

COVER
FEATURE

A close look at refractive lens exchange

by I. Howard Fine, M.D., Richard S. Hoffman, M.D., Mark Packer, M.D.



New IOL technology is developing at an accelerating rate. It seems that there is never a month that goes by without a new design, material, or device appearing on the horizon.

Many of these new IOLs have undergone considerable development, and as you will see in this month's column, are also undergoing some sort of pre-clinical or clinical testing. I think what is available today and what promises to be available in the not-too-distant future are going to create a true renaissance in

After having done clinical research on power modulations for almost six years, my partners and I published an article on refractive lens exchange.¹

We documented that we could use approximately 1/1,000th of the power levels previously reported in the literature and not only achieve the ability to remove cataracts of all nuclear density grades, but also to dramatically enhance our results with respect to clear corneas and uncorrected visual acuities in the two- to 24-hour post-op period.

We also documented in that paper that better levels of visual acuity in the immediate post-op period were inversely related to the amount of energy into the eye, which heightened our interest in power modulations.

We subsequently repeated that study with new phacoemulsification technologies over the next two years and we found, yet again, improvements as a result of the new technologies with an ability to conclude that cataract or lens extraction at this time is inordinately safe and efficacious.²

We also did a comparison of immersion A-scan compared with partial coherence interferometry³ and found a correlation coefficient of 0.997, which means the new IOLMaster (Carl Zeiss Meditec, Dublin, Calif.), which is much easier to use, is as efficacious as immersion A-scans. This led us to conclude that pre-op measurements and calculations for lens power allow for excellent results and continue to improve.

Multifocal IOLs

Our initial venture into refractive lens exchange was with the Array Multifocal IOL⁴ by Advanced Medical Optics (AMO, Santa Ana, Calif.). Our earliest visual acuity data and accuracy of refractive outcomes is demonstrated in Figures 1 and 2 (right). Subsequently, the Alcon (Fort Worth, Texas) AcrySof Multifocal ReStor became available for clinical trials. This lens has the characteristic of being distant dominant for wide pupillary apertures, as in driving at night, and near dominant for small pupils, as in reading, which can be very advantageous.

It is a bifocal rather than a multifocal IOL, but in the clinical trials, the



Figure 1: Visual acuities for patients undergoing refractive lens exchange with the Array Multifocal IOL (Advanced Medical Optics, Santa Ana, Calif.).

ophthalmology. With so much to offer our patients, we will all be participating in a new golden age.

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average visual acuity at intermediate distance, such as for computer screens, was 20/40.

Two new IOLs came under clinical investigation and use: The 1CU (HumanOptics, Erlangen, Germany) and eyeonics' Crystalens (Aliso Viejo, Calif.).

Both of these lenses are believed to move within the eye.

Although we have not been able to reproducibly document with an objective study that they move within the eye, we have excellent data to document their efficacy.

In the Food and Drug Administration-monitored clinical trials of the Crystalens, we implanted 24 patients binocularly and their visual acuities are demonstrated in Figure 3 (page 92).

We subsequently have used this lens as a refractive lens exchange modality and have achieved visual acuities indicated in Figure 4 (page 92).

Interestingly enough, these data correlate exactly with the quality-of-life studies conducted by eyeonics, which document that the same percentage of patients that achieved at least 20/25 at distance, near, and intermediate were also, in their own estimation, spectacle independent. In addition to these modalities, there are a variety

Accuracy of Refractive Lens Exchange



Figure 2: Scattergram demonstrating the accuracy of refractive outcomes for refractive lens exchange utilizing the Array Multifocal IOL (AMO).

Binocular Results

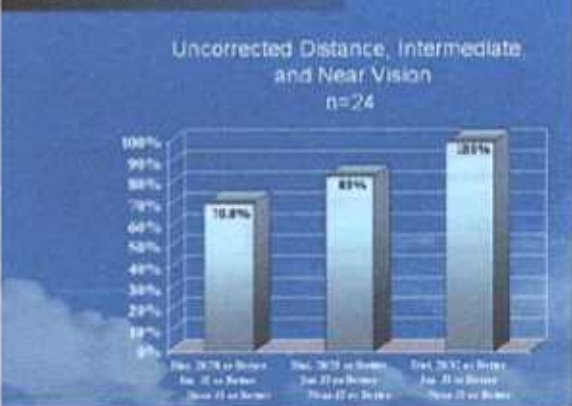


Figure 3: Uncorrected distance, intermediate, and near visual acuities for patients binocularly implanted with the Crystalens (eyeonics, Aliso Viejo, Calif.).

Combined Visual Acuities



Figure 4: Visual acuities of patients implanted with the Crystalens (eyeonics) as a refractive surgery

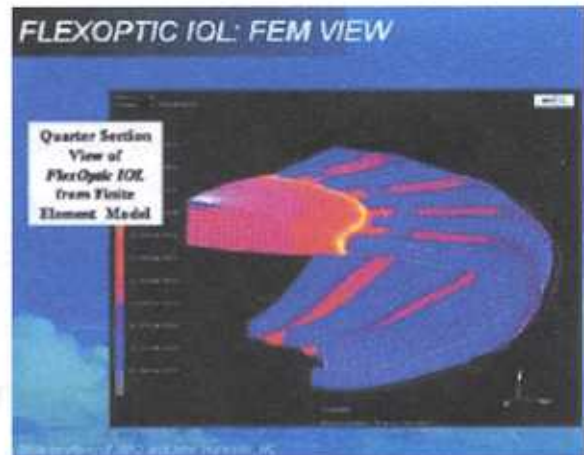


Figure 5: Quarter section view of the FlexOptic IOL (Quest Vision Technology Inc., Tiburon, Calif.) from Finite Element Model.

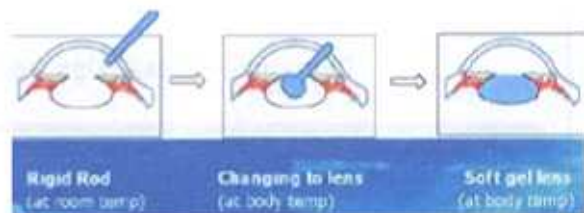


Figure 6: Schematic demonstrating the SmartIOL (Medennium Inc., Irvine, Calif.) being inserted as a stable rod and, under the influence of body temperature, reconstituting to a stable gel entirely filling the capsular bag.



under investigation or in pre-clinical trials that promise to lend themselves to refractive lens exchange.

Among these are aspheric IOL designs that can address and correct the spherical aberration in the cornea.

Two of those are the AMO Tecnis and the Bausch & Lomb (Rochester, N.Y.) SofPort IOL. These work somewhat differently.

The Tecnis corrects positive spherical aberration in the cornea and the Bausch & Lomb SofPort Advanced Optic IOL is aberration-free and so is

not dependent on excellent centration and tilt.

Our ability to correct for corneal spherical aberration has improved the quality of vision by contrast sensitivity in our patients that have been implanted with the Tecnis lens.

Senior citizens implanted with this lens have as good mesopic contrast sensitivity as 20- to 30-year-olds that have never had cataracts, and as good mesopic contrast sensitivity as other senior citizens with spherical IOLs have photopic contrast sensitivity.

We believe this lens confers day-for-night vision and youthful vision for our senior citizens. On

the horizon, there is a new multifocal Tecnis IOL, which has just begun clinical trials and appears to be extremely efficacious.

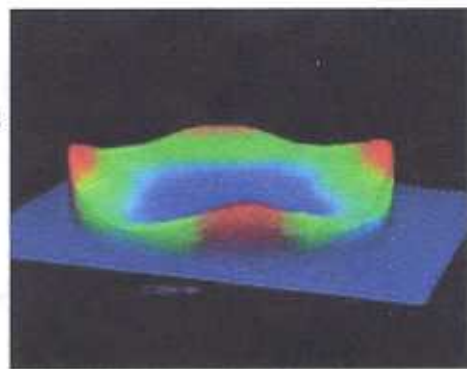


Figure 7: A prototype, digital light delivery device (DLDD) which can be used to correct a tetra foil aberration in the cornea by altering the lens. The three dimensional diagram of the alteration of the lens is shown in color.

Source: I. Howard Fine, M.D.

Dual-optic IOLs

Other accommodative IOLs include dual-optic IOLs.

These lenses have minus-powered lens posteriorly placed from a positive-powered lens joined by compressible, flexible haptics, which allow for close proximity between the two lenses in a non-accommodative state. On accommodation, with laxity of the zonules, the elasticity of the haptics of these lenses allows for a springing forward of the plus-powered lens, creating a Galilean telescope and an increased plus-powered lens within the eye.

Dual-optic lenses include the Synchrony by Visiogen (Irvine, Calif.) and the Sarfarazi Accommodating IOL, licensed by Bausch & Lomb. The data from early studies on the Synchrony lens are excellent.

In addition, there are other deformable IOLs that promise larger amplitudes of accommodation. The Power Vision IOL (Power Vision Inc., Santa Barbara, Calif.) has a fluid reservoir which in a non-accommodative state is in the periphery of the lens, but on accommodation moves centrally increasing the plus-power of that lens.

An extremely promising new IOL technology by NuLens (Herzliya, Israel) is a piston-like in configuration with a soft polymer encased in a flexible membrane. On accommodative effort, it can be deformed by bulging in such a way as to dramatically increase the lens power.

This lens has been demonstrated to achieve up to 30 D of accommodation in primates that have undergone implantation. In my opinion, this is an extremely promising technology.

Another new IOL is the FlexOptic IOL (Quest Vision Technologies, Tiburon, Calif.), which not only has an axial travel, but also an optic shape change on accommodative effort, which promises up to 4.5 D of accommodation (Figure 5).

We have to recognize that injectable polymers are extremely promising, the most important of which is the SmartIOL by Medennium (Irvine, Calif.). This is an accommodative IOL that at body temperature is a stable

gel designed to fill the capsular bag so there will not be decentration or glare from edge effects.

However, at room temperature, the SmartIOL can be converted to a thin rod, which can be implanted through a small incision into the capsular bag. There, under the influence of body temperature, the lens reconstitutes to its original size, shape, and imprinted dioptric power (Figure 6). This is an extremely appealing technology.

Light adjustable

Finally, we have to recognize that light adjustable IOLs, such as the Calhoun Vision lens (Pasadena, Calif.), are capable of adjustment within the eye with respect to both plus or minus power and toricity. They can be treated with a digital light delivery device to actually address higher-order corneal aberrations as seen in Figure 7.

The tetrafoil cornea is treated by changes in the lens intraocularly to neutralize it. It is important to recognize that many of these technologies are possibly cross-licensable. Light adjustability in a lens such as the SmartIOL seems even more efficacious.

Bimanual and refractive lens exchange

We have developed a new technique for the removal of soft lenses in refractive lens exchange by using bimanual microincision phacoemulsification. This is the safest and most efficacious technique we have ever used.⁵

What makes this technique extremely effective is with the irrigating handpiece, we can maintain complete inflation of the eye so that the vitreous face never trampolines during the extraction process.

It is important to realize that not all patients that seek refractive surgery to achieve some measure of spectacle independence or enhanced visual function are candidates for LASIK.

LASIK is limited in that it is not applicable for high myopes, high hyperopes, or presbyopes.

It is also important to recognize that anything done to the cornea, including the most sophisticated wavefront custom contouring, is going to be degraded over time by changing spherical aberration in the crystalline lens as the patient ages.

We also have learned from astrophysics about the degrading of visual function even in the presence of 20/20 visual acuity in a darkened lane. The development of cataracts is associated with a tremendous loss in functional vision as demonstrated by contrast sensitivity in spite of early changes that still allow for 20/20 visual acuity in a darkened lane.

We believe that these improvements in lens removal technology and techniques and IOL technology are going to result in refractive lens exchange becoming the dominant refractive procedure.

This will also be the biggest triple win in the history of medicine.

Patients can enjoy predictable refractive procedures with rapid recoveries that can address all types of refractive errors, including presbyopia, and they will never develop cataracts.

References

- 1 Fine IH, Packer M, Hoffman RS. Use of power modulations in phacoemulsification: choo-choo chop and flip phacoemulsification. J

Cataract Refract Surg February 2001; 27:188-197.

2 Fine IH, Packer M, Hoffman RS. Power modulations in new technology: improved outcomes. J Cataract Refract Surg, May 2004; 30:1014-1019.

3 Packer M, Fine IH, Hoffman RS, Coffman PG, Brown LK. Immersion A-scan compared to partial coherence interferometry: outcome analysis. J Cataract Refract Surg, February 2002; 28:239-242.

4 Packer M, Fine IH, Hoffman, RS. Refractive lens exchange with the Array multifocal lens. J Cataract Refract Surg, March 2002; 28:421-424.

5 Fine IH, Hoffman RS, Packer M. Optimizing refractive lens exchange with bimanual microincision phacoemulsification. J Cataract Refract Surg, March 2004; 30:550-554.

