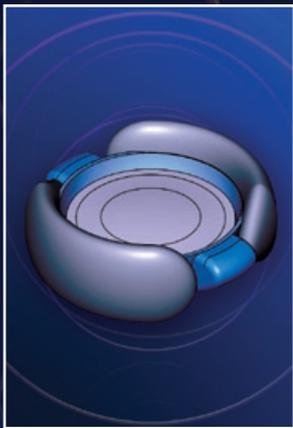
“The lens has not yet received FDA approval, but the company has started the process.”

Dr. Steinert added that the TetraFlex, an accommodating posterior chamber IOL manufactured by Lenstec and already in use in Europe, is currently undergoing clinical trials in the United States.

A bird’s-eye view of the future. Dr. Pepose predicted that the advances in the multifocal lens will involve the development of toric versions of the current IOLs. “However, the major advances in IOL technology will take place five to 10 years into the future, and the focus will be on the accommodative lens,” he said. “And this lens may not necessarily be modeled on the way the human lens accommodates but rather what animals need to change the accommodation of their lens.” He cited as an example the extensive accommodation required by water-diving birds, which, when seeking fish, must identify the target, keep the target in view while they dive from the sky, then enter the water and make immediate contact with the prey. “These birds need super accommodation to keep the target in focus; they may have to use 50 diopters of accommodation throughout the hunt-

ing process. And the way they do this is they have a flexible lens that pushes through a very stiff iris. The protruding lens through the iris creates a central bulge, resulting in increased lens power.”

One innovative lens, he said, made by PowerVision, is called FluidVision and involves haptics that are rounded, soft and fluid-filled. The lens is implanted in the capsular bag, and the fluid-filled haptics create a bulge in the curvature of the lens. It has demonstrated a fair amount of accommodation in animal models, he said. “I think that we are just touching the surface with these new technologies. As more and more technologies are developed, and the demand for premium IOLs continues to increase, the key remains matching patient’s expectations to what is currently available. I still don’t have a lens that can give my 60-year-old patient the vision of a 20-year-old. But I predict that as better and better lenses come down the pike, the demand will go higher—and levels of satisfaction will be higher as well.” But Dr. Steinert suggested that expectations, and perfection, may always hover just over the horizon. “There is always room for improvement, and we are never satisfied.”



FluidVision

Meet the Experts



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